



2024

MnVFC Policies and Procedures Manual

Replacement Method Sites

MnVFC PIN:

Vaccine Coordinator:

BackupVaccine Coordinator:

Update your information if the vaccine coordinator or backup change:



[MnVFC Contact Update Form](https://redcap.health.state.mn.us/redcap/surveys/?s=HTF4FJ7W734XKJWY)

[\(https://redcap.health.state.mn.us/redcap/surveys/?s=HTF4FJ7W734XKJWY\)](https://redcap.health.state.mn.us/redcap/surveys/?s=HTF4FJ7W734XKJWY)

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Checklist for Required Action Steps

Every 24 months requirement

- Medical Director needs to complete and sign a *Minnesota Vaccines for Children (MnVFC) Program Provider Agreement* every 24 months, distributed by MnVFC program staff via online survey.

Every 12 months requirements

Vaccine coordinator and backup vaccine coordinator need to do the following by

Nov. 30, 2023:

- Complete *2024 MnVFC Annual Report of the Number of Immunized Pediatric Patients* (only parent sites need to submit an annual report).
- Complete the 2024 MnVFC Online Training (follow along in the manual as you listen to the training) and print the certificate. Keep it with your records.
- Complete and sign a *2024 Replacement Method of Vaccine Management Agreement*.
- Read the *2024 MnVFC Policies and Procedures Manual* and sign page 7.

Create, review, or update your vaccine management plan and emergency plan.

There are two options:

- Use the *2024 MnVFC Policies and Procedures Manual* for your vaccine management plan and emergency plan.
 - Vaccine Coordinator to read the manual and sign page 8.
 - Vaccine Coordinator to fill out pages 11-15 in this manual and sign page 15 **or** use the fillable PDF on [Vaccine Management Forms \(www.health.state.mn.us/people/immunize/hcp/mnvfc/forms.html\)](http://www.health.state.mn.us/people/immunize/hcp/mnvfc/forms.html).

or

- Use your own institutional policy and procedure for vaccine management.
 - The policy should include all of the elements of the vaccine management and emergency plans found in this manual.
 - Vaccine Coordinator needs to review, date, and sign the policy each year.

Create, review, or update your Anaphylaxis Protocol.

- Medical Director needs to review, date, and sign every three years. See page 37 for more details.

Notes:

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 age 18 years. MnVFC distributes about \$46 million worth of vaccines to enrolled sites each year. It is managed 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.

By Minnesota law (Minnesota Statutes, section 256B.0625, subd. 39), 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 is not permitted to bill the MHCP for the cost of the vaccine or 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) to start the enrollment process.
2. Enrollment information will be emailed to you. Follow instructions to complete required documents.
3. When 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.
4. 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.
5. 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 visit.

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

Introduction to MnVFC Policies and Procedures Manual

This manual lays out the policies established by the federal VFC program. It will help you navigate the requirements to provide access to viable vaccines for eligible individuals. To keep this manual manageable, we do not 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 vaccine coordinator and backup vaccine coordinator read this manual and sign the signature page (page 7), certifying that they have read the manual. This is 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 having a routine vaccine management plan. To do this, the appropriate individual needs to certify that this manual is implemented as your site’s routine vaccine management plan (see page 8).
 - 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 has been implemented if needed (see page 9).
 - A fillable PDF version of the emergency vaccine management plan is available on [Vaccine Management Forms \(www.health.state.mn.us/people/immunize/hcp/mnvfc/forms.html\)](http://www.health.state.mn.us/people/immunize/hcp/mnvfc/forms.html).
 - 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 store and/or administer vaccine to MnVFC-eligible children will be referred to as sites.

Separate stock: This method involves keeping privately purchased vaccine and public vaccine separated. Staff must choose vaccine from the correct vaccine “stock” to administer to patients 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 2024 manual, you have been identified as a replacement method site.

This manual is also available on [MnVFC Required Annual Reports and Trainings \(www.health.state.mn.us/people/immunize/hcp/mnvfc/required.html\)](http://www.health.state.mn.us/people/immunize/hcp/mnvfc/required.html).

Signature Page

By signing below, I certify that I have read the 2024 MnVFC Policies and Procedures Manual and have completed the annual online training (print certificates of completion).

Name	Signature	Title	Date
Vaccine Coordinator*:			
Backup Vaccine Coordinator*:			
Others†:			

*Definitions of vaccine coordinator and backup vaccine coordinator can be found on pages 39-40.

Vaccine coordinate and backup vaccines coordinator are required to read the manual and view the annual online training.

†Optional: Staff whose work relates to immunizations (e.g., the front desk staff who receives immunization shipments and staff giving immunizations).

Routine Vaccine Management Plan

As a MnVFC provider, you are required to 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 as changes occur (e.g., vaccine coordinator and/or backup vaccine coordinator in new role).

The routine vaccine management plan must include:

- Name and contact information of the current vaccine coordinator and backup vaccine coordinator.
- Documentation of staff completing annual online training including the staff member's name and date of training.
- 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).
- Protocol for responding to and reporting vaccine loss).
- Documentation of staff training on elements of the plan.
- Name, signature, and title or role of the person responsible for reviewing and implementing the content.
- 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 vaccine coordinator and backup vaccine coordinator sign and date the signature page (page 7) certifying that they have read the manual.

This manual should be easily accessible and kept near the vaccine storage units.

By signing below, I certify that the 2024 MnVFC manual will be implemented as my site's routine vaccine management plan.

Vaccine Coordinator

MnVFC PIN	
Site name	
Date reviewed	
Name	
Role (e.g., vaccine coordinator)	
Signature	

Emergency Vaccine Management Plan

Whether you use our emergency plan template or your own, it is a requirement for sites to develop, post, and prepare to follow a plan for transporting and storing vaccine in an emergency situation. The plan must be reviewed, signed, and dated each year or more often if there are changes (e.g., reviewer changes or location of supplies has changed).

- If using this manual's emergency plan, remember to sign/date the plan on page 15.
- You may complete an online, fillable version of the [Worksheet for Developing an Emergency Plan for Managing Vaccine \(www.health.state.mn.us/people/immunize/hcp/mnvfc/emplanwrkst.pdf\)](http://www.health.state.mn.us/people/immunize/hcp/mnvfc/emplanwrkst.pdf).

You must develop your own site-specific plan and store it in an easily accessible area near your storage unit(s) and/or emergency transport materials. 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 vaccine coordinator and the backup vaccine coordinator's name, title, contact information, and their responsibilities during an emergency.
 - Emergency staff contact list in order of priority.
 - Vaccine storage unit specifications for your site (type, location, brand, model, and serial number).
 - Emergency procedures for situations such as equipment malfunctions, power failures, or natural disasters.
- Written instructions for how to enter your facility and access vaccine storage units if the building is closed or it's after hours (e.g., what to do if electronic access does not work).
 - 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 breaker location(s).
 - 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. 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 \(www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html\)](http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html).
- Written instructions on location of backup continuous temperature monitoring device and instructions for its use.

- Alternate vaccine storage facility(s) needs to be a medical storage facility that is monitoring temperatures appropriately and preferably has a backup generator.
 - 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.
 - *Storage and Handling Mishap Log* on [Vaccine Management Forms \(www.health.state.mn.us/people/immunize/hcp/mnvfc/forms.html\)](http://www.health.state.mn.us/people/immunize/hcp/mnvfc/forms.html) (see Appendix A).
 - *Storage and Handling Mishap Checklist* on [Vaccine Management Forms \(www.health.state.mn.us/people/immunize/hcp/mnvfc/forms.html\)](http://www.health.state.mn.us/people/immunize/hcp/mnvfc/forms.html) (see Appendix B).
- Emergency resources contact list.

Worksheet for Developing an Emergency Plan for Managing Vaccine

A fillable version of this worksheet is also available on [Vaccine Management Forms \(www.health.state.mn.us/people/immunize/hcp/mnvfc/forms.html\)](http://www.health.state.mn.us/people/immunize/hcp/mnvfc/forms.html).

Name	Phone numbers (home, cell)
Vaccine Coordinator:	
Backup Vaccine Coordinator:	
System-Level MnVFC Contact (if applicable):	

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.		

Vaccine Storage Unit Specifications				
Type of unit (refrigerator or freezer)	Location	Brand	Model number	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.

Materials			
	Location of item	Person responsible for material	Phone number
Flashlights			
Spare batteries			
Hard-sided coolers, Styrofoam vaccine shipping containers, or portable fridge/ freezer			
Insulating materials - bubble wrap, packing foam, or Styrofoam and corrugated cardboard			
Frozen water bottles (conditioned to transport refrigerated vaccine)			
Backup continuous temperature monitoring device with a current and valid Certificate of Calibration			

Written instructions for vaccine packing to maintain the cold chain with appropriate supplies, including continuous temperature monitoring devices.

Alternate Vaccine Storage Facility(s)	
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:		

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.

- *Storage and Handling Mishap Log* on [Vaccine Management Forms \(www.health.state.mn.us/people/immunize/hcp/mnvfc/forms.html\)](http://www.health.state.mn.us/people/immunize/hcp/mnvfc/forms.html) (refer to Appendix A).
- *Storage and Handling Mishap Checklist* on [Vaccine Management Forms \(www.health.state.mn.us/people/immunize/hcp/mnvfc/forms.html\)](http://www.health.state.mn.us/people/immunize/hcp/mnvfc/forms.html) (refer to Appendix B).

Date reviewed	
Reviewed by	
Role (must be signed by the vaccine coordinator)	
Signature	



**How to Administrate
the MnVFC Program**

1. Screen patients for MnVFC eligibility

- Screen all patients age 18 years and younger before administering vaccines to determine if they are eligible for MnVFC vaccine.
- Document and keep the patient’s eligibility status on paper or in the electronic health record for three years.

MnVFC eligibility criteria

- Any child who is age 18 years or younger and meets at least one of eligibility criteria below can receive MnVFC vaccine at MnVFC-enrolled sites:
 - Uninsured.
 - Enrolled in a Minnesota Health Care Program (MHCP): Medical Assistance (MA), MinnesotaCare, and Prepaid Medical Assistance Plan (PMAP). For more information visit [Minnesota Department of Human Services Resources for MHCP members who get care through a health plan \(https://mn.gov/dhs/people-we-serve/adults/health-care/health-care-programs/programs-and-services/resources-for-mhcp-members.jsp#3\)](https://mn.gov/dhs/people-we-serve/adults/health-care/health-care-programs/programs-and-services/resources-for-mhcp-members.jsp#3).
 - American Indian or Alaskan Native.
 - Underinsured:
 - 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 are not 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.
- Children with insurance that does not cover vaccines until a deductible has been met are considered fully insured and are **not** MnVFC-eligible.

