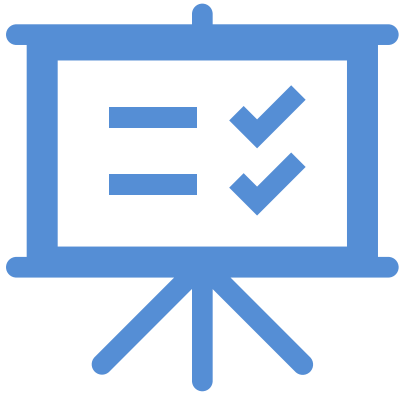
2026 – 2027
Maine Immunization Program
Annual Education Requirement

Maine Immunization Program Learning Objectives

Learning Objectives



At the conclusion of this training, the participant will be able to:

1. Describe MIP program requirements.
2. Describe MIP billing practices.
3. Describe MIP vaccine management practices.
4. Describe the purpose of MIP site visits.
5. Define and explain cold chain management.
6. Describe the components of routine and emergency procedures for vaccine storage and handling.
7. Describe the roles of the primary and backup coordinators and other staff in the storage and handling of vaccines.
8. Describe proper vaccine storage and temperature monitoring equipment.
9. Describe correct vaccine and diluent storage, handling, and returns/disposal of routinely recommended vaccines.
10. Identify actions that should be taken if vaccines have not been stored properly.

Vaccines for Children (VFC) Overview

History of the VFC Program

In 1989 – 1991, a measles epidemic in the United States resulted in tens of thousands of cases of measles and hundreds of deaths. When this epidemic was investigated, the Centers for Disease Control and Prevention (CDC) found that more than half of the children who had measles had not been vaccinated against measles, even though many of them had seen a healthcare provider123. Cost of the vaccine was found to be a primary reason for children going unvaccinated even in families with a regular health care provider.

In response to this measles epidemic, Congress passed the Omnibus Budget Reconciliation Act (OBRA) on August 10, 1993, creating the VFC Program. The VFC Program became operational October 1, 1994. Known as Section 1928 of the Social Security Act, the Vaccines for Children Program is an entitlement program (a right granted by law) for eligible children, ages 18 and younger. The program was an unprecedented approach to improving vaccine availability nationwide by providing vaccine at no cost to VFC Program-eligible children through VFC Program enrolled public and private health care providers. Additional information on the history and benefits of the VFC Program.

What the VFC Program Does

The VFC program helps provide vaccines to children whose parents or guardians might not be able to afford them. This helps ensure that all children have a better chance of getting their recommended vaccinations on schedule. Vaccines available through the VFC program are those recommended by the Advisory Committee on Immunization Practices (ACIP).

Vaccines for Children (VFC) Overview

How VFC Works

CDC buys vaccines at a discount from vaccine manufacturers and distributes them at no charge to private physicians' offices, public health clinics, and other health care facilities enrolled as VFC providers. VFC providers play the important role of properly storing vaccines and administering them to eligible children at no cost for the vaccines.

VFC Vaccine is NOT Free

Even though VFC vaccine is provided at no cost to enrolled providers and eligible children, it should never be considered "free". There is a substantial cost involved with purchasing millions of doses of vaccine and making them available to provider offices.

"The VFC Program: A Retrospective of the Program's First 30 Years" details the impact the program's had on increasing vaccine availability.

Vaccines for Adult Overview

How Adult Works

CDC buys vaccines at a discount from vaccine manufacturers and distributes them at no charge to private physicians' offices, public health clinics, and other health care facilities enrolled in MIP as Adult providers. Adult providers play the important role of properly storing vaccines and administering them to eligible adults 19 – 64 years of age at no cost for the vaccines.

Adult Vaccine is NOT Free

Even though adult vaccine is provided at no cost to enrolled providers and eligible adults, it should never be considered "free". There is a substantial cost involved with purchasing millions of doses of vaccine and making them available to provider offices.

Knowledge Check

Is the statement below true or false?

MIP supplied vaccines are free.

TRUE

FALSE ★

Maine Immunization Program vaccines are purchased for distribution and use in eligible individuals. There is a cost covered by the state and federal government. There is no cost for providers enrolled in the program or for eligible individuals receiving the vaccine from these provider sites.

Provider Profile (Vaccine Need)

The Provider Profile (Vaccine Need)

The provider profile captures the number of eligible individuals and non-eligible individuals served by Maine Immunization Program providers. It supports providers in determining how much vaccine to order for each population served. The data collected in the provider profile also assists the Maine Immunization Program in determining overall vaccine need. This information is also used when reviewing and approving provider vaccine orders.

The provider profile (vaccine need) captures the number of individuals who received vaccines from all providers at the facility during the previous 12 months by age group and program eligibility status.

All providers must complete the provider profile in ImmPact annually between June 1st and June 30th

Providers must submit this form more frequently if :

1. Number of individuals served changes
2. Status of facility changes resulting in an increase or decrease in the amount of vaccine that will be needed during the calendar year

Provider Agreement

The Provider Agreement

The provider agreement is a document that describes the Maine Immunization Program requirements and is used to document the provider's agreement to comply with the requirements. It must be reviewed and signed every other year by the medical director (or equivalent in a group practice.

The healthcare provider signing the agreement must be a practitioner authorized by state law to administer pediatric vaccines. This provider must have the authority to sign on behalf of the organization or practice and ensure that all MIP requirements are met as outlined in the provider agreement.

In addition to the medical director (or equivalent) in a group practice, the following individuals must be listed on the provider agreement:

- All licensed health care providers (MD, DO, NP, PA,) – located at the facility who have prescribing authority
- A Primary Coordinator- individual with the primary responsibility for managing the Maine Immunization Program at the facility
- A Backup Coordinator- individual who is trained equally to the primary coordinator and can step in if the primary is unavailable
- Emergency contact – Person at the facility assigned 24hr access to the building

Knowledge Check

Is the statement below true or false?

The purpose of the provider agreement is to provide a listing of Maine Immunization Program requirements and policies that each provider will follow during the current enrollment cycle.

TRUE 

FALSE

The MIP provider agreement provides a listing of all MIP requirements that each provider must follow.

Knowledge Check

Is the statement below true or false?

The purpose of the vaccine need is to assist the Maine Immunization Program in determining the amount of vaccine supplied through the different program sources.

TRUE 

FALSE

The provider profile (vaccine need) captures the number of eligible individual and non-eligible individuals served by MIP providers. It supports providers in determining how much vaccine to order for each population served.

Knowledge Check

Determine the correct answer.

Who signs the provider agreement?

- The primary vaccine coordinator
- The medical director or equivalent 
- All providers within the practice

The provider signing the agreement must be a practitioner authorized by state law to administer pediatric vaccines and preferably medical director. This person is responsible for ensuring that all MIP requirements are met as outline in the provider agreement.

Vaccines for Children 0 – 18 Years Eligibility Categories

VFC Eligibility Categories:

All Children in the United States 0 – 18 years of age who meet at least one of the following criteria are eligible to receive VFC vaccine from MIP:

- **Medicaid-eligible (MaineCare):** a child who is eligible for the Medicaid program (for the purposes of the VFC program the terms "Medicaid-eligible" and "Medicaid-enrolled" are used interchangeably and refer to children who have health insurance covered by a state Medicaid program)
- **Uninsured:** a child who has no health insurance coverage
- **American Indian or Alaskan Native (AI/AN):** as defined by the Indian Health Care Improvement Act (25 U.S.C.1603)
- **Underinsured:**
  - A child who has health insurance, but the coverage does not include vaccines or
  - A child whose insurance does not cover all vaccines recommended by the Advisory Committee on Immunization Practices (ACIP)

State Vaccine Eligibility:

Maine is a Universal Vaccine State, which means the MIP provides vaccines to healthcare providers at no cost for ALL Maine children with private health insurance.

Children age 0 – 18 years who meet the following criteria are eligible to receive state-eligible vaccine:

- The child does not meet any of the VFC-eligibility categories
- The child has private health insurance
- The child is a Maine resident

VFC Eligibility Screening for 0 – 18 Years

Provider Responsibility to Screen for VFC Eligibility and Document Eligibility Status

Screening to determine VFC/MIP eligibility and documenting the current VFC/MIP eligibility category must take place at each immunization visit prior to administering vaccines. Screening results must be documented at each immunization visit even if there is no change in eligibility status.

The only factors that can be considered when screening for VFC eligibility are age and whether the child meets the definition of at least one of the following categories: Medicaid enrolled, uninsured, American Indian/Alaskan Native, or under- insured. They also need to be 0 – 18 years of age.
To meet VFC criteria they can be a resident of any state or US territory if they meet one of the above categories as VFC is a federal program.

The patient eligibility screening record guides providers to choose the correct eligibility code and provides a method for documenting the eligibility and category for each child, if VFC-eligible or state eligible.

If an EMR has options that don't align with MIP codes, contact your IT provider or MIP to make sure you are choosing appropriate options!

CODE	label	DEFINITION
V01	**NOT VFC STOCK PRIVATE STOCK**	Patient does not qualify for VFC because they do not have one of the statuses below. (V02-V05 or MEA01).
V02	**VFC Eligible- Medicaid/MaineCare under19**	Patient is currently on MaineCare or Medicaid and are under 19 years old.
V03	VFC Eligible- UNINSURED	Patient does not have private insurance coverage and are under 19 years old.
V04	**VFC Eligible- American Indian/Alaskan Native**	Patient is a member of a federally recognized tribe and are under 19 years old.
V05	**VFC Eligible- Patient underinsured**	Patient has insurance, but insurance does not cover vaccines, limits the vaccines covered, or caps vaccine coverage at a certain amount and are under 19 years old.
MEA01	**State Eligible insured- Under 19**	Patient has insurance and are under 19 years old and Maine resident.

Eligibility Screening for Adults 19 -64 Years (Maine Resident Only)

Adults 19 – 64 are eligible for MIP supplied vaccines if they have the following:

1. **Private Insurance -** (including MaineCare)
2. **Secondary insurance -** that covers vaccinations (if primary insurance is Medicare)
3. **Uninsured -** no insurance coverage
4. **Underinsured -** coverage does not include vaccines or whose insurance covers only selected vaccines

Adult Eligibility Immunization Codes 19 – 64 YRS *(Maine Resident Only)*		
Patient Coverage *(Maine Resident Only)*	**Eligible for Maine Immunization Program Vaccines?**	**Code**
No Insurance or Underinsured	YES	**V07**
Insured (Private and MaineCare)	YES	**MEA07**
Medicare A	• If covered only by Medicare – **NO** - **Defer to that coverage plan** ○ Unless vaccines aren't covered by that plan • If covered by secondary insurance - **YES**	**MEA07**
Medicare Part B	***Limited*** - Flu, PCV, COVID-19 and Hep B are covered by Medicare and not eligible for MIP vaccine. Private vaccine will need to be administered. • **If no other insurance coverage, individual would qualify for other routine vaccines under MIP** • If individual has additional supplements, **defer to plan** eligibility	**MEA07**
Medicare Part C and/or D	***Most*** - Vaccines other than those covered by Medicare part B. • Part B covers - Flu, PCV, COVID-19 and Hep B making those vaccines not eligible	**MEA07**

❖ ***Patient must be a Maine Resident 19 – 64 years of age to qualify for MIP supplied vaccines***

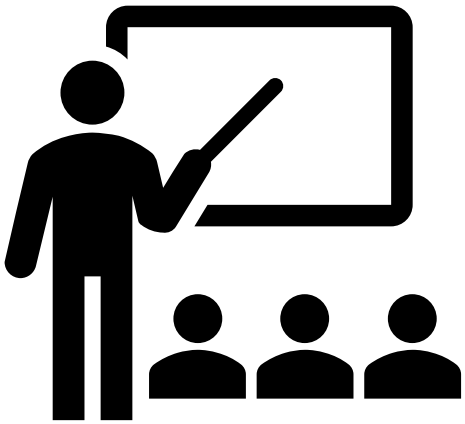
❖ Please note: Adults 65 years and older are not eligible to receive MIP supplied vaccines regardless of insurance status

Knowledge Check

Determine the correct answer.

When should screening for VFC/MIP eligibility be conducted?

- At the first immunization visit only
- At every immunization visit ★
- Once a year
- Every 6 months



MIP providers must screen all patients age 0 – 64 years for VFC eligibility or state eligibility and document eligibility status at each immunization visit. Without accurate information and continued funding, insured Maine individuals would have to receive privately purchased vaccine. Please make sure to stress the importance of choosing appropriate funding information to your staff.

ACIP's role in the Vaccines for Children Program

Complying with the ACIP Immunization Schedule

MIP providers must offer and make available all ACIP-recommended vaccines.

MIP providers must comply with immunization schedules, dosages, and contraindications established by ACIP and included in the VFC program unless:

1. In the provider's medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate for the child.

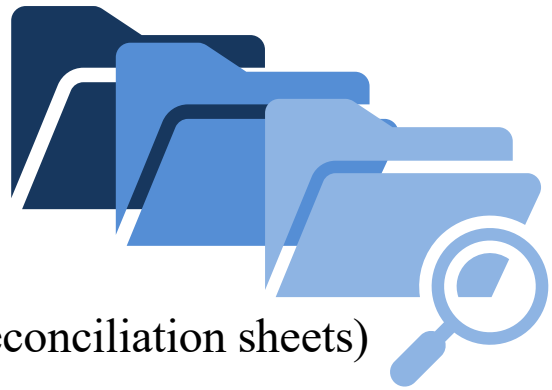
2. The requirements contradict state law.

Maine Immunization Program Record Maintenance

MIP providers must maintain all records related to the MIP program for a minimum of three years and make these records available upon request to public health officials, including the Maine Immunization Program and Department of Health and Human Services Staff.

MIP Program Records include:

- Vaccine storage unit temperature documentation (handwritten logs and DDL downloads)
- MIP vaccine management training records
- MIP eligibility screening documentation
- Routine and emergency vaccine management plan with standard operating procedures
- Provider Agreements
- User Agreements
- Provider Profiles (Vaccine Needs for all individuals)
- Billing records
- Vaccine ordering records
- Vaccine purchase and accountability records (packing slips, reconciliation sheets)



If in doubt, don't throw it out! Call us and we can help you figure out if you need to keep it or not.

Knowledge Check

Determine the correct answer.

What is the minimum amount of time MIP records must be maintained?

- Three months
- Six months
- One year
- Three years 

MIP providers must maintain all records related to the Maine Immunization Program for a minimum of three years. Digital or electronic copies are acceptable **if** everyone in the office has access to them.

Knowledge Check

Determine the correct answer.

Which of the following are considered MIP program records?

- Vaccine emergency plans and standard operating procedures
- Temperature monitoring documentation
- Eligibility screening documentation
- All the above ★

All the above are Maine Immunization Program records. If you are unsure what documents are MIP records, contact the Maine Immunization Program.

MIP-Supplied Vaccine Administration Fee
Ages 0 – 64

MIP vaccine must be provided to an eligible patient ages 0 - 64 at no cost for the vaccine.

State supplied vaccine is provided at no cost to enrolled healthcare providers for administration to eligible patients ages 0 - 64. The administration fee is per vaccine and not per antigen within the vaccine (as in combination vaccines).

Administration fee breakdown for patients ages 0 - 64:

- **Uninsured/Underinsured**: Providers may charge a maximum of **$21.58** per vaccine administration.
- **Privately insured patients**: Providers may charge a reasonable administration fee per vaccine administration.

Patients may not be denied vaccination if they are unable to pay the admin fee.

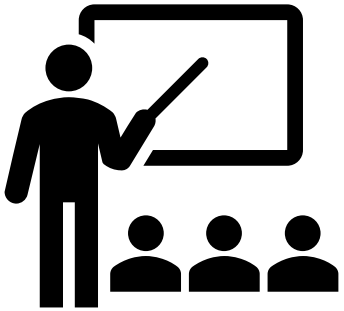
Knowledge Check

Is the statement below true or false?

Patients, Medicaid agencies, and third-party payers can be billed for the cost of MIP vaccine.

