

# Minnesota Vaccines for Children



## Separate Stock Sites: Policies and Procedures Manual

2017



Minnesota  
Department  
of Health

Minnesota Department of Health  
Immunization Program  
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## Minnesota Vaccines for Children (MnVFC) Basics

### What is MnVFC?

The Minnesota Vaccines for Children (MnVFC) program is Minnesota's version of the federal Vaccines for Children (VFC) program which works to make vaccine accessible and affordable for all children from birth through 18 years of age. MnVFC distributes about \$45 million worth of vaccines to enrolled sites each year. It is run by the Immunization Program at the Minnesota Department of Health (MDH).

### Why enroll in MnVFC?

MnVFC provides vaccine at no cost for eligible children and increases patient satisfaction by providing your patients access to vaccine in their health care home. MnVFC participation also helps increase your immunization rates, because you are able to provide vaccine to eligible patients who otherwise could not afford them.

All sites that provide immunizations to children must ensure equal access for children enrolled in a Minnesota Health Care Program (MHCP). We strongly encourage you to do this by enrolling and participating in the MnVFC program.

If a site is not enrolled in the MnVFC program and is providing vaccines to privately insured children, they must provide the same vaccines to MHCP-enrolled children free of charge. The site cannot charge the recipient for the cost of the vaccine or administration fee. Additionally, the site cannot bill the MHCP for the vaccine administration fee if they are not enrolled in the MnVFC program.

### How do you enroll in MnVFC?

1. Call or email the MnVFC program (651-201-5522, [health.mnvfc@state.mn.us](mailto:health.mnvfc@state.mn.us)) to start the enrollment process.
2. A packet of information and forms will be sent to you. Carefully review and complete all documents and return to the address provided.
3. The MnVFC program will review the forms for completeness. MnVFC staff will contact you to get any missing information.
4. Once your forms are complete, MnVFC staff will schedule an enrollment visit for your site. You must have a visit before you are allowed to order MnVFC vaccine from MDH.
5. Once you have met the requirements of the MnVFC program and your site has been assigned a Personal Identification Number (PIN), you will be able to order MnVFC vaccine.
6. Place your first order for MnVFC vaccine within 90 days from your initial site visit. If you wait longer, you may need to have another enrollment site visit.

**If your site will be closing, moving, or changing ownership, contact the MnVFC program.**

## Introduction to MnVFC Policies and Procedures Manual

This manual is your roadmap for the MnVFC program. The manual lays out the policies established by federal law for the VFC program. It will help you navigate the requirements to be able to provide essential vaccines to MnVFC-eligible children.

To keep this manual manageable, we don't cover the full range of general immunization best practices and recommendations, but the Contacts and Resources section at the end gives you a number of great resources with additional information.

### How to use your MnVFC Policies and Procedures Manual

- Have your immunization manager, vaccine coordinator, and their backups read this manual and sign the signature page (page 5), certifying that they have read the manual. (Required)
  - Consider having all staff whose work relates to immunizations read this manual and sign and date the signature page (e.g., the front desk staff who receives immunization shipments and staff giving immunizations).
- Use this manual to fulfill the requirement for a routine vaccine management plan. To do this, the appropriate individual needs to certify that this manual will be implemented as your site's routine vaccine management plan (see page 6).
  - Use of the manual to fulfill this requirement is optional. You can create your own routine vaccine management plan.
- Use this manual to fulfill the requirement for an emergency vaccine management plan. Develop a plan using the documents in this manual and have the appropriate individual certify that it will be implemented if needed (see page 7).
  - Use of the manual to fulfill this requirement is optional. You can create your own emergency vaccine management plan.

### Helpful definitions

**Sites:** In this manual, all organizations that administer vaccine to MnVFC-eligible children and/or store vaccine for MnVFC-eligible children will be referred to as sites.

**Separate stock:** This method involves keeping privately-purchased vaccine separate from MnVFC vaccine purchased through MDH. Patients must receive vaccine from the correct vaccine "stock" based on their eligibility.

**Replacement method:** This method allows a site to use privately-purchased vaccine to vaccinate MnVFC-eligible children and the MnVFC program replaces the private vaccine that was administered. Only sites with grandfathered status are allowed to use the replacement method.

If you received this version of the 2016 manual, you have been identified by MDH as a separate stock site. If you believe this is an error, please contact the MnVFC program at 651-201-5522 or 1-800-657-3970 or email [health.mnvfc@state.mn.us](mailto:health.mnvfc@state.mn.us).

This manual can also be found on the MnVFC website ([www.health.state.mn.us/vfc](http://www.health.state.mn.us/vfc)).

## Requirements Due Each Year for Separate Stock Sites

Each year MnVFC sites need to re-enroll in the program. See below to find out what forms your site needs to complete by Nov. 30 each year. Read sections 14 and 15 of the “How to be Accountable in the MnVFC Program” chapter for more information.

### All sites

- Complete and return the *2017 MnVFC Program Provider Agreement*.
- Watch the 2017 MnVFC Program Separate Stock Online Training and indicate you completed it in the designated area of the *2017 MnVFC Program Provider Agreement*

### Parent sites

- Complete and return the *2017 MnVFC Annual Report of Number of Immunized Pediatric Patients*.
  - Note: Parent sites may complete one report on behalf of all satellite sites.

## Signature Page

***By signing below I certify that I have read the 2017 MnVFC Policies and Procedures Manual.***

Name	Signature	Title	Date
Immunization Manager*:			
Backup Manager*:			
Vaccine Coordinator*:			
Backup Coordinator*:			

\*Duties of the immunization manager, vaccine coordinator, and backups can be found on pages 39-40.

## Routine Vaccine Management Plan

As a MnVFC provider, it is a requirement that you have a routine vaccine management plan that includes the date of review and the reviewer's name, title, and signature. The plan must be reviewed annually or more often if there are changes in staff responsibilities for fulfilling tasks.

The routine vaccine management plan must include:

- Name of the current immunization manager, vaccine coordinator, and backups,
- General operations for proper vaccine storage and handling practices (e.g., temperature monitoring and vaccine storage),
- Vaccine shipping and receiving procedures,
- Vaccine ordering procedures,
- Inventory control (e.g., stock rotation),
- Vaccine expiration, spoilage, and wastage prevention (e.g., protocol for responding to and reporting vaccine loss),
- Documentation of staff training on elements of the plan,
- Name, signature, and title of the individual responsible for reviewing and implementing the content, and
- Recorded review date within the last 12 months.

You can use this manual to fulfill the requirement for a routine vaccine management plan if:

- You have the appropriate individual certify that this manual will be implemented as your site's routine vaccine management plan.
- Your immunization manager, vaccine coordinator, and their backups read this manual and sign the signature page (page 5) certifying that they have read the manual.
  - Consider having all staff whose work relates to immunizations read this manual and sign and date the signature page (e.g., the front desk staff who receives immunization shipments and staff giving immunizations).

***By signing below I certify that the 2017 MnVFC manual will be implemented as my site's routine vaccine management plan.***

MnVFC PIN	
Site name	
Date reviewed	
Name	
Title	
Signature	

## Emergency Vaccine Management Plan

It is a requirement for sites to develop, post, and prepare to follow a plan for transporting and storing vaccine in an emergency situation such as a power outage, natural disaster or storage unit malfunction. The plan must be reviewed, signed, and dated each year or more often if there are changes.

You must develop your own site-specific plan and store it in an easily accessible area near your storage unit(s). Staff should routinely be trained on the emergency plan. They should know where supplies are located, how to pack vaccine for transport, and where to transport vaccine. We encourage you to regularly practice your plan to identify unforeseen problems.

### Essential components for your emergency vaccine management plan:

- General information:
  - Designated immunization manager, vaccine coordinator and their backups with emergency contact information.
  - Emergency staff contact list in order of priority.
  - Vaccine storage unit specifications (type, location, brand, model and serial number).
- Written instructions for how to enter your facility and access vaccine storage units if the building is closed or it's after hours.
  - Include building security after-hours access procedure; a floor diagram; and the locations of keys, locks, light switches, alarms (with instructions for use); and circuit breakers.
  - Include location of flashlights, spare batteries and appropriate packing materials to safely transport and/or temporarily store vaccine.
- Written instructions for vaccine packing to maintain the cold chain with appropriate supplies including temperature monitoring devices. Refer to:
  - *Packing Vaccines for Transport during Emergencies* ([www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf](http://www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf)).
  - *CDC's Vaccine Storage and Handling Toolkit* ([www.cdc.gov/vaccines/recs/storage/toolkit](http://www.cdc.gov/vaccines/recs/storage/toolkit)).
- Alternate vaccine storage facility(s), preferably with back-up generators.
  - Written information for:
    - How to contact the facility(s) during and after business hours.
    - Identifying vehicles and drivers for transporting vaccine to and from the alternate vaccine storage facility(s).
    - Appropriately storing vaccine at the alternate storage facility(s).
- Documentation of incident and actions.
  - *Vaccine Troubleshooting Record* at IAC Clinic Resources ([www.immunize.org/clinic/storage-handling.asp](http://www.immunize.org/clinic/storage-handling.asp)).
  - *Emergency Response Worksheet* (includes list of manufacturers' phone numbers) at IAC Handouts: Clinic Resources ([www.immunize.org/handouts/vaccine-storage-handling.asp](http://www.immunize.org/handouts/vaccine-storage-handling.asp)) and in Appendix B.
- Emergency Resources Contact List.

## Worksheet for Developing an Emergency Plan for Managing Vaccine

Name	Phone numbers (home, cell)
Immunization Manager:	
Immunization Manager Backup:	
Vaccine Coordinator:	
Vaccine Coordinator Backup:	

Emergency Staff Contact List		
Name (in order of priority)	Emergency role (pack, transport, etc.)	Phone numbers (home, cell)
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		

<b>Vaccine Storage Unit Specifications</b>				
Type of unit (refrigerator or freezer)	Location	Brand	Model number	Serial number

<b>Written instructions for how to enter your facility and access vaccine storage units if the building is closed or it's after hours.</b>

<b>Materials</b>			
	Location of item	Person responsible for material	Phone number
Flashlights			
Spare batteries			
Insulated containers or coolers			
Fillers (e.g., bubble wrap, packing paper, newspaper)			
Cold/frozen packs			
Certified, calibrated temperature monitoring devices			

<b>Written instructions for vaccine packing to maintain the cold chain with appropriate supplies, including temperature monitoring devices.</b>

<b>Alternate Vaccine Storage Facility(s)</b>	
Facility name:	
Address:	
Contact person:	
Phone number during business hours:	Phone number after business hours:
Storage capacity:	
Facility name:	
Address:	
Contact person:	
Phone number during business hours:	Phone number after business hours:
Storage capacity:	
Facility name:	
Address:	
Contact person:	
Phone number during business hours:	Phone number after business hours:
Storage capacity:	

Transportation to Alternate Vaccine Storage Facility(s)		
	Contact person	Phone numbers
Vehicle 1:		
Vehicle 2:		
Vehicle 3:		
Vehicle 4:		

Emergency Resources Contact List			
Emergency resources	Company name	Contact person	Phone numbers
Electric power company			
Generator repair company			
Generator fuel source			
Refrigerator repair company			
Local health department			
State health department	MnVFC program		651-201-5522

**Remember to document the incident and your actions.**

- *Vaccine Troubleshooting Record* on IAC Clinic Resources ([www.immunize.org/clinic/storage-handling.asp](http://www.immunize.org/clinic/storage-handling.asp)).
- *Emergency Response Worksheet* (includes list of manufacturers' phone numbers) on IAC Handouts: Clinic Resources ([www.immunize.org/handouts/vaccine-storage-handling.asp](http://www.immunize.org/handouts/vaccine-storage-handling.asp)) and in Appendix B.

Date reviewed	
Reviewed by	
Title	
Signature	



# **How to Administrate the MnVFC Program**



## 1. Screen patients for MnVFC eligibility

- Screen each patient who is 18 years and younger before administering vaccines to determine if they are eligible for MnVFC vaccine.
- Document the patient’s eligibility status and keep a record of the patient’s eligibility for three years.

### MnVFC eligibility criteria

- Children 18 years and younger that fall into any of the following categories can receive MnVFC vaccine at any MnVFC-enrolled site:
  - Uninsured,
  - Enrolled in a Minnesota Health Care Program (MHCP): Medical Assistance (MA), MinnesotaCare, or
  - American Indian or Alaskan Native.
- The following two categories are considered underinsured and are only MnVFC-eligible at local public health (LPH), Federally Qualified Health Centers (FQHC), Rural Health Centers (RHC), Indian Health Services (IHS), and tribal health clinics:
  - Has health insurance that does not cover one or more vaccines, as can be the case with newly licensed vaccines that aren’t yet covered (MnVFC-eligible for non-covered vaccines only).
  - Has health insurance that caps vaccine coverage at a certain amount. Once that amount is reached, the person is MnVFC-eligible.
- Please note: Children with insurance that does not cover vaccines until a deductible has been met are considered to be fully insured and are not MnVFC-eligible.
- For up-to-date details, see the *MnVFC Patient Eligibility Screening Record* forms on MnVFC Forms ([www.health.state.mn.us/divs/idepc/immunize/mnvfc/forms.html](http://www.health.state.mn.us/divs/idepc/immunize/mnvfc/forms.html)).

