2022 Vaccines for Children (VFC)

Maine Immunization Program

Annual Education Requirement

Vaccines for Children Learning Objectives

Learning Objectives

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

1. Describe VFC program requirements.
2. Describe VFC billing practices.
3. Describe VFC vaccine management practices.
4. Describe the purpose of VFC-related site visits performed by the Maine Immunization Program
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 disposal of routinely recommended vaccines.
10. Identify actions that should be taken if vaccines have not been stored properly.

Vaccines for Children 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. Upon investigation, the Centers for Disease Control and Prevention (CDC) found that more than half of the children who had measles had not been vaccinated, even though many of them had seen a health care provider.

In partial response to that epidemic, Congress passed the Omnibus Budget Reconciliation Act (OBRA) on August 10, 1993, creating the Vaccines for Children (VFC) program. VFC became operational October 1, 1994. Known as section 1928 of the Social Security Act, the VFC program is an entitlement program (a right granted by law) for eligible children age 18 years and younger.

Vaccines for Children Overview

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). The vaccines protect babies, young children, and adolescents from 16 diseases.

Vaccines for Children 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.

Vaccines for Children Overview

Availability of VFC Vaccine for Children

The VFC program provides vaccines purchased with public funds to eligible children in all states, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, American Samoa, Guam, and the Commonwealth of the Northern Mariana Islands.

Impact of the VFC program

The VFC program:

- Makes available all vaccines recommended for inclusion in the VFC program by the Advisory Committee on Immunization Practices (ACIP) at no cost for the vaccines
- Saves parents and enrolled providers out-of-pocket expenses for vaccine
- Reduces vaccine cost as a barrier to vaccinating eligible children
- Reduces the practice of referring children from the private sector to the public sector for vaccination
- Allows providers to charge an administration fee based on the child's eligibility

Vaccines for Children Overview

VFC Partners and Collaborating Agencies

Many partners and collaborating agencies work together with the goal of vaccinating VFC-eligible children with viable, properly handled vaccine.

Successful implementation of this program requires close collaboration with people just like you! There are many programs and agencies that also contribute to the program's success:

- Centers for Disease Control and Prevention
- Centers for Medicare & Medicaid Services (CMS)
- State Medical agencies
- Health Resources and Services Administration (HRSA)
- Indian Health Service (HIS)
- National, state and local organizations representing the private health care sector
- State, local, and territorial immunization programs

Knowledge Check

Is the statement below true or false?

VFC vaccine is free.

TRUE

FALSE 

VFC vaccine is purchased by the federal government for distribution and use in VFC-entitled children and, therefore, there is a cost. However, there is no cost for the vaccine for providers enrolled in the program or for eligible children receiving the vaccine.

VFC Provider Enrollment

Enrolling in the VFC Program

All providers enrolling in the VFC program must have an initial VFC enrollment site visit before receiving VFC vaccine.

Representatives from the Maine Immunization Program conduct enrollment visits to ensure providers have access to information needed for implementation of VFC program requirements. Providers must have appropriate resources and processes in place to implement VFC program requirements, including those that support proper vaccine storage units and temperature monitoring equipment.

As of January 1, 2018, all VFC providers are required to use continuous temperature monitoring devices (data loggers) to monitor vaccine that will be administered to VFC-eligible children, including during routine, on-site storage of vaccine, transport of vaccine, and while conducting mass vaccination clinics.

VFC Provider Enrollment

Enrolling in the VFC Program (continued)

Each VFC provider must complete two enrollment forms:

- Provider Profile
- Provider Agreement

These forms must be completed and submitted to the Maine Immunization Program at the time of enrollment and on an annual basis.

VFC Provider Enrollment

The Provider Profile

The provider profile captures the number of VFC-eligible children and non-VFC-eligible children served by VFC 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 and are used when reviewing and approving provider vaccine orders.

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

All VFC providers must complete the provider profile annually. However, providers must submit this form more frequently if the:

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

VFC Provider Enrollment

The Provider Agreement

The provider agreement describes VFC program requirements and is used to document the provider's agreement to comply with the requirements. It must be signed bi-annually by the medical director (or equivalent) in a group practice.

The official VFC-registered health care 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 VFC requirements are met as outlined in the provider agreement.

VFC Provider Enrollment

The Provider Agreement (continued)

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, pharmacist) at the facility who have prescribing authority
- VFC Coordinator (individual with the primary responsibility for managing the VFC program at the facility or practice level)
- VFC Backup Coordinator

Knowledge Check

Is the statement below true or false?

The purpose of the provider profile is to provide a listing of VFC program requirements that each provider will follow during the current enrollment cycle.

TRUE

FALSE 

The VFC provider agreement provides a listing of all VFC requirements that each provider must follow. The provider profile captures the number of VFC-eligible children and non-VFC-eligible children served by VFC providers. It supports providers in determining how much vaccine to order for each population served.

Knowledge Check

Is the statement below true or false?

The purpose of the provider agreement is to assist the Maine Immunization Program in determining the amount of vaccine supplied through the VFC program.

TRUE

FALSE 

The purpose of the provider agreement is to document the provider's agreement to comply with the requirements of the VFC program.

Knowledge Check

Determine the correct answer.

Who signs the provider agreement?

- The VFC Coordinator
- The medical director or equivalent 
- All providers within the practice

The official VFC-registered health care provider signing the agreement must be a practitioner authorized by state law to administer pediatric vaccines. This person is responsible for ensuring that all VFC requirements are met as outline in the provider agreement.