TRUE

FALSE ★



Neither patients nor Medicaid agencies or third-party payers can be billed for the cost of MIP vaccine. MIP vaccine is distributed to providers for use in MIP-eligible patients at no cost for the vaccine.

Knowledge Check

Is the statement below true or false?

The administration fee is per antigen in the vaccine and not per vaccine.

TRUE

FALSE 

The administration fee is per vaccine and not per antigen. MIP enrolled providers can only charge a one-time administration fee for VFC supplied vaccine of no more then $21.58 per vaccine.

A combination vaccine is considered a single vaccine with one administration fee.

Knowledge Check

Is the statement below true or false?

If a MIP-eligible patient is unable to pay the vaccine administration fee, providers can deny administration of the next dose of MIP vaccine until the administration fee is paid.

TRUE

FALSE 

MIP providers cannot deny administration of a MIP vaccine to an established, eligible patient because of inability to pay the administration fee. The administration fee cannot be sent to collections.

Federal Documentation Requirements

Vaccine Information Statements: Required by Federal Law

Federal law requires health care staff to provide a VIS to a patient, parent, or legal representative before each dose of certain vaccines. MIP requires that appropriate VIS be given prior to ALL vaccines prior to administration and must be given for each antigen in a multidose series.

Vaccine Information Statements should be given prior to the patient seeing the provider so it can be reviewed and any questions or concerns can be discussed with the provider. The VIS explains both the benefits and risks of vaccines.

Current VISs | Vaccines & Immunizations | CDC

Dates of Current VISs

A list of the most current dates for each VIS. (PDF)

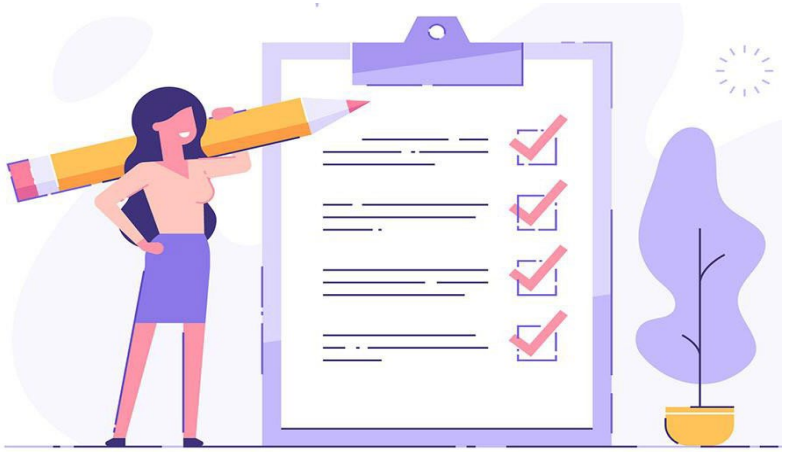
VISs are updated periodically, and it is the provider's responsibility to ensure that the VIS with the most current publication date is used. You can sign up for automatic updates at the bottom of the CDC Current VISs webpage.

Maine Immunization Program Documentation Requirements

Immunization Records

In accordance with federal law, Maine Immunization Program providers must maintain immunization records that include all the following elements:

- Name of the vaccine administered
- Date vaccine was administered
- Date VIS was given
- Publication date of VIS
- Name of vaccine manufacturer
- Vaccine lot number
- Name and title of person who administered the vaccine
- Address of the clinic where vaccine was administered



National Childhood Vaccine Injury Act (NCVIA)

The NCVIA requires healthcare providers to report certain adverse events to the Vaccine Adverse Event Reporting System (VAERS). Adverse events are defined as health effects that occur after vaccination that may or may not be related to the vaccine. VAERS data is monitored continually to detect unknown adverse events or increased rates of known side- effects.

Maine Immunization Program Documentation Requirements

Report an Adverse Event to VAERS

The Vaccine Adverse Event Reporting System (VAERS) is a passive reporting system, meaning it relies on individuals to send in reports of their experiences. Anyone can submit a report to VAERS, including parents and patients.

Healthcare providers are **required by law** to report to VAERS:

- Any adverse event listed in the *VAERS Table of Reportable Events Following Vaccination* that occurs within the specified time after vaccinations
- An adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine

Healthcare providers are strongly encouraged to report to VAERS:

- Any adverse event that occurs after administration of a vaccine licenses in the united state whether even if not clear that a vaccine caused adverse event
- Vaccine administration errors

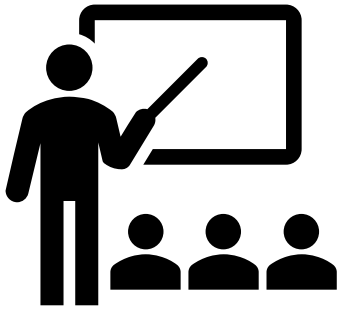
Knowledge Check

Is the statement below true or false?

The vaccine information statement (VIS) should be provided after the vaccine is administered.

TRUE

FALSE ★



The most current VIS should be available to the patient, parent, or legal guardian prior to vaccine administration for each vaccine to be administered during a visit.

Knowledge Check

Determine the correct answer.

Maine Immunization Program providers must maintain immunization records that include which of the following elements?

- Name of vaccine administered
- Address of clinic where vaccine was administered
- Name of manufacturer AND lot number of vaccine administered
- Date when the dose was administered
- Name and title of the individual administering the vaccine
- Date when VIS was given and VIS publication date (or Immunization Information Statements [IIS] or EUA/EUI fact sheet, as applicable)
- All the above 

Maine Immunization Program providers must maintain immunization records that include all the elements listed above.

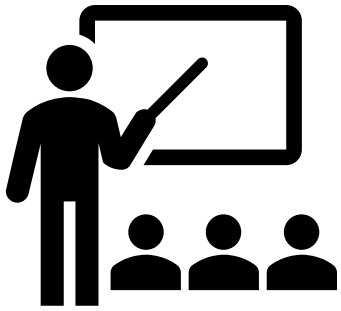
Knowledge Check

Is the statement below true or false?

Healthcare providers are required by federal law to report certain adverse events in accordance with the National Childhood Vaccine Injury Act.

TRUE ★

FALSE



The NCVIA requires health care providers to report certain adverse events to the Vaccine Adverse Event Reporting System (VAERS).

VAERS - Report an Adverse Event

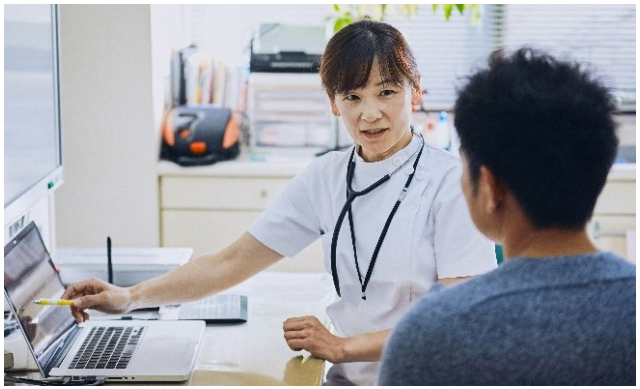
Staff Responsibilities and Vaccine Coordinators

Vaccine storage and handling practices are only as effective and successful as the staff that implements them. A well-trained staff is critical to ensuring the safety of your vaccine supply and patients. Knowledgeable staff can save your practice significant costs of wasted vaccine and prevent loss of credibility among patients who must be revaccinated due to a storage and handling error.

All staff members who receive deliveries and/or handle or administer vaccines should be familiar with storage and handling policies and procedures at their facility. Keep the vaccine management plan for storage and handling on or near storage units and make sure staff know where to find them.

All sites need to designate a primary vaccine coordinator for your facility who will be responsible for ensuring all vaccines are stored and handled correctly. Appoint a second staff member to serve as an alternate in the absence of the primary coordinator (this is particularly important in case of after-hour emergencies).

❖ **Both coordinators should be fully trained in routine and emergency policies and procedures.**

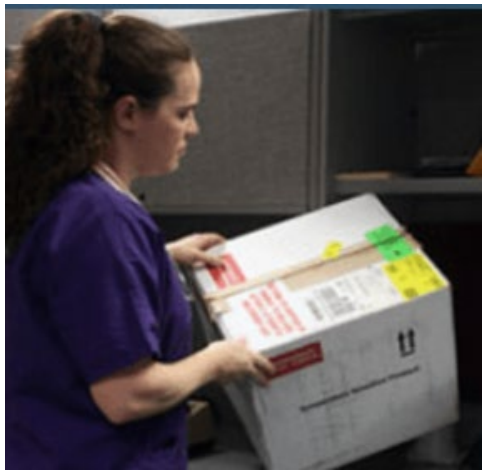


CDC recommends that storage and handling training should be done:

- ✓ As part of new employee orientation
- ✓ Annually as a refresher for all staff involved in immunization and vaccine storage and handling activities
- ✓ Whenever new vaccines are added to inventory
- ✓ Whenever recommendations for storage and handling of vaccines are updated.

Vaccine Coordinators Responsibilities

Vaccine coordinator responsibilities include:



- Ordering vaccines in Immpact
- Overseeing proper receipt, organization and storage of vaccines
- Documenting vaccines within 5 days of administration (same day is best practice)
- Checking and correcting fix tool in Immpact, if applicable
- Setting up VFC800 Wi-Fi temperature monitoring devices and making sure the unit min/max temperatures are recorded on paper log at the beginning of each workday
- Reviewing and analyzing temperature data and entering the cold chain at least every 14 days
- Reconciling stock (including diluents) at least every 14 days and rotating stock so earliest expiration dates are used first
- Removing expired vaccine from storage unit and processing through Immpact to return
- Maintain all documentation including inventory and temperature logs
- Ensuring all staff is trained properly in vaccine storage and handling
- Overseeing proper vaccine transport (if/when necessary)
- Overseeing emergency preparations including tracking inclement weather, ensuring appropriate handling of vaccines during power outage and keeping an updated vaccine management plan on or near the units where anyone can access it as needed

Knowledge Check

Determine the correct answer.

Which staff need to be trained on vaccine storage and handling?

- Only staff members who administer vaccines
- Only the primary and alternate (backup) vaccine coordinator
- Only new staff during orientation
- All staff members who receive deliveries and/or handle or administer vaccines ★

All staff members who receive deliveries and/or handle or administer vaccines should be familiar with storage and handling policies and procedures at your facility. CDC recommends that storage and handling training should be done as part of new employee orientation, annually as a refresher for all staff involved in immunization and vaccine storage and handling activities, whenever new vaccines are added to inventory, and whenever recommendations for storage and handling of vaccines are updated.

Proper Vaccine Storage and Handling

Think of your storage and monitoring equipment as an insurance policy to protect your patients from inadvertent administration of compromised vaccine and your facility against costs of revaccination, replacement of expensive vaccines and loss of patient confidence in your practice.

Proper Vaccine Storage Temperatures

- Refrigerated vaccines should be stored at temperatures between **36° F and 46° F**. The thermostat should be set at mid range to achieve a temperature of about 40° F, which will decrease the likelihood of temperature excursions.
- Vaccines stored in the freezer should maintain temperatures between **-58° F and 5° F**. The thermostat should be at the factory-set or midpoint temperature setting to assure appropriate frozen storage temperatures.

The following equipment is recommended:

- Stand-alone refrigerator(s) with enough space to accommodate your maximum inventory without crowding
- Stand-alone freezer(s) with enough space to accommodate your maximum inventory

Storage and Temperature Monitoring Equipment

Purpose-built units are sometimes referred to as "pharmaceutical grade" and are designed specifically for storage of biologics. These units often have:

- Microprocessor-based temperature control with a digital temperature sensor (thermocouple, resistance temperature detector [RTD], or thermistor)
- Fan-forced air circulation, with powerful fans or multiple cool air vents inside the unit that promote uniform temperature and fast temperature recovery

CDC makes the following recommendations for vaccine storage units:

- Use purpose-built units designed to either refrigerate or freeze (can be compact, under-the-counter-style or large units).

- If a purpose-built unit is not available, use a stand-alone household unit. If you must use a combination household unit as pictured here, use a separate stand-alone freezer to store frozen vaccines. The freezer in these units have cold spots and temperature fluctuations, and air circulating from the freezer could expose refrigerated vaccines to freezing temperatures.

❖ If you have questions about your units, please reach out!

Storage and Temperature Monitoring Equipment

Do not store any vaccine in a dormitory-style or bar-style combined refrigerator/freezer unit under any circumstances.

These units have a single exterior door and an evaporator plate/cooling coil, usually located in an icemaker/freezer compartment. These units have been shown to pose a significant risk of freezing vaccines, even when used for temporary storage.

Not all small storage units are dormitory- or bar-style units. Compact purpose-built units for biologics can be used to store vaccines.

Source: Centers for Disease Control and Prevention

Never use a Dormitory-style unit = a unit that has a single outside door and a refrigerator and freezer both located inside that door

Storage and Temperature Monitoring Equipment

- Make sure the storage unit has enough space to store the largest inventory you might have at the busiest point in the year (e.g., flu season, back to school) without crowding.
- Remove any deli, fruit, and vegetable drawers from refrigerator units if applicable. This provides extra space for water bottles to help maintain stable temperature and prevents use of the drawers for storing food, beverages, or vaccines.
- Use safeguards to ensure the doors of the unit remain closed (for example, self-closing door hinges, door alarms, door locks, etc.).

Keep in mind that it may take up to 7 days to stabilize the temperature in a newly installed or repaired refrigerator or freezer. Before using a unit to store vaccines, check and record the minimum and maximum temperatures each workday for 7 days. Once you have 7 consecutive days of temperatures recorded in ImmPact cold chain that are within the recommended range, your unit is stable and ready to be used. Once this has been completed, vaccines can be ordered through ImmPact.

Storage and Temperature Monitoring Equipment

Good air circulation around the outside of the vaccine storage unit is important.

- Place storage units in a well-ventilated room, leaving space between the unit, ceiling, and wall
- Nothing should block the cover of the motor compartment.
- The unit should be firm and level, with the bottom of the unit above the floor
- Make sure the unit door opens and closes smoothly and fits squarely against the body of the unit

Studies find that most units work best when placed in an area with standard indoor room temperatures, usually considered to be between 68° F and 77° F. Check the manufacturer-supplied owner's manual for additional guidance on placement and spacing.

Regular maintenance of units helps to ensure proper operation and extend the life of the unit. Check the manufactures product information for cleaning instructions and maintenance schedule.

Document all maintenance tasks and repairs and keep all invoices for your records for a minimum of 3 years.

Knowledge Check

Determine the correct answer.

You need to store a vaccine that requires freezer temperatures between -58° F and 5° F. Which type of storage unit would be acceptable for storing these vaccines?

- Freezer compartment of a combination refrigerator/freezer unit, if there is an external freezer door
- Stand-alone freezer unit ★
- Dormitory-style refrigerator with internal freezer area

A stand-alone freezer should be used for storing vaccines that require temperatures between 58° F and 5° F. **DO NOT** use the freezer compartment of a combination refrigerator/freezer unit or a dormitory-style unit to store.

Storage and Temperature Monitoring Equipment

An accurate temperature history that reflects actual vaccine temperature is critical for protecting your vaccines.

- CDC requires the use of a specific type of temperature monitoring device known as a digital data logger (DDL) for continuous temperature monitoring and recording.
- **MIP provides sites with a VFC 800-WiFi DDL which must be used as the primary temperature monitor in any unit storing MIP supplied vaccine.**
- The DDL should be set to measure and record temperatures at least every 30 minutes.
- Each probe for the VFC 800-WiFi should have a current and valid Certificate of Calibration Testing (also known as a Report of Calibration).

Unlike a simple minimum/maximum thermometer, which only shows the coldest and warmest temperatures reached in a unit, DDLs provide detailed information on all temperatures recorded at preset intervals.