### Screening patients for eligibility

- Prior to immunizing each patient who is 18 years and younger, you must inform the patient, parent, or legal representative of the MnVFC eligibility criteria and/or give them an eligibility screening form to complete.
  - The MnVFC Forms ([www.health.state.mn.us/divs/idepc/immunize/mnvfc/forms.html](http://www.health.state.mn.us/divs/idepc/immunize/mnvfc/forms.html)) page has a self-screening form for children that you can have the parent fill out called *Can my child get free or low-cost shots?*
- You are not required to verify the patient’s response to the screening questions. For example, if patients say they have lost their insurance you do not need to call their insurance company to confirm.
- If a patient is eligible for more than one category, the provider must select the category that will require the least amount of out-of-pocket expense for the patient.

**Documenting the patient's eligibility status**

- Document eligibility screening in the patient's medical record (chart) or in a separate file. Documentation means a notation must be made on a record even if the patient is not eligible for MnVFC.
  - The MnVFC program provides screening record forms on MnVFC Forms ([www.health.state.mn.us/divs/idepc/immunize/mnvfc/forms.html](http://www.health.state.mn.us/divs/idepc/immunize/mnvfc/forms.html)). You don't have to use the MnVFC forms, but you do have to collect all the information that is on them.
- You can keep the same form and have the patient, parent, or guardian review it each time the patient receives a vaccination. If the patient's eligibility changes, fill out a new form to reflect the change.
- Document that eligibility screening was completed at each visit.
- Your site can submit your patients' MnVFC eligibility status to the Minnesota Immunization Information Connection (MIIC). The MnVFC program also refers to this information as dose-level eligibility. Reporting eligibility to MIIC is currently optional for sites using the separate stock method of vaccine management; however, sites are encouraged to begin submitting this information. For more technical information, see Vaccine Ordering and Management in MIIC ([www.health.state.mn.us/divs/idepc/immunize/registry/hp/ordering.html](http://www.health.state.mn.us/divs/idepc/immunize/registry/hp/ordering.html)).
- Keep a record of the patient's eligibility for three years.

## 2. Charge only allowable fees for MnVFC

- Do not charge for the cost of vaccine if the patient is MnVFC-eligible.
- Charge only the allowable fees for administering MnVFC vaccine.
- Waive the administration fee if a patient is unable to pay.

Patient's status	MnVFC eligible?	Cost of the vaccine	Administration fee
Minnesota Health Care Program (MHCP)	Yes	<ul style="list-style-type: none"> <li>• Use MnVFC vaccine</li> <li>• Don't bill or charge for the cost of the vaccine.</li> </ul>	<ul style="list-style-type: none"> <li>• Bill the MHCP \$21.22 per dose.</li> <li>• Certain sites including FQHC, RHC, IHS and tribal clinics may bill an encounter fee for the entire visit and this is allowable.</li> </ul>
Uninsured	Yes	<ul style="list-style-type: none"> <li>• Use MnVFC vaccine</li> <li>• Don't charge for the cost of the vaccine.</li> </ul>	<ul style="list-style-type: none"> <li>• Charge the patient \$21.22 or less per dose.</li> </ul>
American Indian/ Alaska Native	Yes	<ul style="list-style-type: none"> <li>• May use MnVFC vaccine.</li> <li>• Don't bill or charge for the cost of the vaccine.</li> <li>• However, if the patient is privately insured and prefers to use insurance, use private vaccine and bill the insurance.</li> </ul>	<ul style="list-style-type: none"> <li>• If covered by a MHCP, bill the MHCP \$21.22 per dose.</li> <li>• If un- or underinsured, charge the patient \$21.22 or less per dose.</li> <li>• If privately insured and prefers to use insurance, bill the insurance for the fee.</li> </ul>
Underinsured	Only at local public health (LPH), Federally Qualified Health Centers (FQHC), Rural Health Centers (RHC), Indian Health Services (IHS), and tribal health clinics:		
	Yes	<ul style="list-style-type: none"> <li>• Use MnVFC vaccine</li> <li>• Don't charge for the cost of the vaccine.</li> </ul>	<ul style="list-style-type: none"> <li>• Charge the patient \$21.22 or less per dose.</li> </ul>
	At a site that is not eligible to see underinsured children:		
	No	<ul style="list-style-type: none"> <li>• Consider sending the patient to a site where they would be eligible for MnVFC.</li> <li>• If the patient stays at a private site, do not use MnVFC vaccine.</li> </ul>	<ul style="list-style-type: none"> <li>• Consider sending the patient to a site where they would be eligible for MnVFC.</li> </ul>
Insured	No	<ul style="list-style-type: none"> <li>• Use private vaccine.</li> <li>• Bill the insurance.</li> </ul>	<ul style="list-style-type: none"> <li>• Bill the usual and customary administration fee to the insurance.</li> </ul>

**Do not bill or charge for the cost of the vaccine**

- You may not bill or charge for the cost of the vaccine for MnVFC-eligible patients.

**Charging allowable administration fees**

- You may bill or charge an administration fee of up to \$21.22 per dose (not per antigen) for administering MnVFC vaccine.
- You may also charge for the office visit.
- To be reimbursed for the administration fee for pediatric patients enrolled in a Minnesota Health Care Program (MHCP), you must follow the billing procedures of each program. MHCPs include Medical Assistance (MA) and MinnesotaCare. For billing questions, call the Minnesota Department of Human Services (DHS) at 651-431-2700.

**Removing vaccine charges from a MnVFC-eligible patient's bill**

- Make sure your billing department is prepared to respond to questions related to MnVFC eligibility and to adjust bills as needed; see Appendix A: *Immunization Billing Guidance for MnVFC* ([www.health.state.mn.us/divs/idepc/immunize/mnvfc/billingtips.html](http://www.health.state.mn.us/divs/idepc/immunize/mnvfc/billingtips.html)).

**Waiving the administration fee**

- You may bill patients an administration fee, but if they are unable to pay this fee it must be removed from their bill. Having these bills go to collections is not acceptable.
- No MnVFC-eligible patient may be denied vaccine for failure to pay an administration fee.

### 3. Give patients a VIS with each immunization

- Provide a current Vaccine Information Statement (VIS) every time a patient receives a vaccine.
  - Document the publication date of the VIS and the date the VIS was given in the patient's medical record.
- 
- You must give a current VIS (either paper or electronic) to the patient or their parent or legal representative before administering each dose of vaccine.
  - Current VISs are available on the Immunization Action Coalition (IAC) ([www.immunize.org/vis/](http://www.immunize.org/vis/)) website.
  - The IAC also offers the IAC Express ([www.immunize.org/subscribe/](http://www.immunize.org/subscribe/)), a weekly email that includes the latest vaccine recommendations and licensures, new and updated VISs, and practical vaccination resources.
  - You must document the publication date of the VIS, located on the bottom corner of each VIS, in the patient's medical record and the date the patient was given the VIS to review.
  - Let the patient, parent, or legal representative keep a paper copy of the VIS, or if they prefer to view the VIS on a tablet or mobile device, direct them to the CDC's Vaccine Information Statements ([www.cdc.gov/vaccines/hcp/vis/](http://www.cdc.gov/vaccines/hcp/vis/)) website during the visit and make sure they have a chance to have their questions answered. Give them a phone number to call in case of any questions or unexpected symptoms after receiving a vaccine.
  - When possible, provide the VIS in the person's native or preferred language. Translated VISs are also available from the IAC. You are encouraged to distribute the current English version at the same time as the translation.
  - You do not need to have the patient, parent, or legal representative sign anything to verify they have received the VIS, unless your site requires this.
  - It is acceptable to make a VIS available to be read before the immunization visit (e.g., by giving the patient or parent a copy to take home during a prior visit, or telling them how to download or view it on the Web). We encourage this when possible. These patients must still be offered a copy (it may be a laminated copy) to read during the immunization visit and a paper copy to take home.

## 4. Administer vaccines in accordance with recommended immunization schedules

Administer vaccines in accordance with immunization schedules, dosage, and contraindications that are established by the Advisory Committee on Immunization Practices (ACIP) and included in the MnVFC program unless:

1. In the provider's medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate, or
2. The particular requirements contradict state law, including laws pertaining to religious and other exemptions.

- MnVFC-enrolled sites must offer all of the ACIP-recommended vaccines that are appropriate for their patient population.
- The current ACIP recommended schedules are available on Immunization Schedules for Health Care Providers ([www.health.state.mn.us/divs/idepc/immunize/hcp/schedules.html](http://www.health.state.mn.us/divs/idepc/immunize/hcp/schedules.html)).
- Use the *Guide to Contraindications and Precautions to Commonly Used Vaccines on A Providers Guide to Immunizations in Minnesota: Screening and Assessing* ([www.health.state.mn.us/divs/idepc/immunize/hcp/provguide/screen.html#screen](http://www.health.state.mn.us/divs/idepc/immunize/hcp/provguide/screen.html#screen)).
- The state laws related to vaccination requirements and acceptable vaccine exemptions can found at Immunization Laws in Minnesota ([www.health.state.mn.us/divs/idepc/immunize/laws/index.html](http://www.health.state.mn.us/divs/idepc/immunize/laws/index.html)).

## 5. Report adverse events to the Vaccine Adverse Events Reporting System (VAERS)

Submit a report to VAERS if a patient has an adverse reaction after receiving a vaccine.

### Vaccine Adverse Event Reporting System (VAERS)

- The Vaccine Adverse Event Reporting System (VAERS) is a national vaccine safety surveillance program co-sponsored by the CDC and the Food and Drug Administration (FDA). It collects information about adverse events that occur after the administration of vaccines licensed for use in the United States.
- VAERS provides a way for adverse events following immunization to be reported, analyzed, and made available to the public.
- VAERS also provides a vehicle for disseminating vaccine safety-related information to parents and guardians, health care providers, vaccine manufacturers, state vaccine programs, and other constituencies.
- Adverse events are defined as health effects that occur after immunization that may or may not be related to the vaccine. By reporting an event, you are not saying that the vaccine caused the event.

### Reporting to VAERS

- The National Childhood Vaccine Injury Act (NCVIA) requires health care providers to report to VAERS:
  - Any adverse event listed by the vaccine manufacturer as a contraindication to further doses of vaccine; or
  - Any adverse event listed by the manufacturer in the VAERS Table of Reportable Events Following Vaccination that occurs within the specified time period after vaccination.
- Anyone is able to file a VAERS report, including health care providers, manufacturers, and vaccine recipients.
- Submit the form as soon as possible after an adverse event following vaccination. The back of the form has a pre-printed address and prepaid postage for mailing. You may also submit information by phone, by fax, or through the VAERS website.
- For more information or a copy of the form and help completing it, visit the VAERS website (<http://vaers.hhs.gov>) or call 800-822-7967.

## 6. Document immunizations in the medical record

Document required information in each patient's medical record for all doses of vaccine administered in accordance with the National Childhood Vaccine Injury Act.

- A patient's medical record must include:
  - Site/facility address where the vaccine was administered
  - Date vaccine was administered
  - Vaccine type
  - Vaccine manufacturer
  - Vaccine lot number
  - Signature and title of person(s) administering vaccine
  - Publication date of VIS (located at the bottom of VIS)
  - Date VIS was given to the patient, parent, or legal representative (usually the same as the vaccine administration date, but still needs to be documented)
- Best practice recommendations also include documenting the following information:
  - Dose
  - Site and route of injection
  - History of vaccine reaction, if the patient has experienced a clinically significant or unexpected event after an immunization (even if there is uncertainty that the vaccine caused the event)
  - Contraindications and precautions that may apply to this patient
  - Serologic test results related to vaccine-preventable diseases
- For combination vaccines, record the vaccine information in the spaces that correspond to each individual antigen in the combination product, indicating the combination type (for example, DTaP-IPV-Hep B) and the name of the combination vaccine (for example, Pediarix).
- You can order patient immunization record forms from the MnVFC program.
- You should give patients/parents a record of each immunization. Fill out an immunization record card (available from MDH) or, if your site is enrolled in the Minnesota Immunization Information Connection (MIIC), print out the MIIC immunization record. You may also be able to print the record from your electronic health record (EHR).
- MIIC cannot serve as the medical record.

## 7. Keep MnVFC program records for three years

Keep all records related to the MnVFC program for at least three years.

- The following MnVFC records must be kept for at least three years:
  - MnVFC eligibility screening information (forms or documentation in the electronic medical record)
  - Temperature logs
  - Certificate of calibration for each temperature monitoring device used including your backup thermometer
  - *Vaccine Storage Unit Troubleshooting Log* or other documentation about storage and handling incidents
  - *Minnesota Department of Health (MDH) Vaccine Transfer Record* forms
  - *Minnesota Department of Health (MDH) Nonviable Vaccine Form*, if you have used them
  - Packing lists of vaccine shipments
  - Monthly inventory log
  - *Vaccine Borrowing Report* or other borrowing documentation
  - *MnVFC Program Annual Report of the Number of Immunized Pediatric Patients*
  - *Minnesota Vaccines for Children (MnVFC) Program Provider Agreement*
  - Certificate of completion of the annual MnVFC online training
- Check your own site's policies about keeping records beyond three years.



# **How to Manage the MnVFC Program**



## 8. Have appropriate storage equipment

- Have and maintain appropriate vaccine refrigerator/freezer(s) to store vaccine.
- Safeguard the power supply to storage units.
- Use a temperature monitoring device that has a current and valid Certificate of Calibration to monitor temperatures in each storage unit.
- Place the temperature probe in the center of the storage unit with the vaccine.
- Have one backup thermometer with a current and valid Certificate of Calibration at each MnVFC site.