Health care sharing ministries

- Health care sharing ministries (HCSMs) are a form of health coverage whose members share a common belief system. Collectively, they “share” health care costs between its members.
- Although HCSMs, in general, are **not** recognized as insurance, their features strongly mimic traditional insurance plans.
 - If you are unsure if a HCSM is recognized as insurance, please call the plan directly.
- MnVFC-eligibility
 - Children with a HCSM plan that is not recognized as insurance are considered uninsured and are MnVFC-eligible.
 - Use MnVFC vaccine and do not bill the patient for the cost of the vaccine. You may charge the patient up to \$21.22 for the administration fee per dose (not per antigen). Waive the administration fee if the patient is unable to pay it.

- However, if a HCSM is not recognized as insurance but has 100% vaccine coverage, you must use private vaccine and bill the HCSM plan.
- Patients enrolled in HCSMs that are recognized as insurance are insured and are **not** MnVFC-eligible.

Screen all patients for eligibility

- MnVFC vaccine must only be used for MnVFC-eligible patients.
- Have a written policy describing your process for identifying and documenting the patient’s eligibility status.
- 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.
- The MnVFC program recommends providing a handout to all patients age 18 years and younger at each immunization visit.
 - The handout should include the MnVFC program eligibility categories and who the patient should contact in your organization with billing questions.
 - The handout should be available for the patient to take home in either paper or electronic format.
 - You can use the MnVFC self-screening form template that includes your billing contact information as the handout. A sample handout that you can customize called “Can my child receive free or low cost shots?” is available on [Free or Low-Cost Shots for Children \(www.health.state.mn.us/people/immunize/basics/howpay.html\)](http://www.health.state.mn.us/people/immunize/basics/howpay.html).

Document the patient’s eligibility status

- Document eligibility screening at each visit in the patient’s medical record (even if the patient is not eligible for MnVFC. Documentation may be done electronically or by using a paper form.
 - The MnVFC program provides screening record forms on [MnVFC Program Resources \(www.health.state.mn.us/people/immunize/hcp/mnvfc/resources.html\)](http://www.health.state.mn.us/people/immunize/hcp/mnvfc/resources.html). You do not have to use the MnVFC forms, but you do have to collect all the information that is on them.
- Your site must 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.
 - For more information, including how to submit dose-level eligibility information to MIIC (either electronically or by manually entering data), refer to [Vaccine Ordering and Management in MIIC \(www.health.state.mn.us/people/immunize/miic/managevax/index.html\)](http://www.health.state.mn.us/people/immunize/miic/managevax/index.html).
- Keep a record of the patient’s eligibility for three years.

2. 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 are required to give the current VIS (either paper or electronic) to the patient or their parent or legal representative before administering each dose of vaccine.
- It is acceptable to make a VIS available to be read before the immunization visit (e.g., 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. You must still offer a copy (which can be an electronic copy) of each appropriate VIS to take away following the vaccination. However, the recipient may decline.

- Current VISs are available on the [Immunize.org Vaccine Information Statements \(https://www.immunize.org/vis/?redirected=1\)](https://www.immunize.org/vis/?redirected=1) website and CDC's [Vaccine Information Statements \(www.cdc.gov/vaccines/hcp/vis/\)](http://www.cdc.gov/vaccines/hcp/vis/) website.
 - Sign up to get email updates when VISs change on CDC's [Vaccine Information Statements \(www.cdc.gov/vaccines/hcp/vis/index.html\)](http://www.cdc.gov/vaccines/hcp/vis/index.html) website.
 - When possible, provide the VIS in the person's native or preferred language. Translated VISs are available on the CDC's [Vaccine Information Statements \(www.cdc.gov/vaccines/hcp/vis/index.html\)](http://www.cdc.gov/vaccines/hcp/vis/index.html) website. You are encouraged to distribute the current English version at the same time as the translation.
 - 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.
- You must document the publication date of the VIS (located on the bottom corner) in the patient's medical record and the date the patient was given the VIS to review.
- 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.

3. Administer vaccines in accordance with recommended immunization schedules

- Administer vaccines in accordance with the *General Recommendations on Immunization* and immunization schedules, dosage, and contraindications that are established by the Advisory Committee on Immunization Practices (ACIP) and included in the MnVFC program unless:
 - In the provider's medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate, or
 - The particular requirements contradict state law, including laws pertaining to religious and other exemptions.

Offer all ACIP-recommended vaccines for your patient population

- As a MnVFC-enrolled site, you must offer all ACIP-recommended vaccines for your patient population, including access to non-routine vaccines as appropriate.
- The current ACIP-recommended schedules are available on CDC's [Assess for Needed Immunizations \(www.cdc.gov/vaccines/hcp/admin/assess-need.html\)](http://www.cdc.gov/vaccines/hcp/admin/assess-need.html).
- Use the Immunize.org's [Guide to Contraindications and Precautions to Commonly Used Vaccines \(www.immunize.org/catg.d/p3072a.pdf\)](http://www.immunize.org/catg.d/p3072a.pdf).
- The state laws related to vaccination requirements and acceptable vaccine exemptions can be found at [Vaccines for Infants, Children, and Adolescents \(www.health.state.mn.us/people/immunize/basics/kids.html\)](http://www.health.state.mn.us/people/immunize/basics/kids.html).

Train staff on how to administer vaccines correctly

- Comprehensive, competency-based staff training and education, including the “rights of medication administration,” patient care, vaccine preparation, and skill validation should occur for all personnel who administer vaccines based on their scope of practice. Sites may have their own internal training program. For those who do not, there are options available:
 - Vaccine Administration chapter in [Epidemiology and Prevention of Vaccine-Preventable Diseases \(Pink Book\) \(www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html\)](http://www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html).
 - CDC eLearn: [Vaccine Administration \(https://www2.cdc.gov/vaccines/ed/vaxadmin/vaccine.asp\)](https://www2.cdc.gov/vaccines/ed/vaxadmin/vaccine.asp).
 - Vaccine Administration lessons from [California VFC Program EZIZ Training \(https://eziz.org/eziz-training/\)](https://eziz.org/eziz-training/).
- To ensure competency, staff training should occur when: new staff are hired, new or different vaccines are added to the site’s usual inventory, new recommendations are published, and when old recommendations are revised. Annual updates and skill review are recommended for all staff.
- Encourage staff to ask questions about vaccine administration if they are unsure.

Immunization administration resources

- Minnesota Department of Health
 - [Immunization Best Practices \(www.health.state.mn.us/people/immunize/hcp/bestpractices.html\)](http://www.health.state.mn.us/people/immunize/hcp/bestpractices.html).
 - [Reliable Sources of Immunization Information \(www.health.state.mn.us/people/immunize/basics/imminfo.html\)](http://www.health.state.mn.us/people/immunize/basics/imminfo.html).
- Centers for Disease Control and Prevention
 - Immunization Education and Training “You Call the Shots” (www.cdc.gov/vaccines/ed/youcalltheshots.html) modules, the Vaccine Administration e-Learn, and Pink Book Webinar Series.
 - [CDC’s Your Child’s Vaccine Visit \(www.cdc.gov/vaccines/parents/visit/index.html\)](http://www.cdc.gov/vaccines/parents/visit/index.html).
- Immunize.org - formerly Immunization Action Coalition (IAC)
 - [Skills Checklist for Immunization \(www.immunize.org/catg.d/p7010.pdf\)](http://www.immunize.org/catg.d/p7010.pdf).
 - [Vaccination Tools for Administering Vaccines \(www.immunize.org/clinic/administering-vaccines.asp\)](http://www.immunize.org/clinic/administering-vaccines.asp).
 - [Vaccines with Diluents: How to use them \(www.immunize.org/catg.d/p3040.pdf\)](http://www.immunize.org/catg.d/p3040.pdf).
- [CDC: One and Only Campaign \(www.cdc.gov/injectionsafety/one-and-only.html\)](http://www.cdc.gov/injectionsafety/one-and-only.html) for safe injection practices.
- [TIDE: Teaching Immunization Delivery Evaluation \(http://tide.musc.edu/\)](http://tide.musc.edu/).

4. 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-HepB) and the name of the combination vaccine (for example, Pediarix).
- You should give patients/parents a record of each immunization.
- MIIC cannot serve as the permanent medical record.

5. Report vaccine administration to MIIC

- Providers are required to report doses administered data to Minnesota Immunization Information Connection (MIIC) within seven days of the vaccine administration date. This is a new requirement for the MnVFC program.
- Visit [Participating in MIIC \(www.health.state.mn.us/people/immunize/miic/participate/index.html\)](http://www.health.state.mn.us/people/immunize/miic/participate/index.html) to determine the best way to submit data to MIIC for your organization. If you do not already submit this data, you may be able to do so with your current electronic health record (EHR) system or other electronic data submissions. We recommend discussing this with your technical staff and/or EHR vendor support.
- For detailed instructions on how to submit this data, please refer to [Reporting Dose-Level Eligibility to MIIC \(www.health.state.mn.us/people/immunize/miic/managevax/reportdle.pdf\)](http://www.health.state.mn.us/people/immunize/miic/managevax/reportdle.pdf).

Resources on [Minnesota Immunization Information Connection \(MIIC\) \(www.health.state.mn.us/people/immunize/miic/index.html\)](http://www.health.state.mn.us/people/immunize/miic/index.html) will assist you with all reporting aspects of MIIC, as well as general user guidance and training.

- [MIIC 101 \(www.health.state.mn.us/people/immunize/miic/train/intro.html\)](http://www.health.state.mn.us/people/immunize/miic/train/intro.html) for logging in, changing passwords, and browser compatibility.
- [Client Search and Printing Immunization Records \(www.health.state.mn.us/people/immunize/miic/train/clientsearch.html\)](http://www.health.state.mn.us/people/immunize/miic/train/clientsearch.html).
- [Interpreting a MIIC Vaccination Record \(www.health.state.mn.us/people/immunize/miic/train/interpret.html\)](http://www.health.state.mn.us/people/immunize/miic/train/interpret.html).
- [Client Records: Frequently Asked Questions \(www.health.state.mn.us/people/immunize/miic/train/clientfaq.pdf\)](http://www.health.state.mn.us/people/immunize/miic/train/clientfaq.pdf).
- Additional guidance includes:
 - Entering New Clients.
 - Managing Clients.
 - Adding Immunizations Not Using Inventory.
 - Adding Immunizations Using Inventory.
 - General Immunization Upload.
 - Capturing Immunizations Not Currently in MIIC.
- The [MIIC User Guidance and Training Resources \(www.health.state.mn.us/people/immunize/miic/train/index.html\)](http://www.health.state.mn.us/people/immunize/miic/train/index.html) page includes a pre-recorded, four-part MIIC webinar series that covers the following topics:
 - MIIC Webinar 1: Introduction to MIIC
 - MIIC Webinar 2: Understanding Client Immunization Records
 - MIIC Webinar 3: Getting Data In and Out of MIIC
 - MIIC Webinar 4: MIIC Tools to Increase Immunization Coverage
- If you need help with data reporting, contact the MIIC Help Desk at health.miichelp@state.mn.us.

