

Hepatitis A Vaccination Guidance for Outbreak Prevention and Response

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Introduction

Vaccination is the best way to proactively address hepatitis A disease in Minnesota. This guidance is meant to serve as a basic reference for health care providers vaccinating with hepatitis A vaccine for outbreak prevention and response. This document was specifically developed for non-traditional vaccination settings such as correctional facilities, homeless shelters, behavioral health or other settings that do not provide routine vaccination but serve people at high risk.

The guidance is tailored to professionals vaccinating using a protocol—in Minnesota, this includes licensed nurses and pharmacists. All vaccinators should practice within the scope of their training, license, and according to Minnesota law.

This guide is a basic tool meant to introduce critical vaccination concepts, and it is not an exhaustive resource for best practices in general vaccination. Periodically check for updates to this guidance and resources at Hepatitis A Outbreak Prevention and Response (www.health.state.mn.us/diseases/hepatitis/a/response.html).

Hepatitis A disease information

- Hepatitis A is an infection of the liver caused by the hepatitis A virus.
- Hepatitis A is spread through the fecal-oral route.
- The incubation period for hepatitis A is between 15-50 days (28 days on average).
- The infectious period is two weeks before symptom onset until two weeks after symptom onset.
- The symptoms of hepatitis A include: fever, headache, fatigue, malaise, nausea, anorexia, abdominal pain, vomiting, diarrhea, dark urine, light colored stool, and jaundice.

Preventing hepatitis A

Vaccination

The best way to prevent hepatitis A is through vaccination. Hepatitis A vaccine is administered as two-doses, separated by 6 months. One dose of hepatitis A vaccine is adequate for outbreak control. It is also recommended as timely post-exposure prophylaxis, i.e., given within 2 weeks of being exposed to a person infected with hepatitis A.

Hepatitis A Vaccine Products Available for Outbreak Prevention and Response			
Formulation	Havrix	Vaqta	Twinrix*
Pediatric			
Age	1 through 18 years	1 through 18 years	18 years and older (see below)
Volume	0.5 mL	0.5 mL	
Dose	720 (EL.U)	25 U	
Number of doses	2	2	
Schedule	0, 6-12 month interval	0, 6-12 month interval	
Adult			
Age	19 years and older	19 years and older	18 years and older
Volume	1.0 mL	1.0 mL	1.0 mL
Dose	1,440 (EL.U)	50 U	720 (EL.U Havrix)
Number of doses	2	2	3 or 4
Schedule	0, 6-12 month interval	0, 6-18 month interval	0-, 1-, 6-month interval or 0, 7, 21 to 30 days, and a booster 12 months after first dose
Presentation	Single-dose vials and pre-filled syringes	Single-dose vials and pre-filled syringes	Pre-filled syringes
Preservative	None	None	None

*Twinrix is a combination hepatitis A and hepatitis B vaccine licensed for persons 18 years and older. There is no information regarding efficacy of Twinrix given for post-exposure prophylaxis. Use of this product may be considered for protection among those at-risk for hepatitis A who have not yet been exposed.

Table information from: Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. Washington D.C. Public Health Foundation, 2015.
 Accessed from: www.cdc.gov/vaccines/pubs/pinkbook/hepa.html#vaccine.

Concurrent vaccination

Hepatitis A vaccine may be given with other vaccines if indicated. For example, during influenza season, both hepatitis A and influenza vaccines may be given at the same visit, in different sites.

Interchangeable products

The single antigen hepatitis A vaccines (Havrix and Vaqta) may be interchanged when necessary. This means that if a person started the series with one product, they can complete the series with another product. The combination vaccine (Twinrix) contains hepatitis A and hepatitis B, is formulated differently, and has a different schedule. It cannot be easily interchanged with the other hepatitis A vaccine products. If someone has previously started the hepA-hepB series using Twinrix and is presenting to a vaccination clinic for hepatitis A vaccination, follow this guide:

- Previously received 1 Twinrix dose: Disregard that dose and give hepatitis A vaccine now and in 6 months. (They will also need 2 doses of hepatitis B vaccine.)
- Previously received 2 Twinrix doses: Give 1 dose of hepatitis A vaccine. (They will also need 1 dose of hepatitis B vaccine.)