VFC Eligibility

VFC Eligibility Categories

Children age birth through 18 years (or those under age 19) who meet at least one of the following criteria are eligible to receive VFC vaccine:

- 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) (the child would be eligible to receive those vaccines not covered by the insurance)

VFC Eligibility

VFC Eligibility Categories (continued)

Children whose health insurance covers the cost of vaccinations are NOT eligible for VFC vaccines. This applies even when a claim for the cost of the vaccine and its administration would be denied for payment by the insurance carrier because the plan's deductible has not been met.

VFC Eligibility

State Vaccine Eligibility

Maine is a Universal Vaccine State, which means the Maine Immunization Program provides vaccines to health care providers at no cost for ALL children.

Children age birth through 18 years (or those under age 19) 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 is a Maine resident

VFC Eligibility

Provider Responsibility to Screen for VFC Eligibility and Document Eligibility Status

Screening to determine VFC eligibility and documenting the current VFC 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-eligible (MaineCare), uninsured, American Indian/Alaskan Native, or under-insured.

The patient eligibility screening record guides VFC eligibility and provides a method for documenting the eligibility and eligibility category for each child, if VFC-eligible.

Patient eligibility screening records should be kept for a minimum of three years after immunization services are provided.

Knowledge Check

Determine the correct answer.

When should screening for VFC eligibility be conducted?

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

VFC providers must screen all patients age birth through 18 years for VFC eligibility and document eligibility status at each immunization visit.

Knowledge Check

Is the statement below true or false?

VFC providers must document eligibility status at every visit.

TRUE 

FALSE

VFC provider must screen all patients age birth through 18 years for VFC eligibility and document eligibility status at each immunization visit.

ACIP's role in the VFC Program

The Advisory Committee on Immunization Practices

The Advisory Committee on Immunization Practices (ACIP) is a federal committee that was established in 1964.

ACIP's overall goals are to provide guidance to assist the Department of Health and Human Services and the nation in reducing the incidence of vaccine-preventable diseases and increasing the safe use of vaccines and related biological products.

ACIP has the statutory authority to determine the recommended vaccines, number of doses, immunization schedule, and vaccine contraindications for the VFC program, as well as for the general population.

ACIP's role in the VFC Program

The Advisory Committee on Immunization Practices (continued)

ACIP also approves the specific recommendations for including a vaccine in the VFC program, which are written in the form of a VFC resolution.

VFC resolutions passed by ACIP form the basis for VFC program policies on vaccine availability and use. After the VFC resolution is in place, CDC establishes a contract for the purchase of the vaccine through the VFC program.

The consolidated resolutions are posted on the VFC website soon after ACIP approval.

ACIP's role in the VFC Program

Complying with the ACIP Immunization Schedule

VFC providers must offer and make available all ACIP-recommended vaccines included in an approved VFC resolution.

VFC 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 particular requirements contradict state law, including any law pertaining to religious or other exemptions.

Knowledge Check

Is the statement below true or false?

VFC resolutions passed by ACIP form the basis for VFC program policies on vaccine availability and use.

TRUE 

FALSE

You can view the consolidated resolutions on the CDC website at:
http://www.cdc.gov/vaccines/programs/vfc/providers/resolutions.html.

Knowledge Check

Determine the correct answer.

VFC providers must comply with which recommendations outlined by ACIP in the VFC resolutions?

- Immunization schedules
- Dosages
- Contraindications
- All of the above 

VFC 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 particular requirements contradict state law, including any law pertaining to religious and other exemptions.

VFC Record Maintenance

VFC providers must maintain all records related to the VFC 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.

VFC Program Records

- Vaccine storage unit temperature documentation
- VFC vaccine management training records
- VFC eligibility screening documentation
- Routine and emergency vaccine management plan with standard operating procedures
- Provider Agreements
- Provider Profiles
- Billing records
- Vaccine ordering records
- Vaccine purchase and accountability records

Knowledge Check

Determine the correct answer.

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

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

VFC providers must maintain all records related to the VFC program for a minimum of three years.

Knowledge Check

Determine the correct answer.

Which of the following are considered VFC program records?

- Vaccine emergency plans and standard operating procedures
- Temperature monitoring documentation
- VFC eligibility screening documentation
- All of the above 

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

VFC-Supplied Vaccine

VFC vaccine must be provided to an eligible child at no cost for the vaccine. Patients, Medicaid agencies, and third-party payers can never be billed for the cost of VFC vaccine.

VFC providers can charge a vaccine administration fee when vaccinating VFC-eligible children. The administration fee is per vaccine and not per antigen within the vaccine (as in combination vaccines).

- For non-Medicaid VFC-eligible children (American Indian/Alaskan Native), uninsured, underinsured), VFC providers cannot charge the eligible child's parent/legal guardian a vaccine administration fee that exceeds $21.58 (Maine's regional charge)
- For Medicaid VFC-eligible children (MaineCare), VFC providers must accept the reimbursement for vaccine administration set by the state Medicaid agency or the contracted Medicaid health plans.

VFC providers cannot deny administration of a federally purchased vaccine to an established VFC-eligible patient because the child's parent/guardian/individual or record is unable to pay the vaccine administration fee.

Knowledge Check

Is the statement below true or false?

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

TRUE

FALSE 

Neither patients nor Medicaid agencies or third-party payers can be billed for the cost of VFC vaccine. VFC vaccine is distributed to providers for use in VFC-eligible children 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 VFC vaccine and not per antigen. VFC providers can only charge one administration fee 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 VFC-eligible patient is unable to pay the vaccine administration fee, providers can deny administration of the next dose of VFC vaccine until the administration fee is paid.

TRUE

FALSE 

VFC providers cannot deny administration of a VFC vaccine to an established, eligible patient because the child's parent or guardian of record is unable to pay the administration fee.

Federal Documentation Requirements

Vaccine information statements (VISs) are fact sheets produced by CDC that explain to vaccine recipients both the benefits and risks of vaccines.