### Vaccine storage units

- If you are purchasing a new storage unit, it's strongly recommended that you purchase a commercial lab or pharmaceutical grade unit or stand-alone household unit.
- Storage units, in order of preference are:
  1. Lab or pharmaceutical grade unit (stand-alone or a combination unit with separate exterior doors and separate controls). Solid doors are preferred to glass doors since they maintain appropriate temperatures longer if a unit loses power.
    - Please note: "Medical grade" unit may only indicate that it can be plugged in near oxygen and has a lock on the door; not that it is necessarily appropriate for vaccine storage.
  2. Household stand-alone refrigerator and/or stand-alone freezer.
  3. Household combination refrigerator/freezer built within the last 10 years, with separate doors and separate temperature controls.
    - It is recommended that only the refrigerator portion of the unit be used for vaccine storage and a separate stand-alone freezer be used to store frozen vaccine.
    - Frost-free or automatic defrost cycle units are preferred.
- The use of dormitory or bar-style units (i.e., combination refrigerator/freezers with one exterior door) are not allowed for storing MnVFC vaccines.
- Must be able to maintain required vaccine storage temperatures:
  - Refrigerator 36°F through 46°F (2°C through 8°C), aim for 40°F (5°C).
  - Freezer -58°F through +5°F (-50°C through -15°C), aim for 0°F (-18°C).
- Must be large enough to hold the year's largest inventory, for example, the back-to-school rush or the flu season, based on how many doses of vaccines you order annually (see Volume-Based Storage Unit Recommendations on page 24).
- Must have sufficient room to store water bottles in the refrigerator and frozen water bottles in the freezer to stabilize the temperature. Likewise must have room for air to circulate so the proper temperature range is maintained.

Volume-Based Vaccine Storage Unit Recommendations		
Volume	Approximate doses/year	Recommended storage units
High	10,000 or more	<ul style="list-style-type: none"> <li>• Large capacity Lab or pharmaceutical grade refrigerator-only or freezer-only unit designed for optimum cooling capacity and stable temperature control.</li> </ul> 
Medium	2,000-10,000	<p>In order of preference, with the first being the best:</p> <ul style="list-style-type: none"> <li>• Lab or pharmaceutical grade refrigerator-only or freezer-only unit designed for optimum cooling capacity and stable temperature control.</li> <li>• Household refrigerator-only or freezer-only unit (can be an under-counter model).</li> </ul> 
Low	2,000 or less	<p>In order of preference, with the first being the best:</p> <ul style="list-style-type: none"> <li>• Smaller, under-counter version of a lab or pharmaceutical grade refrigerator-only or freezer-only unit.</li> <li>• Household refrigerator-only or freezer-only unit.</li> </ul> 

- Should be used only for vaccines or other medical supplies. Storage of food and beverage is not recommended in vaccine storage units. A limited supply of pedalyte or juice for patient use is acceptable.
- Sharing a storage unit with your lab is not recommended because of possible contamination of the vaccine and an increase in temperature fluctuations due to increased frequency of the door opening. If you must store vaccines in a unit that contains lab specimens, store the specimens on a shelf below the vaccines.
- Must be repaired or replaced immediately if there are mechanical problems.
- If you are moving or repairing your storage unit or purchasing a new storage unit, you must closely monitor the temperature for at least one week to ensure that the unit’s temperature has stabilized within the appropriate range. You may also be required to submit temperature logs to the MnVFC program.

## Safeguard the power supply

- The storage unit must be plugged directly into an electrical outlet. Do not use ground fault interrupter (GFI) outlets, extension cords, or power strips.
- Make sure the storage unit is plugged into an outlet where it can't be accidentally unplugged. An outlet that has an electrical plug with a safety lock is ideal. If your building has auxiliary power, use the outlet supplied by that system.
- You must label storage unit and electrical outlets with "Do Not Unplug" stickers. Order stickers for free with the *Immunization Materials for Professional Use* order form ([www.health.state.mn.us/divs/idepc/immunize/ordermat.html](http://www.health.state.mn.us/divs/idepc/immunize/ordermat.html)).
- Fuse box and/or circuit breakers for vaccine storage units must be labeled with "WARNING" stickers to prevent any disruption of the power to vaccine storage units. Order stickers for free with the *Immunization Materials for Professional Use* order form ([www.health.state.mn.us/divs/idepc/immunize/ordermat.html](http://www.health.state.mn.us/divs/idepc/immunize/ordermat.html)).
- In larger sites, we would encourage you to have a generator as a source of back-up power in case of an emergency. You may also want to consider installing a security system to alert appropriate personnel of a power outage.
  - If you have a back-up generator, it should be tested quarterly and receive annual maintenance.
- It is recommended that you have an alternate site with a generator to store your vaccine in case of a lengthy power outage or if your generator fails to work correctly.

## Temperature monitoring devices

- MnVFC providers must have a working calibrated temperature monitoring device with a current and valid Certificate of Calibration in each vaccine storage unit.
- Must have the temperature probe placed in the center of the storage unit with the vaccine.
- In a pharmaceutical unit, it is recommended to place the probe in a central location, but placement in other locations may be suitable because pharmaceutical units maintain more consistent temperatures throughout the unit.
- Should have a temperature probe encased in a vial of biosafe glycol that will measure liquid temperature.
- There are three categories of temperature monitoring devices: thermometers, data loggers, and continuous temperature monitoring systems. Additional information about these devices is available in the *MnVFC Guide to Temperature Monitoring Devices* on the MnVFC website ([www.health.state.mn.us/vfc](http://www.health.state.mn.us/vfc)).
  - Thermometers: An instrument used for measuring temperature. It may display the minimum and maximum temperatures registered, but it does not keep a detailed history.
  - Data loggers: A portable measurement instrument that can be programmed to record temperatures at preset intervals. They are capable of recording and storing thousands of temperature readings that can be retrieved, viewed, and evaluated. Since the temperature is regularly being recorded, a data logger is considered to be continuous temperature monitoring device.

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- Continuous temperature monitoring systems: A system that provides information on temperatures for multiple vaccine storage units throughout an individual site or system, recorded at preset intervals. If you are using a continuous temperature monitoring system you should have written procedures identifying:
  - Who is responsible for maintaining the system.
  - When and how the system is recalibrated.
  - Who responds to out-of-range temperatures (with a backup staff person identified).
  - Who is responsible for documenting the response and where is it documented.
  - A schedule for regularly reviewing temperature logs.
- It is recommended that MnVFC providers use a continuous temperature monitoring device (i.e., a data logger or a continuous temperature monitoring system). Sites that are routinely closed for more than two consecutive days are strongly encouraged to use continuous temperature monitoring devices.
  - MnVFC recommends continuous temperature monitoring devices with:
    - Digital display on outside of storage unit to allow reading temperatures without opening unit door
    - Detachable probe in a bottle filled with a thermal buffer, like biosafe glycol, which more closely reflects vaccine temperatures
    - Alarm to alert out- of- range temperatures
    - Accuracy within +/-1°F (+/- .5°C)
    - Low battery indicator
    - Continuous monitoring and recording capabilities to track and record temperatures over time preset by the user
    - Display of current, as well as minimum and maximum temperatures
- Temperature monitoring devices that are not recommended:
  - Bi-metal stem temperature monitoring devices
  - Food temperature monitoring devices
  - Household mercury temperature monitoring devices
  - Chart recorders
  - Infrared temperature monitoring devices
- **Please note:** You must continue to document the temperature of each vaccine storage unit twice a day with time, temperature and initials. The use of a continuous temperature monitoring device does not exclude you from this requirement.

### New requirement in 2018

Starting Jan. 1, 2018, MnVFC providers will be required to use a continuous temperature monitoring device (i.e., a data logger or a continuous temperature monitoring system) in storage units that hold MnVFC vaccine.

#### Required Features

- Continuous monitoring and recording capabilities to track and record temperatures over time.
- The capacity to routinely download temperature data to a computer (recommended at least weekly).
- Detachable probe in a bottle filled with a thermal buffer (e.g., bio-safe glycol).
- Active temperature display.

#### Recommended Features

- Alarm for out-of-range temperatures.
- Accuracy within +/-1°F (+/- 0.5°C).
- Low battery indicator.
- Display of current, minimum, and maximum temperatures.
- Memory storage of at least 4,000 readings.
- User programmable logging intervals (e.g., the user can set how often the device records the temperature).

For more information on temperature monitoring devices and calibration, see the *MnVFC Guide to Temperature Monitoring Devices* on the MnVFC website ([www.health.state.mn.us/vfc](http://www.health.state.mn.us/vfc)).

### Backup thermometers

- Must have one backup thermometer with a valid Certificate of Calibration that is not in use at each MnVFC site.
  - It must be available in case a thermometer in use is not working properly or current equipment requires calibration testing.
  - The Certificate of Calibration should have a different calibration date than the other thermometers at the site.

## Certificate of Calibration

- Calibration of temperature monitoring devices must be performed at a minimum of every two years from the last calibration testing date or more frequently if recommended by the manufacturer. All temperature monitoring devices will "drift" over time, and normal use can impact their accuracy. Therefore, all devices require recalibration. To be considered "valid," a Certificate of Calibration must have the following required elements:
  - Model and serial number
  - Date of calibration or a calibration report date
  - Whether the instrument passed or failed
  - Documented uncertainty (recommended uncertainty of +/- 1°F [0.5°C])
- Recommended element:
  - Recommended Uncertainty =  $\pm 0.5^{\circ} \text{C} / \pm 1.0^{\circ} \text{F}$
- To determine if a certificate of calibration testing was issued by an appropriate entity, check to see if the certificate indicates one or more of these items:
  - Conforms to ISO 17025.
  - Performed by an ILAC/MRA Signatory body accredited laboratory. You can review this list of the ILAC MRA and Signatories (<http://ilac.org/ilac-mra-and-signatories/>).
  - Traceable to the standards maintained by NIST.
  - Meets specifications and testing requirements for the American Society for Testing and Materials (ASTM) Standard E2877 tolerance Class F ( $\leq 0.5^{\circ} \text{C}$ ) or better.
  - Includes reference to another acceptable accuracy validation method, such as comparison to other traceable reference standards or tests at thermometric fixed points.
- Note: The CDC recommends that certifications be issued for the entire monitoring unit (detachable probe, data logger, etc.) and not individual certificates for each component.

## 9. Receive and store vaccine carefully

- Properly receive and store vaccine.
- Each day the site is open, check and record temperatures twice a day in all storage units used to store MnVFC vaccine at that site.
- Take immediate action on out-of-range temperatures.

### Receiving vaccine shipments

- A provider must be on site with appropriate staff available to receive vaccine shipments at least one day per week other than Monday.
- You must check the condition of all vaccines immediately when they arrive.
  - Open vaccine packages immediately.
  - Inspect the vaccine and packaging for damage.
  - Compare the vaccine received with the vaccine products that appear on the packing list. Report any discrepancies to the MnVFC program at 651-201-5522.
  - Immediately store at appropriate temperatures.
  - Check expiration dates and put vaccines with the earliest expiration date in front to be used first.
  - Check that the vaccine has remained in the correct temperature range.
    - Check the temperature monitor indicator in refrigerated vaccine shipments from McKesson. If the vaccine shipment is compromised in any way, the provider must contact McKesson Specialty Customer Care immediately at 1-877-TEMP123 (1-877-836-7123). It is critical that McKesson Specialty Customer Care be contacted within two hours of the vaccine arrival.
    - For shipments sent from Merck, use the date on the packing list to determine how long the vaccine was in transit. Merck will either send your vaccine in a small shipping container that is qualified for two days in transit, or a larger shipping container qualified for four days in transit. (See the shipping container insert to confirm approved number of days.) If vaccine has been in transit for longer than the approved number of days, or you have any concerns about the condition of the vaccine, call Merck immediately at 1-800-672-6372.
  - Document on your packing slips and/or inventory logs the date and time the shipment was received, packing material condition and temperature indicator status. Keep this documentation for at least three years.
  - If you receive vaccine with an expiration date of six months or less, call the MnVFC program for guidance.
  - MMRV and/or varicella must be shipped directly to all sites.

## Storing vaccine

- Packaging:
  - Vaccines should be kept in their original packaging to:
    - Protect them from light.
    - Help prevent medication errors by making labels easier to read.
    - Provide additional protection in case of an out-of-range temperature, power outage, door left open, or mechanical failure.
    - Simplify managing your vaccine inventory.
  - Open trays and baskets should be used to organize vaccines.
  - Each container should be clearly labeled with the vaccine type
  - MnVFC vaccine should be clearly separated from private vaccine.
  - Do not store “look-alike” and “sound-alike” vaccines next to each other (e.g., Tdap and DTaP, HepA and HepB and Hib).
- Storage unit:
  - Store vaccine with enough space for cold air circulation around it.
  - Store vaccine in the middle of the compartment, two to three inches away from walls, floor, and cold air vent. The temperature near the floor and walls of the unit differs from that in the middle of the compartment and the cold air vent can freeze refrigerated vaccines.
  - Do not store vaccine in the door or drawers of the refrigerator or freezer.
  - Vegetable bins and crisper drawers should be removed from refrigerators or use them for storing other medical supplies or water bottles.
  - If vaccine is stored in a household combination refrigerator/freezer:
    - The top shelf should not be used for storing vaccine because the cold air vent blowing from the freezer will freeze vaccine located there. If you must use the top shelf of this type of unit to store vaccine, place water bottles underneath the cold air vent to prevent vaccine from being stored there.
    - It is recommended that only the refrigerator be used for vaccine storage and a separate stand-alone freezer be used to store frozen vaccine.
  - Must not store food or beverages in the refrigerator or freezer because frequent opening of doors can lead to temperature variations that may affect vaccine viability. There is also a risk of contaminating vaccines.
- Water bottles:
  - Store water bottles in the doors, on the floor and near the cold air vent in the refrigerator and frozen water bottles in the freezer to help maintain a stable temperature if there is a power failure and when the door is opened frequently.
  - Too many water bottles in the door can prevent the door from closing tightly.
  - Mark water bottles “Do Not Drink.”