Temperature Data Logger with Smart Probes - Zero Downtime

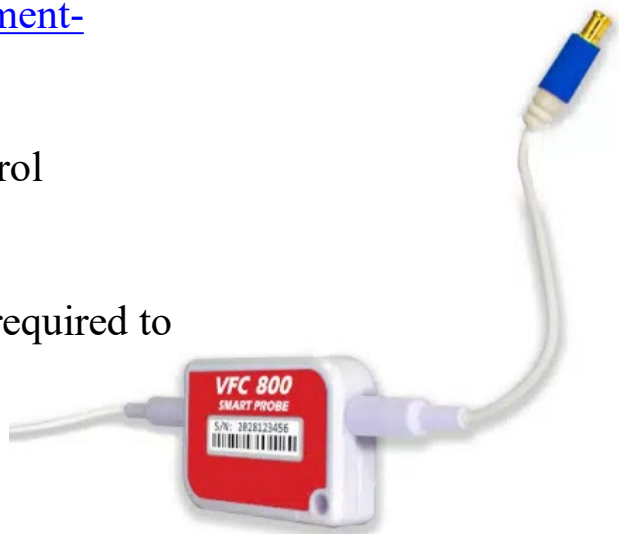
Temperature Monitoring Device Calibration

Temperature Monitoring Device Calibration Testing

- All VFC 800 Wi-Fi smart probe data loggers must be up to date with calibration. Prior to expiration date, provider locations are required to order a 5ft or 10 ft replacement at https://www.vfcdataloggers.com/product/vfc800wifi-replacement-probe/ that is good for up to two years.

- Replacement calibration certificates are available from Control Solutions if a copy is needed.

- All back up data loggers (including the old blue loggers) are required to have a calibrated certificate valid for up to two years.



To order replacement:
https://www.vfcdataloggers.com/product/vfc800wifi-replacement-probe/

- If re-calibrating the old blue logtag data loggers for backup/transfer use, send to TMDE Calibration or Control Solutions.

Storage and Temperature Monitoring Equipment

The following are additional characteristics for the VFC 800 Wi-Fi smart probe DDL provided by the Maine Immunization Program:

- Calibrate easily with hot-swappable smart probes.
- Wi-Fi uploads data to cloud instantly.
- View current and Min-Max temps fast.
- Alarms signal excursions with LED flash and sound.
- At-a-glance alarm status for up to 30 days
- Current, minimum, and maximum temperature indicator
- Low-battery indicator
- Accuracy of +/- 0.5° C (+/- 1° F)

❖ The smart temperature probe in buffered solution should be in the center of the unit where vaccines are stored for the most accurate temperatures.

Storage and Temperature Monitoring Equipment

Certain types of temperature monitoring devices, such as the ones shown here, have significant limitations and should never be used to measure temperature in a vaccine storage unit. These devices are not only difficult to read, but they also only show the temperature at the exact moment they are checked. They may fail to detect temperatures outside of the recommended range that can occur throughout the duration of storage.

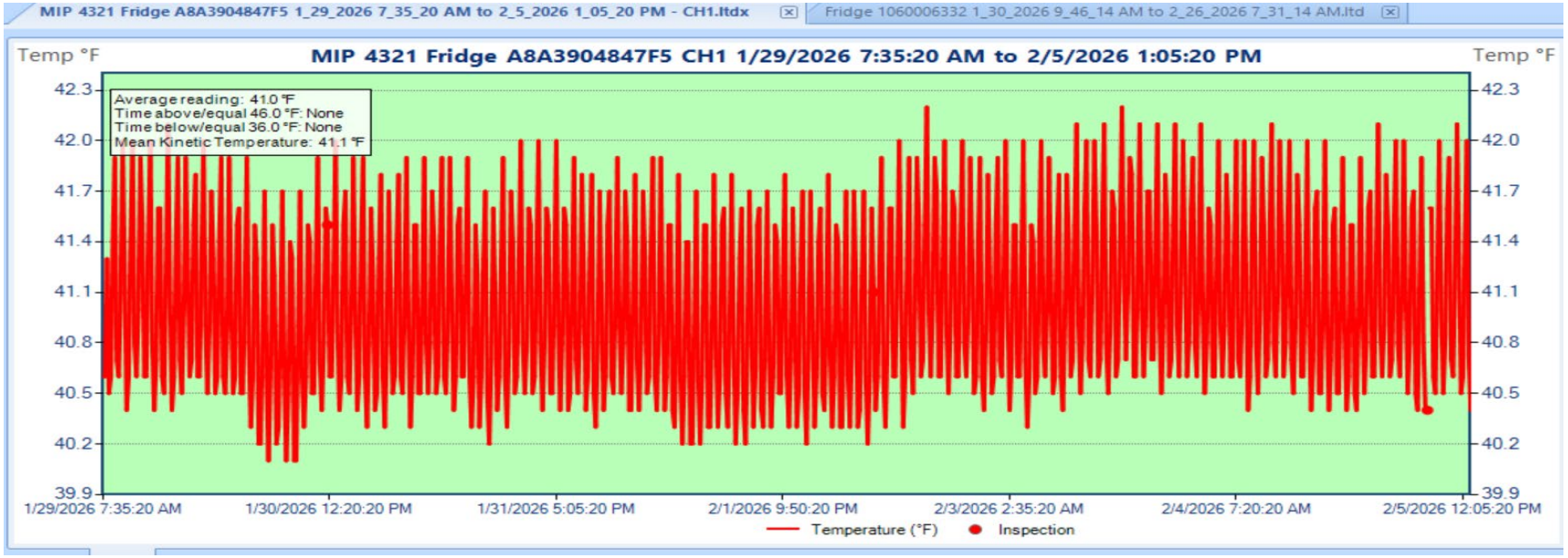
The following is required for use as a back up/vaccine transfer data logger:

- an alarm for out-of-range temperatures
- temperature display showing current temp, min and max temp
- low battery indicator
- accuracy of +/-1 F
- user programable logging interval with set to record at least once every 30 minutes
- must have a valid certificate of calibration

Storage and Temperature Monitoring Equipment

Mishandling a temperature monitoring device can affect its accuracy. If a temperature monitoring device is dropped, hit against the side of a storage unit, or potentially damaged in anyway, its accuracy should be checked against another calibrated temperature monitoring device. If there is any question about accuracy, please contact the MIP education team.

It is common with some devices to see a slight variation in temperature from one reading to another, even when the unit thermostat is set at a particular temperature. Temperatures within any storage unit will vary at least slightly, even with normal use. If you observe no fluctuation in your temperature monitoring device, the device may be faulty and may need replacement.



Knowledge Check

Determine the correct answer.

Which temperature monitoring device is required by MIP for use in any and all units containing MIP vaccines?

- Alcohol or mercury thermometers, even if placed in a fluid-filled biosafe liquid vial
- Infrared temperature monitoring device
- Chart recorder
- VFC800 Wi-Fi digital data logger with detachable probe ★

Any DDL used for back up/transfer needs to have an alarm for out-of-range temperatures and a low-battery indicator as well as an indicator for current, minimum, and maximum temperatures. Logging intervals must be at least every 30 minutes.

Knowledge Check

Is the statement below true or false?

Calibrated temperature monitoring devices require periodic calibration testing to ensure accuracy.

TRUE ★

FALSE

Because all temperature monitoring devices experience "drift" over time that affects their accuracy, calibration testing should be done every 1-3 years or according to the manufacturer's suggested timeline.

Storage and Temperature Monitoring Equipment

Do not use power outlets that can be tripped or switched off, including:

- Built-in circuit switches (may have reset buttons)
- Outlets that can be activated by a wall switch
- Multi-outlet power strips

If the entire storage unit is impacted by a temperature excursion because of a power outage or unit malfunction, refer to your facility's emergency storage and handling SOPs.

Take the following precautions to protect the storage unit's power supply:

- Plug in only **one storage unit per electrical outlet** to avoid creating a fire hazard or triggering a safety switch that would turn off power.
- Use a safety-lock plug or an outlet cover to prevent the unit from being unplugged.
- Post "DO NOT UNPLUG" warning signs at outlets and on storage units.
- Label fuses and circuit breakers to alert people not to turn off power to storage units. Labels should include immediate steps to take if power is interrupted. If your building is owned by a third party and you do not have access to the circuit breakers, work with your building manager in advance to label your circuit breakers accordingly .

Knowledge Check

Determine the correct answer.

Which action will help to prevent an interruption of the power supply for a vaccine storage unit?

- Use only outlets that have built-in circuit switches (with red reset buttons)
- Monitor temperatures at least 2 times each workday
- Have a backup storage unit available nearby
- Not plugging your units into a power strip 

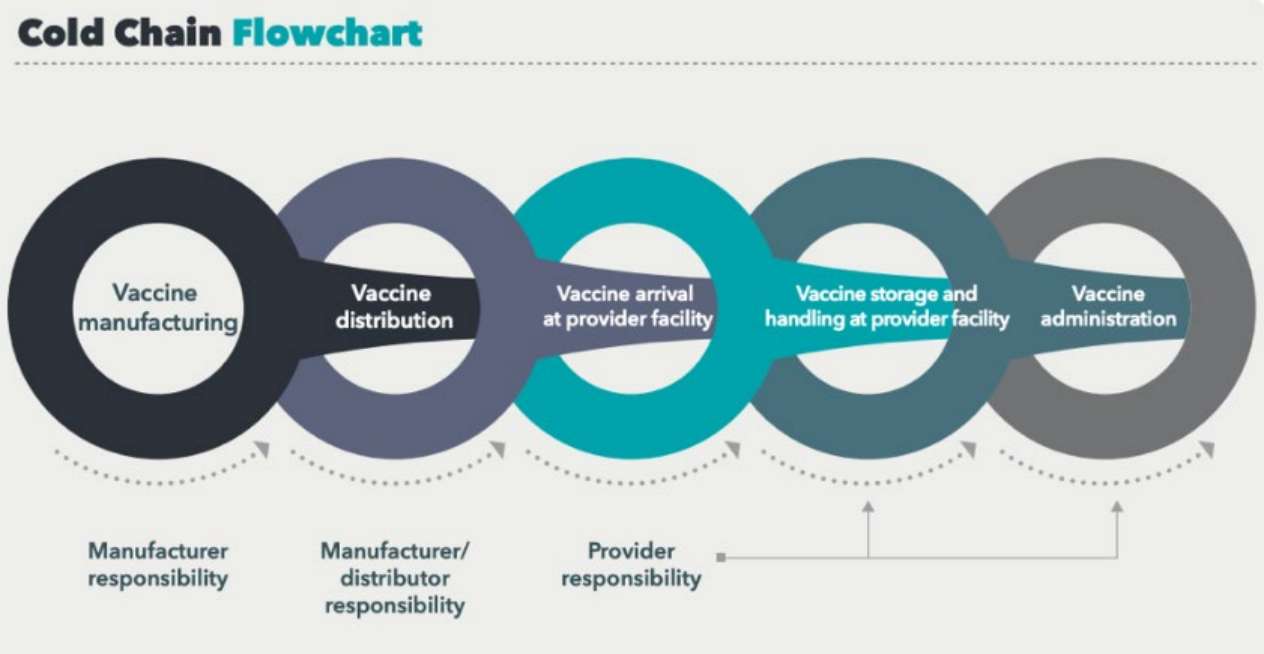
Power strips can accidentally be turned off causing the unit to be lose power.

Vaccine Cold Chain

The vaccine cold chain is a temperature-controlled environment used to maintain and distribute vaccines in optimal condition.

The cold chain begins with the cold storage unit at the manufacturing plant, extends through the transport of vaccines to the distributor and delivery to and storage at the provider facility, and ends with the administration of vaccine to the patient.

Appropriate storage and handling conditions must be maintained at every link in the cold chain.



Vaccine Cold Chain

Too much exposure to heat, cold, or light at any step in the cold chain can damage vaccines, resulting in loss of vaccine potency. Potency cannot be restored. Each time vaccines are exposed to improper conditions, potency is reduced further. If the cold chain is not properly maintained, potency will be lost completely, and the vaccine will be useless.

A single exposure to freezing temperatures 32° F or colder will destroy some refrigerated vaccines. Liquid vaccines that contain an adjuvant can permanently lose potency when exposed to freezing temperatures.

Vaccine appearance is not a reliable indicator that vaccines have been stored in appropriate conditions. For example, inactivated vaccines, even when exposed to freezing temperatures, may not appear frozen, giving no indication of reduced or lost potency.

Before administering any vaccine, inspect it for particulate matter and discoloration. Do not administer if potentially contaminated or compromised. Contact MIP for further instruction.

Storage and Temperature Monitoring Equipment

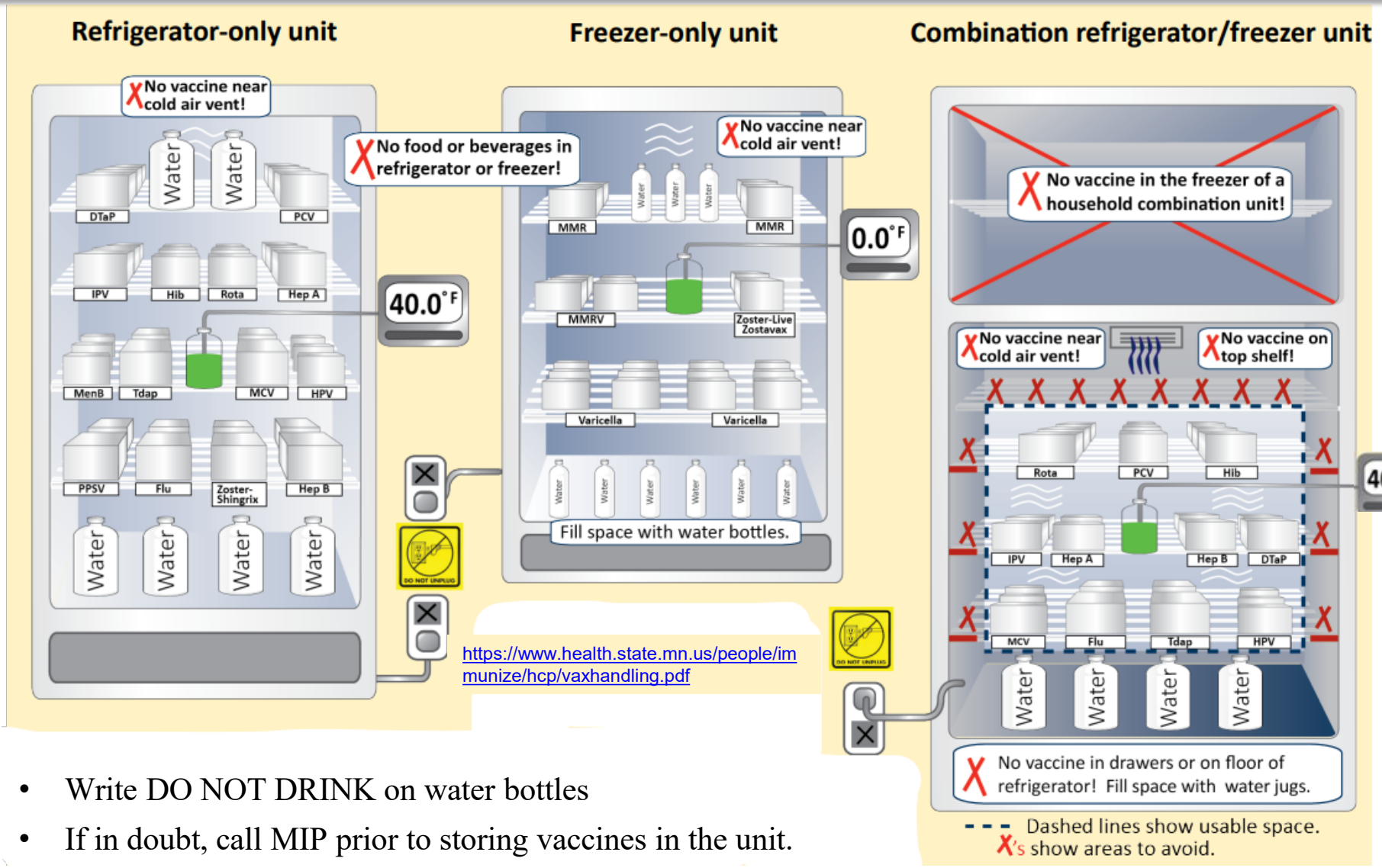
Following recommended guidelines and best practices for placement of vaccines in a storage unit will help to prevent conditions that could reduce vaccine potency or cause vaccine failure.