Federal law requires health care staff to provide a VIS to a patient, parent, or legal representative before each dose of certain vaccines. The appropriate VIS must be given prior to the vaccination and must be given prior to each dose of a multidose series.

Federal Documentation Requirements

Vaccine Information Statements: Required by Federal Law

Federal law requires that VISs for the following vaccines must be given when vaccinating patients of all ages:

- Diphtheria, tetanus, and pertussis-containing vaccine (DTaP, DT, Td, Tdap)
- Haemophilus influenzae type b (Hib)
- Hepatitis A
- Hepatitis B
- Human papillomavirus (HPV)
- Influenzae (both inactivated and live intranasal vaccines)
- Measles, mumps, and rubella (MMR)
- Meningococcal
- Pneumococcal conjugate (PCV13)
- Polio
- Rotavirus
- Varicella

CDC encourages the use of ALL VISs, whether the vaccine is covered by the law or not. VISs are updated periodically, and it is the provider's responsibility to ensure that the VIS with the most current publication date is used.

Federal Documentation Requirements

Immunization Records

In accordance with federal law, VFC providers must maintain immunization records that include all of 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

Federal Documentation Requirements

VAERS is the nation's early warning system for vaccine safety

CDC + FDA

VAERS

Vaccine Adverse Event Reporting System

co-managed by CDC and FDA

vaers.hhs.gov

Federal Documentation Requirements

National Childhood Vaccine Injury Act (NCVIA)

The NCVIA requires health care 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 are monitored continually to detect unknown adverse events or increased rates of known side effects.

The VAERS form should include the following information:

- Type of vaccine received
- Date and time of vaccination
- Date of onset of the adverse event
- Current illnesses or medications
- History of adverse events following vaccination
- Demographic information about the recipient (age, gender, etc.)

Federal Documentation Requirements

How to report an adverse event to VAERS

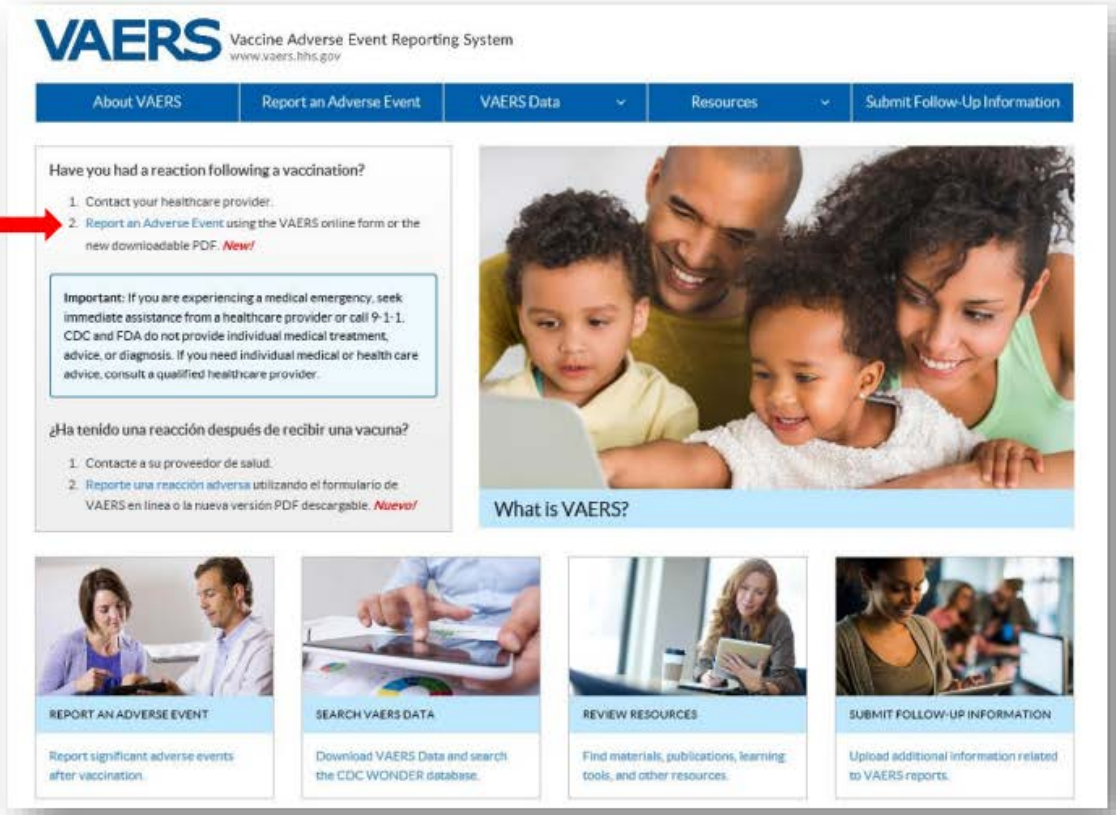
- Go to vaers.hhs.gov
- Submit a report online

For help:

call
[1-800-822-7967](1-800-822-7967)

email
info@VAERS.gov

video instructions
https://youtu.be/sbCWhcQADFE



For COVID-19, FDA will issue VAERS reporting requirements under EUA; in addition, CDC encourages reporting of any clinically important adverse event following immunization

Federal Documentation Requirements

Report an Adverse Event to VAERS

Click here for VAERS reporting requirements for healthcare providers administering COVID-19 vaccines

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 period 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 the administration of a vaccine licensed in the United States, whether it is or is not clear that a vaccine caused the adverse event
- Vaccine administration errors

VAERS accepts all reports, including reports of vaccination errors. Guidance on reporting vaccination errors is available if you have additional questions.

