

# 2023 Vaccine Storage and Handling

## Maine Immunization Program Education Training



# Learning Objectives

1. Define and explain cold chain management.
2. Describe the components of routine and emergency procedures for vaccine storage and handling.
3. Describe the roles of the primary and backup coordinators and other staff in the storage and handling of vaccines.
4. Describe proper vaccine storage and temperature monitoring equipment.
5. Describe correct vaccine and diluent storage, handling, and disposal of routinely recommended vaccines.
6. Identify actions that should be taken if vaccines have not been stored properly.

# Introduction

Proper vaccine storage and handling has been an important factor in preventing and eradicating many common vaccine-preventable diseases, however, each year, storage and handling errors result in revaccination of many patients and significant financial loss due to wasted vaccine.

Failure to store and handle vaccines properly can:

- Reduce vaccine potency, resulting in inadequate immune response in patients and poor protection against disease.
- Loss of confidence in vaccines and providers if a patient needs be revaccinated

This education provides an overview of approved vaccine storage and handling best practices.

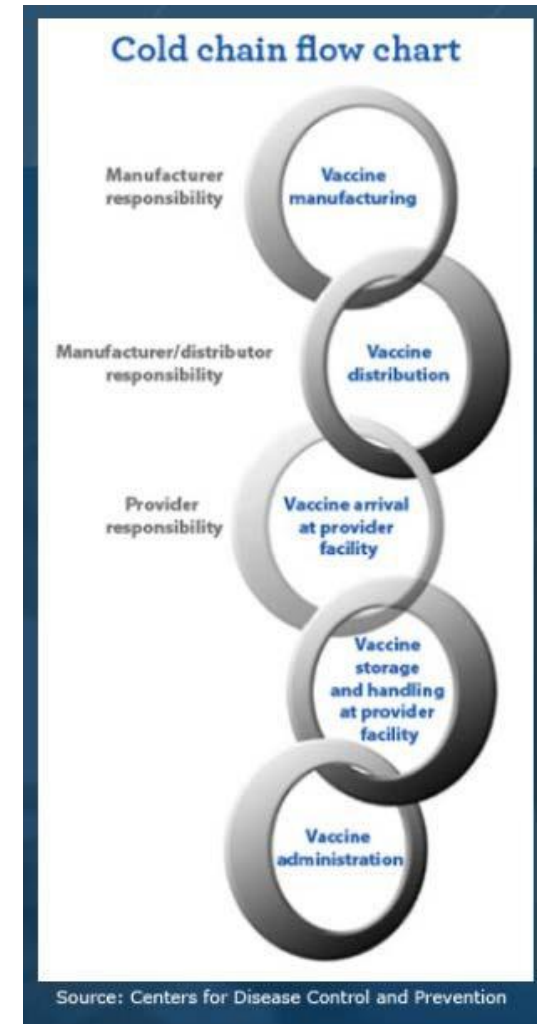
For more detailed information, refer to the CDC's Vaccine Storage and Handling Toolkit:

<https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>

# 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.



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 plans and standard operating procedures (SOPs) for storage and handling near storage units and make sure staff knows where to find them.

All staff members 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 them, considering holidays, vacations, and any changes in the facility's hours of operation. Ideally, the vaccine coordinator or alternate should be available to receive deliveries.

Never leave a vaccine shipping container unpacked or unattended.

# Staff

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.



Coordinator responsibilities include:

- Ordering vaccines
- Documenting vaccine inventory information
- Checking minimum and maximum temperatures at the start of each workday
- Reviewing and analyzing temperature data at least weekly for any shifts in temperature trends
- Rotating stock upon delivery, so vaccines with the earliest expiration dates are used first
- Returning expired vaccines
- Responding to temperature excursions (out-of-range temperatures)
- Maintaining all documentation, such as inventory and temperature logs
- Ensuring staff is properly trained
- Overseeing proper vaccine transport (when necessary)
- Overseeing emergency preparations:
  - Ensuring appropriate handling of vaccines during a disaster or power outage

# Storage and Temperature Monitoring Equipment

## Proper Vaccine Storage Temperatures:

- Refrigerated vaccines should be stored at temperatures between 2° C and 8° C (36° F and 46° F). The thermostat should be set at midrange to achieve a temperature of about 5° C (40° F), which will decrease the likelihood of temperature excursions.
- <https://www.maine.gov/dhhs/mecdc/infectious-disease/immunization/providers/manual/2015Contact%20Information.pdf>