Always refer to manufacturers' product information/package inserts for the most up-to-date storage and handling recommendations for specific vaccines and diluents.

- Place vaccines in labeled bins that allow air flow around the vaccines
- **Do not** place on floor or door of unit
- **Do not** place vaccines directly under a fan on top shelf of unit
- **Do not** pack vaccines tightly
- Vaccine boxes should not touch walls of the unit
- Line any areas where vaccines can not be stored with water bottles labeled DO NOT DRINK*

*Water bottles are not recommended for all pharmaceutical-grade units. Make sure to check manufactures guide if your unit is pharmaceutical-grade

Storage and Temperature Monitoring Best Practice



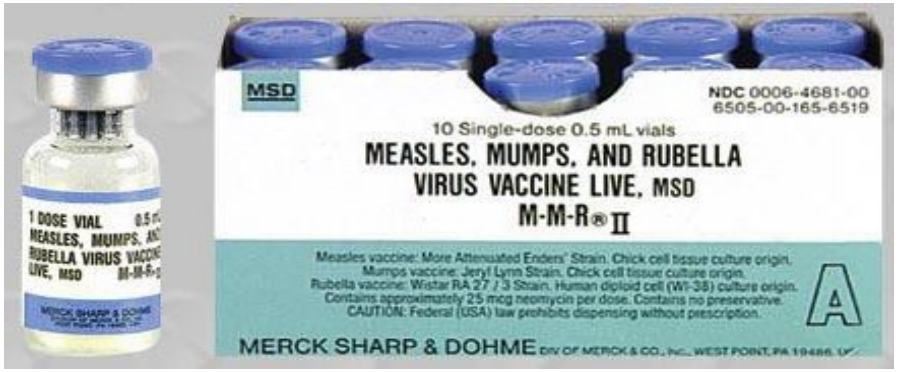
https://www.health.state.mn.us/people/immunize/hcp/vaxhandling.pdf

- Write DO NOT DRINK on water bottles
- If in doubt, call MIP prior to storing vaccines in the unit.

Storage and Temperature Monitoring- Refrigerator

Refrigerated vaccines should be stored between 36°F and 46°F, with a desired target temperature of about 40°F.

Measles, Mumps, and Rubella Virus Vaccine manufactured by Merck (MMR II) is the **only** vaccine that may be stored in either a refrigerator or a freezer. Some diluents must be refrigerated, while others may be stored in the refrigerator or at room temperature (no warmer than 77°F).



NEVER FREEZE DILUENTS

Source: Centers for Disease Control and Prevention

Storage and Temperature Monitoring Best Practice

Best practices for storing vaccine and diluent in a refrigerated unit include:

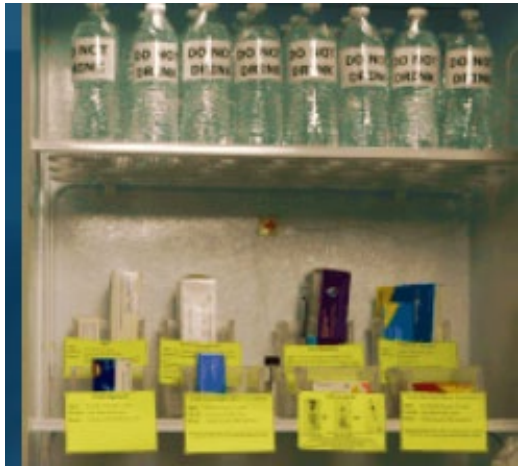
- Always store vaccines in their original packaging with lids closed until ready for administration. This protects them from light and provides additional thermal protection/stability.
- Never store loose vials or manufacturer-filled syringes outside of their packaging. This increases the risk of administration errors and exposing vaccine to light. It makes it more difficult to track expiration dates and manage inventory as well.
- Place water bottles on the top shelf, floor and in the door racks. Putting water bottles in the unit can help maintain stable temperatures when unit doors are frequently opening /closing or in the event of a power failure. It can also prevent vaccines from being stored in areas where there is a greater risk of out-of-range temperatures (such as the top shelf, floor, and door).
- Place water bottles carefully so they cannot dislodge, preventing the door from closing securely or weighing the door down so the seals are not tight.
- Label all water bottles “DO NOT DRINK”


Source: Centers for Disease Control and Prevention

Storage and Temperature Monitoring Best Practice

Best practices for storing vaccine and diluent in a refrigerated unit (continued):

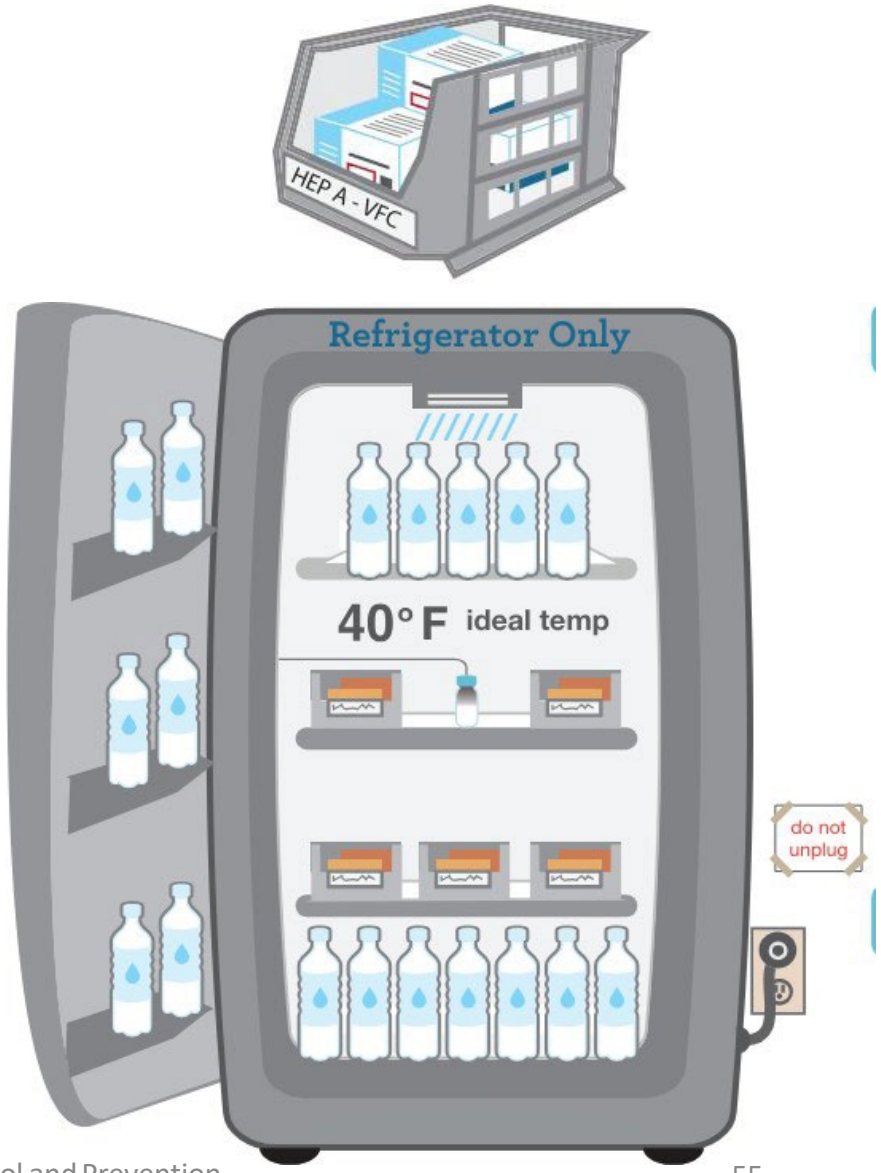
- Whenever possible, store diluent for refrigerated vaccines with the corresponding refrigerated vaccine.
- Store each type of vaccine or diluent in a separate container.
- Attach labels to shelves and containers to clearly identify where each type of vaccine and diluent is stored.
- Store vaccines and diluent with similar packaging or names or with both pediatric and adult formulations on different shelves. Make sure to label the formulation "pediatric" or "adult", if applicable.
- Place vaccines and diluent in the center of the unit, 2 to 3 inches away from walls, ceiling, floor, and door.
- Avoid storing vaccines and diluent in any part of the unit that may not provide stable temperatures or sufficient air flow, such as directly under cooling vents, in drawers, or in shelves on the door.



Storage and Temperature Monitoring Best Practices

Best practices for storing vaccine and diluent in a refrigerated unit (continued):

- Do not store vaccines in deli, fruit, or vegetable drawers, or in the door. Temperatures in these areas are not stable and can differ from those inside the main part of the unit.
- Arrange vaccines and diluents in rows, allowing space between rows to promote air circulation. This helps each vaccine and diluent maintain a consistent temperature.
- Place vaccines and diluents with the earliest expiration dates in front of those with later expiration dates.
- Do not pack a storage unit too tightly. This can restrict circulation and impact vaccine temperature.

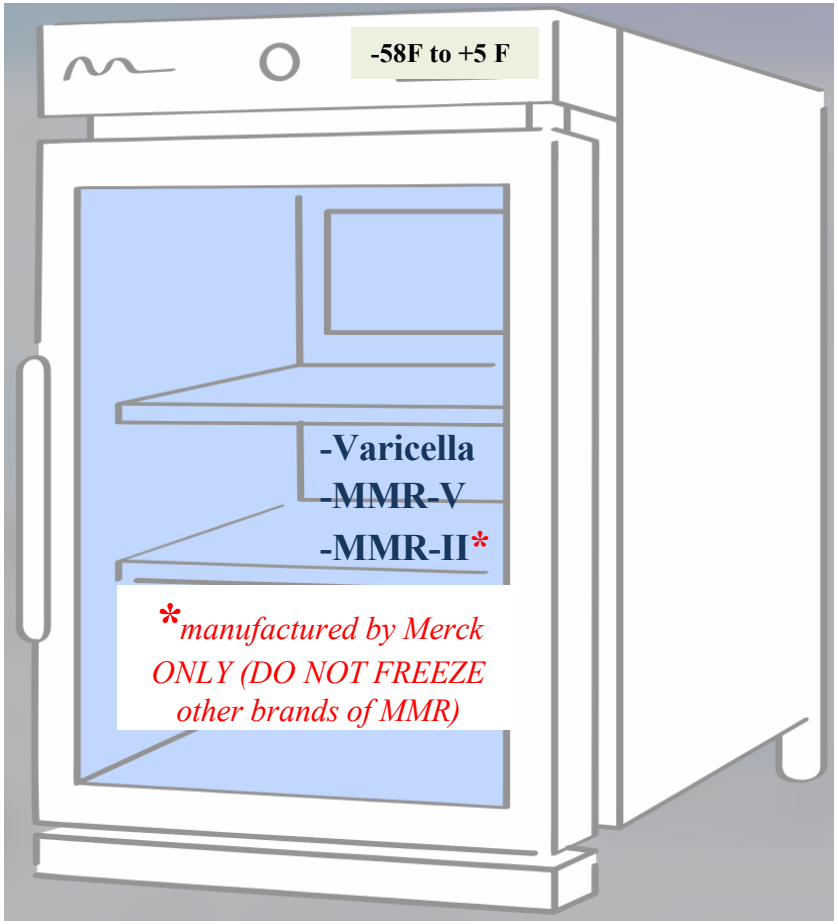


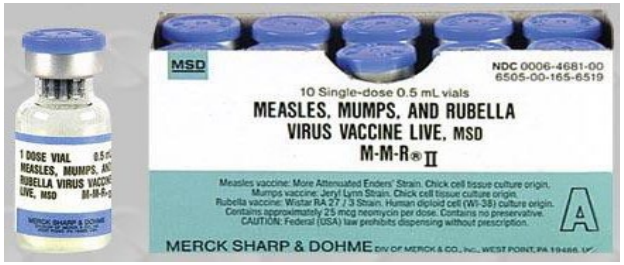
Storage and Temperature Monitoring- Freezer

Freezers should maintain temperatures between -58°F and 5°F. The thermostat should be set at the factory set or midpoint temperature to assure appropriate frozen storage temperatures.

Frozen vaccines should always be stored in a freezer unit between -58°F and 5°F until reconstitution and administration.

Measles, Mumps, and Rubella vaccine, MMRII manufactured by Merck is the only MMR vaccine that may be stored in either a refrigerator or freezer.





Never store any diluent in the freezer!

Storage and Temperature Monitoring Best Practice

- No items other than vaccines, diluents, and labeled water bottles should be placed or stored in the vaccine units.

- Food and beverage should never be stored in the unit with vaccines. Doing so can lead to frequent opening of the door to access food, putting vaccines at risk of temperature fluctuations and excessive light exposure. It can also result in spills and contamination.

- If other medications and biological products **must** be stored in the same unit as vaccines:


Source: Centers for Disease Control and Prevention

- ❑ NEVER store these products in the same container with vaccines
- ❑ NEVER store these products on the same shelf as vaccines
- ❑ ALWAYS store them below vaccines and on a different shelf in a container to prevents contamination and reduces the likelihood of medication errors

LABEL shelves clearly and appropriately!

Knowledge Check

Determine the correct answer.

The temperature inside the freezer unit used to store vaccines must be:

- 0° For colder
- -58° F or colder
- -58° F and 5° F 
- -73° F and 15° F

The freezer temperature for vaccine storage must be between -58° F and 5° F. This helps ensure optimal conditions for maintaining the potency of vaccines that require storage in the freezer.

Knowledge Check

Is the statement below true or false?

Placing water bottles on the top shelf, in the door racks, and on the floor of the refrigerator helps maintain stable temperatures.

- TRUE 
- FALSE

Putting water bottles in the unit can help maintain stable temperatures caused by frequently opening and closing unit doors or a power failure. It can also prevent vaccines from being stored in areas where there is a greater risk of out-of-range temperatures (such as the top shelf, floor, and door). Some purpose-built/pharmaceutical units do not recommend water bottles. Always check the manufactures information regarding water bottles if you have a purpose-built/pharmaceutical unit.

Knowledge Check

Determine the correct answer.

Which of the following vaccines should be stored in the freezer between -58° F and 5° F until reconstitution?

- VAR, Hib, MMR, and MMRV
- VAR, HPV, and MMRV
- VAR and MMRV 

Frozen vaccines should be stored in the freezer between -58° F and 5° F until reconstitution. Varicella (VAR) and Measles, Mumps, Rubella and Varicella (MMRV) are all vaccines that should be stored in the freezer.
Haemophilus Influenzae type B (Hib) and Gardasil (HPV) should be stored in the refrigerator.

❖ ***Only MMRII manufactured by Merck can be stored in the freezer or in the refrigerator.***

Knowledge Check

Determine the correct answer.

Which vaccine has been stored correctly?

- Vaccine that is stored in a drawer inside the refrigerator
- Vaccine that is stored in a labeled container/bin on the middle shelf a few inches from the wall 
- Two different vaccines stored in the same container/bin on the middle shelf
- Vaccine that is stored in the refrigerator door next to the diluent

Vaccines need to be placed in the central area of the unit, allowing 2-3 inches away from walls, vents, and coils. Each vaccine also needs to be stored separately to avoid confusion or mistakes.

Knowledge Check

Determine the correct answer.

Which statement best defines cold chain management?

- Checking that vaccines are potent and effective when used
- Maintaining appropriate storage and handling conditions at every link in the cold chain 
- Minimizing exposure to excessive heat and cold
- Checking vaccines for physical evidence of lost potency before administration

Cold chain management means maintaining appropriate storage and handling conditions at every link in the chain. The cold chain begins with the cold storage unit at the manufacturing plant, extends through transport of vaccines to the distributor and delivery to and storage at the provider facility, and ends with administration of vaccine to the patient.