Federal Documentation Requirements

VAERS Reporting Requirements for COVID-19 Vaccines

The reporting requirements for COVID-19 vaccines are the same for those authorized under emergency use or licensed by the FDA. Healthcare providers who administer COVID-19 vaccines are **required** to report the following to VAERS:

- Vaccine administration errors, whether or not associated with an adverse event (AE).
  - If the incorrect mRNA COVID-19 vaccine product was inadvertently administered for a second dose in a 2-dose series, VAERS reporting **is** required.
  - If a different product from the primary series is inadvertently administered for the additional or booster (third dose), VAERS reporting **is** required.
  - **VAERS reporting is not required for the following situations:**
    - If a mixed series is given intentionally (e.g., due to hypersensitivity to a vaccine ingredient)
    - Mixing and matching of booster doses (as of October 21, 2021, mixing and matching of booster doses is allowed)

Federal Documentation Requirements

- Serious AEs regardless of whether the reporter thinks the vaccine caused the AE. Serious AEs per FDA are defined as:
  - Death
  - A life-threatening AE
  - Inpatient hospitalization or prolongation of existing hospitalization
  - A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
  - A congenital anomaly/birth defect
  - An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above
- Cases of Multisystem Inflammatory Syndrome
- Cases of COVID-19 that result in hospitalization or death

Healthcare providers should also report any additional selected AEs and/or any revised safety reporting requirements per FDA's conditions of authorized use of vaccine(s) throughout the duration of any COVID-19 vaccine's Emergency Use Authorization (EUA) or any approved COVID-19 vaccine as outlined in the Fact Sheet for Healthcare Providers.

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.

In accordance with federal law, VFC providers must maintain immunization records that include which of the following elements?

- 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
- All of the above 

In accordance with federal law, VFC providers must maintain immunization records that include all of the elements listed above.

Knowledge Check

Is the statement below true or false?

Health care providers must 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.

Proper Vaccine Storage and Handling

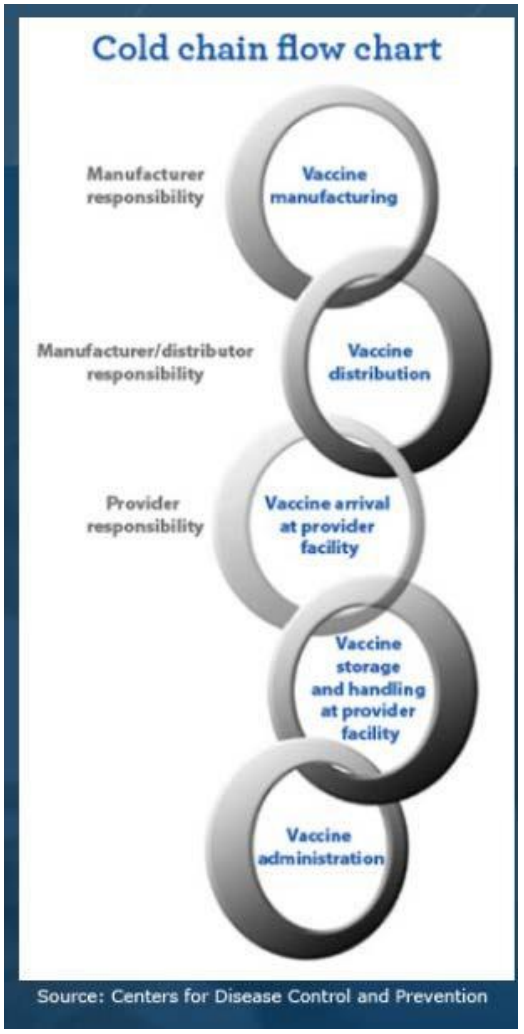
Proper vaccine storage and handling has been an important factor in preventing and eradicating many common vaccine-preventable diseases. Yet, each year, storage and handling errors result in re-vaccination of many patients and significant financial loss due to wasted vaccine. Failure to store and handle vaccines properly can reduce vaccine potency, resulting in inadequate immune response in patients and poor protection against disease. Patients can lose confidence in vaccines and providers if they have to be re-vaccinated because the vaccines they have received may have been compromised.

This following slides provide an overview of approved vaccine storage and handling best practices. For more detailed information, refer to the CDC's Vaccine Storage and Handling Toolkit.

Cold Chain

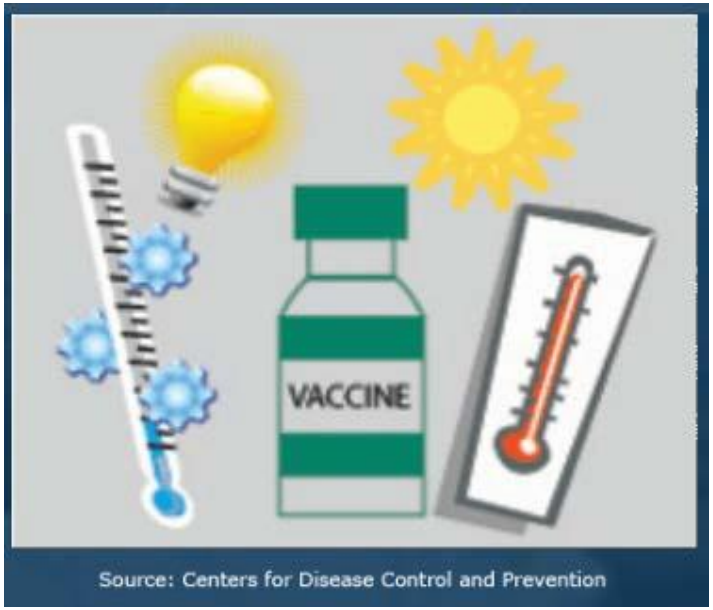
The vaccine cold chain is a temperature-controlled environment used to maintain and distribute vaccines in optimal condition.

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.