Setting up vaccination activities

Establishing program oversight

Ensure a qualified staff person is assigned to compile and implement policies and procedures on components in this guide. They will facilitate the management of the vaccine, including ordering, storage and handling, and inventory. This person ensures that staff receive proper training on vaccine-related procedures and have the supplies necessary to provide vaccination. For a list of supplies, see the *Hepatitis A Vaccination Clinic Supply List* on Hepatitis A Outbreak Prevention and Response (www.health.state.mn.us/diseases/hepatitis/a/response.html).

Protocols

Prescription by protocol templates are available for nurses and pharmacists to use on the MDH Vaccine Protocols website (www.health.state.mn.us/people/immunize/hcp/protocols/). This site also includes guidance for adopting vaccine protocols. Be sure that a licensed prescriber fully completes the protocol, signs it, and instructs the vaccinator how to get questions addressed.

Participate in MIIC

The Minnesota Immunization Information Connection (MIIC) (www.health.state.mn.us/miic) is Minnesota's immunization information system. It stores electronic immunization records that combine immunizations individuals received at different locations across the state. MIIC's combined immunization records help make sure Minnesotans get the right vaccines at the right times.

It is a best practice for all Minnesota providers to enter immunizations they administer into MIIC. To enroll your organization, go to Participating in MIIC (www.health.state.mn.us/people/immunize/miic/participate/index.html). Please contact the MIIC Help Desk at 651-201-5207 or health.miichelp@state.mn.us with any questions.

Managing vaccine supply

Obtaining/ordering vaccine

MDH can supply vaccine free of cost when needed for outbreak prevention and response. Clinics enrolled in MDH's Uninsured and Underinsured Adult Vaccine (UUAV) program should order vaccine directly in MIIC.

If you are not enrolled in UUAV, but are interested in vaccinating, email: health.uuadultvax@state.mn.us.

For UUAV sites:

- Screening individuals for program eligibility (insurance status) is recommended but not required for hepatitis A vaccine while national outbreaks and local transmission persist. Screen if it is not a barrier to vaccination.
- Do not bill for the cost of the vaccine.
- Doses must be documented in MIIC.

Estimating doses needed

Most adults are not vaccinated against hepatitis A and are eligible to receive vaccine. The high-risk groups in the national outbreaks are hard to reach and at times may be reluctant to get vaccine. Work with your partners to estimate how many doses you'll need based on uptake of other medical services and how many people you are likely to reach.

Receiving vaccine

Vaccine from MDH will only be delivered to sites in which vaccine staff are present for 4 consecutive hours for at least one day between Tuesday through Friday.

- Check the condition of all vaccines immediately when they arrive.
 - Check the temperature indicator to be sure that the vaccine has remained in the correct temperature range.
 - Check whether the vaccine shipment is compromised in any way (e.g., broken syringes or vials, indication of exposure to warm or freezing temperatures, visibly frozen vaccine, etc.). Contact McKesson Specialty Customer Care at 1-877-836-7123 within 2 hours of vaccine arrival if you identify an issue.
- Document the date and time the shipment was received, the packing material condition, and temperature indicator status.

Vaccine storage

Proper storage and handling of vaccine is critical to its effectiveness. Inactivated vaccines, like hepatitis A, are especially sensitive to freezing temperatures, and once frozen the vaccine is no longer effective.

Here are some tips to help ensure that your vaccine remains effective:

- Store vaccine according to CDC and manufacturer specifications. Store hepatitis A vaccine at the recommended temperature range of 36° through 46°F or 2° through 8°C — aim for 40°F/5°C.
- Refrigerator-only or pharmacy-grade units are optimal for storing vaccine; they provide uniform temperatures inside the unit. If using a combination unit (a unit that has both a refrigerator and freezer compartment that are separate from each other), do not use the freezer and set the freezer temperature to the warmest setting.
- **Do not** use dorm-style units (small refrigerators with one door and a small freezer compartment inside the refrigerator) to store vaccine.
- Include water bottles in the refrigerator to help stabilize temperature.
- Use a calibrated temperature monitoring device. A continuous temperature monitoring device, such as a data logger, is recommended.
- Check and document the temperature of the storage unit twice a day or record the minimum and maximum temperature once a day. Take action if the temperature goes out of range.
- See the CDC's Vaccine Storage and Handling Toolkit (www.cdc.gov/vaccines/hcp/admin/storage/toolkit/) for full guidance on storage and handling of vaccines.

You can order some vaccine storage resources from MDH free of charge through our Order Immunization Materials website (www.health.state.mn.us/people/immunize/ordermat.html).