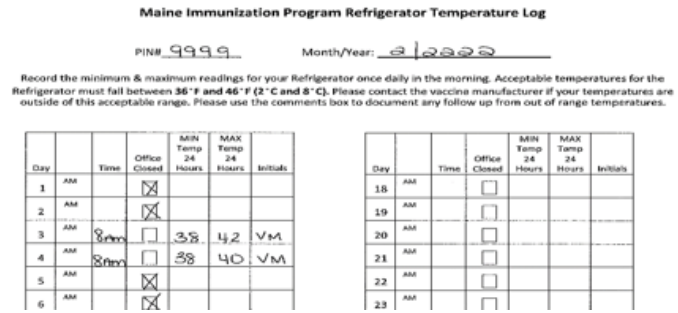
Temperature Recording Logs

Recording temperatures and inspecting the vaccine unit:

Check and record storage unit minimum and maximum temperatures at the start of each workday. This is a requirement for MIP providers. This should be done even if there is a temperature alarm.

A temperature monitoring log sheet should be placed on each storage unit door (or nearby), and the following information should be recorded:

- Min/max temperatures
- Date
- Time
- Name or initials of person who checked and recorded the temperatures
- Any actions taken if a temperature excursion occurred



Maine Immunization Program Refrigerator Temperature Log

PIN# 9999 Month/Year: 3/2022

Record the minimum & maximum readings for your Refrigerator once daily in the morning. Acceptable temperatures for the Refrigerator must fall between 36°F and 46°F (2°C and 8°C). Please contact the vaccine manufacturer if your temperatures are outside of this acceptable range. Please use the comments box to document any follow up from out of range temperatures.

Day		Time	Office Closed	MIN Temp 24 Hours	MAX Temp 24 Hours	Initials
1	AM		☒			
2	AM		☒			
3	AM	8am	☐	38	42	VM
4	AM	8am	☐	38	40	VM
5	AM		☒			
6	AM		☒			

Day		Time	Office Closed	MIN Temp 24 Hours	MAX Temp 24 Hours	Initials
18	AM		☐			
19	AM		☐			
20	AM		☐			
21	AM		☐			
22	AM		☐			
23	AM		☐			

- If a reading is missed, leave a blank entry in the log.
- Visually check the current temperature each time vaccines are accessed in the storage unit. This helps ensure temperature excursions are identified quickly and corrections are made to prevent vaccine loss and to ensure vaccine is viable before use.
- These checks provide an opportunity to inspect the storage unit, reorganize any misplaced vaccines and remove any expired vaccines.
- Any staff member can be trained to record and monitor/document the temperature logs if they are trained on what how to identify excursion and what steps to take if there is one.

How to Obtain Daily Minimum and Maximum Temperatures

The minimum and maximum temperatures showing on the DDL screen are the overall min/max since the DDL was last configured, NOT current min/max.

To obtain current min/max for your data logger:

- Press **REVIEW/MARK** button once. This will show maximum temperature from the past 24 hours. It will show where the current temperature was previously displayed. Log this temp.
- Press **REVIEW/MARK** button again. This will replace the maximum with the minimum temperature. Log this temp.
- To return to the main screen, press the **START/CLEAR/STOP** button.

If your current min/max continues to show an excursion after already addressed and acknowledged:

- Press and hold the **REVIEW/MARK** button.
- After 1 second the number values alternate with dashes, after 4 seconds, the dashes remain on.
- Release the buttons within 2 seconds. The values will be reset, and the dashes remain on screen.
- If you keep holding the button beyond the 2 seconds, the currently stored min/max values will be retained.

Storage and Handling

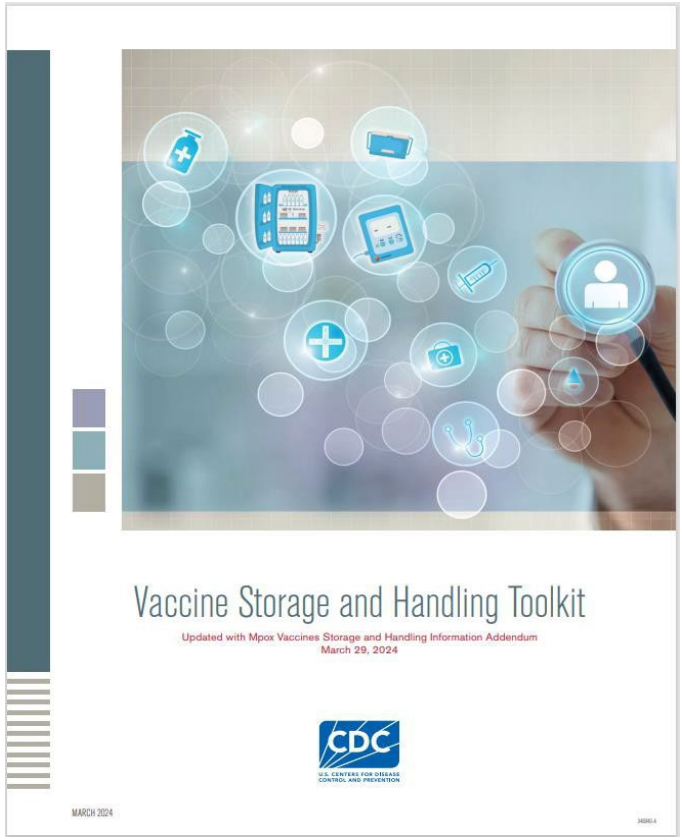
CDC recommends the following be completed on a <u>weekly</u> basis:

- Review storage unit temperature readings and review cloud data for changes in temperature trends that might require action such as adjusting unit temperature or repairing/replacing storage unit or temperature monitoring equipment.

- File this information so it an be analyzed for long-term trends and/or recurring problems. Temperature data must
- be kept for a minimum of 3 years.

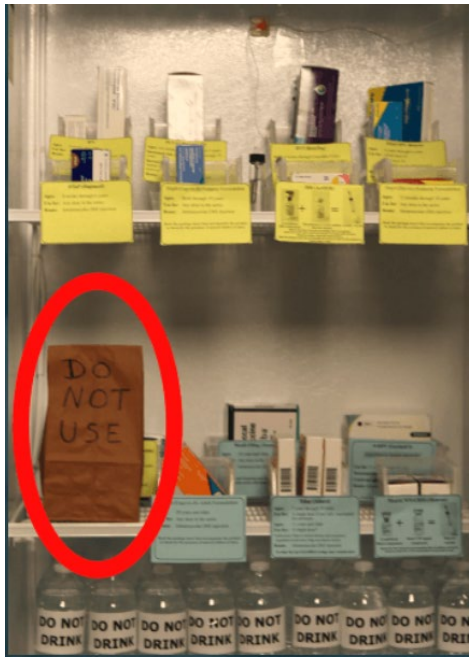
- If there appears to be any fluctuation in temperature, troubleshoot the problem based on additional information provided in CDC's Vaccine Storage and Handling Toolkit, manufacturer manuals, and/or your storage and handling SOPs.

- Call MIP if you need any assistance.



Temperature Excursions

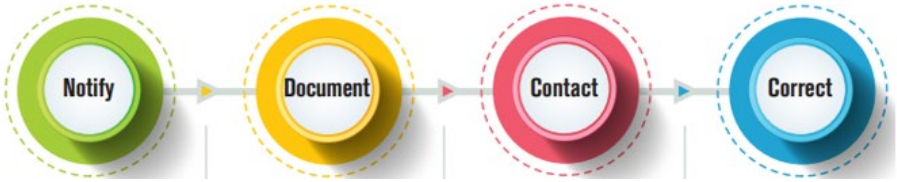
Temperature excursions or inappropriate conditions for any vaccine require immediate action. **Any** temperature reading outside ranges recommended in the manufacturers' package inserts are considered a temperature excursion.



Manufacturers must be contacted with EACH temperature excursion!!!

Required Action:

- Notify the vaccine coordinator or supervisor immediately.
- To stop the data logger alarm beeping, simply hold the "START, CLEAR, STOP" until the "X" turns back into a check mark.
- Label the vaccines "Do Not Use".
  - Store the vaccines in a unit where they can be kept under appropriate storage, if necessary.
- Log in to LogTag Online https://logtagonline.com/login
- "Acknowledge" the excursion in LogTag online and review temperatures.
- Consult each vaccines manufacturer to obtain documentation for the viability of the vaccine. Be prepared to provide min/max temperatures, duration out of range, and the vaccine involved with lot numbers.
  - Follow manufacture guidance based on viability information provided by the manufacturers. Vaccine Manufacturers | Immunize.org
- Contact the Maine Immunization Program to discuss vaccine viability
- Document all steps taken on the paper temperature log and in ImmPact cold chain.
- Determine and address the cause of the temperature excursion.
- If the thermometer fails, implement the back-up thermometer. If the storage unit fails, implement the emergency plan.
  - If vaccines were moved to another unit due to unit failure, please provide seven days of stable in-range temperatures before moving vaccine back into unit.
- You can review Vaccine Storage and Handling Toolkit here.



Knowledge Check

Determine the correct answer.

How often do you need to check and record the minimum and maximum temperatures in each vaccine storage unit?

- Monthly when monthly tasks are done
- Only when data are downloaded to the computer
- At the start of each workday ★
- 2 times each workday

Check and record storage unit minimum and maximum temperatures reading at the start of each workday. You should also check the current temperature prior to accessing and administering vaccines.

Knowledge Check

Is the statement below true or false?

Temperature data should be kept for 3 years?

TRUE 

FALSE

File temperature data so it can be analyzed for long-term trends and/or recurring problems. Temperature data is considered MIP data and is required to be kept for 3 years minimum.

Knowledge Check

Determine the correct answer.

You are a staff member and notice that a vaccine storage unit is not working correctly. What action needs to be taken immediately?

- Move the vaccines to the staff lounge refrigerator.
- Notify the primary or backup vaccine coordinator immediately or report the problem to your supervisor. 
- Throw out all the vaccines in the failed unit.
- Attempt to fix the unit.

The first action you need to take is to immediately notify the primary or backup vaccine coordinator or immediately report the problem to your supervisor.

Knowledge Check

Determine the correct answer.

The temperature within a vaccine unit is found to be out of the recommended range. You record the current storage unit temperature, along with the minimum and maximum temperatures since the last reading. What other temperature reading can provide helpful information?

- The prior vaccine storage unit temperature
- The room temperature 
- The current temperature outside

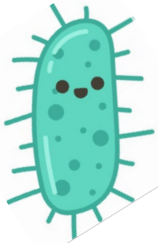
The room temperature can be helpful information when determining if the vaccines in the storage unit can still be used.

Storage Unit Maintenance

The following routine maintenance tasks are recommended for all storage units:

- Check storage unit door seals regularly for signs of wear and tear. If seals need to be replaced, contact a repair technician immediately.
- Check door hinges and adjust so that the door opens and closes smoothly and fits squarely against the body of the unit.

- Clean unit coils and motor. Dust and dirt buildup can prevent the unit from working efficiently.



- Clean inside of units to discourage bacterial and fungal growth. Cleaning must be done quickly to minimize the risk of the temperature going out of range.
- Defrost manual-defrost freezers when the frost exceeds either 1cm or the manufacturer's suggested limit. Follow the manufacturer's instructions.
- While defrosting, store vaccines temporarily in another unit with appropriate freezer temperatures.

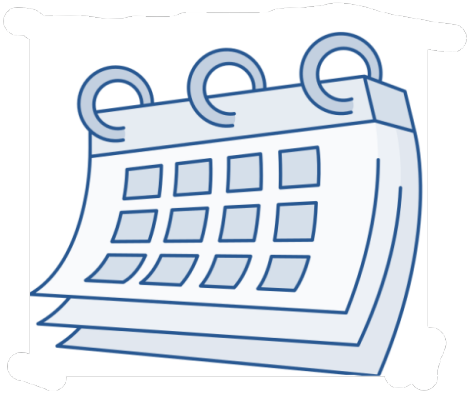
Storage Unit Doors and Generators

- Unit doors pose a particular risk to maintaining appropriate internal temperatures of vaccine storage units. A door that is not sealed properly or that is left open unnecessarily not only affects the temperatures in a unit, but it also exposes vaccines to light, which can reduce potency of some vaccines.

- Leaving the door open can cause the thermostat to respond to warmer room temperatures, and the unit will work harder to maintain the correct temperature inside.

- The unit will continue to adjust its output of cool air, and the temperature may become very cold in some parts of the unit, possibly freezing refrigerated vaccine. Using an open-door alarm and/or a self-closing door may be helpful.

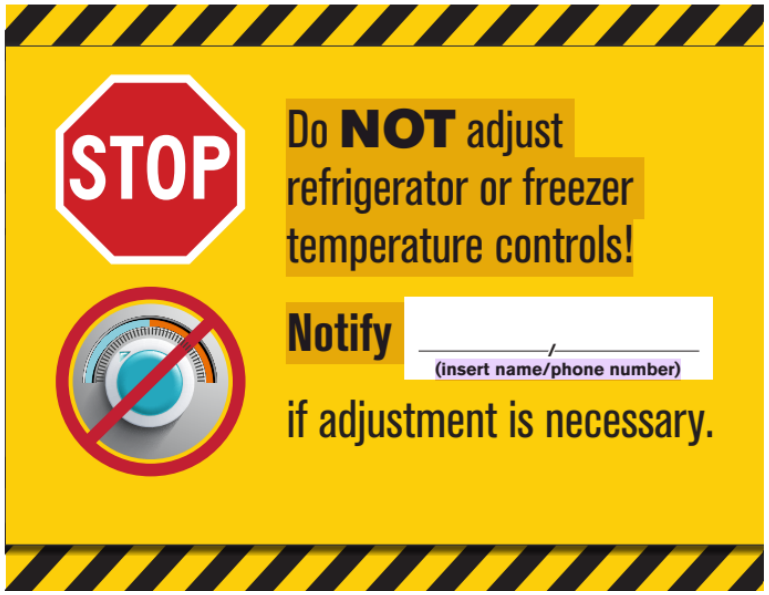
If your facility has a backup generator, it should be tested quarterly and serviced annually (check the manufacturer's guidance for testing procedures and maintenance schedules).



Storage and Temperature Monitoring Equipment

Storage unit temperatures will likely need to be adjusted over time. In some situations, thermostats may need to be reset in summer and winter, depending on room temperature.

- Thermostat adjustments should only be made by the primary or alternate vaccine coordinator, based on temperature monitoring devices and temperature monitoring logs.
- Post a warning sign on all storage units stating, "DO NOT adjust temperature controls. Notify (name of vaccine coordinator) if adjustments are necessary."
- Temperature adjustments should not be done during a busy clinic day when the unit door is being frequently opened and closed.



Storage and Temperature Monitoring Equipment

Remember that temperatures within any storage unit will vary at least slightly, even with normal use. Therefore, before making adjustment:

- Confirm the unit is securely plugged into a power source.
- Check the temperature inside the storage unit.
- Wait 30 minutes, without opening the door, and check it again. Use your backup device if you think there might be a problem with your monitoring device.

If you confirm that an adjustment is needed:

- Refer to the owner's manual for detailed instructions.
- Turn the thermostat knob slowly to avoid going outside the correct temperature range and make a small adjustment, as necessary.
- Allow the temperature inside the unit to stabilize for 30 minutes without opening the door.
- Recheck the temperature.
- Repeat these steps as needed.
- Consider placing additional water bottles in the unit to help improve temperature stability (if you have pharmaceutical unit, please check the unit handbook to see if water bottles are recommended).

Storage and Temperature Monitoring Equipment

NEVER leave vaccines in a storage unit that does not maintain temperature within the recommended range!!!

If you are unable to stabilize the temperature in your unit within the required range, or temperatures in the unit are consistently at the extreme high or low end of the range, your vaccine supply is at high risk. Use your emergency storage and handling plan to identify an alternative unit with appropriate temperatures and sufficient storage space until the primary unit can be repaired or replaced.