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. Once lost, potency cannot be restored. Each time vaccines are exposed to improper conditions, potency is reduced further. Eventually, if the cold chain is not properly maintained, potency will be lost completely, and vaccines will be useless.



While exposure to any inappropriate conditions can affect potency of refrigerated vaccines, a single exposure to freezing temperatures (0° C [32° F] or colder) will destroy some. Liquid vaccines that contain an adjuvant can permanently lose potency when exposed to freezing temperatures.

The Rights of Medication Administration Adapted for Vaccines

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.

The Rights of Medication Administration Adapted for Vaccines

Results of a cold chain failure can be costly. ACIP's General Best Practice Guidelines for Immunizations state, "Vaccine exposed to inappropriate temperatures that is inadvertently administered should generally be repeated." Inappropriate storage can mean extra doses for patients, increased costs for providers, and damage to public confidence in vaccines. More importantly, patients who refuse re-vaccination can remain unprotected from serious, vaccine-preventable diseases. By maintaining the vaccine cold chain, your facility can avoid incurring the additional costs associated with loss and replacement of vaccines, as well as the resources needed to recall patients for re-vaccination.

"The vaccine we gave you last week was not stored properly and may not protect you from disease. To make sure you are protected, we need to give you another dose."

Source: Centers for Disease Control and Prevention

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.

Cold Chain

An effective cold chain relies on three main elements:

- A well trained staff
- Reliable storage and temperature monitoring equipment
- Accurate vaccine inventory management

Staff

Vaccine storage and handling practices are only as effective and successful as the staff that implements them. A well-trained staff, familiar with key storage and handling principles, is critical to ensuring the potency of your vaccine supply and the safety of your patients. Knowledgeable staff can also 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.

Staff

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 know where to find them.

Source: Centers for Disease Control and Prevention

Staff

CDC recommends that storage and handling training should be done:

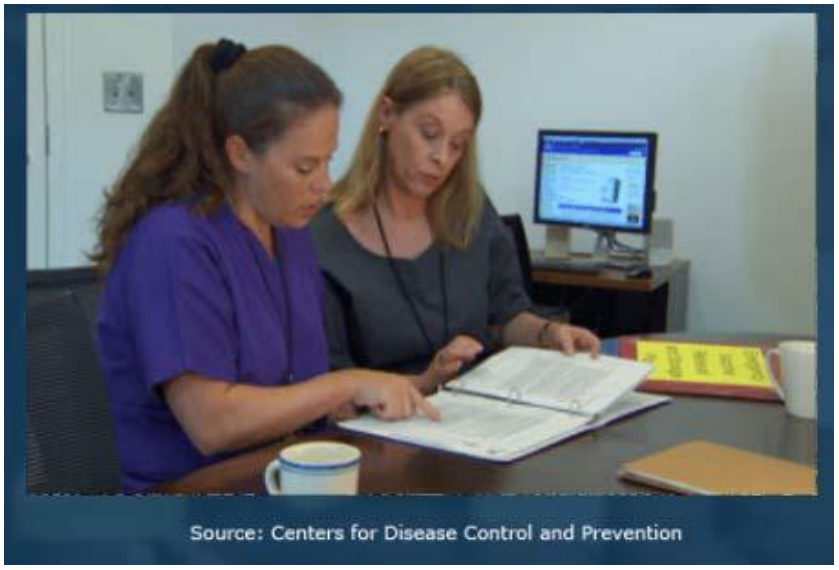
- As part of new employee orientation
- Annually as a refresher for all staff involved in immunization and vaccine storage and handling activities
- Whenever new vaccines are added to inventory
- Whenever recommendations for storage and handling of vaccines are updated.


Source: Centers for Disease Control and Prevention

If you are a VFC provider, it is required that both the vaccine coordinator and backup vaccine coordinator complete an annual storage and handling training.

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.



Source: Centers for Disease Control and Prevention

Staff

Coordinator responsibilities include:

- Ordering vaccines
- Overseeing proper receipt and storage of vaccine deliveries
- Documenting vaccine inventory information
- Organizing vaccines within storage units
- Setting up temperature monitoring devices
- Checking and recording storage unit temperatures
- Checking current temperature each time vaccines are accessed in the storage unit
- Reviewing and analyzing temperature data at least weekly for any shifts in temperature trends
- Rotating stock at least weekly so vaccines with the earliest expiration dates are used first

Staff

Coordinator responsibilities include (continued):

- Removing expired vaccine for storage units
- Responding to temperature excursions (out-of-range temperatures)
- Maintaining all documentation, such as inventory and temperature logs
- Ensuring staff is properly trained
- Monitoring operation of storage equipment and systems
- Overseeing proper vaccine transport (when necessary)
- Overseeing emergency preparations:
  - Tracking inclement weather conditions
  - Ensuring appropriate handling of vaccines during a disaster or power outage

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.

Storage and Temperature Monitoring Equipment

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. For the best protection, your facility needs appropriate equipment that is set up correctly and maintained and repaired as needed.