## **Monitoring temperatures twice a day**

- The temperature in each storage unit:
  - Must be checked and recorded twice a day every day the site is open by a staff person on site.
  - The date, time, and name or initials of the individual checking the temperatures must be recorded with each temperature reading.
- Check the temperature first thing in the morning and just before you leave and record it on a temperature log specific to the unit.
  - If you are recording the twice a day temperature checks in a continuous temperature monitoring system, you must be able to produce a report including the information above.
- Minimum and maximum temperatures should be checked and recorded for each storage unit at the beginning of the day.
  - The minimum temperature is the lowest temperature that your temperature monitoring device has read since you last reset your device. Similarly, the maximum temperature is the highest temperature that your temperature monitoring device has read since you last reset your device.
  - The minimum and maximum temperatures should be reset after recording them. Some data loggers automatically reset the minimum and maximum temperatures daily and this is acceptable.
- Take immediate action if there is an out of range temperature discovered during a temperature check or when checking the minimum and maximum temperatures.
- You must keep temperature logs for three years.
- At any time, the MnVFC program may ask you to send a copy of your temperature logs to check temperature control, or to assist in troubleshooting and diagnosing problems.
- If you fail to check and record temperatures twice a day, the MnVFC program will hold your vaccine orders until you can verify that the vaccine storage unit has stable temperatures and you are consistently recording temperatures twice a day.
- When monitoring temperatures, a physical inspection of the storage unit should also be performed. Inspect the following:
  - Thermometer probe is located in the center of the unit with the vaccine
  - Vaccines are in their original boxes
  - Vaccines are stored away from the walls or vents
  - No vaccine is stored in the door or in the drawers
  - The door of the unit is tightly closed

## Taking immediate action on out-of-range temperatures and mishaps

- Vaccine must be stored within the following temperature ranges:
  - Refrigerator 36°F through 46°F (2°C through 8°C), aim for 40°F (5°C).
  - Freezer -58°F through +5°F (-50°C through -15°C), aim for 0°F (-18°C).
- If you find an out-of-range temperature, take immediate action:
  - Determine and fix the cause, if possible. It might be easily corrected (e.g., door not shut, power outage, unit malfunction, etc.).
  - Adjust the thermostat, if necessary.
  - Monitor the temperature.
  - If the temperature doesn't stabilize in the correct range within 30 minutes:
    - Stop using the vaccine.
    - Move the vaccine to a storage unit that's maintaining the correct temperature.
    - Mark the vaccine "DO NOT USE" so it is not inadvertently administered.
    - Call the MnVFC program (651-201-5522) to report out-of-range temperature incidents.
    - Call the vaccine manufacturer and ask to speak to a medical consultant or quality assurance staff.
    - Be ready to share the lot numbers, expiration dates, temperature logs, the room temperature and the time the unit may have been out-of-range.
    - Document your actions. You can use the *Vaccine Troubleshooting Record* ([www.immunize.org/clinic/storage-handling.asp](http://www.immunize.org/clinic/storage-handling.asp)) or your own site's form to document out-of-range temperatures and actions taken. Keep these logs for three years.
  - When an out-of-range temperature mishap occurs, the MnVFC program may hold your vaccine orders until all issues are resolved.
  - All vaccine received through MnVFC that is wasted, nonviable, or lost must be reported to MDH. Wasted or expired vaccine in its original vial or pre-filled syringe must be returned to McKesson Distribution within six months of expiration.  
(See section 10.)

## Consequences of mishandling vaccine

- You may be required to replace lost vaccine doses, provide staff training, and/or review and revise your related policies if you:
  - Fail to ensure that vaccines are promptly stored when received,
  - Leave vaccine doses out overnight,
  - Leave the refrigerator/freezer door open overnight, or
  - Fail to follow appropriate procedures for transporting vaccine.
- If vaccine has been exposed to out-of-range temperatures due to staff negligence, you may be required to replace any nonviable doses from the MnVFC program.  
(See section 17.)
- If you must revaccinate patients because nonviable vaccine has been administered, you may be responsible for covering the cost of vaccine needed to revaccinate. The MnVFC program may not be able to supply the additional doses. (See section 17.)

- If storage and handling incidents occur due to negligence, your participation in the MnVFC program may be suspended. To re-establish your participation after being suspended, the MnVFC program may require any or all of the following:
  - Providing additional staff training.
  - Documenting your policies and procedures to prevent future problems.
  - Emailing or faxing temperature logs to the MnVFC program.

### **More detailed information about receiving and storing vaccine**

- MDH's *Vaccine Storage Guide*:  
[www.health.state.mn.us/divs/idepc/immunize/hcp/vaxhandling.html](http://www.health.state.mn.us/divs/idepc/immunize/hcp/vaxhandling.html)
- CDC's *Vaccine Storage and Handling Toolkit*:  
[www.cdc.gov/vaccines/recs/storage/toolkit/](http://www.cdc.gov/vaccines/recs/storage/toolkit/)

## 10. Manage MnVFC vaccine efficiently

- Take monthly vaccine inventory, order only the amount of vaccine you need, rotate stock and transfer vaccine that's nearing expiration to other sites to prevent wasting vaccine.
- Keep privately purchased vaccine separate from MnVFC vaccine.
- Avoid borrowing between your public and private vaccine stocks; however, if it is necessary, document why the vaccine was borrowed and the date it was replaced.
- Report all MnVFC vaccine that becomes nonviable or lost to MDH.
- Return all spoiled or expired vaccine in its original vial or pre-filled syringe to McKesson Distribution within six months of expiration.

### Managing inventory

- Physical inventory of your MnVFC vaccine should be done weekly and must be done at least monthly and before placing a vaccine order.
  - Record the number of doses, lot numbers and expiration dates.
- Rotate your vaccine stock.
  - Vaccine must be rotated when inventory is done.
  - Make sure that vaccine due to expire first is in front so it will be used first.
- Keep vaccine in the original packaging to make managing inventory easier.

### Order the amount of vaccine you actually need

- We recommend placing an order when you have a four week supply of vaccine remaining to ensure that you have enough vaccine to allow for any potential delays.
- It is also encouraged to place smaller, more frequent orders rather than large orders to minimize the amount of vaccine loss if an incident occurs during shipment or in the vaccine storage unit. While we recommend frequent orders, please do not order more frequently than once a month.
- There are two ways to order MnVFC vaccine ([www.health.state.mn.us/divs/idepc/immunize/vaxorder.html](http://www.health.state.mn.us/divs/idepc/immunize/vaxorder.html)).
  - MIIC: Order vaccine online through the Minnesota Immunization Information Connection (MIIC) ([www.health.state.mn.us/miic](http://www.health.state.mn.us/miic)).
    - If your site is not set up for ordering in MIIC, contact the MIIC Help Desk at [health.miichelp@state.mn.us](mailto:health.miichelp@state.mn.us).
  - Paper: Use the most current vaccine order form from the MnVFC website and follow the instructions on it.
- You must include current storage unit temperatures with each order.

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- You are also required to provide doses on hand, lot number, and expiration date of vaccine in stock with each MDH vaccine order.
  - If you are ordering through MIIC, you can print out the doses on hand page and bring it to your storage unit to collect your doses on hand information.

**Keep privately purchased vaccine separate from MnVFC vaccine**

- MnVFC vaccine must only be used for MnVFC eligible patients.
- Select the dose from the MnVFC supply when you see a patient who is eligible for MnVFC vaccine.
- Clearly mark the MnVFC boxes or vials or keep them in a clearly marked open tray or basket.

**Transferring vaccine**

- You must call the MnVFC program if you have vaccine that will expire within three months that you cannot use.
- To prevent wasting MnVFC vaccine, you are responsible for transferring any vaccine you will be unable to use to another MnVFC provider before it expires.
  - If you have frozen vaccines (MMRV and varicella) that will expire within three months that you cannot use, call the MnVFC program for guidance.
- Only full, sealed vials or unopened prefilled syringes can be redistributed.
- Once a site has been identified, call them to make sure they can use the vaccine, have space to store it, and someone will be there to receive it.
- Report all MnVFC vaccine that is transferred to another site using the *Minnesota Department of Health (MDH) Vaccine Transfer Record (Appendix C)* from MnVFC Forms ([www.health.state.mn.us/divs/idepc/immunize/mnvfc/forms.html](http://www.health.state.mn.us/divs/idepc/immunize/mnvfc/forms.html)).
- Keep one copy, enclose one copy with the vaccine, and send one copy to the MnVFC program.
  - Whether you are sending or receiving a vaccine transfer, you must keep your copy of the *Minnesota Department of Health (MDH) Vaccine Transfer Record* for three years.
- Follow CDC and manufacturer specifications for maintaining the recommended temperature range (36°-46°F or 2°-8°C) during transport of vaccine.
  - Guidance for packing and transporting vaccine is available in *Packing Vaccines for Transport during Emergencies* ([www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf](http://www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf)).
  - It is recommended that you use a continuous temperature monitoring device with a valid certificate of calibration.

Minnesota Department of Health (MDH) Vaccine Transfer Record				
<p><b>Don't let vaccine go to waste!</b> You must transfer MDH vaccine that will expire within three months that you cannot use to another provider where it can be used before it expires. Notify MDH of the transfer by completing and emailing <a href="mailto:health.mnvcfc@state.mn.us">health.mnvcfc@state.mn.us</a> or by faxing (651-201-5522) this form to an individual:</p> <ul style="list-style-type: none"> <li>Only full, sealed vial or unopened prefilled syringes can be redistributed.</li> <li>Once a MnVFC eligible site has been identified, call them to make sure they can store and use the vaccine and that someone will be there to receive it.</li> <li>Keep one copy of this form, enclose one copy with the vaccine, and send one copy to us via email (<a href="mailto:health.mnvcfc@state.mn.us">health.mnvcfc@state.mn.us</a>) or fax (651-201-5522).</li> <li>Whether you are sending or receiving a vaccine transfer, you must keep your copy for three years.</li> <li>Follow CDC and manufacturer specifications for maintaining the recommended temperature range during transport of vaccine.</li> <li>Guidance for packing and transporting vaccine is available in <a href="http://www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf">Packing Vaccines for Transport during Emergencies</a> (<a href="http://www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf">www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf</a>).</li> <li>If you have frozen vaccines (MMRV and varicella) that you cannot use, call MDH at 651-201-5522 for additional guidance.</li> </ul>				
Name and address of site SENDING vaccine:		MIIC #:	Signature/Title:	Date:
Name and address of site RECEIVING vaccine:		MIIC #:	Signature/Title:	Date:
Vaccine type:	MDCA *	Lot number**	Expiration date:	Number of doses:
Vaccine type:	MDCA *	Lot number**	Expiration date:	Number of doses:
Vaccine type:	MDCA *	Lot number**	Expiration date:	Number of doses:
Vaccine type:	MDCA *	Lot number**	Expiration date:	Number of doses:
Temperature during transport:		Condition of vaccine upon receipt:		
<p><small>* Listed on the box. For more information, contact the MnVFC program: 651-201-5522 or 1-800-645-3870 email <a href="mailto:health.mnvcfc@state.mn.us">health.mnvcfc@state.mn.us</a></small></p> <p><b>MDH Minnesota Department of Health</b></p> <p style="text-align: right;"><small>JUL 2016</small></p>				

## How to Manage the MnVFC Program

### Borrowing vaccine

- Borrowing occurs when a provider borrows vaccine from MnVFC stock to administer to a patient not eligible for the program, or when a provider borrows vaccine from private stock to use on MnVFC-eligible patients.
- This should be a rare, unplanned occurrence.
- Use the *Vaccine Borrowing Report* (Appendix D) to document every time MnVFC vaccine is borrowed to administer to a non-eligible patient or when private stock is used for a MnVFC-eligible child.
  - Document the vaccine type borrowed, the vaccine stock used, the patient's name and date of birth, the date the dose was administered, why the vaccine was borrowed, and the date the vaccine was replaced.
  - You will find the *Vaccine Borrowing Report* on MnVFC Forms ([www.health.state.mn.us/divs/idepc/immunize/mnvfc/forms.html](http://www.health.state.mn.us/divs/idepc/immunize/mnvfc/forms.html)).