Celsius to Fahrenheit Conversion Chart

°C	°F	°C	°F	°C	°F	°C	°F
50	122.0	27	80.6	4	39.2	-19	-2.2
49	120.2	26	78.8	3	37.4	-20	-4.0
48	118.4	25	77.0	2	35.6	-21	-5.8
47	116.6	24	75.2	1	33.8	-22	-7.6
46	114.8	23	73.4	0	32.0	-23	-9.4
45	113.0	22	71.6	-1	30.2	-24	-11.2
44	111.2	21	69.8	-2	28.4	-25	-13.0
43	109.4	20	68.0	-3	26.6	-26	-14.8
42	107.6	19	66.2	-4	24.8	-27	-16.6
41	105.8	18	64.4	-5	23.0	-28	-18.4
40	104.0	17	62.6	-6	21.2	-29	-20.2
39	102.2	16	60.8	-7	19.4	-30	-22.0
38	100.4	15	59.0	-8	17.6	-31	-23.8
37	98.6	14	57.2	-9	15.8	-32	-25.6
36	96.8	13	55.4	-10	14.0	-33	-27.4
35	95.0	12	53.6	-11	12.2	-34	-29.2
34	93.2	11	51.8	-12	10.4	-35	-31.0
33	91.4	10	50.0	-13	8.6	-36	-32.8
32	89.6	9	48.2	-14	6.8	-37	-34.6
31	87.8	8	46.4	-15	5.0	-38	-36.4
30	86.0	7	44.6	-16	3.2	-39	-38.2
29	84.2	6	42.8	-17	1.4	-40	-40.0
28	82.4	5	41.0	-18	-0.4	-	-



# Storage and Temperature Monitoring Equipment

## Proper Vaccine Storage Temperatures:

- Frozen vaccines should be stored at temperatures between  $-50^{\circ}\text{C}$  and  $-15^{\circ}\text{C}$  ( $-58^{\circ}\text{F}$  and  $+5^{\circ}\text{F}$ ).
- <https://www.maine.gov/dhhs/mecdc/infectious-disease/immunization/providers/manual/2015Contact%20Information.pdf>

**Celsius to Fahrenheit Conversion Chart**

$^{\circ}\text{C}$	$^{\circ}\text{F}$	$^{\circ}\text{C}$	$^{\circ}\text{F}$	$^{\circ}\text{C}$	$^{\circ}\text{F}$	$^{\circ}\text{C}$	$^{\circ}\text{F}$
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46	114.8	23	73.4	0	32.0	-23	-9.4
45	113.0	22	71.6	-1	30.2	-24	-11.2
44	111.2	21	69.8	-2	28.4	-25	-13.0
43	109.4	20	68.0	-3	26.6	-26	-14.8
42	107.6	19	66.2	-4	24.8	-27	-16.6
41	105.8	18	64.4	-5	23.0	-28	-18.4
40	104.0	17	62.6	-6	21.2	-29	-20.2
39	102.2	16	60.8	-7	19.4	-30	-22.0
38	100.4	15	59.0	-8	17.6	-31	-23.8
37	98.6	14	57.2	-9	15.8	-32	-25.6
36	96.8	13	55.4	-10	14.0	-33	-27.4
35	95.0	12	53.6	-11	12.2	-34	-29.2
34	93.2	11	51.8	-12	10.4	-35	-31.0
33	91.4	10	50.0	-13	8.6	-36	-32.8
32	89.6	9	48.2	-14	6.8	-37	-34.6
31	87.8	8	46.4	-15	5.0	-38	-36.4
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# Storage and Temperature Monitoring Equipment

There are several types of vaccine storage units available. Purpose-built units are specifically designed to store vaccines. However, household-grade units are also an acceptable option for vaccine refrigeration under the right conditions.

Purpose-built units are sometimes referred to as “pharmaceutical grade” and are designed specifically for storage of biologics.

If a purpose-built unit is not available, use a stand-alone unit.