6. 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"> • Don't bill or charge for the cost of the vaccine. 	<ul style="list-style-type: none"> • Bill the MHCP \$21.22 per dose. • Certain sites including FQHC, RHC, IHS* and tribal clinics may bill an encounter fee for the entire visit and this is allowable.
Uninsured	Yes	<ul style="list-style-type: none"> • Don't charge for the cost of the vaccine. 	<ul style="list-style-type: none"> • Charge the patient \$21.22 or less per dose. Do not issue more than a single bill; waive the fee if the patient is unable to pay it.
American Indian/ Alaska Native	Yes	<ul style="list-style-type: none"> • Don't bill or charge for the cost of the vaccine. • However, if the patient is privately insured and prefers to use insurance, use private vaccine and bill the insurance. 	<ul style="list-style-type: none"> • If covered by a MHCP, bill the MHCP \$21.22 per dose. • If un- or underinsured, charge the patient \$21.22 or less per dose. Do not issue more than a single bill; waive the fee if the patient is unable to pay it. • If privately insured and prefers to use insurance, bill the insurance for the fee.
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"> • Don't charge for the cost of the vaccine. 	<ul style="list-style-type: none"> • Charge the patient \$21.22 or less per dose. Do not issue more than a single bill; waive the fee if the patient is unable to pay it.
	At a site that is not eligible to see underinsured children:		
	No	<ul style="list-style-type: none"> • Consider sending the patient to a site where they would be eligible for MnVFC. • If the patient stays at a private site, do not use MnVFC vaccine. 	<ul style="list-style-type: none"> • Consider sending the patient to a site where they would be eligible for MnVFC.
Insured	No	<ul style="list-style-type: none"> • Bill the insurance. 	<ul style="list-style-type: none"> • Bill the usual and customary administration fee to the insurance.

*Federally Qualified Health Centers (FQHC), Rural Health Centers (RHC), Indian Health Services (IHS).

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.

Charge allowable office visit and administration fees

- You may bill or charge for the office visit.
- You may bill or charge an administration fee of up to \$21.22 per dose (not per antigen) for administering MnVFC vaccine.
 - For patients who are not enrolled in an MHCP, **you can bill them only one time** (within 90 days of vaccine administration) for the administration fee. If the bill is not paid, the administration fee must be waived.
- 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 health plan directly or call the Minnesota Department of Human Services (DHS) at 651-431-2700.

Waive the administration fee

- You may bill or charge patients an administration fee one time, but if they are unable to pay it, 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 inability or failure to pay an administration fee.

Remove 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 C: [Immunization Billing Guidance for MnVFC Replacement Sites \(www.health.state.mn.us/people/immunize/hcp/mnvfc/billingtipsrep.html\)](http://www.health.state.mn.us/people/immunize/hcp/mnvfc/billingtipsrep.html).

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

- Report adverse events following immunization to VAERS.

Vaccine Adverse Event Reporting System (VAERS)

- [VAERS \(https://vaers.hhs.gov/\)](https://vaers.hhs.gov/) 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 and analyzed.
- Adverse events are 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.
 - Any event listed by the manufacturer in the [VAERS Table of Reportable Events Following Vaccination \(https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf\)](https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf) that occurs within the specified time period after vaccination.
- Health care providers are encouraged to report:
 - Any adverse event that occurs following the administration of a vaccine licensed in the U.S., whether or not it is clear that a vaccine caused the adverse event.
 - Vaccine administration errors.
- Anyone is able to file a VAERS report, including health care providers, manufacturers, vaccine recipients, or families.
- Submit the form as soon as possible after an adverse event following vaccination. Information about VAERS is on the back of every VIS. For more information or to report an event, visit the [VAERS website \(https://vaers.hhs.gov/\)](https://vaers.hhs.gov/) or call 800-822-7967.
- For more information, see CDC's [VAERS website \(https://vaers.hhs.gov/\)](https://vaers.hhs.gov/).

8. Keep MnVFC program records for three years

- Keep all records related to the MnVFC program for at least three years, even in the case of provider retirement or provider closure (electronic or hard copies; you do not need to do both).
- The following MnVFC records must be kept for at least three years:
 - Routine and emergency vaccine management plans, including the *Policies and Procedures Manual* as appropriate.
 - MnVFC eligibility screening information (forms or documentation in the electronic medical record).
 - Storage unit temperature documentation. Provider locations must maintain all paper temperature logs or a backup system of electronic data (both hard copy and electronic copy) for a minimum of three years, unless state statutes or rules require longer retention. This requirement applies even in the case of provider retirement or provider location closure.
 - Certificate of Calibration for each continuous temperature monitoring device used including your backup device.

- All forms related to vaccine management:
 - *Storage and Handling Mishap Log.*
 - *Storage and Handling Mishap Checklist.*
 - *Minnesota Department of Health (MDH) Vaccine Transfer Record.*
 - *Minnesota Department of Health (MDH) Nonviable Vaccine Form.* (If you submit the nonviable form via MIIC, you do not need to keep paper copies.)
 - *Vaccine Borrowing Report* or other borrowing documentation.
- Monthly ordering records.
- Packing lists of vaccine shipments.
- Monthly inventory log.
- *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

9. Have appropriate storage equipment

- Have and maintain appropriate vaccine refrigerator/freezer(s) to store vaccine.
- Safeguard the power supply to storage units.
- Use a continuous 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 continuous temperature monitoring device with a current and valid Certificate of Calibration readily available for each MnVFC site.

Vaccine storage units

- Storage units, in order of preference, are:
 1. Purpose-built or pharmaceutical/medical-grade units, including doorless and dispensing units.
 2. Stand-alone refrigerator and freezer units—these units can vary in size from a compact, under-the-counter style to a large, stand-alone, pharmaceutical-grade storage unit.
 3. Household combination refrigerator/freezer unit, using only the refrigerator compartment to store vaccines. Store frozen vaccine in a stand-alone freezer. Household combination units will need to be replaced with option #1 or #2 above in the following situations:
 - When purchasing new storage unit equipment (e.g., unit stops functioning, etc.).
 - Vaccine loss due to storage unit failure.
- Newly enrolled sites are required to store vaccine in a pharmaceutical unit (combo or stand-alone), stand-alone refrigerator or stand-alone freezer.
- Dormitory units (i.e., combination refrigerator/freezers with one exterior door) are not allowed for storing MnVFC vaccines. Vaccine stored in this type of unit are considered unusable due to a significant risk of freezing vaccine.

Features and use of vaccine storage units

- Must be able to maintain required vaccine storage temperatures:
 - Refrigerator between 36°F and 46°F (between 2°C and 8°C), aim for 40°F (5°C).
 - Freezer between -58°F and +5°F (between -50°C and -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.
- Must have sufficient room to store water bottles in the refrigerator and frozen water bottles in the freezer to help stabilize the temperature.
 - Note: This does not apply to pharmaceutical grade units if the manufacturer indicates that water bottles negatively impact the functionality of the unit.
- Must have room for air to circulate so the proper temperature range is maintained.
- 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 Pedialyte or juice for patient use is acceptable, ideally on the top shelf or bottom of the unit.
- 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.
- Before using a unit for vaccine storage, check and record the minimum and maximum temperatures each workday. Once you have two consecutive days of temperatures recorded within the recommended range, your unit is stable and ready for use:
 - Refrigerators: Two to seven days
 - Freezers: Two to three days

Safeguard the power supply

- Do not use ground fault interrupter (GFI) outlets, extension cords, or power strips.
 - Plug in only one storage unit per electrical outlet.
- Make sure the storage unit is plugged into an outlet where it cannot 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 on [Order Printed Immunization Materials \(www.health.state.mn.us/people/immunize/ordermat.html\)](http://www.health.state.mn.us/people/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 on [Order Printed Immunization Materials \(www.health.state.mn.us/people/immunize/ordermat.html\)](http://www.health.state.mn.us/people/immunize/ordermat.html).
- In larger sites, we encourage you to have a generator as a source of backup power in case of an emergency. You may also want to install an alert system to notify appropriate personnel of a power outage.
 - If you have a backup generator, it should be tested quarterly and receive annual maintenance.

Continuous temperature monitoring devices

- There are two categories of continuous temperature monitoring devices: data loggers and continuous temperature monitoring systems. Technology for these devices and systems is evolving.
 - 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 then be retrieved, viewed, and evaluated.
 - Continuous temperature monitoring systems: A system that provides information on temperatures for multiple vaccine storage units throughout a clinic or system, recorded at preset intervals. It transmits real-time data to a computer and has the ability to alert multiple people via text and/or email. There should be a written procedure to address who is notified when out-of-range temperatures occur and how the contact list is updated.
- Use a continuous temperature monitoring device with a current and valid Certificate of Calibration (in each storage unit).
 - Thermometers are not allowed for monitoring MnVFC vaccine.

Features of continuous temperature monitoring devices

- **Required features**
 - A temperature probe placed in the center of the storage unit with the vaccine.
 - In a pharmaceutical unit, placement of the probe in other locations may be suitable because pharmaceutical units maintain more consistent temperatures throughout the unit.
 - Continuous monitoring and recording capabilities to track and record temperatures over time.
 - The capacity to routinely download/save temperature data to an electronic file or folder (recommended at least weekly).
 - Temperature (current, minimum, and maximum) display that is easily read from outside the unit, including on a computer monitor.
- **Recommended features**
 - We *strongly recommend* a probe in buffered material (e.g., biosafe glycol).
 - Alarm for out-of-range temperatures.
 - Accuracy within +/-1°F (+/- 0.5°C).
 - Low battery indicator.
 - User programmable logging intervals (e.g., the user can set how often the device records the temperature) recommended at a maximum time interval of every 30 minutes.

Backup continuous temperature monitoring device

- Each MnVFC site must have one readily available backup continuous temperature monitoring device that has a valid Certificate of Calibration and meets the above requirements.
 - Use this device in case your main continuous temperature monitoring device is not working properly or current equipment requires calibration testing.
 - If the device is not onsite, it must be available within a reasonable timeframe. Clearly communicate to staff how to access the device and include this information in your vaccine management plan.
 - The Certificate of Calibration for the backup device should have a different calibration date than the main continuous temperature monitoring devices at the site unless you have onsite calibrations performed all on the same day.
 - Use the backup device if you need to transport vaccine.

Certificate of Calibration

- Calibration of continuous temperature monitoring devices must be performed at a minimum of every two to three years from the last calibration testing date or more frequently if recommended by the manufacturer. All continuous 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/device name or number.
 - Serial number.
 - Date of calibration.
 - Whether the instrument passed or failed testing (or instrument in tolerance).

- Recommended element:
 - Documented uncertainty (recommended uncertainty = $\pm 0.5^{\circ}\text{C}$ / $\pm 1.0^{\circ}\text{F}$). If the DDL is no longer accurate within these parameters, it must be replaced; adjusting the DDL is not recommended.
- 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 \(http://ilac.org/ilac-mra-and-signatories/\)](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: CDC recommends that certifications be issued for the entire monitoring unit (detachable probe, data logger, etc.) and not individual certificates for each component.