Resources include a "Protect Your Vaccines!" magnet (pictured on the right) showing the recommended temperature range, and "Do Not Unplug" stickers for storage units.

Our more detailed Vaccine Storage Guide (www.health.state.mn.us/people/immunize/hcp/vaxhandling.html) also includes helpful tips and reminders for properly storing vaccine.

Protect Your Vaccines!
Take action on any out-of-range temperatures!
Including daily minimum/maximum temperatures.

- 1 Stop using the vaccine**
 - ✓ Mark vaccines, "Do Not Use"
 - ✓ Notify your vaccine coordinator
 - ✓ Follow your Vaccine Emergency Management Plan
- 2 Document the details**
 - ✓ Date and time
 - ✓ Temperatures and length of time out-of-range
 - ✓ Description of event
 - ✓ Vaccines affected
- 3 Contact**
 - ✓ Manufacturers to find out if vaccines can be used
 - ✓ MDH to report and for guidance, 1-800-657-3970
- 4 Correct**
 - ✓ Identify problem
 - ✓ Service unit, if needed
 - ✓ Move vaccines if problem cannot be corrected quickly

Refrigerator 36°F through 46°F 2°C through 8°C ▶ Aim for 40°F (5°C)	Freezer 5°F or colder -15°C or colder ▶ Aim for 0°F (-18°C)
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MDH STATE OF MINNESOTA Immunization Program 1-800-657-3970 08-0008

Screening and assessing

Screening for contraindications and precautions

In general, most people will be able to receive hepatitis A vaccine. Do not administer hepatitis A vaccine to patients who have a contraindication. Patients that have a precaution should generally not be vaccinated unless the benefits outweigh the risks as advised by their health care provider. A sample screening form can be found on Hepatitis A Outbreak Prevention and Response (www.health.state.mn.us/diseases/hepatitis/a/response.html).

Contraindications to hepA vaccine:

- Persons that have experienced a life threatening reaction to a previous dose of hepatitis A vaccine should not be vaccinated.
- Persons with a severe or life-threatening reaction to a vaccine component should not receive hepatitis A vaccine. A vaccine excipient table is below to assess allergies to a specific component.

Hepatitis A Product Excipients	
Havrix	MRC-5 cellular proteins, formalin, aluminum hydroxide, amino acid supplement, phosphate buffered saline solution, polysorbate 20, neomycin sulfate, aminoglycoside antibiotic
Vaqta	Amorphous aluminum hydroxyphosphate sulfate, non-viral protein, DNA, bovine albumin, formaldehyde, neomycin, sodium borate, sodium chloride, other process chemical residuals
Twinrix	MRC-5 human diploid cells, formalin, aluminum phosphate, aluminum hydroxide, amino acids, sodium chloride, phosphate buffer, polysorbate 20, neomycin sulfate, yeast protein, water

Precautions to hepA vaccine:

- Moderate to severe acute illness is a precaution for hepatitis A vaccination. The prescriber shall determine the guidelines for illness symptoms that preclude vaccination. Among persons that may not seek regular medical care, using every opportunity to administer vaccine is critical and guidelines should be carefully considered.

If you are using a protocol from a licensed prescriber to administer vaccine, make sure that the patient screening questions for contraindications and precautions match the criteria for vaccination stated in the protocol. Protocol information and templates can be found on MDH Vaccine Protocols website (www.health.state.mn.us/people/immunize/hcp/protocols/).

Provide the Vaccine Information Statement (VIS)

Make sure you give each patient the hepatitis A VIS before you vaccinate so the patient can read about the benefits and risks. The hepatitis A VIS and translations can be found on the Immunization Action Coalition's Vaccine Information Statements (www.immunize.org/vis/vis_hepatitis_a.asp) website.

There are multiple ways that a patient can receive the VIS:

- A permanent, laminated, office copy, which may be read by recipients prior to vaccination.
- Showing the VIS on a computer monitor (or any video display).
- The patient may download the VIS to a smartphone or other electronic device to read at his or her convenience. (VISs have been specially formatted for this purpose.)
- VISs may be made available to be read before the immunization visit (e.g., by giving the patient or parent a copy to take home during a prior visit, or telling them how to download or view a copy from the Internet).

Health care providers must still offer a copy (which can be an electronic copy) of each appropriate VIS to take away following the vaccination.

Administering vaccine

All available hepatitis A vaccines are administered intramuscularly (IM). Proper intramuscular injection ensures the vaccine will be most effective, cause the patient the least amount of discomfort, and reduce potential injury.