Source: Centers for Disease Control and Prevention

# 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.



# Storage and Temperature Monitoring Equipment

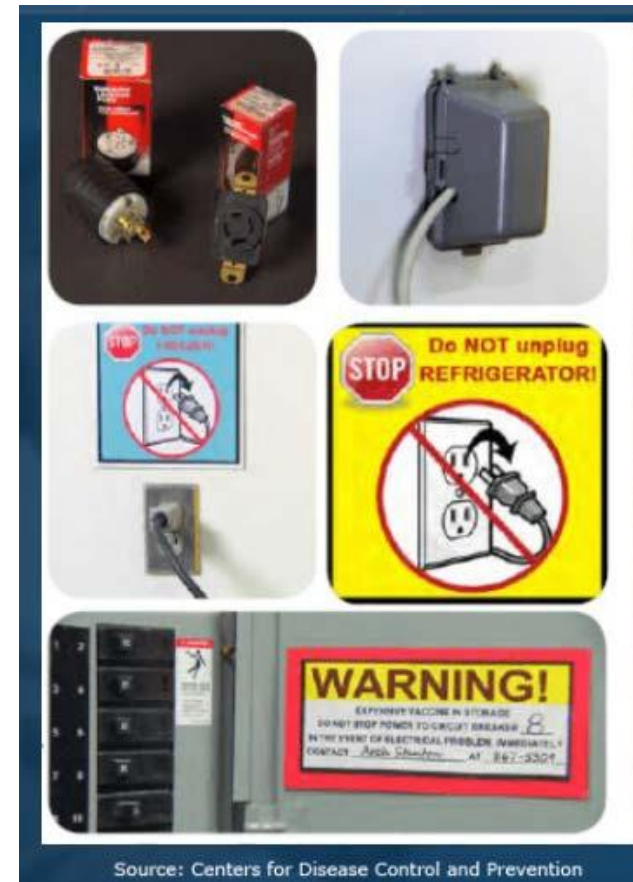
- Make sure the storage unit has enough space to store the largest inventory you might have at the busiest point in the year (e.g., flu season) without crowding.
- Remove any deli, fruit, and vegetable drawers from refrigerator units. This provides extra space for water bottles to help maintain stable 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. Before using a unit to store vaccines, check and record the minimum and maximum temperatures each workday for at least a week. In addition, check and record temperatures min and max a minimum of 1 time each workday. Once you have at least 5 consecutive days of temperatures recorded within the recommended range, your unit is stable and ready to be used.

# Storage and Temperature Monitoring Equipment

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.
- 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.



# Storage and Temperature Monitoring Equipment

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.
- Place water bottles on the top shelf and floor and in the door racks. Putting water bottles in the unit can help maintain stable temperatures caused by frequently opening and closing unit doors or a power failure. Label all water bottles, “DO NOT DRINK.”
- Do not store vaccines in deli, fruit, or vegetable drawers, or in the door.
- Arrange vaccines in rows, allowing space between rows to promote air circulation. This helps each vaccine maintain a consistent temperature.
- Place vaccines with the earliest expiration dates in front of those with later expiration dates.



Source: Centers for Disease Control and Prevention



# Storage and Temperature Monitoring Equipment

The diagram illustrates the internal layout of a refrigerator with three shelves labeled 'Top', 'Main', and 'Bottom'. It features three callout boxes with arrows pointing to specific areas:

- Top:** A red-bordered box states, "NO vaccine directly under cooling vent = 2°C to 5°C colder and only MMR on the top shelf." An arrow points to a small compartment under the top shelf.
- Top Shelf:** A yellow-bordered box states, "Avoid storage on top shelf near cooling vent. Likely location to exceed max allowed temp during outages." An arrow points to the top shelf area.
- Bottom:** A red-bordered box states, "No storage in crisper drawers: fill floor space with water bottles." Two arrows point to the crisper drawers at the bottom.
- Center:** A yellow-bordered box states, "This can be an area of caution in some pharmaceutical units." An arrow points to the central area between the shelves.
- Bottom Shelf:** A red-bordered box states, "Can be 1°C to 2°C colder than main refrigerator space." An arrow points to the bottom shelf.

A green-bordered box at the bottom provides the best storage practice: "Best storage practice—place vaccines in center refrigerator space, contained in original packaging, inside designated storage trays positioned 2 to 3 inches from refrigerator walls."

# Storage and Temperature Monitoring Equipment

It is important to follow recommended best practices for placement of a temperature monitoring device to ensure that the device reflects the temperature of the vaccines.

If using a digital data logger (DDL) in a storage unit:

- Place the buffered probe of the DDL in the center of the unit with the vaccines surrounding it.
- Place the DDL's active digital display outside the unit so temperatures can be read without opening the door and disturbing the probe. CDC recommends that DDLs be set to measure and record temperatures no less frequently than every 30 minutes.





# Storage and Temperature Monitoring Equipment

CDC recommends that provider who are using a DDL should:

- Record the minimum & maximum readings for your refrigerator once daily in the morning. This is a requirement for VFC providers. Acceptable temperatures for the refrigerator must fall between 36°F and 46°F. Please contact the vaccine manufacturer if your temperatures are outside of this acceptable range.
- 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

If a reading is missed, leave a blank entry in the log.

<https://www.maine.gov/dhhs/mecdc/infectious-disease/immunization/providers/manual/Refrigerator-Temp-Log.pdf>

These checks provide an opportunity to inspect the storage unit, reorganize any misplaced vaccines, and remove any expired vaccines.