10. Receive and store vaccine carefully

- Properly receive and store vaccine and diluents.
- On site staff record minimum and maximum temperatures for each storage unit at the start of each clinic day.
- Take immediate action on out-of-range temperatures.

Receive vaccine shipments

- Appropriate staff must be on site to receive vaccine shipments at least one day per week other than Monday.
- You must check the condition of all vaccines and diluents immediately when they arrive.
 - Open vaccine packages immediately and store at appropriate temperatures.
 - Inspect the vaccine and packaging for damage.
 - Compare the vaccine received with the packing list. Report any discrepancies to the MnVFC program at 651-201-5522.
 - Check expiration dates and put vaccines and diluents with the earliest expiration date in front to be used first.
 - Check that the vaccine has remained in the correct temperature range.
 - Check the cold chain monitor for any indication of a temperature excursion 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 varicella must be shipped directly to all sites.

Store vaccine

- Vaccine packaging.
 - Keep vaccine or diluent 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.
- Organizing storage unit.
 - Store vaccine and diluents with enough space for cold air circulation.
 - Store vaccine and diluents in the middle of the compartment, two to three inches away from walls, ceiling, floor, door, 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.
 - Use open trays and baskets to organize vaccines.
 - Clearly label each container with the vaccine type.
 - Do not store “look-alike” and “sound-alike” vaccines and diluents next to each other (e.g., Tdap and DTaP, HepA and HepB and Hib).
 - Never store diluents in the freezer.
 - Do not store “look-alike” and “sound-alike” vaccines or diluents in the door or drawers of the refrigerator or freezer.
 - For vaccine or diluent stored in a household combination refrigerator/freezer:
 - You cannot store vaccine in the freezer section of a combination household unit.
 - For vaccine stored in the refrigerator section, do not use the top shelf for storing vaccine because the cold air vent blowing from the freezer may freeze vaccine located there. If you must use the top shelf of this type of unit, place water bottles underneath the cold air vent to prevent vaccine from being stored there.
 - Do 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.
 - Water bottles are especially important in household units. They are not recommended for use in all purpose-built or pharmaceutical-grade units (refer to manufacturer guidance).
 - 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. Water bottles in the refrigerator help stabilize temperatures.
 - Add or subtract water bottles one at a time to prevent temperature fluctuations.
 - Too many water bottles in the door can prevent the door from closing tightly.
 - Mark water bottles “Do Not Drink.”

Monitor and document temperatures

- Temperature monitoring and documentation requirements.
 - Record for each storage unit **at the start of each work day**:
 - Minimum (lowest) and maximum (highest) temperature.
 - Date and time.
 - Name or initials of **on-site staff** reviewing and recording the min/max temperatures.
 - Temperatures can be recorded either electronically or on a paper temperature log. Record actual temperatures and do not record alarm settings.
 - Based on the type of continuous temperature monitoring device in use, the min/max may or may not need to be reset. Follow the manufacturer’s instructions specific to your device.
 - Review storage unit temperature readings **weekly** for out of range temperatures or changes in temperature trends that might require action (e.g., adjusting unit temperature or repairing/replacing storage or continuous temperature monitoring equipment).
- Temperature monitoring best practices.
 - Record current temperatures in each storage unit twice each day.
 - View temperatures throughout the day and take immediate action on out of range temperatures.
 - Document any actions taken on out-of-range temperatures.
 - Check that:
 - 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, floor, or vents.
 - Vaccine is not stored in the door or in the drawers.
 - The door of the unit is tightly closed.
 - Paper logs note when site is closed and missed readings are left blank.
 - A copy of your temperature logs/reports may be requested by the MnVFC program to check temperature control or to assist in troubleshooting issues.

Take immediate action on out-of-range temperatures and mishaps

When your continuous temperature monitoring device is reading a temperature that falls outside the recommended range, it is considered an excursion or out-of-range temperature. Vaccines exposed to out-of-range temperatures may become nonviable (unusable, especially if frozen).

- Vaccine must be stored within the following temperature ranges:
 - Refrigerator between 36°F and 46°F (between 2°C and 8°C), aim for 40°F (5°C).
 - Freezer between -58°F and +5°F (between -50°C and -15°C), aim for 0°F (-18°C).

Move vaccine immediately for refrigerated vaccine that is less than 2 degrees Celsius (36 degrees Fahrenheit) and follow action steps for out-of-range temperatures. Vaccines exposed to freezing temperatures for even a brief time may become nonviable (unusable).

- **If you find an out-of-range temperature, take immediate action:**
 - Determine the problem. Attempt to fix the cause, if possible. It might be easily corrected (e.g., door not shut, power outage, unit malfunction).
 - Adjust the storage unit's temperature, if necessary.
 - Report the excursion to the vaccine coordinator or backup vaccine coordinator, if available.
- Monitor the temperature. If the temperature is too warm and doesn't stabilize in the correct range within 30 minutes, follow these action steps:
 - Stop using the vaccine.
 - Mark the vaccine "Do Not Use" so no one administers it.
 - Move the vaccine to a storage unit that is maintaining the correct temperature.
 - Collect the lot numbers, expiration dates, storage unit temperatures, the room temperature, and the time the unit was out-of-range.
 - Evaluate the temperature log (download data or review CTM information) to determine the length of time the storage unit was out of range and how high/low the temperature got.
 - Determine if any of this vaccine was involved in a previous storage and handling mishap.
 - Be aware that open multidose vials and refrigerated MMR vaccine are especially sensitive to out-of-range temperatures. Confirm viability with vaccine manufacturer(s) with every excursion even if the temperature stabilized within 30 minutes.
 - Call the vaccine manufacturer(s) and ask to speak to a medical consultant or quality assurance staff. Manufacturer contact information is available on CDC's [Vaccine Manufacturer Distributor Contact List \(www.cdc.gov/vaccines/hcp/admin/storage/downloads/manufact-dist-contact.pdf\)](http://www.cdc.gov/vaccines/hcp/admin/storage/downloads/manufact-dist-contact.pdf).
 - Call the MnVFC program at 651-201-5522 or email at health.mnvfc@state.mn.us to report the mishap, get instructions on how to return nonviable MDH vaccine, and help with patient recall, if applicable.
- If a temperature excursion occurs that results in a large amount of nonviable vaccine, please contact the MnVFC program for information on how to replace vaccine.

- Document your actions. You can use the *Storage and Handling Mishap Log* (Appendix A), the *Storage and Handling Mishap Checklist* (Appendix B), both on [Vaccine Management Forms \(www.health.state.mn.us/people/immunize/hcp/mnvfc/forms.html\)](http://www.health.state.mn.us/people/immunize/hcp/mnvfc/forms.html), 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.
- Vaccine that is expired or exposed to out-of-range temperatures and is in its original vial or pre-filled syringe can be returned to McKesson Specialty Distribution within six months of expiration. (See section 11.)
- Return or dispose of privately purchased nonviable vaccine per your site's policy.

More detailed information about receiving and storing vaccine

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

11. Manage MnVFC vaccine efficiently

- Take monthly vaccine inventory, order only the amount of vaccine you need, rotate stock, and transfer vaccine that is nearing expiration to other sites to prevent wasting vaccine.

Manage 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 so vaccine due to expire first is in front.
 - Vaccine must be rotated every week or when a new shipment comes in (whichever happens more frequently).
- Keep vaccine in the original packaging to make managing inventory easier.

Order MnVFC vaccine based on administration data

- Run a monthly report that shows doses of private vaccine given to MnVFC-eligible children. Analyze the vaccine administration data to track doses and determine your MnVFC vaccine order. Every dose administered must be documented and be reportable to determine the number of doses needed to order.
 - The preferred report to use is the Doses Administered by Eligibility Report (DAER) in MIIC. This handout explains how to run this MIIC report: [Reporting Dose-Level Eligibility to MIIC \(www.health.state.mn.us/people/immunize/miic/managevax/reportdle.pdf\)](http://www.health.state.mn.us/people/immunize/miic/managevax/reportdle.pdf).
 - Another option is to run your own report (e.g., through electronic health record or billing data, etc.), but to use this option, you must periodically compare your data to make sure it aligns with the DAER.
- When providers have administered the minimum order amount of a given vaccine to MnVFC-eligible patients, they may place an order to replenish those privately purchased doses.

MnVFC vaccine ordered must replace doses previously administered to MnVFC-eligible patients; vaccine ordered cannot exceed the number of doses given.

- For example, you can only order polio after administering 10 doses of polio to MnVFC-eligible patients. If you have administered 12 doses of polio you can order 10 doses now and after you administer 8 more doses you can order an additional 10 doses.
- Order the same vaccine type that was administered to MnVFC-eligible patients.
 - For example, if patients have received Infanrix vaccine, you can replace the doses with any of the DTaP vaccines regardless of presentation or brand. You are not able to replace those doses with a different vaccine like Hepatitis A or a combination vaccine like DTaP-HepB-IPV.
- It is an expectation that enrolled sites will order vaccine at least every 12 months.
 - If your site does not order vaccine in a twelve-month period, MnVFC staff may follow-up with you to discuss the reason behind the lack of ordering.
- 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.
- You must include current storage unit temperatures with each order.

Track your MnVFC vaccine orders in MIIC

- In MIIC, select *View Vaccine Management* to track the shipment status of your MnVFC vaccine orders.
- Influenza and COVID-19 vaccine requests can also be tracked under *manage special vaccine event* in MIIC.
- Go to [Vaccine Ordering and Management in MIIC \(www.health.state.mn.us/people/immunize/miic/managevax/index.html\)](http://www.health.state.mn.us/people/immunize/miic/managevax/index.html) for a detailed guide on how to create and view the shipping status of your MnVFC vaccine orders in MIIC.

Transferring vaccine

- If you want to receive MnVFC vaccine from a site that is not within your system, you need to have administered at least as many doses of that type of vaccine to MnVFC-eligible children. These will count as doses from the MnVFC program in the same way as doses ordered from MDH.
- Only full, sealed vials or unopened pre-filled syringes can be transferred.
- If you want to send vaccine to another site, identify a site, 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 D) from [Vaccine Management Forms \(www.health.state.mn.us/people/immunize/hcp/mnvfc/forms.html\)](http://www.health.state.mn.us/people/immunize/hcp/mnvfc/forms.html).
- Keep one copy, enclose one copy with the vaccine, and send one copy to the MnVFC program.

Minnesota Department of Health (MDH) Vaccine Transfer Record

Don't let vaccines go unused! If you have Minnesota Vaccines for Children (MnVFC) vaccine that will expire within three months, you must transfer it to another MnVFC site within one year.

Before completing this form, identify a MnVFC-eligible site and contact them to make sure they can use, store, and receive the vaccine.