Select the appropriate needle length

Appropriate needle length depends on age and body mass. For IM injections, the needle should be long enough to reach the muscle mass and prevent vaccine from seeping into subcutaneous tissue, but avoid underlying nerves, blood vessels, or bone.

See the table below for guidance on needle length for adolescents and adults.

Gender and weight of patient	Needle gauge	Needle length	Preferred injection site
Female or male less than 130 lbs	22-25	$\frac{5}{8}$ "–1"	Deltoid muscle
Female or male 130-152 lbs	22-25	1"	Deltoid muscle
Female 153-200 lbs	22-25	1-1½"	Deltoid muscle
Male 153-260 lbs	22-25	1-1½"	Deltoid muscle
Female 200+ lbs	22-25	1½"	Deltoid muscle
Male 260+ lbs	22-25	1½"	Deltoid muscle

Prevent injection injuries

To identify the thickest portion of the deltoid muscle, place three fingers from the top of the shoulder. Have the patient lift their arm (you should be able to see and feel the muscle contract). Once you have located the middle of the muscle, have the patient relax their arm and give the injection at a 90-degree angle at that point.

Giving the IM injection too close to the shoulder joint can cause bursitis, fasciitis, and other injury. See How to Administer IM (Intramuscular) Injections (www.health.state.mn.us/people/immunize/hcp/admim.pdf) for more information.

Managing acute vaccine reactions

- Administer vaccines in settings where staff are trained to recognize and respond to reactions.
- Have a signed hard copy of a medical management of vaccine reaction plan and protocol that staff have reviewed and are ready to implement.
- Immediate systemic reactions can include syncope (fainting) and anaphylaxis.
 - To minimize syncope, have a place for patients to sit down while they are vaccinated, and be ready to lower them to a laying position if needed.
 - Although rare, anaphylaxis to a vaccine can occur and is a life-threatening event. Have the appropriate equipment on hand, and have trained staff available to administer epinephrine and maintain an airway in settings where vaccinations are given.
- The Immunization Action Coalition has examples of emergency plans. See Medical Management of Vaccine Reactions in Adult Patients (www.immunize.org/catg.d/p3082.pdf) for more information.

Vaccine Adverse Event Reporting System (VAERS)

Health care providers are required to report any event after vaccination that requires medical attention, regardless of whether it is related to vaccination. While it is relatively rare to experience any kind of event, CDC relies on reports of adverse events to signal any problems with vaccines. Report events electronically to the Vaccine Adverse Event Reporting System (VAERS) (<https://vaers.hhs.gov/index>).

Documenting hepatitis A vaccination

Document the following information in your permanent electronic or paper records.

Federal law requires:

- Published date of the VIS.
- Date the VIS was given to the patient.
- Name, address (office address), and title of the person who administers the vaccine.
- Date the vaccine is administered.
- Vaccine type, manufacturer, and lot number of each dose administered.

Best practice includes:

- Site.
- Route.
- Dose.

Enter immunizations into MIIC

It is a best practice for all Minnesota providers to enter immunizations they administer into MIIC. Providers can enter immunizations into MIIC in several ways:

- **Upload** an Excel template titled "MIIC Flu Spreadsheet": The MIIC Flu Spreadsheet was originally created for flu immunizations, but providers can use it to quickly record and upload any administered vaccines. The template is especially useful for mass vaccination clinics and targeted vaccination campaigns.
- **Manually enter** immunizations: Providers who administer only a few doses of vaccine may enter these data directly into the MIIC application (<https://miic.health.state.mn.us/miic>).
- **Electronically submit** immunizations directly from an electronic health record system: This option should be considered for providers who plan to administer many vaccines in the future. Find more information about setting up an electronic connection with MIIC at Process for Working on Data Exchange with MIIC (www.health.state.mn.us/people/immunize/miic/data/dxprocess.html).

MIIC offers several other tools to support immunization practice, including a tool to help you identify who needs a specific vaccine. If you need help, contact the MIIC Help Desk:

- Email: health.miichelp@state.mn.us
- Phone: 651-201-5207 or 800-657-3970

Information for specific groups

Additional guidance for specific groups is available on Hepatitis A Outbreak Prevention and Response (www.health.state.mn.us/diseases/hepatitis/a/response.html).

- Appendix A: Vaccination in Correctional Settings
- Appendix B: Field Teams