Reason for Borrowing MnVFC Dose		Code	Reason for Borrowing Private Dose	Code
Private vaccine shipment delay (vaccine order placed on time/delay in shipping)	1		MnVFC vaccine shipment delay (order placed on time/delay in shipping)	8
Private vaccine not usable on arrival (vials broken, temperature monitor out of range)	2		MnVFC vaccine not usable on arrival (vials broken, temperature monitor out of range)	9
Manufacture of private vaccine between orders (not due to shipping delay)	3		Not out of MnVFC vaccine between orders (not due to shipping delay)	10
Short-dated private dose was exchanged with MnVFC dose	4		Short-dated MnVFC dose was exchanged with private dose	11
Accidental use of Private dose for MnVFC-eligible child	5		Accidental use of a MnVFC dose for a child not eligible for the MnVFC program	12
Replacement of Private dose with MnVFC when insurance plan did not	6		Other—Describe—	13/Other

### Management of nonviable vaccine

- There are two categories of nonviable vaccine: expired/spoiled and wasted.
- Expired or spoiled vaccine is nonviable vaccine in its original vial or syringe that can be returned. This includes:
  - Expired vaccine,
  - Vaccine that is recalled by the manufacturer, and
  - Vaccine that is nonviable due to exposure to out-of-range temperatures.
- Wasted vaccine is nonviable vaccine that is not able to be returned for excise tax credit. This includes:
  - Vaccine drawn into the syringe but not administered,
  - Vaccine in open vial but doses not administered, and
  - Compromised vial (e.g., due to a drop causing damage to vial integrity or sterility), broken vial, or lost vial.
- Please note that vaccines are exempted from The Joint Commission's rule indicating that unused prescription drugs in multi-dose vials should be discarded 28 days after opening or puncture. CDC states that vaccines are to be discarded per the manufacturer's expiration date.
- Remove any nonviable vaccine from your storage unit.
- Mark the vaccine 'Do Not Use' to avoid using it unintentionally.

## How to Manage the MnVFC Program

- Return expired or spoiled MnVFC vaccine to McKesson.
  - Complete the *Minnesota Department of Health (MDH) Nonviable Vaccine Form* (Appendix E) from MnVFC Forms ([www.health.state.mn.us/divs/idepc/immunize/mnvfc/forms.html](http://www.health.state.mn.us/divs/idepc/immunize/mnvfc/forms.html)). State the reason the vaccine is nonviable.
  - Fax or email the *Minnesota Department of Health (MDH) Nonviable Vaccine Form* to the MnVFC program at 651-201-5501 or [health.mnvfc@state.mn.us](mailto:health.mnvfc@state.mn.us).
  - Pack the vaccine to protect it from breaking and include the original *Minnesota Department of Health (MDH) Nonviable Vaccine Form* in the package. Refrigerated gel packs are not necessary.
  - Keep a copy of the *Minnesota Department of Health (MDH) Nonviable Vaccine Form* for three years.
- Expired vaccine should be returned within six months of the expiration date.
- Certain nonviable vaccines should be reported to MDH but not returned to McKesson Specialty Distribution. Follow your internal procedure for disposing of the following types of nonviable vaccines:
  - Syringes drawn up but not used,
  - Any syringes from administered vaccines with or without needles attached,
  - Broken vials,
  - Any multidose vial from which some doses have already been withdrawn, or
  - Any doses that are more than six months past the expiration date.

**Minnesota Department of Health (MDH) Nonviable Vaccine Form**

After you have determined what vaccine is nonviable, remove the vaccine from the storage unit and mark it "nonviable" to avoid unintentional use.

Complete this form making sure to:

- State the reason vaccine is nonviable - see nonviable vaccine code reason\*.
- Make a copy of the completed form for your records.
- Include the original form with the vaccine to be returned and pack the vaccine to protect it from breakage, and
- Send a copy of this form to MDH or email [SpecialtyDistribution@hs.state.mn.us](mailto:SpecialtyDistribution@hs.state.mn.us).

MDH will contact McKesson Specialty Distribution to coordinate a UPS pickup within one to two weeks. No refrigerated gel packs needed.

All vaccine received through MDH that becomes nonviable (i.e., spoiled or expired or lost) must be reported to MDH.

Spoiled or expired product in its original vial or pre-filled syringe must be returned to McKesson Specialty Distribution within six months of expiration. Do not return any vaccine, including infusions, prior to the expiration date.

Patient name:		Date:		MDH ID#:	
Vaccine:		Expiry date:		MDH ID# of the vaccine:	
Lot number:		Lot number:		MDH ID# of the vaccine:	
Vaccine type:		Lot number:		MDH ID# of the vaccine:	
NDC:		Lot number:		MDH ID# of the vaccine:	
Expiration date:		Lot number:		MDH ID# of the vaccine:	
Number of doses:		Lot number:		MDH ID# of the vaccine:	
Nonviable vaccine code reason*:		Lot number:		MDH ID# of the vaccine:	

**Items to be disposed of at your site**  
Report these items to MDH and properly dispose of them at your site (no pick up will be scheduled):

- syringes drawn up but not used,
- any used syringes with or without needles attached,
- any multidose vial from which some doses have already been withdrawn, or
- any doses that are more than six months past expiration date.

**Nonviable vaccine code reason:**

1. Expired vaccine
2. Failure to store properly upon receipt
3. Temperature failure
4. Natural disaster/power outage
5. Recall
6. Storage unit too cold
7. Storage unit too warm
8. Vaccine spoiled in transit (freezer/warm)
9. Spoiled - other
10. Other - please state reason

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## Consequences of failing to manage vaccine efficiently

- You may be required to replace lost vaccine doses, provide staff training, and/or review and revise your related policies if you fail to manage your vaccine appropriately.
- If vaccine becomes nonviable due to staff negligence, you may be required to replace any nonviable doses from the MnVFC program. (See section 17.)
- If you must revaccinate patients because nonviable vaccine has been administered, you may be responsible for covering the cost of vaccine needed to revaccinate. The MnVFC program may not be able to supply the additional doses. (See section 17.)
- If vaccine becomes nonviable due to negligence, your participation in the MnVFC program may be suspended. To re-establish your participation after being suspended, the MnVFC program may require any or all of the following:
  - Provide additional staff training.
  - Document your policies and procedures to prevent future problems.

## 11. Post an anaphylaxis protocol

- Be prepared to respond to an emergency related to vaccine administration.
  - Develop and clearly post an anaphylaxis protocol.
  - Ensure staff is properly trained on your anaphylaxis protocol so that you are prepared to respond to an emergency related to vaccine administration.
- 
- An anaphylaxis protocol must be clearly posted in the area where vaccines are administered. For an example of a protocol, see *Medical Management of Vaccine Reactions in Children and Teens* (Appendix F) and *Medical Management of Vaccine Reactions in Adult Patients* (Appendix G) by the Immunization Action Coalition.
  - The protocol should be reviewed annually and signed and dated by your medical provider.
  - All staff who administer vaccines should maintain current emergency response skills:
    - Review the protocol with all staff that administer vaccine and care for patients who receive vaccine – both when you hire them and each year after that.
    - All staff who administer vaccines should be trained on how to respond to anaphylaxis and be currently certified in cardiopulmonary resuscitation (CPR).
  - Emergency supplies must be readily available where vaccines are administered. Assign a staff member to check that emergency supplies have not expired on a monthly basis and to replenish supplies after an anaphylaxis event has occurred.
  - Assign a staff member to submit a report to VAERS (<http://vaers.hhs.gov>) in the event of an adverse reaction following vaccine administration. (See section 5.)

**How to be Accountable  
in the MnVFC Program**



## 12. Assign an immunization manager and a vaccine coordinator

- Designate an immunization manager and backup to oversee site administrative immunization activities.
- Designate a vaccine coordinator and backup to oversee ordering and vaccine management activities.
- Notify the MnVFC program at [health.mnvfc@state.mn.us](mailto:health.mnvfc@state.mn.us) if the immunization manager or vaccine coordinator changes.
- Have written immunization staff responsibilities. (This manual can fulfill this requirement if staff read the entire manual and sign page 6.)
- The immunization manager, vaccine coordinator, and backups must complete the MnVFC Separate Stock Online Training.

### Assign an immunization manager, vaccine coordinator and backups

- Assign staff to the roles of immunization manager, vaccine coordinator, and backups. Train them on the required activities list below. Note: The immunization manager and vaccine coordinator may be the same person in a small practice as long as there is a backup for them.
- Email the MnVFC program at [health.mnvfc@state.mn.us](mailto:health.mnvfc@state.mn.us) if the immunization manager or vaccine coordinator changes.

### Immunization manager (and backup) must:

- Be the point person for immunization-related activities in each site that administers vaccine to patients.
- Communicate with the MnVFC program. (This person will receive regular communications from the MnVFC program by mail, phone, email, and fax. They will need to share some of it with other staff.)
- Sign up to receive MnVFC Announcements ([www.health.state.mn.us/divs/idepc/immunize/mnvfc/bfax.html](http://www.health.state.mn.us/divs/idepc/immunize/mnvfc/bfax.html)) via email. Click on the envelope near the top of the page.
- Sign up for *Got Your Shots? News* ([www.health.state.mn.us/divs/idepc/newsletters/gys/index.html](http://www.health.state.mn.us/divs/idepc/newsletters/gys/index.html)) and the *IAC Express* ([www.immunize.org/subscribe/](http://www.immunize.org/subscribe/)).
- Train other staff that have vaccine-related responsibilities (for example, the front desk staff who receives immunization shipments and providers giving immunizations), and keep a log to document attendance.
- Develop policies and procedures related to immunizations. This manual can fulfill this requirement if your staff read the entire manual, sign page 6, and complete the emergency plan and attach an anaphylaxis protocol to the manual. (See page 3 for more information.)
- Review temperature logs weekly.
- Complete the MnVFC Separate Stock Online Training ([www.health.state.mn.us/vfc](http://www.health.state.mn.us/vfc)). See page 43 for more information.

**Vaccine coordinator (and backup) must:**

- Sign up to receive MnVFC Announcements ([www.health.state.mn.us/divs/idepc/immunize/mnvfc/bfax.html](http://www.health.state.mn.us/divs/idepc/immunize/mnvfc/bfax.html)) via email. Click on the envelope near the top of the page.
- Sign up for *Got Your Shots? News* ([www.health.state.mn.us/divs/idepc/newsletters/gys/index.html](http://www.health.state.mn.us/divs/idepc/newsletters/gys/index.html)) and the *IAC Express* ([www.immunize.org/subscribe/](http://www.immunize.org/subscribe/)).
- Make sure vaccines are ordered, received, stored, and handled properly.
- Document or designate other staff to document the temperature in each storage unit twice daily.
- Conduct inventory of vaccines at least monthly and with each order.
- Keep a file of vaccine inventory logs and packing slips.
- Keep a list of names and phone numbers of key contacts like the generator repair company and packing materials suppliers.
- Assist in developing and updating policies and procedures related to vaccine management.
- Complete the MnVFC Separate Stock Online Training ([www.health.state.mn.us/vfc](http://www.health.state.mn.us/vfc)). See page 43 for more information.

## 13. Follow up on feedback you receive from site visits

- Receive a MnVFC site visit every one to two years to ensure that you are meeting MnVFC program requirements.
- Follow up on improvement or corrective plans you receive as a result of the MnVFC site visit.
- Cooperate with MnVFC and IPI staff performing an unscheduled storage and handling site visit if your site is selected to be visited.

### MnVFC site visits

- You will receive a site visit by an MDH or local public health staff person, called an Immunization Practice Improvement (IPI) advisor, at least once every two years.
- They offer you support and guidance and ensure you are meeting the federal and state MnVFC requirements listed in this manual.
- Site visits take approximately two hours.
- The IPI advisor will:
  - Contact you in advance of each visit.
  - Encourage you to invite other staff members who could contribute to the visit.
  - Bring resource materials to the visit.
  - Discuss your site's immunization strengths and make recommendations to enhance your immunization practices and support MnVFC program requirements.
  - Provide you with a site visit summary.
- If your site is not meeting a specific program requirement, they will work with you to develop a corrective action plan that you will need to follow within a specified time frame, usually 30 days.
- You may receive a follow-up phone call, email, letter, or an additional site visit, depending on your needs.
- You may also call on IPI advisors and MnVFC staff for in-service training, guidance in developing policies and procedures, and troubleshooting vaccine-related concerns.

### Unscheduled site visits

- The MnVFC program is required by CDC to perform unscheduled storage and handling visits to serve as "spot checks" for proper storage and handling practices.
- These visits ensure all VFC-eligible children are receiving properly managed, viable vaccines and provide education about requirements and best practices related to storage and handling.

**Consequences of not meeting MnVFC requirements**

- If you fail to take action to meet corrective-plan objectives, the MnVFC program may suspend your participation in the program. However, to avoid that, the MnVFC staff will work with you to develop a plan to meet the requirement.
- Not meeting MnVFC program requirements could be considered fraud or abuse. (See section 16).

## 14. Renew your enrollment in MnVFC each year

- Each MnVFC site must annually complete and sign a *MnVFC Program Provider Agreement* form and submit it to the MnVFC program by Nov. 30.
- The site's immunization manager, vaccine coordinator, and backups must complete MnVFC online training annually by Nov. 30.

### Renew your enrollment in MnVFC each year

- Each site that stores and/or administers MnVFC vaccine must be enrolled in the MnVFC program and have its own personal identification number (PIN).
- Each site must renew their enrollment in the MnVFC program annually by submitting a signed *MnVFC Program Provider Agreement* and completing the annual online training.