- Only full, sealed vials or unopened pre-filled syringes can be redistributed.
- If you have frozen vaccine (MnVFC) and expired the vaccine, call us at 651-261-5522 for additional guidance.
- Keep one copy of this form, enclose one copy with the vaccine, and send one copy to us via email: vaccine@state.mn.us. Both parties must keep a copy of the transfer record for three years.
- Follow CDC and manufacturer specifications for maintaining the recommended temperature range during transport of vaccine.
- Guidelines is available in Tracking System for Transport during Emergencies: [www.cdc.gov/emergency-preparedness-response-recovery/](http://www.cdc.gov/emergency-preparedness-response-recovery/emergency-preparedness-response-recovery/)

Name and address of the MINNESOTA vaccinee		MnVFC PIN	Expiration Date	Doses
Vaccine type	Lot number	Expiration date	Number of doses	
Vaccine type	Lot number	Expiration date	Number of doses	
Vaccine type	Lot number	Expiration date	Number of doses	
Vaccine type	Lot number	Expiration date	Number of doses	
Transfer date of vaccine administration	Signature and print name of recipient site contact	Date of vaccine administration	If yes, Action taken:	

For more information, contact the MnVFC program at 651-261-5522 or vaccine@state.mn.us.
 For additional information, visit www.health.state.mn.us/people/immunize/hcp/mnvfc/forms.html.
 MDH DEPARTMENT OF HEALTH
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- 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 (between 36°F and 46°F or between 2°C and 8°C) during transport of vaccine.
- Guidance for packing and transporting vaccine is available in [Packing Vaccines for Transport during Emergencies \(www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf\)](https://www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf).
- You must use a continuous temperature monitoring device with a valid Certificate of Calibration.

Borrowing vaccine

- This should be a rare, unplanned occurrence.
- Use the *Vaccine Borrowing Report* (Appendix E) 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, vaccine stock used, patient’s name and date of birth, 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 [Vaccine Management Forms \(www.health.state.mn.us/people/immunize/hcp/mnvfc/forms.html\)](http://www.health.state.mn.us/people/immunize/hcp/mnvfc/forms.html).
- Keep a copy of the *Vaccine Borrowing Report* for three years.

The form is titled "Vaccine Borrowing Report" and includes a header with "Date" and "MDH File" fields. Below the header is a paragraph of instructions. The main body of the form contains a table with two columns: "Reason for Vaccine Borrowing" and "Assignment Coding Legend". The table lists various reasons such as "Patient vaccine not available on arrival date" and "Vaccine not available on arrival date" with corresponding codes. At the bottom, there are fields for "Vaccine Type", "Vaccine Lot", "Vaccine Expiration Date", and "Vaccine Manufacturer".

Manage nonviable vaccine

- All nonviable MDH vaccine can be reported to MDH. We recommend you report wastage on a monthly basis. Vaccine that is expired or exposed to out-of-range temperatures and is in its original, unopened vial or pre-filled syringe can be returned to McKesson Specialty Distribution within six months of expiration.
- There are two categories of nonviable vaccine: returned and wasted.
 - **Returned:** This is nonviable vaccine in its original, unopened vial or syringe. Examples of vaccine that should be reported for return include:
 - Expired vaccine. Note: Do not return vaccine as “expired vaccine” before its expiration date, including influenza vaccine, unless it was short dated by the manufacturer.
 - Vaccine that is recalled by the manufacturer.
 - Vaccine that is nonviable due to exposure to out-of-range temperatures.
 - **Wasted:** This is nonviable vaccine that should not be returned and should be properly disposed of according to your policy. Examples of vaccine that should be reported as wastage include:
 - Vaccine drawn into the syringe but not administered.
 - Vaccine in open vial but doses not administered.
 - Compromised vial (e.g., due to a drop causing damage to vial integrity or sterility), broken vial, or lost vial.

- There are two ways to report nonviable MDH vaccine:
 - Minnesota Immunization Information Connection or MIIC online (preferred): [Reporting Nonviable MDH Vaccine to MIIC \(www.health.state.mn.us/people/immunize/miic/managevax/nonviable.pdf\)](http://www.health.state.mn.us/people/immunize/miic/managevax/nonviable.pdf).
 - If you report vaccine for return, you will receive an email with shipping labels from “UPS Quantum View [pkginfo@ups.com]”.
 - *Minnesota Department of Health (MDH) Nonviable Vaccine Form* on [Vaccine Management Forms \(www.health.state.mn.us/people/immunize/hcp/mnvfc/forms.html\)](http://www.health.state.mn.us/people/immunize/hcp/mnvfc/forms.html).
- Keep nonviable vaccine documentation for three years. (If you report nonviable vaccine via MIIC, you do not need to keep a paper copy).
- Once you have determined vaccine is nonviable, remove it from your storage unit and mark it “Do Not Use” to avoid unintentional use.
- For multiple dose vials, refer to the product’s package insert regarding the expiration and beyond-use date. Package inserts for vaccines can be found on IAC’s [Package Inserts & FDA Product Approvals page \(www.immunize.org/fda/\)](http://www.immunize.org/fda/).

12. Post an anaphylaxis protocol

- Develop and clearly post an anaphylaxis protocol.
 - Ensure staff are properly trained on your anaphylaxis protocol 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 Immunize.org.
 - The protocol must be reviewed at least every three years and signed and dated by your medical provider.
 - All staff who administer vaccines should maintain current emergency response skills:
 - Know the signs of anaphylaxis and be currently certified in cardiopulmonary resuscitation (CPR).
 - Review the protocol with all staff that administer vaccine and care for patients who receive vaccine – both when they are hired and each year after that.
 - Emergency supplies must be readily available where vaccines are administered. On a monthly basis, assign staff to check that emergency supplies have not expired and to replenish supplies after an anaphylaxis event has occurred.
 - Provider should plan for the availability of at least three doses of epinephrine.
 - Assign a staff member to submit a report to [VAERS \(vaers.hhs.gov/\)](http://vaers.hhs.gov/) in the event of an adverse reaction following vaccine administration. (See section 7.)



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

13. Assign a vaccine coordinator and backup vaccine coordinator

- Designate a vaccine coordinator and backup vaccine coordinator to oversee site administrative immunization activities, ordering and vaccine management activities.
- Notify us of all vaccine coordinator and backup vaccine coordinator changes by completing the [MnVFC Contact Update Form \(https://redcap.health.state.mn.us/redcap/surveys/?s=HTF4FJ7W734XKJWY\)](https://redcap.health.state.mn.us/redcap/surveys/?s=HTF4FJ7W734XKJWY).
- Have written immunization staff responsibilities. This manual can fulfill this requirement if staff read the entire manual and sign page 7.

Assign a vaccine coordinator and backup vaccine coordinator

- Assign staff to the roles of vaccine coordinator and backup vaccine coordinator. Train them on the required activities listed below. Vaccine coordinator is responsible for all activities and can assign some activities to the backup vaccine coordinator (or other designee).
- Vaccine coordinator is the primary MnVFC/UUAV contact at each site. All sites are required to have a vaccine coordinator on-site. This person is ultimately responsible for the management of vaccine and ensuring their site complies with MnVFC program requirements. They receive MIIC vaccine order confirmation emails for MnVFC orders.
- Backup vaccine coordinator is the secondary MnVFC contact at each site. All sites are required to have a fully trained backup vaccine coordinator who is responsible when the primary vaccine coordinator is unavailable. They receive MIIC vaccine order confirmation emails for MnVFC orders.
- Notify us of all vaccine coordinator and backup vaccine coordinator changes by completing the [MnVFC Contact Update Form \(https://redcap.health.state.mn.us/redcap/surveys/?s=HTF4FJ7W734XKJWY\)](https://redcap.health.state.mn.us/redcap/surveys/?s=HTF4FJ7W734XKJWY).

Vaccine coordinator and backup vaccine coordinator responsibilities:

The vaccine coordinator is responsible for overseeing all vaccine management within the facility, (or backup vaccine coordinator if the vaccine coordinator is unavailable) including:

- Develop and maintain the Vaccine Management Plan.
- Monitor storage and handling and vaccine administration practices in the facility.
- Oversee vaccine ordering and transfer vaccine that is nearing expiration to another MnVFC-enrolled site to avoid wastage.
- Ensure and document annual management training for designated staff, as well as train new staff upon hire.
- Participate in and document completion of annual training on VFC requirements.
- Store all required documentation for three years, or longer if required by state statutes or rules, even in the case of provider retirement or provider location closure.
- To effectively perform their duties, the vaccine coordinator and backup vaccine coordinator must be fully trained on routine and emergency standard operating procedures (SOPs) for vaccine ordering, storage, handling, transport, and inventory management.
- Communicate with the MnVFC program. These people will receive regular communications from the MnVFC program by mail, phone, and email. They will need to share some of it with other staff.

- Complete the MnVFC Replacement Method Sites Online Training on [Required Annual Reports and Trainings \(www.health.state.mn.us/people/immunize/hcp/mnvfc/required.html\)](http://www.health.state.mn.us/people/immunize/hcp/mnvfc/required.html) (see page 42).
- Sign up to receive [MnVFC Announcements \(www.health.state.mn.us/people/immunize/hcp/mn-vfc/announcements.html\)](http://www.health.state.mn.us/people/immunize/hcp/mn-vfc/announcements.html) via email. Click on the envelope near the top of the page.
- Sign up for [Got Your Shots? News \(www.health.state.mn.us/people/immunize/hcp/gys/index.html\)](http://www.health.state.mn.us/people/immunize/hcp/gys/index.html) and the [Immunize.org IZ 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) as well as new staff upon hire and keep a log to document attendance.
- Develop policies and procedures related to vaccine management. This manual can fulfill this requirement if your staff read the entire manual, sign page 7 and complete the emergency plan and attach an anaphylaxis protocol to the manual (see page 6 for more information).
- Download and review temperature data weekly.
- Make sure all ACIP-recommended vaccines for your patient population are ordered, received, stored, and handled properly.
- Designate on-site staff to document the min/max temperature in each storage unit at the start of each day the site is open.
- Respond to temperature excursions (out-of-range temperatures).
- Conduct inventory of vaccines at least monthly and with each order.
- Check expiration dates and rotate stock weekly.
- 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.

14. Follow up on feedback you receive from site visits

- Participate in 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 after a MnVFC site visit.
- Cooperate with MnVFC site reviewer staff performing an unscheduled storage and handling site visit if your site is selected to be visited.

MnVFC compliance site visits

- You will participate in a site visit by an MDH or local public health staff person, called a MnVFC site reviewer, every one to two years.
- Site visits take approximately 2 hours.
- They will offer you support and guidance and ensure you are meeting the federal and state MnVFC requirements.
- The MnVFC site reviewer will:
 - Contact you in advance of each visit.
 - Encourage you to invite other staff members who could contribute to the visit.

- Share resource materials during the visit.
- 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 also call on MnVFC site reviewers 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 MnVFC-eligible children are receiving properly managed, viable vaccines and provide education about requirements and best practices related to storage and handling.
- As part of your signed *MnVFC Provider Agreement*, your participation in unscheduled visits is required. We appreciate your cooperation when we arrive at your site unannounced.