# Inventory Management, Transport, and Preparation

Medical waste disposal requirements are set by state environmental agencies.

General disposal guidelines for:

- Vaccine doses that have expired or been compromised – contact the Maine Immunization Program. Sometimes unused vaccine and diluent doses, unopened vials, and potentially compromised vaccine may be returned for credit, even if they must be discarded.
- Open vials and broken vials and syringes, as well as manufacturer-filled syringes that have been activated and vaccine predrawn by providers – these cannot be returned and should be discarded as medical waste.
- Empty vaccine vials – most are not considered hazardous or pharmaceutical waste and do not require disposal in a biomedical waste container.

# 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 temperature monitoring device. If this is not available, qualified containers and pack-outs can be used with a temperature monitoring device.

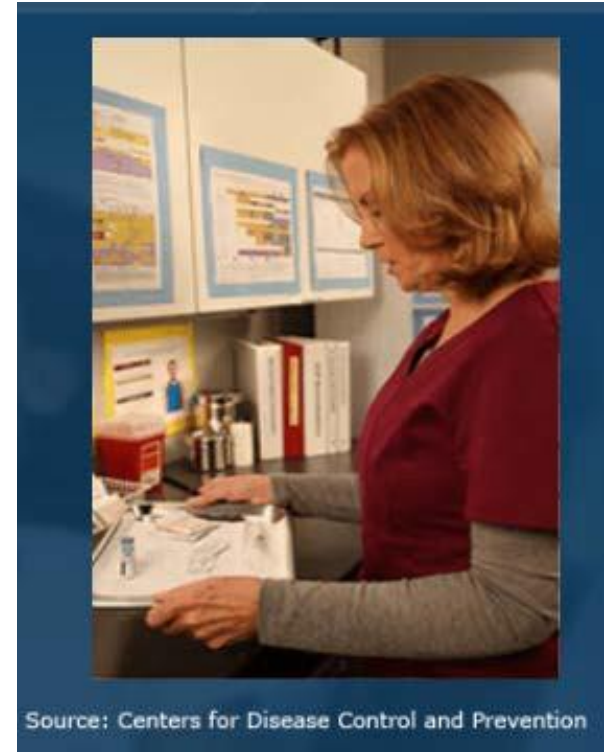
Immediately upon arrival at an off-site/satellite facility, vaccines should be stored in an appropriate storage unit with a temperature monitoring device. If vaccines cannot be stored in an on-site storage unit, they should be kept in the portable vaccine refrigerator during an off-site clinic:

- Place a temperature monitoring device (preferably with a probe in a thermal buffer) as close as possible to the vaccines, and read and record temperatures at least hourly.
- Keep the container closed as much as possible.
- Remove only 1 multidose vial or 10 doses at a time for preparation and administration by each person administering vaccines.

# 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.
- Only prepare vaccines when you are ready to administer them. Always check expiration dates and confirm that you have selected the correct vaccine.
- Only administer vaccines you have prepared yourself.
- Never use partial doses from two or more vials to obtain a dose of vaccine.



# 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 nonfunctioning unit for an extended period of time. Therefore, 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. An agreement with an alternative facility should allow you to store vaccines.

At a minimum, every facility should have:

- Backup temperature monitoring device(s)
- Spare batteries
- Flashlights (in case of a power outage)
- Vaccine transport containers and materials

# Emergency Preparations

For the safe transport and storage of vaccines, proper supplies are essential. Your facility should 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 4° C to 5° C phase change materials (PCMs)
- Insulating materials such as bubble wrap or corrugated cardboard – enough to form two layers per container
- Temperature monitoring device for each container

# Emergency Preparations

Frozen water bottles can 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 4° C - 5° C (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.

# Storage and Handling Plans and SOPs

Each Facility should have a clearly written, detailed, and up-to-date storage and handling plans and standard operating procedures (SOPs). This can be found here:

<https://www.maine.gov/dhhs/mecdc/infectious-disease/immunization/providers/manual/MIP-Routine-and-Emergency-Vaccine-Storage-and-Handling-Plan.pdf>

Storage and handling plans and SOPs should be reviewed and updated annually. All staff should know where this can be found. Plan and information contain of 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



# Maine Immunization Program Contacts

**Website: [www.immunizeme.org](http://www.immunizeme.org)**

**Maine Immunization Program Contact:**

**E-mail: [ImmunizeME.DHHS@maine.gov](mailto:ImmunizeME.DHHS@maine.gov)**

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Center for Disease Control and Prevention