### Submit the *MnVFC Program Provider Agreement*

- Complete and sign the *MnVFC Program Provider Agreement*, including the list of additional providers in your practice, and have your medical director sign it.
- If you fail to submit the *MnVFC Program Provider Agreement* by Nov. 30, the MnVFC program will hold your vaccine orders until you submit it.
- Each site with a PIN number must have a signed *MnVFC Program Provider Agreement*.
- Each year the site must indicate the immunization manager, vaccine coordinator, and backups have completed the MnVFC online training by checking the appropriate box on the *MnVFC Program Provider Agreement*.
- The *MnVFC Program Provider Agreement* is available on MnVFC Forms ([www.health.state.mn.us/divs/idepc/immunize/mnvfc/forms.html](http://www.health.state.mn.us/divs/idepc/immunize/mnvfc/forms.html)).

### Complete the MnVFC Separate Stock Online Training

- Your site's immunization manager, vaccine coordinator, and backups must complete the MnVFC Separate Stock Online Training each year by Nov. 30. This training highlights the MnVFC program requirements and storage and handling best practices.
- After completing the training, print the completion certificate and keep it with your MnVFC documents for three years.
- The MnVFC Separate Stock Online Training is available on the MnVFC website ([www.health.state.mn.us/vfc](http://www.health.state.mn.us/vfc)).

## 15. Submit an annual report

Submit an annual report.

### Annual report of immunized pediatric patients

- Complete the *Minnesota Vaccines for Children (MnVFC) Program Annual Report of the Number of Immunized Pediatric Patients* found on the MnVFC Forms ([www.health.state.mn.us/divs/idepc/immunize/mnvfc/forms.html](http://www.health.state.mn.us/divs/idepc/immunize/mnvfc/forms.html)) page, and send it to the MnVFC program by Nov. 30. This report is an unduplicated count of all patients 0 through 18 years of age that received an immunization between Oct. 1 and Sept. 30.
- Count each patient only once for the entire year. For example, an infant may receive multiple immunizations during several visits his/her first year of life. This infant would be counted only once on this report.
- Sites that track immunizations with dose-level eligibility (DLE) information in MIIC can use the MnVFC Reports in MIIC feature to produce data for this report. For more information see the MnVFC Reports in MIIC user guidance on Vaccine Ordering and Management in MIIC ([www.health.state.mn.us/divs/idepc/immunize/registry/hp/ordering.html](http://www.health.state.mn.us/divs/idepc/immunize/registry/hp/ordering.html)).
- If you do not submit the *MnVFC Annual Report of Immunized Pediatric Patients* by Nov. 30, the MnVFC program will hold your vaccine orders until you submit it.

## 16. Avoid fraud and abuse

- Take responsibility for being aware of and following MnVFC requirements.
- Call the MnVFC program if you have questions about MnVFC requirements, policies and procedures.
- Cooperate with any investigation/inquiry related to potential fraud and/or abuse of the MnVFC program and any follow-up requirements, such as additional staff training.

### Potential fraud and abuse

- Fraud is an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person.
- Abuse is provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicaid program, or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care.
- Report fraud and abuse to the MnVFC program by calling 651-201-5522 or emailing [health.mnvfc@state.mn.us](mailto:health.mnvfc@state.mn.us).
- All instances of possible fraud and abuse will be investigated on a case-by-case basis.
- If you have not met MnVFC requirements or followed MnVFC procedures as outlined in this manual, but the MnVFC program finds no intentional deception, misrepresentation, or negligence on your part, you may be required to participate in training and/or to take other actions to rectify the situation.
- If the MnVFC program finds evidence of intentional deception, misrepresentation, or negligence on your part, the situation will be further investigated for potential enforcement of relevant laws including fraud and abuse, consumer protection, and professional licensure.
- Examples of potential fraud and/or abuse:
  - Providing MnVFC vaccine to non-eligible patients
  - Selling or otherwise misdirecting MnVFC vaccine
  - Billing a patient or third party for MnVFC vaccine
  - Charging more than the maximum allowable charge for administration of a MnVFC vaccine
  - Not providing MnVFC vaccine to an eligible patient because they are unable to pay the administration fee
  - Failing to screen and document patients for MnVFC eligibility at every visit
  - Failing to maintain MnVFC records
  - Failing to fully account for MnVFC vaccine
  - Failing to properly store and handle MnVFC vaccine
  - Wasting MnVFC vaccine
  - Over ordering vaccine
  - Failing to implement requirements of the program

## 17. Replace MnVFC vaccine wasted due to negligence

- MnVFC vaccine that has been wasted due to negligence must be replaced on a dose for dose basis with privately purchased vaccine. If nonviable vaccine was administered, you may also be required to purchase vaccine to revaccinate patients.

### Replacing wasted MnVFC vaccine

- The MnVFC program will review all instances of spoiled or expired MnVFC vaccine on a case-by-case basis. This review will help determine whether negligence was involved. Negligent waste of vaccine may be considered fraud or abuse of the MnVFC program.
- If negligence is found and restitution is necessary, the MnVFC program will send you a letter informing you of the number of doses of each vaccine that must be replaced on a dose for dose basis with privately purchased vaccine.
- You must replace vaccine upon receipt of the letter. The MnVFC program will stop supplying you with vaccine until all of the nonviable vaccine is replaced.
- Providers must submit receipt of purchase to the MnVFC program within 90 days demonstrating that all doses were replaced appropriately.
- You may file an appeal with the MnVFC program by mail or fax if you believe you can offer proof that the waste of vaccine was not due to negligence.
  - Use the *MDH Vaccine Restitution Appeal Form* ([www.health.state.mn.us/vfc](http://www.health.state.mn.us/vfc)), or include the same information contained on the form.
  - The appeal must be signed by your medical director or by your local health director if you are a public health department.
- Examples of situations that may require restitution:
  - Failure to rotate or transfer vaccine that results in expired vaccine
  - Drawing up vaccine before screening patients
  - Not receiving or storing vaccine properly
  - Leaving a refrigerator or freezer unplugged or an electrical breaker switched off
  - Leaving a refrigerator or freezer door open or ajar
  - Not repairing or replacing a broken refrigerator/freezer immediately
- Examples of situations that do not require restitution because they are out of your control:
  - A shipment is not delivered to you on time or is damaged in transit
  - You are unable to take action during a power outage
  - A vial is accidentally dropped or broken
  - Vaccine drawn after screening for contraindications and parental education, but not administered due to parental refusal or a change in the physician orders

**Contacts  
and  
Resources**



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*Contacts and Resources***Phone/Email/Fax**

**CDC Immunization Information Contact Center**, for general immunization and vaccine questions:

- 800-232-4636 (English and Spanish)
- 800-232-6348 (TTY)

**MnVFC Program**

- Phone: 651-201-5522
- Email: [health.mnvfc@state.mn.us](mailto:health.mnvfc@state.mn.us)
- Fax: 651-201-5501

**MDH Immunization Program**, for Minnesota-specific questions, including MnVFC, Minnesota Immunization Information Connection (MIIC), Minnesota School Law, and to order immunization materials:

- Toll free phone: 800-657-3970
- Metro: 651-201-5503
- Fax: 651-201-5501

**Web**

- MDH MnVFC home page. Includes MnVFC overview, forms used by MnVFC providers, and an archive of update notices sent to MnVFC providers.  
[www.health.state.mn.us/vfc](http://www.health.state.mn.us/vfc)
- MDH immunization home page. Contains links to other pages listed below.  
[www.health.state.mn.us/immunize](http://www.health.state.mn.us/immunize)
- MDH *Got Your Shots? A Providers Guide to Immunization in Minnesota* has all the information needed to make sure patients are properly immunized and vaccine is stored correctly.  
[www.health.state.mn.us/divs/idepc/immunize/hcp/provguide/index.html](http://www.health.state.mn.us/divs/idepc/immunize/hcp/provguide/index.html)
- Manufacturer phone numbers from the Immunization Action Coalition's Vaccine Policy and Licensure web pages at [www.immunize.org/fda](http://www.immunize.org/fda).
- MDH immunization information for health care providers.  
[www.health.state.mn.us/divs/idepc/immunize/hcp/index.html](http://www.health.state.mn.us/divs/idepc/immunize/hcp/index.html)
- MDH Minnesota Immunization Information Connection (MIIC) registry.  
[www.health.state.mn.us/divs/idepc/immunize/registry/index.html](http://www.health.state.mn.us/divs/idepc/immunize/registry/index.html)
- Immunization Action Coalition. Non-profit agency that provides CDC-approved resource materials, including: Vaccine Information Statements (VIS's) in 32 languages, screening questionnaires, newsletter for health professionals, anaphylaxis standing orders. 651-647-9009. [www.immunize.org](http://www.immunize.org)
- CDC National Center for Immunization and Respiratory Diseases. Includes links to VFC program, vaccine safety information, resource materials for parents and health professionals, and information on the National Childhood Vaccine Injury Act. [www.cdc.gov/vaccines](http://www.cdc.gov/vaccines)
- CDC Vaccine Storage and Handling. Online training videos and resource materials including checklists, logs, records, and posters. [www.cdc.gov/vaccines/recs/storage](http://www.cdc.gov/vaccines/recs/storage)
- VAERS reporting information. Report online or download the report form.  
<http://vaers.hhs.gov>; phone 800-822-7967; toll-free fax 1-877-721-0366.



# Appendices

- A. *Immunization Billing Guidance for MnVFC*, Minnesota Department of Health  
[www.health.state.mn.us/divs/idepc/immunize/mnvfc/billingtips.pdf](http://www.health.state.mn.us/divs/idepc/immunize/mnvfc/billingtips.pdf)
- B. *Emergency Response Worksheet*, Immunization Action Coalition  
[www.immunize.org/catg.d/p3051.pdf](http://www.immunize.org/catg.d/p3051.pdf)
- C. *Minnesota Department of Health (MDH) Vaccine Transfer Record*  
[www.health.state.mn.us/divs/idepc/immunize/mnvfc/transfer.pdf](http://www.health.state.mn.us/divs/idepc/immunize/mnvfc/transfer.pdf)
- D. *Vaccine Borrowing Report*, Centers for Disease Control and Prevention  
[www.health.state.mn.us/divs/idepc/immunize/mnvfc/vfcborrowrpt.pdf](http://www.health.state.mn.us/divs/idepc/immunize/mnvfc/vfcborrowrpt.pdf)
- E. *Minnesota Department of Health (MDH) Nonviable Vaccine Form*  
[www.health.state.mn.us/divs/idepc/immunize/mnvfc/vfcret.pdf](http://www.health.state.mn.us/divs/idepc/immunize/mnvfc/vfcret.pdf)
- F. *Medical Management of Vaccine Reactions in Children and Teens*, Immunization Action Coalition  
[www.immunize.org/catg.d/p3082a.pdf](http://www.immunize.org/catg.d/p3082a.pdf)
- G. *Medical Management of Vaccine Reactions in Adult Patients*, Immunization Action Coalition  
[www.immunize.org/catg.d/p3082.pdf](http://www.immunize.org/catg.d/p3082.pdf)



## Immunization Billing Guidance for MnVFC

This document provides guidance for your site's billing office if they get calls from patients who have questions about the MnVFC program or who request that their bill be adjusted.

### 1: Charge only allowable fees for MnVFC.

There are three costs that may be associated with each immunization. The cost of the vaccine, administering the vaccine, and the office visit. MnVFC vaccine is provided to your site at no charge. You cannot bill a Minnesota Health Care Program (MHCP) or charge the patient for the cost of this vaccine. The program caps the administration fee you may charge MnVFC-eligible patients at \$21.22 per dose (not per vaccine antigen) for MnVFC vaccine. This fee limit is set by federal law. You may also charge for the office visit.

Permissible MnVFC Vaccine Administration Fees and Charges			
Patient's status	MnVFC eligible?	Cost of vaccine	Administration fee
Minnesota Health Care Program (MHCP)	Yes	<ul style="list-style-type: none"> <li>Use MnVFC vaccine.</li> <li>Don't bill or charge for the cost of the vaccine.</li> </ul>	<ul style="list-style-type: none"> <li>Bill the MHCP \$21.22 per dose.</li> <li>Certain sites including FQHC, RHC, IHS and tribal clinics may bill an encounter fee for the entire visit and this is allowable.</li> </ul>
Uninsured	Yes	<ul style="list-style-type: none"> <li>Use MnVFC vaccine.</li> <li>Don't charge for the cost of the vaccine.</li> </ul>	<ul style="list-style-type: none"> <li>Charge the patient \$21.22 or less per dose.</li> </ul>
American Indian/Alaska Native	Yes	<ul style="list-style-type: none"> <li>May use MnVFC vaccine.</li> <li>Don't bill or charge for the cost of the vaccine.</li> <li>However, if the patient is privately insured and prefers to use insurance, use private vaccine and bill the insurance.</li> </ul>	<ul style="list-style-type: none"> <li>If covered by an MHCP, bill the MHCP \$21.22 per dose.</li> <li>If un- or underinsured, charge the patient \$21.22 or less per dose.</li> <li>If privately insured and prefers to use insurance, bill the insurance for the fee.</li> </ul>
Underinsured	Only at local public health (LPH), Federally Qualified Health Centers (FQHC), Rural Health Centers (RHC), Indian Health Services (IHS), and tribal clinics:		
	Yes	<ul style="list-style-type: none"> <li>Use MnVFC vaccine.</li> <li>Don't charge for the cost of the vaccine.</li> </ul>	<ul style="list-style-type: none"> <li>Charge the patient \$21.22 or less per dose.</li> </ul>
	At a site that is not eligible to see underinsured children:		
	No	<ul style="list-style-type: none"> <li>Consider sending the patient to a site where they would be eligible for MnVFC.</li> <li>If the patient stays at a private site, do not use MnVFC vaccine.</li> </ul>	<ul style="list-style-type: none"> <li>Consider sending the patient to a site where they would be eligible for MnVFC.</li> </ul>
Insured	No	<ul style="list-style-type: none"> <li>Use private vaccine</li> <li>Bill the insurance</li> </ul>	<ul style="list-style-type: none"> <li>Bill the usual and customary administration fee to the insurance</li> </ul>

## IMMUNIZATION BILLING GUIDANCE FOR MNVFC

To be reimbursed for the administration fee for patients enrolled in an MHCP, you must follow the billing procedures of each program. MHCP programs include Medical Assistance (MA) and MinnesotaCare. For billing questions, call the Minnesota Department of Human Services (DHS) at 651-431-2700.