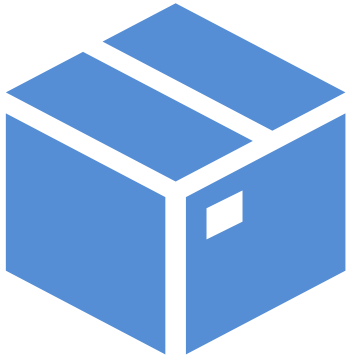
- If the temperature alarm goes off repeatedly, do not disconnect the alarm until you have determined and addressed the cause.
- Do basic checks of the unit door, power supply, and thermostat setting.
- If the alarm continues to trigger or the temperature remains out of range, transfer vaccines to a backup unit as directed by your emergency storage and handling plan and SOPs.
- Have a repair technician check your equipment to determine the need for repair or replacement.

Inventory Management, Transport, and Preparation

All staff members who might receive vaccine deliveries must be aware of the importance of maintaining the cold chain. They should be trained to immediately notify the vaccine coordinator or alternate when deliveries arrive so that vaccines are checked in and stored quickly.

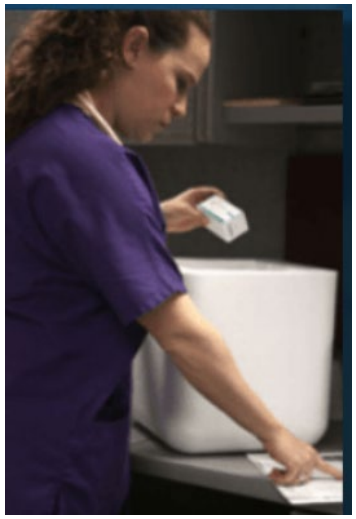
The person arranging for deliveries should know which staff member will be available to receive the vaccine orders, considering holidays, vacations and any changes in the facility's hours of operation. Ideally, the primary vaccine coordinator or back up coordinator should be available to receive deliveries.

Never leave a vaccine shipping container unpacked or unattended. If vaccines and diluents inside get too warm, they cannot be used. Be sure **all** staff members know that vaccine deliveries require immediate attention and that they know who to contact as soon as deliveries are received.



Inventory Management, Transport, and Preparation

Vaccines and diluents must be carefully unpacked, stored at recommended temperature, and documented immediately after they arrive. Do not place an unopened and/or unpacked shipment box in a vaccine storage unit.



If there are any discrepancies between the contents and the packing slip or other concerns about the contents, immediately notify the vaccine manufacturer.

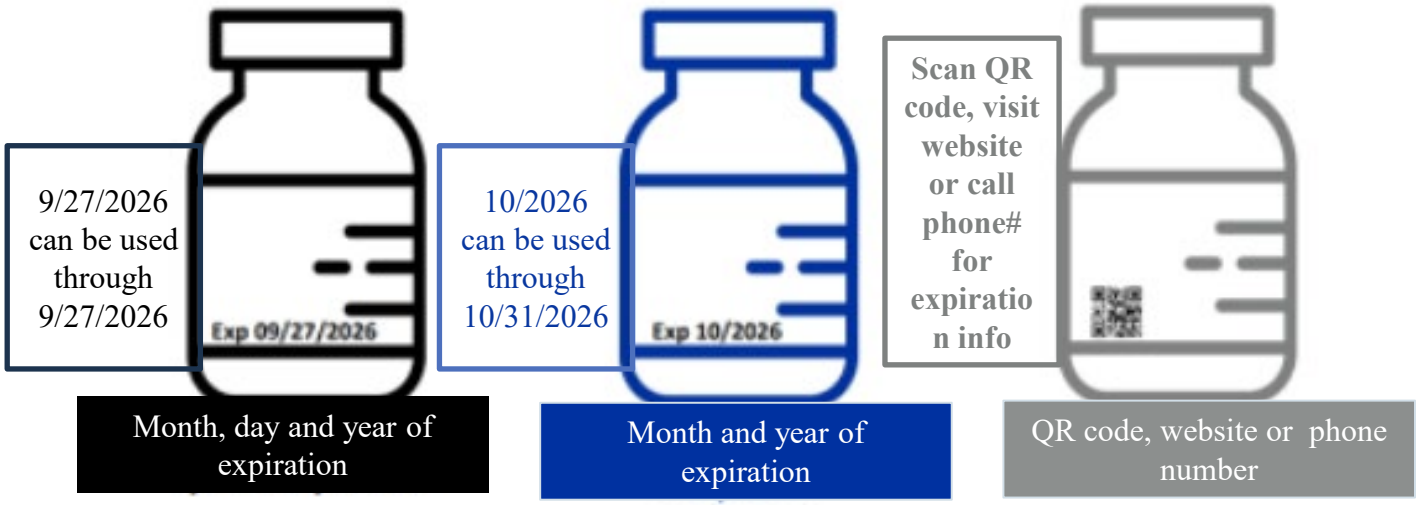
When unpacking deliveries:

- Examine the shipping container and vaccines for signs of physical damage.
- Check the contents against the packing list to be sure they match, including lot number and quantity shipped/received.
- If the shipment includes lyophilized (freeze-dried) vaccines, make sure they came with the correct type and quantity of diluents.
- Check both the vaccine and diluent expiration dates to ensure you have not received any expired or soon-to-expire products.
- Check the cold chain monitor (CCM) for any indication of a temperature excursion during transit.
- Initial the packing slip and save for at least 3 years.

Inventory Management, Transport, and Preparation

Understanding expiration dates is a key component of managing your vaccine inventory. Vaccine and diluent expiration dates indicate when the product must be discarded if it has not been used. These dates are printed on vials, manufacturer-filled syringes, and packages.

When the expiration date contains only a month and year, the product may be used up to and including the last day of that month. If an expiration date has a month, day and year, the product may only be used through the end of that day.



Inventory Management, Transport, and Preparation

Be aware of instances when vaccines expire before the expiration date on the label. Sometimes vaccines must be used before the expiration date is reached. This earlier date is known as the "beyond use date" (BUD). The BUD is calculated based on the date the vial is first entered and the storage information in the package insert. The BUD replaces the expiration date and should be noted on the label along with the initials of the person making the change.

Examples include:

- Reconstituted vaccines have a limited time frame for use once the vaccine is mixed with a diluent. This time frame or BUD is noted in the package insert. For example, if the package insert states that the reconstitution vaccine must be used within 30 minutes, it must be discarded if not used by that time.

- Manufacturer-shortened expiration dates may apply when vaccine is exposed to inappropriate storage conditions. The manufacturer might determine that the vaccine can still be used but will expire on an earlier date than the date on the label.

Beyond use date labels can be found at:
https://www.cdc.gov/vaccines/hcp/admin/storage/guide/vaccine-storage-labels.pdf

Knowledge Check

Determine the correct answer.

Today is October 19th and the date on the single-dose vaccine vial you are about to give is also October 19th of the current year. Can this vial of vaccine be used?

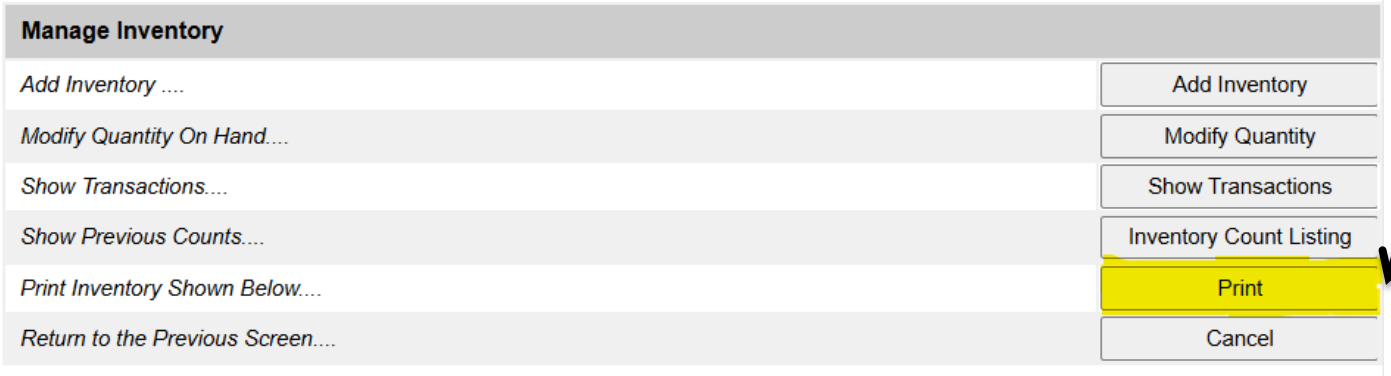
YES ★

NO

Vaccines can be used until the end of the expiration date listed. This vaccine can be used today, but would be invalid if used tomorrow, October 20th .

Inventory Management, Transport, and Preparation

MIP vaccine inventory must be reconciled at least every two weeks (14 days). Reconciliation is a chance to find any discrepancies between the vaccines in your storage units, Immpact and you EMR.



To reconcile inventory, print a list of vaccines to compare Immpact to inventory on hand.

You will get a printed list of all the vaccines Immpact has documented as being in each vaccine storage unit. Reconcile by matching the vaccines in the storage unit to what is showing as "inventory on hand" and what was physically counted in the "physical count" column of ImmPact reconciliation sheet.

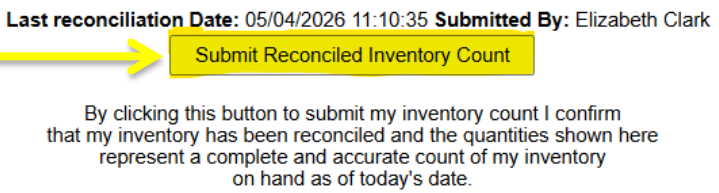
Vaccine Group	Trade Name	NDC	Lot Number	Funding Source	Intent	Packaging	Expiration Date	Active	Inventory on Hand	Doses Administered	Physical Count
Influenza-seasnl	Fluzone Pres-Free	49281-0425-50	UT8792MA	PUBLIC	PED	10 pack - 1 dose syringe	06/30/2026	Y	16	0	
Meningococcal B	Trumenba	00005-0100-10	HJ1517	PUBLIC	PED	10 pack - 1 dose syringe	06/30/2026	Y	3	0	
Rotavirus	RotaTeq	00006-4047-41	2164396	PUBLIC	PED	10 pack - 1 oral dose	03/30/2027	Y	10	0	
Td/Tdap	Boostrix	58160-0842-52	CX4HL	PUBLIC			11/09/2026	Y	7	0	

If any doses of the vaccines are missing or there is more vaccine on hand than what is listed in Immpact, each discrepancy must be found. If you need assistance, you can reach out to ImmPact Support who can help run transactions report in ImmPact.

Inventory Management, Transport, and Preparation

Once the vaccines on hand matches exactly what Immpact has listed, press the "submit reconciled inventory count" button below the inventory in ImmPact. This will record that your vaccines have been reconciled.

*Within 24 hours, the reconciliation date will update to reflect date clicked



DO NOT press the reconciliation button if the physical vaccine count does not match what Immpact has listed. This can be considered fraud.

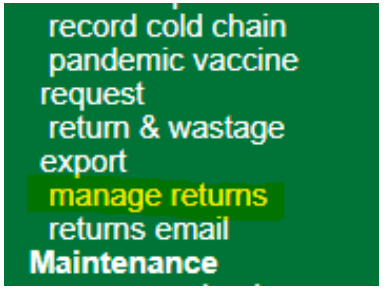
- Vaccine stock should be rotated and checked for expired doses regularly.
- Check expiration dates on vaccines and diluents at least once a week. **Immediately remove any expired vaccines and diluents to avoid inadvertently administering them.**
- Be sure to document expired doses as well as doses that have been wasted. Expired vaccine must be reconciled out of inventory using the "manage returns" module in Immpact.
- Wasted vaccine must be reconciled out of inventory as well.
- Once the returns have been processed you will receive a return label to via email to return the vaccines.

If you need assistance with returns or what to pick for a wastage option, please contact Immpact Support.
Immpact.support@maine.gov

Inventory Management, Transport, and Preparation

General disposal guidelines:

If you have vaccine doses that have expired, been compromised, wasted or are unopened vials or un-activated manufacturer filled syringes, they need to be returned to address on return label provided by MIP. This needs to be done within 6 months of expiration per federal requirements, recommended to be done ASAP.



- Vaccine returns are processed through "manage returns" module in Immpact.
- The following can not be returned :Open vials, broken vials/syringes, syringes that have been drawn up and manufacturer-filled syringes that have been activated (safety cap removed).
- These should be discarded as medical waste. This includes multidose vials that have been open and met expiration date.
- Medical waste disposal requirements are set by state environmental agencies.
- Empty vaccine vials– most are not considered hazardous or pharmaceutical waste and do not require disposal in a biomedical waste container.

❖ **Never dispose of any vaccine without consulting the Maine Immunization Program team**

Inventory Management, Transport, and Preparation

Vaccine that will be used at an off-site or satellite facility should be delivered directly to that facility. If that is not possible, vaccines should be transported using a portable vaccine refrigerator with a digital data logger to monitor temperature. If this is not available, qualified containers and pack-outs can be used with a digital data logger.

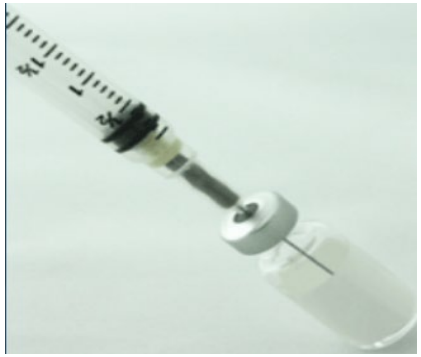
If you must transport vaccines:

- Transport only what is needed for the workday.
- The total time for transport and workday should be a maximum of 8 hours.
- If you must transport vaccines in non-commercial vehicles, use the passenger compartment – not the trunk.

Immediately upon arrival at an off-site/satellite facility, vaccines should be stored in an appropriate storage unit with a digital data logger. Minimum and maximum temperatures need to be recorded.

If vaccines cannot be stored in an on-site storage unit, they should be kept in the portable vaccine refrigerator during an off-site clinic if:

- A data logger is placed inside the unit as close as possible to the vaccines and read and record temperatures at least every 30 minutes.
- The unit is kept closed as much as possible.
- Only 1 multidose vial is removed or 10 doses removed at a time for preparation and administration by each person administering vaccines.



Inventory Management, Transport, and Preparation

- Transport diluents with their corresponding vaccines to ensure there are always equal amounts of vaccine and diluents for reconstitution. Follow the manufacturer's guidance for specific temperature requirements.

- If diluents that are stored at room temperature (68°F to 77°F) are going to be transported with refrigerated vaccines, they should be refrigerated in advance for as long as possible, so they do not raise the container temperature when placed with refrigerated vaccines.

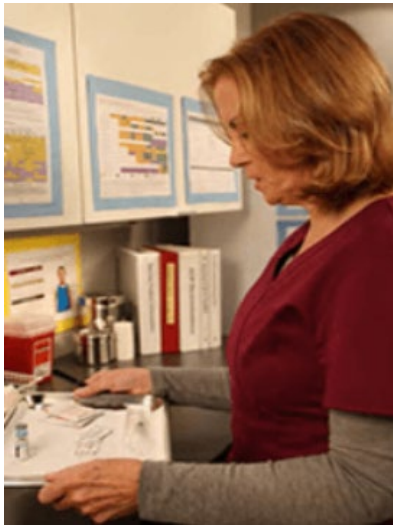
- If you have concerns about vaccines or diluents that may have been compromised (exposed to inappropriate conditions/temperatures or handled improperly), label them "DO NOT USE" and store them in appropriate refrigerated conditions (set apart from other vaccines). Immediately contact the vaccine manufacture for guidance. Contact the Maine Immunization Program and DO NOT discard the vaccine or diluents unless directed to do so by MIP.

- An open multidose vials can be transferred to or from an off-site or satellite facility operated by the same provider if the cold chain is maintained.