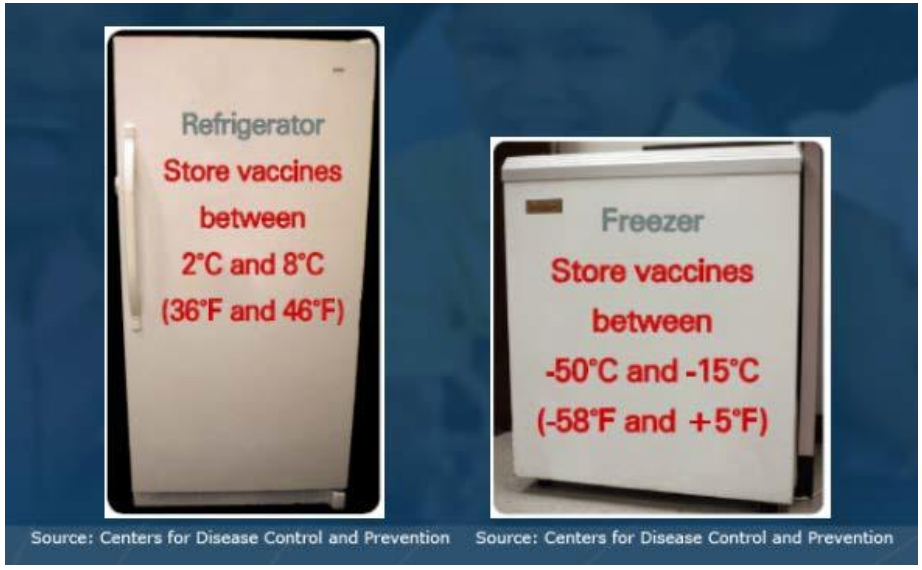
Proper Vaccine Storage Temperatures

- 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.
- Vaccines stored in the freezer should maintain temperatures between -50° C and -15° C (-58° F and 5° F). The thermostat should be at the factory-set or midpoint temperature setting to assure appropriate frozen storage temperatures.

Storage and Temperature Monitoring Equipment

To fully ensure the safety of vaccines, 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 without crowding
- Digital data logger (DDL) with a current and valid Certificate of Calibration Testing for each unit and at least one backup in case of a broken or malfunctioning device



Storage and Temperature Monitoring Equipment

Refrigerators and freezers typically used for vaccine storage are available in different grades (household and purpose-built) and types (stand-alone and combination refrigerator/freezer). In addition to traditional refrigeration units, there are also purpose-built auto-dispensing units without doors.

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

Storage and Temperature Monitoring Equipment

CDC make 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 household-grade combination refrigerator/freezer unit, only use the refrigerator compartment for storing vaccines. These units have cold spots and temperature fluctuations, and air circulating from the freezer could expose refrigerated vaccines to freezing temperatures. Use a separate stand-alone freezer to store frozen vaccines.

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 2 to 7 days to stabilize the temperature in a newly installed or repaired refrigerator or 2 to 3 days for a freezer. Before using a unit to store vaccines, check and record the minimum and maximum temperatures each workday for 2 to 7 days. In addition, check and record temperatures a minimum of 2 times each workday. Once you have 5 consecutive days of temperatures recorded within the recommended range, your unit is stable and ready to be used.

Knowledge Check

Determine the correct answer.

You need to store a vaccine that requires freezer temperatures between -50° C and -15° C (-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, as long as 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 -50° C and -15° C (-58° F and 5° F). Best practice is to NOT use the freezer compartment of a combination refrigerator/freezer unit or a dormitory-style unit to store vaccines at any time.

Storage and Temperature Monitoring Equipment

An accurate temperature history that reflects actual vaccine temperature is critical for protecting your vaccines. Every vaccine storage unit must have a temperature monitoring device, and investing in reliable devices is less expensive than replacing vaccines wasted due to inaccurate temperature readings.

Storage and Temperature Monitoring Equipment

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. The DDL should be set to measure and record temperatures no less frequently than every 30 minutes and should have a current and valid Certificate of Calibration Testing (also known as a Report of Calibration).

Source: Centers for Disease Control and Prevention

Storage and Temperature Monitoring Equipment

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.

Many DDLs use a buffered temperature probe, which is the most accurate way to measure actual vaccine temperatures. Temperatures measured by a buffered probe match vaccine temperatures more closely than those measured by standard thermometers, which tend instead to reflect air temperature. DDLs provide the most accurate storage unit temperature information, including details on how long a unit has been operating outside the recommended temperature range (referred to as a temperature excursion).

Storage and Temperature Monitoring Equipment

Your facility should have a temperature monitoring device (DDL) for:

- Each vaccine storage unit
- Each emergency transport unit (this is particularly important if there are more transport units than storage units)
- At least one backup temperature monitoring device in case a primary device malfunctions or is out for calibration testing (make sure the backup device has a different calibration testing schedule than the primary device so it is available when the primary device is being tested)

Storage and Temperature Monitoring Equipment

CDC recommends DDLs with the following features:

- Detachable probe that best reflects vaccine temperatures (e.g., a probe buffered with glycol, glass beads, sand, or Teflon®)
- Alarm for out-of-range temperatures
- Low-battery indicator
- Current, minimum, and maximum temperature display
- Recommended uncertainty of +/-0.5° C (+/-1° F)
- Logging interval (or reading rate) that can be programmed by the user to measure and record temperature no less frequently than every 30 minutes

Source: National Institute of Standards and Technology (NIST)

Source: Centers for Disease Control and Prevention

Storage and Temperature Monitoring Equipment

CDC recommends that a DDL's current and valid Certificate of Calibration Testing (Report of Calibration) should include:

- Model/device name or number
- Serial number
- Date of calibration (report or issue date)
- Confirmation that the instrument passed testing (or instrument in tolerance)
- Recommended uncertainty of +/-0.5° C (+/-1° F) or less

Storage and Temperature Monitoring Equipment

Certain types of temperature monitoring devices have significant limitations and should not be used to measure temperatures in a vaccine storage unit. These devices can be difficult to read and, because they only show the temperature at the exact time they are checked, may fail to detect temperatures outside the recommended range.