### **2: Be prepared to respond to questions about MnVFC eligibility.**

Your site screens patients to find out if they are eligible for the MnVFC program before giving them immunizations and keeps that screening information on file. For up-to-date details on eligibility, see the [MnVFC Patient Eligibility Screening Record \(www.health.state.mn.us/vfc\)](http://www.health.state.mn.us/vfc) forms. Click on MnVFC Forms and select the form for your site type.

The MnVFC program has a self-screening form for children that parents can fill out called *Can my child get free or low-cost shots?* You might find it a useful reference as well.

### **3: Waive the administration fee if a patient is unable to pay it.**

MnVFC-eligible patients may not be denied vaccine for failure to pay an administration fee. You may charge a patient for the administration fee, but if they are unable to pay this fee it should be removed from their bill. Do not send these bills to collections.

### **4: Enter the correct CPT code for each vaccine.**

This not only affects the patient's bill but also their immunization record in the statewide immunization registry (called the Minnesota Immunization Information Connection, or MIIC), which is often derived directly from billing data. Add the SL modifier to the CPT code when billing for MnVFC-eligible children.

### **5: Information for complex billing questions for MnVFC-eligible patients:**

1. Call the number on the back of the health care plan card.
2. For billing questions about MHCP program, call the DHS provider helpdesk at 651-431-2700.
3. For questions about the MnVFC program, call: 651-201-5522 or 1-800-657-3970 or see [Immunization Program Billing \(www.health.state.mn.us/divs/idepc/immunize/billing/index.html\)](http://www.health.state.mn.us/divs/idepc/immunize/billing/index.html).

Minnesota Vaccines for Children (MnVFC) Program  
PO Box 64975  
St. Paul, MN 55167-0975  
651-201-5522 or 1-800-657-3970  
[health.mnvfc@state.mn.us](mailto:health.mnvfc@state.mn.us)  
[www.health.state.mn.us/vfc](http://www.health.state.mn.us/vfc)

To obtain this information in a different format, call: 651-201-5414.

## Emergency Response Worksheet

### What to do in case of a power failure or other event that results in vaccine storage outside of the recommended temperature range

**Follow these procedures:**

1. Close the door tightly.
2. Ensure the vaccine is kept at appropriate temperatures. Make sure the refrigerator or freezer is plugged in and working properly, or move the vaccines into proper storage conditions as quickly as possible.
3. Do NOT discard the affected vaccines unless directed to by your state/local health department and/or the manufacturer(s). Label the vaccines "Do Not Use" so that the potentially compromised vaccines can be easily identified.
4. Notify the state/local health department or call the manufacturer (see manufacturers' phone numbers below).
5. Document the inventory of affected vaccines below and document the circumstances of the event and the actions taken on the *Vaccine Storage Troubleshooting Record* (see [www.immunize.org/catg.d/p3041.pdf](http://www.immunize.org/catg.d/p3041.pdf)).

#### Vaccines Stored in Refrigerator

Vaccine	Manufacturer	Lot #	Expiration Date	# of Doses (i.e., <i>not</i> # of vials)

#### Vaccines Stored in Freezer

Vaccine	Manufacturer	Lot #	Expiration Date	# of Doses (i.e., <i>not</i> # of vials)

**Important Contact Information:**

**Vaccine Manufacturers**

- |   |   |                                       |
|---|---|---------------------------------------|
| CruceII Vaccine Inc. ★1 (800) 533-5899  | GlaxoSmithKline (888) 825-5249          | Novartis Vaccines (800) 244-7668      |
| CSL Biotherapies, Inc. (refer to Merck) | InterceII Biome dicaI ★3 (301) 556-4500 | Pfizer Inc. (800) 438-1985            |
| Emergent BioSolutions ★2 (877) 246-8472 | MedImmune, Inc. (877) 633-4411          | Protein Sciences Corp. (800) 488-7099 |
|   | Merck & Co., Inc. ● (800) 672-6372      | sanofi pasteur (800) 822-2463         |

★Manufacturer for less commonly used vaccine:

1. typhoid
2. anthrax
3. Japanese encephalitis

●Questions on Afluria (CSL Biotherapies, Inc.) should be directed to Merck & Co., Inc.

**Health Departments**

Local Health Department phone \_\_\_\_\_ State Health Department phone \_\_\_\_\_

Adapted by the Immunization Action Coalition, courtesy of the Michigan Department of Community Health

Technical content reviewed by the Centers for Disease Control and Prevention



# Minnesota Department of Health (MDH) Vaccine Transfer Record

**Don't let vaccine go to waste!** You must transfer MDH vaccine that will expire within three months that you cannot use to another provider where it can be used before it expires. Notify MDH of the transfer by completing and emailing ([health.mnvfc@state.mn.us](mailto:health.mnvfc@state.mn.us)) or faxing (651-201-5501) this form to us.

**Instructions:**

- Only full, sealed vials or unopened prefilled syringes can be redistributed.
- Once a MnVFC-enrolled site has been identified, call them to make sure they can store and use the vaccine and that someone will be there to receive it.
- Keep one copy of this form, enclose one copy with the vaccine, and send one copy to us via email ([health.mnvfc@state.mn.us](mailto:health.mnvfc@state.mn.us)) or fax (651-201-5501).
- Whether you are sending or receiving a vaccine transfer, you must keep your copy for three years.
- Follow CDC and manufacturer specifications for maintaining the recommended temperature range during transport of vaccine.
- Guidance for packing and transporting vaccine is available in [Packing Vaccines for Transport during Emergencies](#) ([www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf](http://www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf)).
- If you have frozen vaccines (MMRV and varicella) that you cannot use, call MDH at 651-201-5522 for additional guidance.

<b>Name and address of site SENDING vaccine:</b>		MnVFC PIN:	Signature/Title:	Date:
<b>Name and address of site RECEIVING vaccine:</b>		MnVFC PIN:	Signature/Title:	Date:
Vaccine type:	NDC# *:	Lot number*:	Expiration date:	Number of doses:
Vaccine type:	NDC# *:	Lot number*:	Expiration date:	Number of doses:
Vaccine type:	NDC# *:	Lot number*:	Expiration date:	Number of doses:
Vaccine type:	NDC# *:	Lot number*:	Expiration date:	Number of doses:
Temperature during transport:		Condition of vaccine upon receipt:		

\*Located on the box.

For more information, contact the MnVFC program:  
 651-201-5522 or 1-800-657-3970  
 Email: [health.mnvfc@state.mn.us](mailto:health.mnvfc@state.mn.us)



July 2016



Site Name: \_\_\_\_\_  
 MnVFC Pin #: \_\_\_\_\_

## Vaccine Borrowing Report

MnVFC-enrolled providers are expected to manage and maintain an adequate inventory of vaccine for both their MnVFC and non-MnVFC-eligible patients. Borrowing occurs when a provider borrows vaccine from MnVFC or UUAV stock to administer to a patient not eligible for the program, or when a provider borrows vaccine from private stock to use on MnVFC or UUAV eligible patients. **Planned borrowing of MnVFC is not permissible.**

MnVFC-enrolled providers must ensure borrowing MnVFC vaccine will not prevent a MnVFC-eligible child from receiving a needed vaccination. Infrequent exchanging between MnVFC, UUAV, and private stock of a short-dated vaccine dose may be performed if the provider serves a small number of private pay patients, the dose is one month from expiration, or the dose of vaccine cannot be used for the population it is intended for prior to the expiration date.

**Complete this form when:**

- A dose of MnVFC vaccine is administered to a non MnVFC-eligible patient, or a dose of UUAV vaccine is administered to a non UUAV-eligible adult.
- A dose of privately-purchased vaccine is administered to a MnVFC-eligible child or UUAV-eligible adult.

**How to complete this form:**

- Enter information on each dose of vaccine borrowed in a separate row in the Vaccine Borrowing Report Table.
- All columns must be completed for each dose borrowed.
- The provider must sign and date at the bottom of this report once the form is completed.
- Enter the corresponding reason code in column F of the Borrowing Report Table on page 2.
- Enter details of reason in column F if an "Other" code (7/Other or 13/Other) is entered in the Vaccine Borrowing Report Table.
- If borrowing a dose to or from UUAV stock, record the reason under "Other."

**Reason for Vaccine Borrowing and Replacement Coding Legend**

Reason for Borrowing MnVFC Dose	Code	Reason for Borrowing Private Dose	Code
Private vaccine shipment delay (vaccine order placed on time/delay in shipping)	1	MnVFC vaccine shipment delay (order placed on time/delay in shipping)	8
Private vaccine not useable on arrival (vials broken, temperature monitor out of range)	2	MnVFC vaccine not useable on arrival (vials broken, temperature monitor out of range)	9
Ran out of private vaccine between orders (not due to shipping delays)	3	Ran out of MnVFC vaccine between orders (not due to shipping delays)	10
Short-dated private dose was exchanged with MnVFC dose	4	Short-dated MnVFC dose was exchanged with private dose	11
Accidental use of Private dose for MnVFC-eligible child	5	Accidental use of a MnVFC dose for a child not eligible for the MnVFC program	12
Replacement of Private dose with MnVFC when insurance plan did not cover vaccine	6	Other – Describe:	13/Other
Other – Describe:	7/Other		

**What to do with this form:**

- Completed forms must be retained as a MnVFC program record for at least 3 years and made available to the State/Local or Territorial Immunization Program upon request.







# Medical Management of Vaccine Reactions in Children and Teens

All vaccines have the potential to cause an adverse reaction. In order to minimize adverse reactions, patients should be carefully screened for precautions and contraindications before vaccine is administered. Even with careful screening, reactions may occur. These reactions can vary from trivial and inconvenient (e.g., soreness, itching) to severe and life threatening (e.g., anaphylaxis). If reactions occur, staff should be prepared with procedures for their management. The table below describes procedures to follow if various reactions occur.

REACTION	SYMPTOMS	MANAGEMENT
Localized	Soreness, redness, itching, or swelling at the injection site	Apply a cold compress to the injection site. Consider giving an analgesic (pain reliever) or antipruritic (anti-itch) medication.
	Slight bleeding	Apply an adhesive compress over the injection site.
	Continuous bleeding	Place thick layer of gauze pads over site and maintain direct and firm pressure; raise the bleeding injection site (e.g., arm) above the level of the patient's heart.
Psychological fright and syncope (fainting)	Fright before injection is given	Have patient sit or lie down for the vaccination.
	Extreme paleness, sweating, coldness of the hands and feet, nausea, lightheadedness, dizziness, weakness, or visual disturbances	Have patient lie flat or sit with head between knees for several minutes. Loosen any tight clothing and maintain an open airway. Apply cool, damp cloths to patient's face and neck.
	Fall, without loss of consciousness	Examine the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated.
	Loss of consciousness	Check the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated. Call 911 if patient does not recover immediately.
Anaphylaxis	Sudden or gradual onset of generalized itching, erythema (redness), or urticaria (hives); angioedema (swelling of the lips, face, or throat); severe bronchospasm (wheezing); shortness of breath; shock; abdominal cramping; or cardiovascular collapse	See "Emergency Medical Protocol for Management of Anaphylactic Reactions in Children and Teens" on the next page for detailed steps to follow in treating anaphylaxis.

CONTINUED ON NEXT PAGE ►

**Needed medications for a community immunization clinic****FIRST-LINE medication**

- Epinephrine**, aqueous 1:1000 dilution, in ampules, vials of solution, or prefilled syringes, including epinephrine auto-injectors (e.g., EpiPen and Auvi-Q). If autoinjectors are stocked, at least three should be available (both pediatric and adult formulations).

**Optional medication: H<sub>1</sub> antihistamines**

- Diphenhydramine (e.g., Benadryl) oral (12.5 mg/5 mL liquid, 25 or 50 mg capsules/tablets) or injectable (50 mg/mL solution).
- Hydroxyzine (e.g., Atarax, Vistaril) oral (10 mg/5 mL or 25 mg/5 mL liquid, 10 mg or 25 mg tablets, or 25 mg capsules).