  - **An open multidose vial cannot be transferred to another provider or across state lines**.

Inventory Management, Transport, and Preparation

Vaccine preparation is the final step in the cold chain before administration. Handling vaccines with care is equally as important as storing them properly.

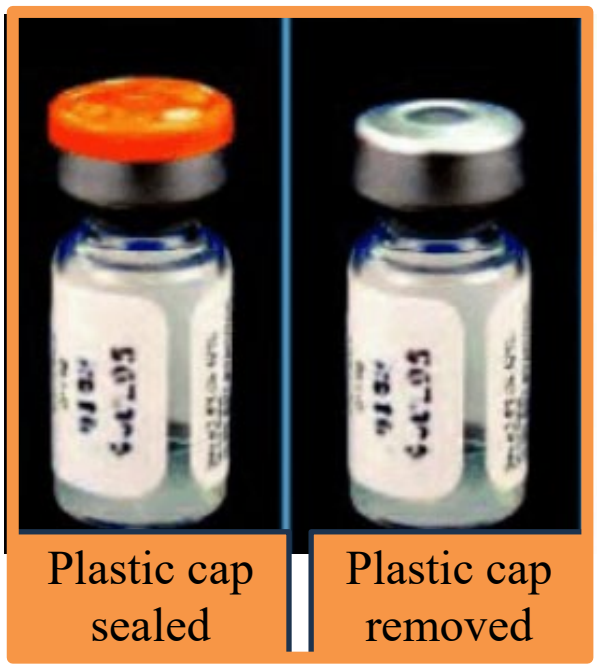


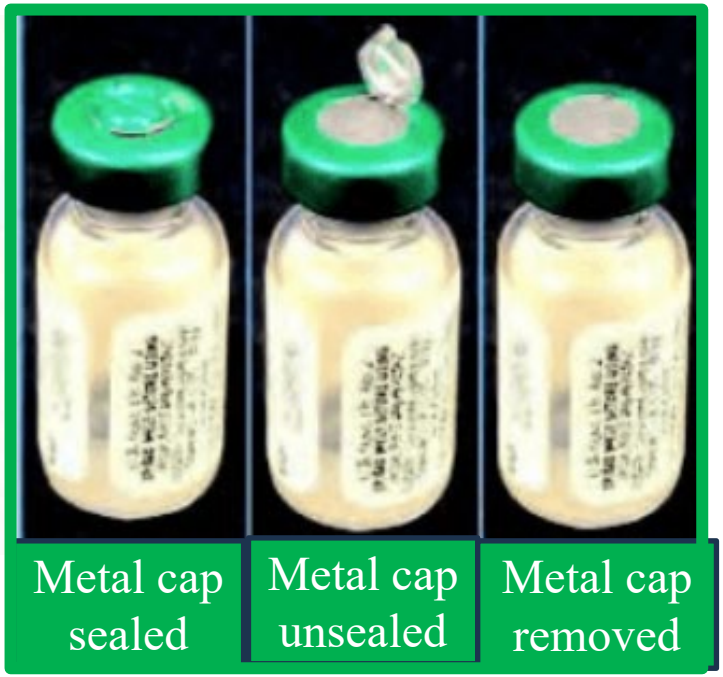
- Vaccines should be prepared in a designated area away from any space where potentially contaminated items are placed.
- Make sure you pick the correct vaccines ordered for the correct patient.
- Always check expiration dates and confirm that you have selected the correct vaccines prior to drawing them up.
- Only prepare vaccines when you are ready to administer them to the patient.
- Only administer vaccines you have prepared. This is a quality control and patient safety issue and a best practice standard of medication administration. If vaccine is drawn up by one person but administered by another, the person administering the vaccine cannot be sure what is in the syringe and whether it is safe.

Inventory Management, Transport, and Preparation

A single-dose vial (SDV) dose not contain a preservative to help prevent the growth of microorganisms. A SVD contains ONE dose and should be used ONE time for ONE patient. Do not combine leftover vaccine from one SDV with another to obtain a dose.

Do not open an SDV until ready to use. Before you remove the protective cap, always check the vial to make sure you have the correct vaccine. Make sure it is not expired. Once you remove the cap, you must use the vaccine because it may not be possible to determine if the rubber seal has been punctured. Discard any unused SDVs without a protective cap at the end of the workday.



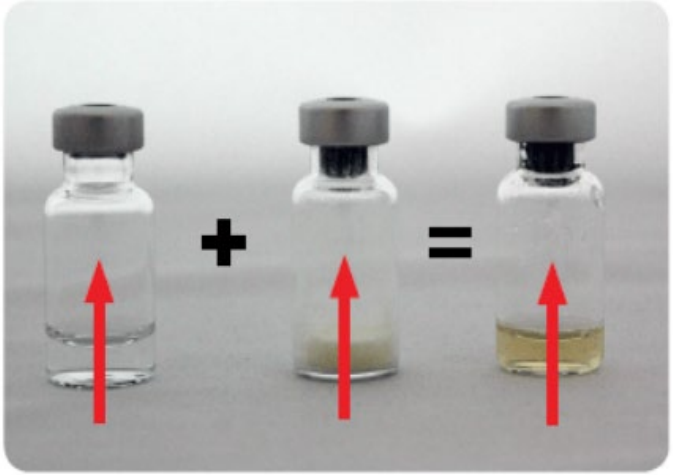


Inventory Management, Transport, and Preparation

Lyophilized (freeze-dried) vaccine may be in the form of a powder or pellet that must be mixed with a liquid (diluent) in a process known as "reconstitution" before being administered.

Diluents are not interchangeable unless specified by the manufacturer!

- Only use the diluent supplied with the vaccine to reconstitute.
- Never use a stock vial of sterile water or normal saline to reconstitute vaccines.
- Liquid diluents vary in volume and composition and are specifically designed to meet the requirements of their corresponding vaccine.
- Some diluents contain antigen or an adjuvant (refer to manufacturer's package insert for guidance on storage and handling).



Diluent + lyophilized powder = Reconstituted vaccine

Never administer vaccine reconstituted with the wrong diluent. If the vaccine has already been administered, contact your immunization program and/or vaccine manufacturer for guidance on revaccination.

Always check expiration dates on both diluents and vaccines before reconstituting them!

Inventory Management, Transport, and Preparation

A multidose vial (MDV) contains more than one dose of vaccine. Because MDVs typically contain a preservative to help prevent the growth of microorganisms, they can be entered/ punctured more than once. Only the number of doses indicted in the manufacturer's package insert should be withdrawn from the vial. After the maximum number of doses has been withdrawn, the vial should be discarded, even if there is residual and the expiration date has not been reached.

MDVs can be used until the expiration date printed on the vial unless the vaccine is contaminated or compromised in some way or there is a beyond use date (BUD) noted in the package insert.

- Never use partial doses from two or more vials to obtain a dose of vaccine.

Storage and Expiration Dating for Multidose Vial (MDV):

Vaccines are exempt from the 28-day multidose vial discard after opening rule. The Immunization Program states that vaccines are to be discarded per the manufacturer's expiration date. The Joint Commission (J C A H O) applies this approach to all vaccines - whether a part of the CDC or state immunization program or purchased by healthcare facilities - with the expectation that vaccines are managed in accordance with the product manufacturer's instructions for use (correct temperature, frequency of temperature checks, etc.) and any applicable regulatory requirements.

DO NOT discard a multidose vial after 28 days of being open.

Inventory Management, Transport, and Preparation

Draw up vaccines only at the time of administration. Once vaccines are inside syringes, it is difficult to tell them apart, which can lead to administration errors. Pre-drawing can also result in vaccine waste if more is drawn up than is needed.

General-use syringes are designed for immediate administration – not for storage. Contamination and growth of microorganisms can occur in syringes with pre-drawn vaccine that does not contain a preservative. In addition, vaccine components may interact with polymers in a plastic syringe over time, potentially reducing vaccine potency.

Vaccine manufacturers do not recommend pre-drawing vaccines in advance of influenza vaccination clinics because no data exists on the stability of vaccines stored in general- use syringes that been filled by providers.

As an alternative to pre-drawing vaccines, CDC recommends using manufacturer- filled syringes for large immunization clinics.

Inventory Management, Transport, and Preparation

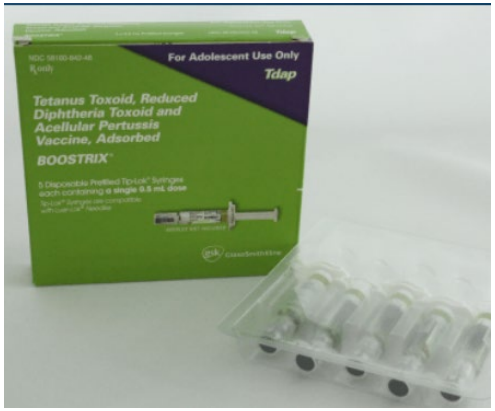
A manufacturer-filled syringe (MFS) is prepared and sealed under sterile conditions by the manufacturer.

- Do not activate an MFS (i.e., remove the syringe cap or attach the needle) until ready to use.
- MFSs do not contain a preservative to help prevent the growth of microorganisms.
- Once the sterile seal has been broken, the vaccine should be used or discarded at the end of the workday.

Some manufacturer-filled single dose syringes come with an air pocket in the syringe chamber. **You do not need to expel the air pocket. The air will be absorbed.**

This is only true for manufacturer prefilled syringes and NOT syringe you draw out of a vial.

If you are concerned about a prefilled syringes appearance, contact MIP for guidance.



Knowledge Check

Is the statement below true or false?

In general, open muti-dose vials (MDVs) can be used until the expiration date unless contaminated.

TRUE 

FALSE

MDVs can be used until the expiration date printed on the vial unless the vaccine is contaminated or compromised in some way or there is a beyond use date (BUD) noted in the package insert.

Knowledge Check

Is the statement below true or false?

Diluents are interchangeable, as most are only sterile water.

TRUE

FALSE ★

Diluents vary by volume and ingredients. Use only the specific diluent provided by the manufacturer with the specific vaccine.

Knowledge Check

Is the statement below true or false?

In setting where a large volume of several vaccines will be administered, such as a back- to- school immunization clinic, it is better to use manufacturer-filled syringes as opposed to pre-drawing vaccine from vials.

TRUE 

FALSE

Manufacturer-filled syringes have been designed for prolonged storage times to ensure potency.

Emergency Preparations

Emergencies usually happen without warning. Various situations – equipment failures, power outages, severe weather conditions, or natural disasters – may compromise vaccine storage conditions.

Vaccines should never be allowed to remain in a non-functioning unit for an extended period. Preparing in advance to retrieve and/or protect vaccines as quickly as possible during a potentially compromising situation could save your facility costly vaccine loss.
Suspend vaccination activities and implement emergency procedures in advance of the event if there is reasonable cause to believe that weather conditions, natural disasters, or other emergencies might disrupt power or accessibility to a facility. This will help ensure the vaccine supply is protected and available for use.

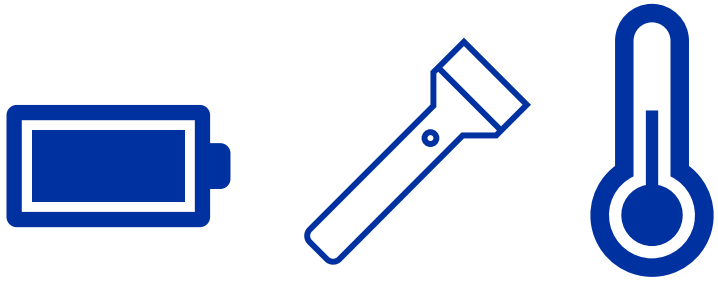
Improper packing for transport is as risky for vaccines as a failed storage unit. To help make sure your vaccines arrive safely, follow your facility's emergency storage and handling plan and SOPs. These should include the procedures and protocols outlined on the following pages.

Emergency Preparations

No piece of vaccine storage equipment is infallible. At some point equipment will fail because of a power outage, breakdown, or normal wear and tear.

At a minimum, every facility should have:

- Backup digital data logger(s)
- Spare batteries
- Flashlights (in case of a power outage)
- Vaccine transport containers and materials



Your facility may also choose to have a backup storage unit so that vaccine may not have to be packed and/or moved to an alternative storage facility if the primary storage equipment fails.

An on-site generator can prevent having to transport vaccine to an alternative storage facility during a power outage. Keep sufficient fuel on hand to continuously run the generator for at least 72 hours.

A backup battery power source can also be utilized in lieu of a generator. If your facility has a backup battery power source, it should be tested quarterly and serviced annually (check the manufacturer's guidance for testing procedures and maintenance schedules).

Emergency Preparations

Even if you have backup equipment or a generator, you need to establish a working agreement with at least one alternative storage facility with a backup generator where vaccines can be appropriately stored and monitored in an emergency. Hospitals, long-term care facilities, state depots, the Red Cross, fire stations, packing plants, and commercial pharmacies are some of the facilities that may be able to assist you.

An agreement with an alternative facility should allow you to store vaccines when:

- Severe weather conditions are expected
- Equipment fails or power cannot be restored before the storage unit temperature rises above the recommended range

Always make sure you can have 24-hour access to the alternative facility and **that they use a calibrated digital data logger in their units and that the units are at appropriate temperature settings**.

If you cannot find an alternative vaccine storage facility with a backup generator within a reasonable distance or if you cannot reach your alternative facility, you can use qualified containers and pack-outs to store vaccines temporarily and safely at your facility.


Qualified Container and Pack-out

Emergency Preparations

During a power outage, never open the storage unit door until power is restored **or** it is determined that vaccines need to be packed in separate storage containers and/or transported to an alternative storage facility. Storage unit temperatures can be monitored from the outside without opening the door using the digital data logger (make sure back up batteries are not low!). Record room temperature (if possible) and the temperature of the unit as soon as the power goes out.

- Record minimum and maximum temperatures reached inside the unit during the outage.
- If necessary, follow your procedures for temperature excursions (out-of-range temperatures).

If the DDL battery dies during power outage or goes out of range, move vaccines to a back up site with power/generator.

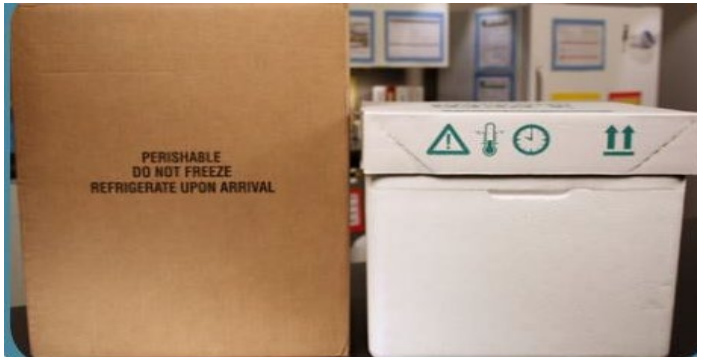
If you are unsure how long the power interruption will last or determine power will not be restored in time to maintain proper temperatures inside the unit, implement your emergency vaccine storage, handling and transport procedures.

Always place a calibrated digital data logger with the vaccines!!!

Temporary storage containers should remain closed, and vaccines should only be stored for as long as the qualified containers and pack-outs are validated to maintain proper storage temperatures.

Emergency Preparations

Temporary storage containers should remain closed, and vaccines should only be stored for as long as the qualified containers and pack-outs are validated to maintain proper storage temperatures.
For the safe transport and storage of vaccines, proper supplies are essential. Your facility needs to have a sufficient supply of materials needed for emergency vaccine transport of your largest annual inventory.



Appropriate materials include:

- Portable vaccine refrigerator/freezer units (recommended)
- Qualified containers and pack-outs
- Hard-sided insulated or Styrofoam
- Coolant materials: frozen 16.9- or 8-ounce water bottles that can be conditioned or prepared phase change materials (PCMs)
- Insulating materials such as bubble wrap or corrugated cardboard – enough to form two layers per container
- Digital data logger for each container
- **Do not use soft-sided coolers**. Most commercially available soft-sided coolers are poorly insulated and likely to be affected by room or outdoor temperatures.