15. Maintain your enrollment in the MnVFC program

- Sites must complete the following required reports and trainings to maintain their enrollment:
 - *MnVFC Program Provider Agreement*
 - *MnVFC Annual Report of Immunized Pediatric Patients*
 - *Replacement Method of Vaccine Management Agreement*
 - MnVFC Replacement Method Sites Online Training

Maintain your enrollment in MnVFC

Each site that stores and/or administers MnVFC vaccine must enroll in the MnVFC program and have their own personal identification number (PIN). Sites are responsible for maintaining their enrollment in the program by completing the requirements below.

Every 24 months requirement

Submit the *MnVFC Program Provider Agreement*

- All sites need to complete and have their medical director sign a *MnVFC Program Provider Agreement* every 24 months.
- A link to complete the *MnVFC Program Provider Agreement* will be emailed. More information is available on [MnVFC Required Annual Reports and Trainings \(www.health.state.mn.us/people/immunize/hcp/mnvfc/required.html\)](http://www.health.state.mn.us/people/immunize/hcp/mnvfc/required.html).

Every 12 months requirements

Submit the *MnVFC Annual Report of Immunized Pediatric Patients*

- Complete and submit the *Minnesota Vaccines for Children (MnVFC) Program Annual Report of the Number of Immunized Pediatric Patients* 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.
- If you redistribute to satellite sites, submit one annual report that includes data from those sites.
- A link to complete the *MnVFC Annual Report of Immunized Pediatric Patients* will be emailed to your system-level contact (if you have one), or it will be emailed to your vaccine coordinator when

it becomes available. More information is available on [MnVFC Required Annual Reports and Trainings \(www.health.state.mn.us/people/immunize/hcp/mnvfc/required.html\)](http://www.health.state.mn.us/people/immunize/hcp/mnvfc/required.html).

- Sites that track immunizations with dose-level eligibility (DLE) information in MIIC can use the *Request MnVFC Reports in MIIC* to produce data for this report. For more information, see the MnVFC Reports in MIIC user guidance on [Vaccine Ordering and Management in MIIC \(www.health.state.mn.us/people/immunize/miic/managevax/index.html\)](http://www.health.state.mn.us/people/immunize/miic/managevax/index.html).
- Ordering privileges may be suspended if the *MnVFC Annual Report of Immunized Pediatric Patients* is not submitted by Nov. 30.

Submit the MnVFC Replacement Method Agreement

- Complete and sign a *Replacement Method of Vaccine Management Agreement* by Nov. 30 of each year.
- The *Replacement Method of Vaccine Management Agreement* is available on [MnVFC Required Annual Reports and Trainings \(www.health.state.mn.us/people/immunize/hcp/mnvfc/required.html\)](http://www.health.state.mn.us/people/immunize/hcp/mnvfc/required.html).
- Systems may sign one *Replacement Method of Vaccine Management Agreement* on behalf of all sites using the replacement method within the system. A list of the MnVFC PINs for all of the sites included in the agreement must be attached.
- If you don't submit the *Replacement Method of Vaccine Management Agreement* and/or meet the requirements of the agreement, you will be required to switch to the separate stock method of vaccine management.

Complete the MnVFC Replacement Method Online Training

- Your site's vaccine coordinator and backup vaccine coordinator must complete the MnVFC Replacement Method Sites Online Training each year by Nov. 30 to meet the federal VFC education requirement.
- The MnVFC Replacement Method Online Training is available on [MnVFC Required Annual Reports and Trainings \(www.health.state.mn.us/people/immunize/hcp/mnvfc/required.html\)](http://www.health.state.mn.us/people/immunize/hcp/mnvfc/required.html).
- After completing the training, print the completion certificate and keep it with your MnVFC documents for three years. You will be asked to show your certificate during your MnVFC site visit.

16. Avoid fraud and abuse

- Take responsibility for being aware of and following MnVFC requirements.
- Call the MnVFC program if you have questions about 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. It results 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 or abuse to the MnVFC program by calling 651-201-5522 or emailing

health.mnvfc@state.mn.us.

- All instances of possible fraud or 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:
 - Failing to identify MnVFC-eligible patients.
 - Charging more than the maximum allowable fee for administration of a vaccine to a MnVFC-eligible patient.
 - Not providing vaccine to a MnVFC-eligible patient because they are unable to pay the administration fee.
 - Billing or charging for vaccine given to a MnVFC-eligible child.
 - Failing to maintain MnVFC records for a minimum of three years.
 - Failing to properly store and handle vaccine that could be administered to a MnVFC-eligible child, including not responding appropriately to temperature excursions.
 - Ordering more vaccine from the MnVFC program than was administered to MnVFC-eligible children.
 - Failing to comply with any part of the provider agreement.



Contacts and Resources

Contacts and Resources

Phone/Email

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

- Phone: 800-232-4636 (English and Spanish)
- Phone: 800-232-6348 (TTY)
- Contact CDC-INFO online form: <https://wwwn.cdc.gov/dcs/ContactUs/Form>

MnVFC Program

- Phone: 651-201-5522
- Email: health.mnvfc@state.mn.us

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

Web

- Minnesota Department of Health
 - MnVFC website. Includes MnVFC overview, forms used by MnVFC providers, and an archive of update notices sent to MnVFC providers.
www.health.state.mn.us/vfc
 - Vaccine Ordering and Management in MIIC. Includes user guides on how to create and view vaccine orders, report dose-level eligibility to MIIC, and how to use MnVFC reports in MIIC.
www.health.state.mn.us/people/immunize/miic/managevax/index.html
 - Immunization home page. Contains links to other pages listed below.
www.health.state.mn.us/immunize
 - Immunization Best Practices has all the information needed to make sure patients are properly immunized and vaccine is stored correctly.
www.health.state.mn.us/people/immunize/hcp/bestpractices.html
 - Immunization Information for Health Care Providers.
www.health.state.mn.us/people/immunize/hcp/index.html
 - Minnesota Immunization Information Connection (MIIC).
www.health.state.mn.us/miic

- Immunize.org - formerly Immunization Action Coalition (IAC)
 - Immunize.org is a non-profit agency that provides CDC-approved materials, including: Vaccine Information Statements (VISs) in 32 languages, screening questionnaires, anaphylaxis standing orders.
www.immunize.org
 - Immunize.org IZ Express is a weekly email that includes the latest vaccine recommendations and licensures, new and updated VISs, and practical vaccination resources.
www.immunize.org/subscribe/
 - Vaccine Manufacturers: Contact and product information
www.immunize.org/resources/manufact_vax.asp
 - Food and Drug Administration: Package Inserts & FDA Product Approvals
www.immunize.org/fda/
- Centers for Disease Control and Prevention
 - Vaccines & Immunizations. 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
 - Vaccine Storage and Handling. Online training videos and resource materials including checklists, logs, records, and posters.
www.cdc.gov/vaccines/hcp/admin/storage/index.html
- Vaccine Adverse Events Reporting System (VAERS)
 - VAERS reporting information. Report online or download the report form.
<https://vaers.hhs.gov/>

Appendices

- A. *Storage and Handling Mishap Log*, Minnesota Department of Health
www.health.state.mn.us/people/immunize/hcp/mnvfc/mishaplog.pdf
- B. *Storage and Handling Mishap Checklist*, Minnesota Department of Health
www.health.state.mn.us/people/immunize/hcp/mnvfc/vaxchk1st.pdf
- C. *Immunization Billing Guidance for MnVFC Replacement Method Sites*,
Minnesota Department of Health
www.health.state.mn.us/people/immunize/hcp/mnvfc/billingtipsrep.pdf
- D. *Minnesota Department of Health (MDH) Vaccine Transfer Record*
www.health.state.mn.us/people/immunize/hcp/mnvfc/transfer.pdf
- E. *Vaccine Borrowing Report*, Centers for Disease Control and Prevention
www.health.state.mn.us/people/immunize/hcp/mnvfc/vfcborrowrpt.pdf
- F. *Medical Management of Vaccine Reactions in Children and Teens in a Community Setting*,
Immunization Action Coalition
www.immunize.org/catg.d/p3082a.pdf
- G. *Medical Management of Vaccine Reactions in Adult in a Community Setting*,
Immunization Action Coalition
www.immunize.org/catg.d/p3082.pdf

Storage and Handling Mishap Log

	Date and time	Storage unit location and temperature	Problem	* Action taken	Outcome	Completed Storage and Handling Mishap Checklist?*	Notified supervisor	Initials
Example	3/8/2023 2:15 p.m.	Med room 2 fridge 9.4C.	Refrigerator door found open.	Door closed. Vaccine marked "Do Not Use" and quarantined. Emergency Plan implemented. Called vaccine manufacturers.	Open IPV vial nonviable. Reminder placed on unit to check door, facilities to adjust unit's feet, door latch ordered.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	AL
1						<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
2						<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
3						<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
4						<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	

*The Storage and Handling Mishap Checklist is available on [Vaccine Management Forms \(www.health.state.mn.us/people/immunize/hcp/mnvc/forms.html\)](http://www.health.state.mn.us/people/immunize/hcp/mnvc/forms.html).

Take action to keep vaccines safe!

For more information about vaccine storage and handling, see your MnVFC Policies and Procedures Manual on [Required Annual Reports and Trainings \(www.health.state.mn.us/people/immunize/hcp/mnvc/required.html\)](http://www.health.state.mn.us/people/immunize/hcp/mnvc/required.html) or [CDC's Vaccine Storage and Handling Toolkit \(www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html\)](http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html).



Minnesota Department of Health
Minnesota Vaccines for Children Program
651-201-5522 | health.mnvc@state.mn.us



Storage and Handling Mishap Checklist

A storage and handling mishap can happen when your continuous temperature monitoring device records a temperature that falls outside the recommended range, even for a short amount of time. This is considered an excursion or out-of-range temperature. Vaccines exposed to out-of-range temperatures may become nonviable (ineffective).

Move vaccine immediately for refrigerated vaccine that is less than 2°C (36°F) and follow action steps below for out-of-range temperatures. Vaccines exposed to freezing temperatures for even a brief time may be nonviable (unusable).

Immediate actions when a storage and handling mishap has occurred.

- Determine the problem. Attempt to fix the cause (e.g., door not shut, unit malfunction, etc.).
- Adjust the storage unit's temperature, if necessary.
- Report the excursion to the vaccine coordinator or backup vaccine coordinator, if available.

Monitor the temperature. If the temperature is too warm and doesn't stabilize in the correct range within 30 minutes, follow these action steps*:

- Stop using the vaccine.
- Mark the vaccine "Do Not Use" and quarantine it until viability is determined.
- Consult and execute your Emergency Vaccine Management Plan.
- Move the vaccine to a storage unit that is maintaining the correct temperature.
- Gather vaccine information, storage unit, temperatures, room temperature, and duration of excursion.