Source: Centers for Disease Control and Prevention

Storage and Temperature Monitoring Equipment

Specifically, CDC does not recommend the following temperature monitoring devices:

- Alcohol or mercury thermometers, even if placed in a fluid-filled biosafe liquid vial
- Bi-metal stem temperature monitoring devices
- Food temperature monitoring devices
- Chart recorders
- Infrared temperature monitoring devices
- Temperature monitoring devices that do not have a current and valid Certificate of Calibration Testing

Devices sold in hardware and appliance stores are generally designed to monitor temperature for household food storage. They are not calibrated and not accurate enough to ensure vaccines are stored within the correct temperature range. Using these devices can pose a significant risk of damaging expensive vaccines.

Knowledge Check

Determine the correct answer.

Which temperature monitoring device is recommended by CDC for use in a vaccine storage unit?

- Alcohol or mercury thermometers, even if placed in a fluid-filled biosafe liquid vial
- Infrared temperature monitoring device
- Chart recorder
- DDL with detachable probe that best reflects vaccine temperatures 

The DDL should have an alarm for out-of-range temperatures and a low-battery indicator. The DDL should have an indicator for current, minimum, and maximum temperatures and a logging interval that can be programmed by the user to measure and record temperatures no less frequently than every 30 minutes.

Storage and Temperature Monitoring Equipment

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

- Place storage units in a well-ventilated room, leaving space between the unit, ceiling, and any 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 20° C and 25° C (68° F and 77° F).

Check the manufacturer-supplied owner's manual for additional guidance on placement and spacing.

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.

Source: Centers for Disease Control and Prevention

Storage and Temperature Monitoring Equipment

Avoid using 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.


Source: Centers for Disease Control and Prevention

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
- Use a safety-lock plug or outlet cover to prevent the unit from being unplugged 

Using safety-lock plugs and outlet covers helps to prevent the unit from being accidentally unplugged.

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.

Storage and Temperature Monitoring Equipment

Refrigerated vaccines should be stored between 2° C and 8° C (36° F and 46° F), with a desired target temperature of about 5° C (40° F). Measles, mumps, and rubella (MMR) vaccine 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 25° C [77° F]).

Source: Centers for Disease Control and Prevention

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 unit 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, exposes vaccine to light, and makes it more difficult to track expiration dates and manage inventory.
- 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. 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.”

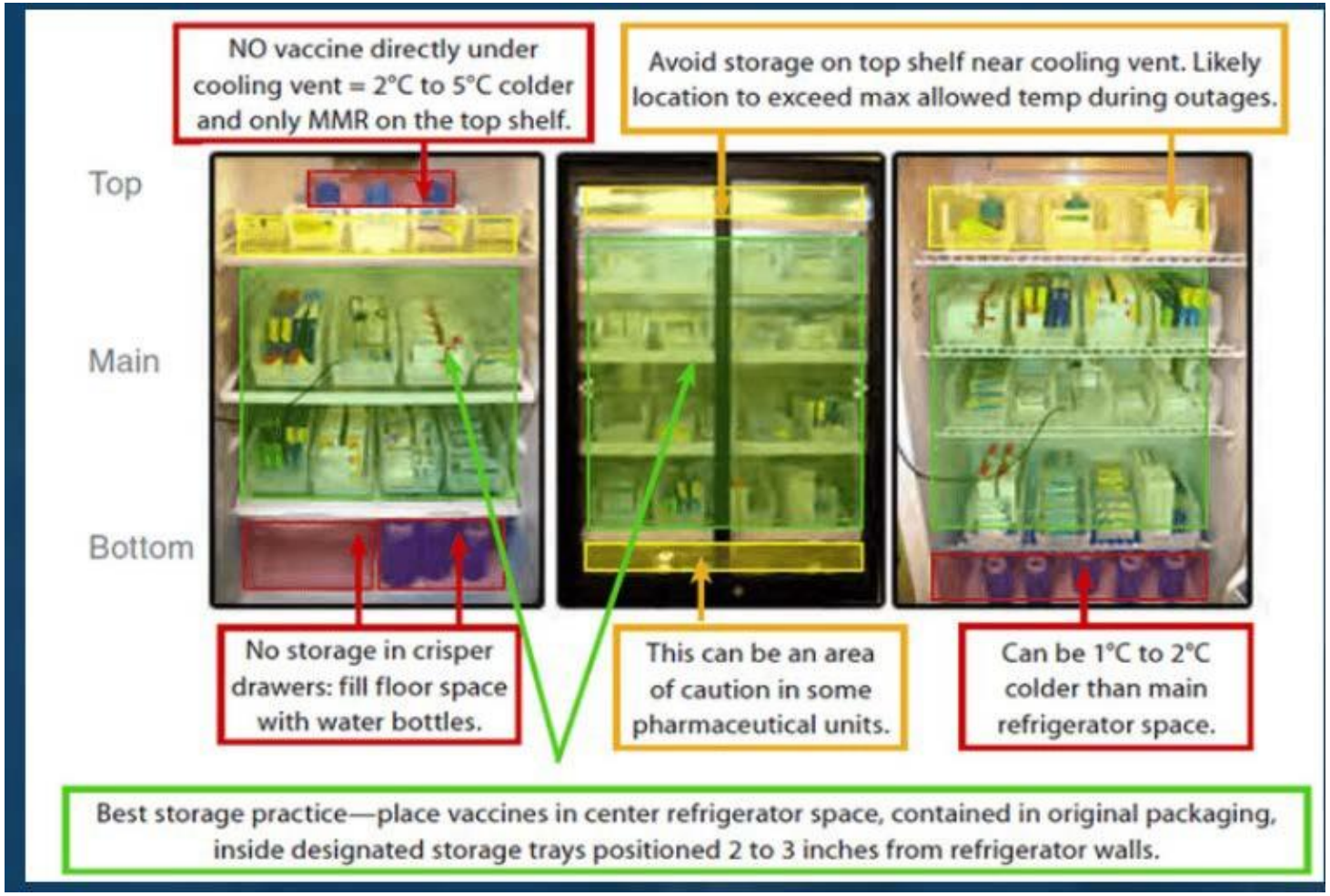
Source: Centers for Disease Control and Prevention