**Needed supplies for a community immunization clinic**

- Syringes (1 and 3 cc) and needles (22 and 25 g, 1", 1½", and 2") for epinephrine, diphenhydramine, or hydroxyzine. For ampules, use filtered needles.
- Alcohol wipes
- Tourniquet
- Pediatric and adult airways (small, medium, and large)
- Pediatric and adult size pocket masks with one-way valve
- Oxygen (if available)
- Stethoscope
- Sphygmomanometer (blood pressure measuring device) with child, adult, and extra-large cuffs
- Tongue depressors
- Flashlight with extra batteries (for examination of the mouth and throat)
- Wristwatch with a second hand or other timing device
- Cell phone or access to onsite phone

**Emergency medical protocol for management of anaphylactic reactions in children and teens**

- 1** If itching and swelling are confined to the injection site where the vaccination was given, observe patient closely for the development of generalized symptoms.
- 2** If symptoms are generalized, activate the emergency medical system (EMS; e.g., call 911) and notify patient's physician. This should be done by a second person, while the primary healthcare professional assesses the airway, breathing, circulation, and level of consciousness of the patient.
- 3 DRUG DOSING INFORMATION: The first-line and most important therapy in anaphylaxis is epinephrine. There are NO contraindications to epinephrine in the setting of anaphylaxis.**
  - a First-line treatment:** Administer aqueous epinephrine 1:1000 dilution (i.e., 1 mg/mL) intramuscularly; the standard dose is 0.01 mg/kg body weight, up to 0.5 mg maximum single dose in children and adolescents. See dosing chart on page 3.
  - b Optional treatment: H<sub>1</sub> antihistamines** for hives or itching, you may also administer diphenhydramine (either orally or by intramuscular injection; the standard dose is 1–2 mg/kg body weight, up to 50 mg maximum dose in children and adolescents\*) or hydroxyzine (orally; the standard dose is 0.5–1 mg/kg/dose up to 50–100 mg maximum per day in children and adolescents). See dosing charts on page 3.

\* According to AAP's Red Book, for children age ≥12 years, the diphenhydramine maximum single dose is 100 mg.
- 4** Monitor the patient closely until EMS arrives. Perform cardiopulmonary resuscitation (CPR), if necessary, and maintain airway. Keep patient in supine position (flat on back) unless he or she is having breathing difficulty. If breathing is difficult, patient's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs. Monitor blood pressure and pulse every 5 minutes.
- 5** If EMS has not arrived and symptoms are still present, repeat dose of epinephrine every 5–15 minutes for up to 3 doses, depending on patient's response.
- 6** Record all vital signs, medications administered to the patient, including the time, dosage, response, and the name of the medical personnel who administered the medication, and other relevant clinical information.
- 7** Notify the patient's primary care physician.

CONTINUED ON NEXT PAGE ►

These standing orders for the medical management of vaccine reactions in child and teenage patients shall remain in effect for patients of the \_\_\_\_\_ until rescinded or until \_\_\_\_\_

NAME OF CLINIC DATE

MEDICAL DIRECTOR'S SIGNATURE DATE OF SIGNING

For your convenience, approximate dosages based on weight and age are provided in the following charts. Please confirm that you are administering the correct dose for your patient.

First-Line Treatment: Epinephrine				Epinephrine Dose		
	Age group	Range of weight (lb)	Range of weight (kg)*	1 mg/mL injectable (1:1000 dilution); intramuscular Minimum dose: 0.05 mL	Epinephrine auto-injector, 0.15 mg or 0.3 mg	
Recommended dose is 0.01 mg/kg body weight up to 0.5 mg maximum dose. May be repeated every 5–15 minutes for a total of 3 doses.	Infants and children	1–6 months	9–19 lb	4–8.5 kg	0.05 mL (or mg)	off label
		7–36 months	20–32 lb	9–14.5 kg	0.1 mL (or mg)	off label
		37–59 months	33–39 lb	15–17.5 kg	0.15 mL (or mg)	0.15 mg/dose
		5–7 years	40–56 lb	18–25.5 kg	0.2–0.25 mL (or mg)	0.15 mg/dose
		8–10 years	57–76 lb	26–34.5 kg	0.25–0.3 mL (or mg)	0.15 mg or 0.3 mg/dose
Teens	11–12 years	77–99 lb	35–45 kg	0.35–0.4 mL (or mg)	0.3 mg/dose	
	13 years & older	100+ lb	46+ kg	0.5 mL (or mg) – max. dose	0.3 mg/dose	

**NOTE:** If body weight is known, then dosing by weight is preferred. If weight is not known or not readily available, dosing by age is appropriate.

\* Rounded weight at the 50th percentile for each age range

Optional Treatment: Diphenhydramine				Diphenhydramine Dose	
	Age group	Range of weight (lb)	Range of weight (kg)*	Liquid: 12.5 mg/5 mL Tablets: 25 mg or 50 mg Injectable: 50 mg/mL (IV or IM)	
commonly known as Benadryl	Infants and children	7–36 months	20–32 lb	9–14.5 kg	10–15 mg/dose
		37–59 months	33–39 lb	15–17.5 kg	15–20 mg/dose
		5–7 years	40–56 lb	18–25.5 kg	20–25 mg/dose
		8–12 years	57–99 lb	26–45 kg	25–50 mg/dose†
		Teens	13 years & older	100+ lb	46+ kg

Recommended dose is 1–2 mg/kg body weight every 4–6 hrs

**NOTE:** If body weight is known, then dosing by weight is preferred. If weight is not known or not readily available, dosing by age is appropriate.

\* Rounded weight at the 50th percentile for each age range

† According to AAP's *Red Book*, for children age ≥12 years, the diphenhydramine maximum single dose is 100 mg.

Optional Treatment: Hydroxyzine				Hydroxyzine Dose	
	Age group	Range of weight (lb)	Range of weight (kg)*	Liquid: 10 mg/5 mL or 25 mg/5 mL Tablets: 10 mg or 25 mg Capsules: 25 mg	
commonly known as Atarax, Vistaril	Infants and children	7–36 months	20–32 lb	9–14.5 kg	5–7.5 mg/dose
		37–59 months	33–39 lb	15–17.5 kg	7.5–10 mg/dose
		5–7 years	40–56 lb	18–25.5 kg	10–12.5 mg/dose
		8–10 years	57–76 lb	26–34.5 kg	12.5–15 mg/dose
		Teens	11–12 years	77–99 lb	35–45 kg
13 years & older	100+ lb		46+ kg	25 mg/dose (50–100 mg, maximum per day)	

Recommended oral dose is 0.5–1 mg/kg body weight every 4–6 hrs

**NOTE:** If body weight is known, then dosing by weight is preferred. If weight is not known or not readily available, dosing by age is appropriate.

\* Rounded weight at the 50th percentile for each age range

#### REFERENCES

- Simons FE, Camargo CA. Anaphylaxis: Rapid recognition and treatment. In: UpToDate, Bochner BS (Ed). UpToDate: Waltham, MA, 2013.
- Charts adapted from American Academy of Pediatrics. *Red Book: 2012 Report of the Committee on Infectious Diseases*. Pickering LK, ed. 29th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2012. pp. 67–69.
- Boyce JA, Assa'ad A, Burks AW, et al. Guidelines for the Diagnosis and Management of Food Allergy in the United States: Report of the NIAID-Sponsored Expert Panel. *Allergy Clin Immunol* 2010; 126(6): S1–S57.



# Medical Management of Vaccine Reactions in Adult Patients

All vaccines have the potential to cause an adverse reaction. In order to minimize adverse reactions, patients should be carefully screened for precautions and contraindications before vaccine is administered. Even with careful screening, reactions may occur. These reactions can vary from trivial and inconvenient (e.g., soreness, itching) to severe and life threatening (e.g., anaphylaxis). If reactions occur, staff should be prepared with procedures for their management. The table below describes procedures to follow if various reactions occur.

REACTION	SYMPTOMS	MANAGEMENT
Localized	Soreness, redness, itching, or swelling at the injection site	Apply a cold compress to the injection site. Consider giving an analgesic (pain reliever) or antipruritic (anti-itch) medication.
	Slight bleeding	Apply an adhesive compress over the injection site.
	Continuous bleeding	Place thick layer of gauze pads over site and maintain direct and firm pressure; raise the bleeding injection site (e.g., arm) above the level of the patient's heart.
Psychological fright and syncope (fainting)	Fright before injection is given	Have patient sit or lie down for the vaccination.
	Extreme paleness, sweating, coldness of the hands and feet, nausea, light-headedness, dizziness, weakness, or visual disturbances	Have patient lie flat or sit with head between knees for several minutes. Loosen any tight clothing and maintain an open airway. Apply cool, damp cloths to patient's face and neck.
	Fall, without loss of consciousness	Examine the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated.
	Loss of consciousness	Check the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated. Call 911 if patient does not recover immediately.
Anaphylaxis	Sudden or gradual onset of generalized itching, erythema (redness), or urticaria (hives); angioedema (swelling of the lips, face, or throat); severe bronchospasm (wheezing); shortness of breath; shock; abdominal cramping; or cardiovascular collapse.	See "Emergency Medical Protocol for Management of Anaphylactic Reactions in Adults" on the next page for detailed steps to follow in treating anaphylaxis.

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### Needed medications for a community immunization clinic

#### FIRST-LINE medication

- Epinephrine**, aqueous 1:1000 (i.e., 1 mg/mL) dilution, in ampules, vials of solution, or prefilled syringes, including epinephrine autoinjectors (e.g., EpiPen and Auvi-Q). If autoinjectors are stocked, at least three should be available.

#### Optional medication: H<sub>1</sub> antihistamines

- Diphenhydramine (e.g., Benadryl) oral (12.5 mg/5 mL liquid, 25 or 50 mg capsules/tablets) or injectable (50 mg/mL solution).
- Hydroxyzine (e.g., Atarax, Vistaril) oral (10 mg/5 mL or 25 mg/5 mL liquid, 25 mg capsules).

### Needed supplies for a community immunization clinic

- Syringes (1 and 3 cc) and needles (22 and 25 g, 1", 1½", and 2") for epinephrine, diphenhydramine, or hydroxyzine. For ampules, use filtered needles.
- Alcohol wipes
- Tourniquet
- Adult airways (small, medium, and large)
- Adult size pocket mask with one-way valve
- Oxygen (if available)
- Stethoscope
- Sphygmomanometer (blood pressure measuring device) with adult-size and extra-large cuffs
- Tongue depressors
- Flashlight with extra batteries (for examination of the mouth and throat)
- Wristwatch with a second hand or other timing device
- Cell phone or access to onsite phone

### REFERENCES

Simons FE, Camargo CA. Anaphylaxis: Rapid recognition and treatment. In: UpToDate, Bochner BS (Ed). UpToDate: Waltham, MA, 2013.

Boyce JA, Assa'ad A, Burks AW, et al. Guidelines for the Diagnosis and Management of Food Allergy in the United States: Report of the NIAID-Sponsored Expert Panel. *Allergy Clin Immunol* 2010; 126(6): S1–S57.

immunization  
action coalition



Saint Paul, Minnesota • 651-647-9009 • [www.immunize.org](http://www.immunize.org) • [www.vaccineinformation.org](http://www.vaccineinformation.org)

## Emergency medical protocol for management of anaphylactic reactions in adults

- 1 If itching and swelling are confined to the injection site where the vaccination was given, observe patient closely for the development of generalized symptoms.
- 2 If symptoms are generalized, activate the emergency medical system (EMS; e.g., call 911) and notify the patient's physician. This should be done by a second person, while the primary healthcare professional assesses the airway, breathing, circulation, and level of consciousness of the patient.
- 3 **DRUG DOSING INFORMATION: The first-line and most important therapy in anaphylaxis is epinephrine. There are NO contraindications to epinephrine in the setting of anaphylaxis.**
  - a **First-line treatment:** Administer aqueous **epinephrine** 1:1000 dilution intramuscularly, 0.01 mL/kg/dose (adult dose ranges from 0.3 mL to 0.5 mL, with maximum single dose of 0.5 mL).
  - b **Optional treatment: H<sub>1</sub> antihistamines** for hives or itching; you may also administer **diphenhydramine** (either orally or by intramuscular injection; the standard dose is 1–2 mg/kg every 4–6 hrs, up to 50 mg maximum single dose) or **hydroxyzine** (standard oral dose is 0.5–1 mg/kg every 4–6 hrs up to 100 mg maximum single dose).
- 4 Monitor the patient closely until EMS arrives. Perform cardiopulmonary resuscitation (CPR), if necessary, and maintain airway. Keep patient in supine position (flat on back) unless he or she is having breathing difficulty. If breathing is difficult, patient's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs. Monitor blood pressure and pulse every 5 minutes.
- 5 If EMS has not arrived and symptoms are still present, repeat dose of epinephrine every 5–15 minutes for up to 3 doses, depending on patient's response.
- 6 Record all vital signs, medications administered to the patient, including the time, dosage, response, and the name of the medical personnel who administered the medication, and other relevant clinical information.
- 7 Notify the patient's primary care physician.

These standing orders for the medical management of vaccine reactions in adult patients shall remain in effect for patients of the

\_\_\_\_\_ until rescinded or until \_\_\_\_\_  
NAME OF CLINIC DATE

\_\_\_\_\_ DATE OF SIGNING  
MEDICAL DIRECTOR'S SIGNATURE

Technical content reviewed by the Centers for Disease Control and Prevention

[www.immunize.org/catg.d/p3082.pdf](http://www.immunize.org/catg.d/p3082.pdf) • Item #P3082 (9/14)





Minnesota Department of Health  
Immunization Program  
625 N Robert Street  
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651-201-5522 or 1-800-657-3970  
Email: [health.mnvfc@state.mn.us](mailto:health.mnvfc@state.mn.us)  
Fax: 651-201-5501