*Open multidose vials and refrigerated MMR vaccine are especially sensitive to out-of-range temperatures. Confirm viability with vaccine manufacturer(s) with every excursion even if the temperature stabilized within 30 minutes.

Date:	Room temperature (if available):
Reason for excursion, if known:	

Refrigerator: between 36°F and 46°F (between 2°C and 8°C)

Refrigerator name/location:	Time out of range:
Highest or lowest out-of-range temp: °F or °C (circle)	<input type="checkbox"/> Too cold <input type="checkbox"/> Too warm

Vaccines stored in this refrigerator

Vaccine name	Manufacturer	Lot number	Expiration date

STORAGE AND HANDLING MISHAP CHECKLIST

Freezer: between -58°F and +5°F (between -50°C and -15°C)

Freezer name/location:	Time out of range:
Highest or lowest out-of-range temp: °F or °C (circle)	<input type="checkbox"/> Too cold <input type="checkbox"/> Too warm

Vaccines stored in this freezer

Vaccine name	Manufacturer	Lot number	Expiration date

- Determine if any of this vaccine was involved in a previous storage and handling mishap.
- Call the vaccine manufacturer(s) for stability data to determine viability. Ask to speak to the medical consultant or quality assurance staff. Manufacturer contact information is available at [CDC Vaccine Manufacturer Distributor Contact List \(www.cdc.gov/vaccines/hcp/admin/storage/downloads/manufact-dist-contact.pdf\)](http://www.cdc.gov/vaccines/hcp/admin/storage/downloads/manufact-dist-contact.pdf).

Vaccine manufacturer recommendation.

- Vaccine is viable to current expiration date. If only certain vaccines are viable, list them here: _____
- Vaccine is viable to a modified expiration date (write the date on the box). Note the vaccine name and new expiration date here: _____
- Vaccine is nonviable. If only certain vaccines are nonviable, list them here: _____

Contact the MnVFC program at 651-201-5522 to report the mishap, for instructions on how to return nonviable MnVFC vaccine, and help with patient recall, if applicable. Do not discard or remove vaccine from the storage unit before speaking to MnVFC staff.

If vaccine is determined to be nonviable:

- Remove nonviable vaccine from the storage unit with the “Do Not Use” marking still in place.
- Determine if affected vaccine was administered to patients. If so, identify patients to contact for revaccination.
- Return MDH nonviable vaccine by following instructions in your *MnVFC Policies and Procedures Manual* in section 10 “Manage MnVFC vaccine efficiently.”
- Return or dispose of privately purchased nonviable vaccine per your site’s policy.

Minnesota Department of Health
 Minnesota Vaccines for Children (MnVFC) Program
 PO Box 64975, St. Paul, MN 55164-0975
 651-201-5522
health.mnvfc@state.mn.us
www.health.state.mn.us/vfc

08/28/2023

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



Immunization Billing Guidance for MnVFC Replacement Method Sites

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"> Don't bill or charge for the cost of the vaccine. 	<ul style="list-style-type: none"> Bill the MHCP \$21.22 per dose. Certain sites including FQHC, RHC, IHS and tribal clinics may bill an encounter fee for the entire visit, and this is allowable.
Uninsured	Yes	<ul style="list-style-type: none"> Use MnVFC vaccine. Don't charge for the cost of the vaccine. 	<ul style="list-style-type: none"> Charge the patient \$21.22 or less per dose. <ul style="list-style-type: none"> Do not issue more than a single bill; waive the fee if the patient is unable to pay it.
American Indian/Alaskan Native	Yes	<ul style="list-style-type: none"> Don't bill or charge for the cost of the vaccine. However, if the patient is privately insured and prefers to use insurance, use private vaccine and bill the insurance. 	<ul style="list-style-type: none"> If covered by an MHCP, bill the MHCP \$21.22 per dose. If un- or underinsured, charge the patient \$21.22 or less per dose. Do not issue more than a single bill; waive the fee if the patient is unable to pay it. If privately insured and prefers to use insurance, bill the insurance for the fee.
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"> Don't charge for the cost of the vaccine. 	<ul style="list-style-type: none"> Charge the patient \$21.22 or less per dose. Do not issue more than a single bill; waive the fee if the patient is unable to pay it.
Underinsured: At a site that is not eligible to see underinsured children	No	<ul style="list-style-type: none"> Consider sending the patient to a site where they would be eligible for MnVFC. If the patient stays at a private site, do not use MnVFC vaccine. 	<ul style="list-style-type: none"> Consider sending the patient to a site where they would be eligible for MnVFC.

IMMUNIZATION BILLING GUIDANCE FOR MNVFC REPLACEMENT METHOD SITES

Patient's status	MnVFC eligible?	Cost of vaccine	Administration fee
Insured	No	▪ Bill the insurance.	▪ Bill the usual and customary administration fee to the insurance.

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 forms on [MnVFC Program Resources](http://www.health.state.mn.us/people/immunize/hcp/mnvfc/resources.html) (www.health.state.mn.us/people/immunize/hcp/mnvfc/resources.html).

The MnVFC program has a self-screening form that parents can fill out on [Free or Low-Cost Shots for Children](http://www.health.state.mn.us/people/immunize/basics/howpay.html) (www.health.state.mn.us/people/immunize/basics/howpay.html). It may be 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 more than one bill and do not send 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](http://www.health.state.mn.us/people/immunize/hcp/billing/) (www.health.state.mn.us/people/immunize/hcp/billing/).

Minnesota Vaccines for Children Program
 PO Box 64975
 St. Paul, MN 55164-0975
 651-201-5522 or 1-800-657-3970
 Email: health.mnvfc@state.mn.us
www.health.state.mn.us/vfc

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

9/2021

2

Minnesota Department of Health (MDH) Vaccine Transfer Record

Don't let vaccine go to waste! If you have Minnesota Vaccines for Children (MnVFC) vaccine that will expire within three months, you must transfer it to another MnVFC site who can use it. **Before completing this form, identify a MnVFC-enrolled site and contact them to make sure they can use, store, and receive the vaccine.**

- Only full, sealed vials or unopened pre-filled syringes can be redistributed.
- If you have frozen vaccine (MIMRV and varicella) that you cannot use, call us at 651-201-5522 for additional guidance.
- Keep one copy of this form, enclose one copy with the vaccine, and send one copy to us via email at health.mnvfc@state.mn.us. Both parties must keep a copy of the transfer record for three years.
- Follow CDC and manufacturer specifications for maintaining the recommended temperature range during transport of vaccine.
- Guidance is available in [Packing Vaccines for Transport during Emergencies \(www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf\)](https://www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf).

Name and address of site **SENDING** vaccine:

MnVFC PIN:

Signature/title:

Date:
(mm/dd/yyyy)

Name and address of site **RECEIVING** vaccine:

MnVFC PIN:

Signature/title:

Date:
(mm/dd/yyyy)

Vaccine type:	NDC #*:	Lot #*:	Expiration date: (mm/dd/yyyy)	Number of doses:
Vaccine type:	NDC #*:	Lot #*:	Expiration date: (mm/dd/yyyy)	Number of doses:
Vaccine type:	NDC #*:	Lot #*:	Expiration date: (mm/dd/yyyy)	Number of doses:
Vaccine type:	NDC #*:	Lot #*:	Expiration date: (mm/dd/yyyy)	Number of doses:

* Located on the box.

Time and Temperature of vaccine upon departure (Fahrenheit or Celsius):

Time and Temperature of vaccine upon arrival (Fahrenheit or Celsius):

Out-of-range temperature during transport (review alarms, min./max): Yes No If yes, action taken:

Notes:

For more information, contact the MnVFC program:
651-201-5522 | health.mnvfc@state.mn.us
www.health.state.mn.us/vfc
To obtain this information in a different format, call: 651-201-5414



4/2023

Site name: _____
MnVFC PIN: _____

Vaccine Borrowing Report

Minnesota Vaccines for Children (MnVFC)-enrolled providers are expected to manage and maintain an adequate inventory of vaccine for their MnVFC and non-MnVFC-eligible patients. Borrowing means using a dose of vaccine from the MnVFC or Uninsured/Underinsured Adult Vaccine (UUAV) stock to administer to a patient not eligible for the program, or when a provider borrows a dose of vaccine from private stock to use on MnVFC or UUAV eligible patients. **Planned borrowing of MnVFC or UUAV vaccine is not permissible.** MnVFC-enrolled providers must ensure borrowing MnVFC vaccine will not prevent a MnVFC-eligible patient from receiving a needed vaccination. Infrequent exchanging between MnVFC or UUAV and private stock of a short-dated vaccine dose may be performed if the site 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 a MnVFC dose for a privately insured patient.	5	Accidental use of private dose for MnVFC-eligible child.	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:

- Retain completed forms for at least 3 years and make them available to the State/Local or Territorial Immunization Program upon request.

Medical Management of Vaccine Reactions in Children and Teens in a Community Setting

The table below describes steps to take if an adverse reaction occurs after vaccination.

Administering any medicine, including vaccines, can cause an adverse reaction. Always verify container labels to ensure the correct product is being administered. To reduce the risk an adverse reaction, screen patients for vaccine contraindications and precautions before vaccination (see “Screening Checklist for Contraindications to Vaccines for Children and Teens” at www.immunize.org/catg.d/p4060.pdf).

When adverse reactions do occur, they can range from minor (e.g., soreness, itching) to serious (e.g., anaphylaxis). Be prepared.

Vaccinators should know how to recognize allergic reactions, including anaphylaxis. Have a plan and supplies ready to provide appropriate medical care if an event occurs.

REACTION	SIGNS AND SYMPTOMS	MANAGEMENT
Injection site	Soreness, redness, itching, or swelling	Apply a wet cloth to the injection site. Consider giving medication to reduce pain (e.g., Tylenol) or itching (e.g., Benadryl) if needed.
	Slight bleeding	Apply pressure and 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)	Anxiety before injection	Have patient sit or lie down for the vaccination.
	Paleness, sweating, coldness of the hands and feet, nausea, light-headedness, dizziness, weakness, or visual disturbances	Have patient lie flat. Loosen any tight clothing and maintain open airway. Apply cool, damp cloth to patient's face and neck. Keep patient under close observation until full recovery.
	Fall, without loss of consciousness	Check the patient for injury before trying to move the patient. Place patient flat on back with feet elevated.
	Loss of consciousness	Check the patient for injury before trying to move the patient. Place patient flat on back with feet elevated. Call 911 if patient does not recover promptly.
Anaphylaxis	Skin and mucosal symptoms such as generalized hives, itching, or flushing; swelling of lips, face, throat, or eyes. Respiratory symptoms such as nasal congestion, change in voice, sensation of throat closing, stridor, shortness of breath, wheeze, or cough. Gastrointestinal symptoms such as nausea, vomiting, diarrhea, cramping abdominal pain. Cardiovascular symptoms such as collapse, dizziness, tachycardia, hypotension.	See next page for details on treating anaphylaxis.