Emergency Preparations

Frozen water bottles should be used as coolant packs if they are properly conditioned, which should take only a few minutes:

- Hold the bottles under running tap water or submerge them in a sink filled with tap water until you can see a layer of water forming near the surface of the plastic.
- Once the ice block inside the bottle can spin freely, the bottle is ready to be used for packing.
- Use appropriate insulating materials, such as bubble wrap, to protect vaccines from direct contact with the water bottles.

Phase change materials (PCMs) at 39°F - 41°F can also be purchased to maintain proper temperatures. Follow the manufacturer's instruction for use to reduce the risk of freezing vaccines during transport.

Do not use frozen gel packs or coolant packs from vaccine shipments to pack refrigerated vaccines.

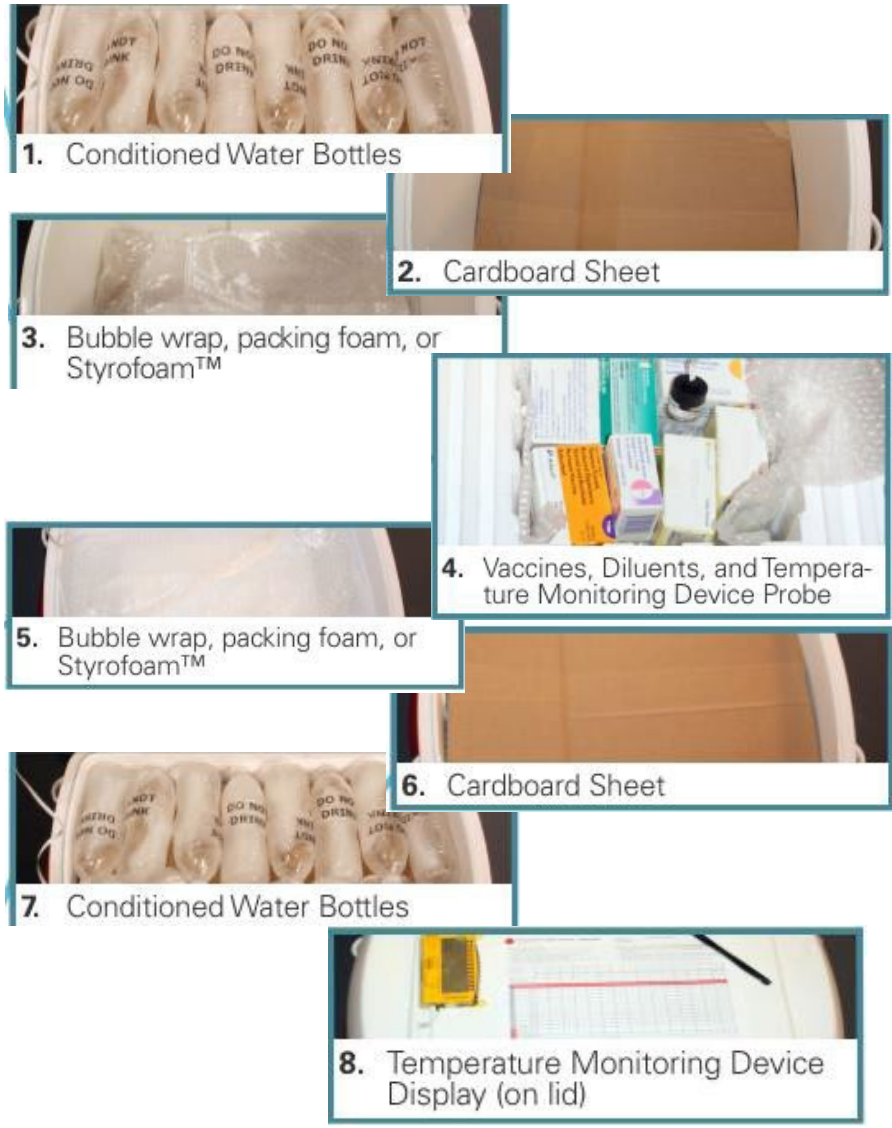
Conditioned frozen water bottles and corrugated cardboard used along with one inch of insulating material such as bubble wrap keeps refrigerated vaccines at the right temperature and prevents them from freezing. **Reusing vaccine coolant packs from original vaccine shipping containers can freeze and damage refrigerated vaccines.**

Emergency Preparations

Packing Vaccines for Transport:

- If possible, suspend vaccination activities before the onset of emergency conditions.
- Contact the alternative vaccine storage facility before packing any vaccine to confirm they can accept your vaccines for storage.
- Take an inventory of your vaccines and record actions taken to protect the vaccines.
- Open unit doors only when necessary and after completing all preparations for packing and moving vaccines.
- Use appropriate materials for packing.

CDC has compiled recommendations on the methods and materials to use for emergency vaccine transport, Packing Vaccines for Transport during Emergencies.



Emergency Preparations

Transport

- Identify primary and backup vehicles and drivers in advance.
- Consider renting a refrigerated truck if you have a large quantity of vaccines or need to transport vaccines an extended distance.
- If using a noncommercial vehicle, only transport vaccines inside the passenger compartment (not in the trunk or truck bed).
- Move transport containers directly to a preheated or precooled vehicle.
- Avoid leaving containers in areas where they are exposed to direct sunlight.
- Check vaccine temperature upon arrival at the alternative vaccine storage facility, and store vaccines at recommended temperatures immediately.
- Check with the Maine Immunization Program for additional guidance and resources on emergency transport of vaccines, particularly in major emergencies.

Transport of Diluents

- Transport diluents with their corresponding vaccines. Follow the manufacturer's guidance for specific temperature requirements.
- If diluents that are stored at room temperature (68°F to 77°F) are going to be transported with refrigerated vaccines, they should be refrigerated in advance for as long as possible, so they do not raise the container temperature when placed with refrigerated vaccines. Place an insulated barrier (e.g., bubble wrap) between the diluents and conditioned water bottles or phase change materials.

NEVER FREEZE DILUENTS!!!

Emergency Preparations

ALWAYS use a digital data logger for monitoring and recording while transporting vaccines:

- Place buffered probe vial directly with the vaccines.
- Keep the digital data logger display outside of the storage container so you can easily see the temperatures.

If you have concerns about vaccines or diluents that may have been compromised (exposed to inappropriate conditions or temperatures or handled improperly), label them as "DO NOT USE" and store them in appropriate temperature conditions (set apart from other vaccines).
Immediately contact the vaccine manufacturer(s) for guidance. Do not discard the vaccines.

Keep a written log of temperatures when transporting vaccine. You want to record date, time, minimum and maximum temperature and your initials.
Do this prior to placing vaccines in the transport unit, every time the container is open and when transfer is complete.

Travel temperature logs can be found on MIP's website:
https://www.maine.gov/dhhs/mecdc/health-professionals/immunization/compliance-and-immunization-resources

Knowledge Check

Is the statement below true or false?

Emergency storage and handling plans need to be in place and implemented in advance of possible emergencies.

TRUE 

FALSE

Emergencies usually happen without warning. Various situations – equipment failures, power outages, severe weather conditions, or natural disasters – may compromise vaccine storage conditions. Preparing in advance to retrieve and/or protect vaccines as quickly as possible during a potentially compromising situation could save your facility costly vaccine loss. If possible, suspend vaccination activities before the onset of emergency conditions to allow more time for packing and transport.

Knowledge Check

Determine the correct answer.

Severe weather is expected in your area. Your facility frequently encounters long-term power outages during storms and does not have a backup generator. What action should you take first?

- Make the vaccine storage units colder in case of a power outage.
- Consult your facility's emergency storage and handling plan. ★
- Move vaccine inventory into temporary storage containers.
- Take a count of existing vaccine inventory.

The emergency storage and handling plan will provide details on what steps to take. The first step should be to review this plan. Then implement the plan as outlined for your facility. This will usually include alerting the primary and alternate vaccine coordinators so they can assist with securing the vaccine inventory.

Knowledge Check

Determine the correct answer.

Which of the following containers is the best option for emergency vaccine transport?

- Any container if it contains dry ice
- Portable vaccine freezers and vaccine refrigerators ★
- Lunch containers
- Soft-sided collapsible coolers

CDC recommends using portable vaccine freezers and vaccine refrigerators for emergency vaccine transport. If these are not available, qualified containers and pack-outs, hard-sided coolers, or Styrofoam vaccine shipping containers can be used, including the original boxes from the manufacturer.

Storage and Handling Plans

Storage and handling plans should be reviewed and updated annually and should contain plans and information for three major areas:

- General information – includes contact information for vaccine manufacturers, equipment service providers, and important facility staff, as well as job descriptions, regularly used forms, and staff training requirements
- Routine storage and handling – includes all routine aspects of vaccine inventory management, from ordering to monitoring storage conditions
- Emergency vaccine storage, handling, and transport – outlines steps to be taken in the event of equipment malfunctions, power failures, natural disasters, or other emergencies that might compromise vaccine storage conditions

The emergency plan should be located on or near the vaccine units and everyone should be familiar with them incase the vaccine coordinators are not available during an emergency.

MIP-Routine-and-Emergency-Vaccine-Storage-and-Handling-Plan

Maine Immunization Program (MIP)
Routine and Emergency Vaccine Storage and Handling Plan

Instructions for Maine Immunization Program (MIP) providers: All MIP providers are responsible for proper routine management of their vaccine inventory and during the event of an emergency. Once completed, this template will serve as the required Routine and Emergency Vaccine Storage and Handling Plan.

MIP providers must review and update this plan annually or more frequently if there are any changes to the plan, changes in equipment used to store MIP-supplied vaccine, or changes to staff responsible for vaccine management storage and handling. The most current Routine and Emergency Vaccine Storage and Handling Plan will be reviewed during MIP Compliance Site Visits and Unannounced Storage and Handling Visits.

A copy of this plan must be posted on or near any refrigerator or freezer used to store MIP-supplied vaccine.

Practice Name:	Practice Address:
MIP PIN #:	Email Address:
Telephone Number:	Fax Number:
Healthcare Provider signing MIP Agreement:	Practice Manager:
Primary Vaccine Coordinator:	Secondary Vaccine Coordinator:
Primary Vaccine Coordinator Emergency Contact Number:	Secondary Vaccine Coordinator Emergency Contact Number:
Person Responsible for Receiving Vaccine Shipments:	Person Responsible for Vaccine Inventory and Ordering:
Person Responsible for Temperature Documentation:	Person Responsible for Vaccine Reconciliation:

Routine and Emergency Vaccine Storage and Handling Plan reviewed and updated by:

Name:	Title:
Signature:	Date of Last Review:

Knowledge Check

Is the statement below true or false?

Dormitory-style refrigerator/freezer units can be used to temporarily store vaccines in patient rooms during the clinic day.

TRUE

FALSE 

Dormitory-style refrigerator/freezer units CAN NEVER be used to store vaccine at ANY time.

Knowledge Check

Determine the correct answer.

What is the recommended temperature range for refrigerators?

- Between 32° F and 41° F
- Between 36° F and 46° F 
- Between 46° F and 54° F
- Between 50° F and 68° F

The recommended temperature range for refrigerators is between 36° F and 46° F

Knowledge Check

Determine the correct answer.

What is the recommended temperature range for freezers?

- Between -103° F and -58° F
- Between -76° F and -31° F
- Between -58° F and +5° F ★
- Between -30° C and 5° C (-22° F and 41° F)

The recommended temperature range for freezers is between -58° F and +5° F

Knowledge Check

Is the statement below true or false?

Minimum and maximum temperatures should be checked and recorded at least once a day and written on paper temperature log.

TRUE ★

FALSE

Designated staff must check and record the minimum and maximum temperatures at the start of each clinic day and then reset the minimum and maximum temperatures. This helps to ensure temperature excursions are identified quickly and corrections are made to prevent vaccine loss.

Knowledge Check

Is the statement below true or false?

Vaccine storage units used to store MIP supplied vaccines must be able to maintain proper temperatures, be large enough to store the largest inventory at the busiest point of the year without overcrowding and be protected against loss of power from the designated power source.

TRUE 

FALSE

Appropriate vaccine storage units must meet ALL requirements to safeguard vaccines.

MIP Site Visits and Provider Education

MIP Compliance Site Visits

A site visit is an opportunity for MIP staff to educate and support VFC and/or adult vaccine providers who vaccinate eligible individuals using state and federally purchased vaccines. The purpose of these visits is to assess a provider's understanding and implementation of each MIP requirement. The visit also offers an opportunity to address any changes in program requirements and creates an environment for sharing current information on available immunization resources and proper storage and handling of vaccines.

Each MIP enrolled provider will receive an on-site visit at least once every 24 months.

What Happens During a Site Visit?

MIP staff will contact the assigned vaccine coordinator to schedule a site visit. During the visit, MIP staff will evaluate the staffs understanding and implementation of MIP requirements. This is done by verifying vaccine ordering and inventory processes, reviewing records of children who have been vaccinated, and assessing vaccine storage and handling practices and implementation of program requirements. Site visits are also opportunities for staff to ask questions and for MIP staff to offer resources to support providers efforts in immunization practices.

MIP Site Visits and Provider Education

Practices Not Meeting Maine Immunization Program Requirements

Overall, MIP site visit results confirm that MIP enrolled providers understand and are successfully implementing the program in their practices. On occasion, some issues and educational needs are identified and require additional follow-up and communication with MIP staff to ensure the provider's success with the program. MIP program staff will work with the provider to develop a follow-up plan that outlines specific actions that need to be taken to address any issues identified during the visit.

Unannounced Vaccine Storage and Handling Visits

Some MIP enrolled provider sites may receive an unannounced storage and handling visit. The goals of unannounced storage and handling visits are to provide education, support, and resources related to proper vaccine storage and handling. This helps ensure all MIP-eligible individuals are receiving viable vaccine that protects them from vaccine-preventable diseases.

Vaccines For Adults

Annual Vaccine Coordinator Education

MIP requires all enrolled sites primary and back up vaccine coordinator complete the on-line Maine Immunization Educational Training (formerly Vaccines for Children training) on an annual basis.

- **Education must be completed between July 1st and July 31st each year.**

Reminders will be sent out via MIP Listserv. The on-line educational training are available on the MIP website. Once the training is complete, you are required to complete a quiz in order to receive credit.

New vaccine coordinators must complete this training and quiz when assigned as a vaccine coordinator and annually after that.

Vaccine Coordinator 1:1 Educational Training is a lunch and learn available quarterly and is required for all newly assigned vaccine coordinator. It can be attended by anyone who may want/need a refresher on MIP requirements. If the date/time of quarterly trainings does not work within your schedule, contact MIP to schedule an individual 1:1 training.

Knowledge Check

Is the statement below true or false?

MIP enrolled providers will only receive a compliance site visit from the Maine Immunization Program if it is requested by the provider.

TRUE

FALSE 

Each MIP enrolled provider will receive a compliance site visit at least every 24 months.

Knowledge Check

Is the statement below true or false?

The goals of unannounced storage and handling visits are to provide education, support, and resources related to proper vaccine storage and handling.

TRUE ★

FALSE

Unannounced storage and handling visits ensure that all MIP eligible patients are receiving viable vaccine and are protected against vaccine- preventable diseases.

Knowledge Check

Is the statement below true or false?

MIP enrolled providers must complete the mandatory on-line educational training covering all VFC and MIP requirements every 24 months.

TRUE

FALSE ★

All assigned primary and secondary vaccine coordinators are required to complete the on-line educational training covering all VFC and MIP requirements every 12 months.

Post – Test Requirements

- Please complete the post-test to receive annual credit to meet the VFC and MIP annual educational training requirement.

- Returning vaccine coordinators must complete the educational quiz annually between July 1st and July 31st.

MIP annual training and quiz will be updated and posted to the website on July 1st.
Required Training | Maine Center for Disease Control & Prevention

❖ Email immunizeme.dhhs@maine.gov or call 207-287-3746 for individual vaccine coordinator training, additional education and or resources.