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www.immunize.org/catg.d/p3082a.pdf

Item #P3082a (4/19/23)



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Supply List for Managing Anaphylaxis**FIRST-LINE medication**

- Epinephrine** 1 mg/mL aqueous solution (1:1000 concentration) in prefilled autoinjector or various vials or ampules. At least three epinephrine doses should be available on site, dosages as appropriate for patient population.

OPTIONAL medications: H₁ antihistamines

- Diphenhydramine** (e.g., Benadryl) oral, 12.5 mg/5 mL liquid; 25 or 50 mg capsules or tablets

Additional emergency supplies

- Syringes (1 and 3 mL) and needles (22 and 25 g, 1", 1¼", 1½", and 2") if needed for epinephrine
- Alcohol wipes
- Stethoscope
- Blood pressure measuring device (with a variety of cuff sizes as needed)
- Light with extra batteries (for examination of the mouth and throat)
- A timing device, such as wristwatch, for measuring pulse
- Cell phone or access to onsite phone
- CPR rescue mask with one-way valve
- Oxygen (if available)

See also "Supplies You May Need at an Immunization Clinic" at www.immunize.org/catg.d/p3046.pdf.

REFERENCES

American Academy of Pediatrics. *Red Book: 2021–2024 Report of the Committee on Infectious Diseases*. 32nd edition, p. 64–67.

Campbell RL, Kelso JM. Anaphylaxis: Emergency treatment, updated August 4, 2022 in UpToDate, www.uptodate.com/contents/anaphylaxis-emergency-treatment

Kroger A, Bahta L, Long S, Sanchez P. General Best Practice Guide-lines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP) at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html.

Emergency medical protocol for managing anaphylaxis in children and teens

- 1 If itching and swelling are limited to the injection site, observe patient closely for the development of generalized symptoms.
- 2 If symptoms are generalized, alert the lead clinical healthcare professional on-site and call 911. A healthcare professional should assess the airway, breathing, circulation, and level of consciousness of the patient. Monitor vital signs at 5-minute intervals.
- 3 **DRUG DOSING INFORMATION: The most important therapy in anaphylaxis is epinephrine. There are NO absolute contraindications to epinephrine in the setting of anaphylaxis.**
 - a **First-line treatment: EPINEPHRINE is the first-line treatment for anaphylaxis.** Use **epinephrine** in a 1 mg/mL aqueous solution (1:1000 concentration). See page 3 to determine correct dose to be used based on child's weight. If using an autoinjector, administer a dose of 0.1 mg, 0.15 mg, or 0.3 mg IM (as appropriate for the patient's weight) into the anterolateral thigh. If using another epinephrine formulation, the recommended dose is 0.01 mg/kg per dose, up to a maximum single dose of 0.5 mg. Administer IM, preferably in the anterolateral thigh.

Epinephrine dose may be repeated every 5–15 minutes intervals while waiting for EMS to arrive.
 - b **Optional treatment: H₁ ANTIHISTAMINES** relieve itching and urticaria (hives). These medications **DO NOT** relieve upper or lower airway obstruction, hypotension, or shock. Consider giving **diphenhydramine** (e.g., Benadryl) for relief of itching or hives.

Administer **diphenhydramine** orally, standard dose of 1–2 mg/kg every 4–6 hours. See dosing chart on page 3.
- 4 Monitor the patient closely every 5 minutes. Perform cardiopulmonary resuscitation (CPR), if necessary, and maintain airway. Keep patient in recumbent 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.
- 5 Record the patient's reaction (e.g., hives, anaphylaxis) to the vaccine, 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.
- 6 Notify the patient's primary care physician.
- 7 Report the incident to the Vaccine Adverse Event Reporting System (VAERS) at <https://www.vaers.hhs.gov/reportevent.html>.

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Medical Management of Vaccine Reactions in Children and Teens in a Community Setting

page 3 of 3

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.

Recommended dose is 0.01 mg/kg body weight up to 0.5 mg maximum dose. May be repeated at 5–15 minute intervals up to 3 times while waiting for EMS to arrive.

First-Line Treatment: Epinephrine				Epinephrine Dose	
	Age group	Range of weight (lb)	Range of weight (kg)*	1 mg/mL aqueous solution (1:1000 concentration); intramuscular. Minimum dose: 0.05 mL	Epinephrine autoinjector (0.1 mg, 0.15 mg, 0.3 mg)
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)	0.1 mg [†]
	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

[†] 0.1 mg autoinjector is approved for use in 7.5 to 14 kg infants and children

► commonly known as Benadryl

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

Optional Treatment: Diphenhydramine				Diphenhydramine dose calculations based on 1 mg/kg [†]	
	Age group	Range of weight (lb)	Range of weight (kg)*	Liquid: 12.5 mg/5 mL	Capsules or tablets: 25 mg or 50 mg
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	50 mg/dose (up to 50 mg or 100 mg single 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

[†] AAP. Red Book: 2021–2024, 32nd ed. (p. 66). Diphenhydramine maximum single dose for children younger than age 12 years is 40 mg, for children age 12 years and older, 100 mg.

This policy and procedure shall remain in effect for all patients of the _____			
NAME OF PRACTICE OR CLINIC			
effective _____	DATE	until rescinded or until _____	DATE
Medical Director _____	PRINT NAME	/ _____	SIGNATURE
			DATE

Medical Management of Vaccine Reactions in Adults in a Community Setting

The table below describes steps to take if an adverse reaction occurs after vaccination.

Administering any medicine, including vaccines, can cause an adverse reaction. Always verify container labels to ensure the correct product is being administered. To reduce the risk of an adverse reaction, screen patients for vaccine contraindications and precautions before vaccination (see "Screening Checklist for Contraindications to Vaccines for Adults" at www.immunize.org/catg.d/p4065.pdf).

When adverse reactions do occur, they can range from minor (e.g., soreness, itching) to serious (e.g., anaphylaxis). Be prepared.

Vaccinators should know how to recognize allergic reactions, including anaphylaxis. Have a plan and supplies ready to provide appropriate medical care if an event occurs.

REACTION	SIGNS AND SYMPTOMS	MANAGEMENT
Injection site	Soreness, redness, itching, or swelling	Apply a wet cloth to the injection site. Consider giving medication to reduce pain (e.g., Tylenol) or itching (e.g., Benadryl) if needed.
	Slight bleeding	Apply pressure and 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, presyncope, and syncope (fainting)	Anxiety before injection	Have patient sit or lie down for the vaccination.
	Patient feels "faint" (e.g., light-headed, dizzy, weak, nauseated, or has visual disturbance)	Have patient lie flat. Loosen any tight clothing and maintain open airway. Apply cool, damp cloth to patient's face and neck. Keep patient under close observation until full recovery.
	Fall, without loss of consciousness	Check the patient for injury before trying to move the patient. Place patient flat on back with feet elevated.
	Loss of consciousness	Check the patient for injury before trying to move the patient. Place patient flat on back with feet elevated. Call 911 if patient does not recover promptly.
Anaphylaxis	Skin and mucosal symptoms such as generalized hives, itching, or flushing; swelling of lips, face, throat, or eyes. Respiratory symptoms such as nasal congestion, change in voice, sensation of throat closing, stridor, shortness of breath, wheeze, or cough. Gastrointestinal symptoms such as nausea, vomiting, diarrhea, cramping abdominal pain. Cardiovascular symptoms such as collapse, dizziness, tachycardia, hypotension.	See next page for details on treating anaphylaxis.

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www.immunize.org/catg.d/p3082.pdf
Item #P3082 (4/19/2023)



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Supply List for Managing Anaphylaxis**FIRST-LINE medication**

- Epinephrine** 1 mg/mL aqueous solution (1:1000 concentration) in prefilled autoinjector or various vials or ampules. At least three epinephrine doses should be available onsite.

OPTIONAL medications: H₁ antihistamines

- Diphenhydramine** (e.g., Benadryl) oral, 12.5 mg/5 mL liquid, 25 or 50 mg capsules or tablets

Additional emergency supplies

- Syringes (1 and 3 mL) and needles (22 and 25 g, 1", 1½", and 2") if needed for epinephrine
- Alcohol wipes
- Stethoscope
- Blood pressure measuring device (with a variety of cuff sizes as needed)
- Light with extra batteries (for examination of the mouth and throat)
- A timing device, such as wristwatch, for measuring pulse
- Cell phone or access to onsite phone
- CPR rescue mask with one-way valve
- Oxygen (if available)

See also "Supplies You May Need at an Immunization Clinic" at www.immunize.org/catg.d/p3046.pdf.

REFERENCES

Campbell RL, Kelso JM. Anaphylaxis: Emergency treatment, updated August 4, 2022 in UpToDate, www.uptodate.com/contents/anaphylaxis-emergency-treatment

Kroger A, Bahta L, Long S, Sanchez P. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP) at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html.

Emergency medical protocol for managing anaphylaxis in adults

- 1 If itching and swelling are limited to the injection site, observe patient closely for the development of generalized symptoms.
- 2 If symptoms are generalized, alert the lead clinical healthcare professional on-site and call 911. A healthcare professional should assess the airway, breathing, circulation, and level of consciousness of the patient. Monitor vital signs at 5-minute intervals.
- 3 **DOSING INFORMATION: The most important therapy in anaphylaxis is epinephrine. There are NO absolute contraindications to epinephrine in the setting of anaphylaxis.**

a First-line treatment: EPINEPHRINE is the first-line treatment for anaphylaxis.

Use **epinephrine** in a 1 mg/mL aqueous solution (1:1000 concentration). Administer a 0.3 mg dose IM using an autoinjector in the mid-outer thigh. If using another epinephrine formulation, the recommended dose is 0.01 mg/kg, ranging for adults from 0.3 mg to maximum dose of 0.5 mg. Administer IM, preferably in the mid-outer thigh.

Epinephrine doses may be repeated 2 additional times at 5–15 minute intervals while waiting for EMS to arrive.

b Optional treatment: H₁ ANTIHISTAMINES relieve itching and urticaria (hives).

These medications **DO NOT** relieve upper or lower airway obstruction, hypotension, or shock. Consider giving diphenhydramine (e.g., Benadryl) for relief of itching and hives. Administer orally 1–2 mg/kg every 4–6 hours, up to a maximum single dose of 100 mg.

- 4 Monitor blood pressure and pulse every 5 minutes. Perform cardiopulmonary resuscitation (CPR), if necessary, and maintain airway. Keep patient in recumbent 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.
- 5 Record the patient's reaction (e.g., hives, anaphylaxis) to the vaccine, 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.
- 6 Notify the patient's primary care physician.
- 7 Report the incident to the Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov/reportevent.html.

This policy and procedure shall remain in effect for all patients of the _____
NAME OF PRACTICE OR CLINIC

effective _____ until rescinded or until _____ .
DATE DATE

Medical Director _____ / _____
PRINT NAME SIGNATURE DATE