Storage and Temperature Monitoring Equipment

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

- Whenever possible, store diluent 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 Equipment



Storage and Temperature Monitoring Equipment

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

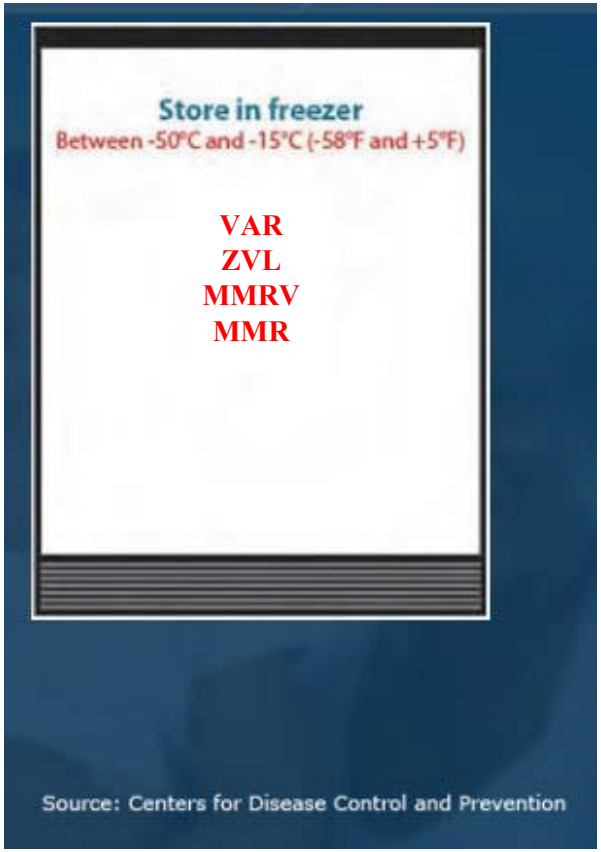
- Do not store vaccines in deli, fruit, or vegetable drawers, or in the door. Temperatures in these areas are not stable and can differ from those inside the main part of the unit.
- Arrange vaccines and diluents in rows, allowing space between rows to promote air circulation. This helps each vaccine 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 Equipment

Freezers should maintain temperatures between -50° C and -15° C (-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 -50° C and -15° C (-58° F and 5° F) until reconstitution and administration. Measles, mumps, and rubella (MMR) vaccine may be stored in either a refrigerator or freezer.

Never store any diluent in the freezer



Storage and Temperature Monitoring Equipment

Best practices for storing vaccine in a freezer unit include:

- Always store vaccines in their original packaging with lids closed until ready for administration. Never store loose vials or manufacturer-filled syringes outside of their packaging.
- Place water bottles against the walls, in the back, on the floor, and in the door racks. 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 Equipment

Best practices for storing vaccine in a freezer unit (continued):

- Store each type of vaccine in a separate container.
- Attach labels to shelves and containers to clearly identify where each type of vaccine is stored.
- Store vaccines 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 in the center of the unit, 2 to 3 inches away from walls, ceiling, floor, and door. Avoid storing vaccines in any part of the unit that may not provide stable temperatures or sufficient air flow, such as directly under cooling vents or shelves on the door.
- Arrange vaccines in rows, allowing space between rows to promote air circulation.
- Place vaccines with the earliest expiration dates in front.
- Do not pack a storage unit too tightly. This can restrict air circulation and impact vaccine temperature.

Storage and Temperature Monitoring Equipment

If possible, no items other than vaccines, diluents, and water bottles should be placed or stored in the 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, never store these products in the same container with vaccines. Always store them below vaccines and on a different shelf. This prevents contamination and reduces the likelihood of medication errors.

Knowledge Check

Determine the correct answer.

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

- 18° C (0° F) or colder
- -50° C (-58° F) or colder
- -50° C and -15° C (-58° F and 5° F) 
- -58° C and -10° C (-73° F and 15° F)

The freezer temperature for vaccine storage must be between -50° C and -15° C (-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).

Knowledge Check

Determine the correct answer.

Which of the following vaccines should be stored in the freezer between -50° C and -15° C (-58° F and 5° F) until reconstitution?

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

Frozen vaccines should be stored in the freezer between -50° C and -15° C (-58° F and 5° F) Until reconstitution. VAR, ZVL, and MMRV are all vaccines that should be stored in the freezer. Hib and HPV should be stored in the refrigerator. MMR 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, away from walls, vents, and coils. Each vaccine also needs to be stored separately to avoid confusion or mistakes.

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. A device placed near the walls, floor, vent, ceiling, or door may indicate temperatures that are colder or warmer than the actual vaccine temperature. This may not be true for pharmaceutical units because air flow and temperature are better regulated. Refer to your owner's manual for instructions on temperature monitoring device placement.
- 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 providers who are using a DDL should:

- Check and record storage unit minimum and maximum temperatures at the start of each workday. This is a requirement for VFC providers. The min/max temperatures recorded should be those obtained since the last workday when the min/max temperatures were reset. 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

Also check the current temperature each time vaccines are accessed in the storage unit. If a reading is missed, leave a blank entry in the log.

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

Storage and Temperature Monitoring Equipment

CDC recommends on a weekly basis:

- Review storage unit temperature readings and review continuous DDL software or website information for changes in temperature trends that might require action (adjusting unit temperature or repairing/replacing storage or temperature monitoring equipment).
- File this information so it an be analyzed for long-term trends and/or recurring problems. Temperature data should be kept for 3 years (unless state statutes or rules require a longer period).

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.

Storage and Temperature Monitoring Equipment

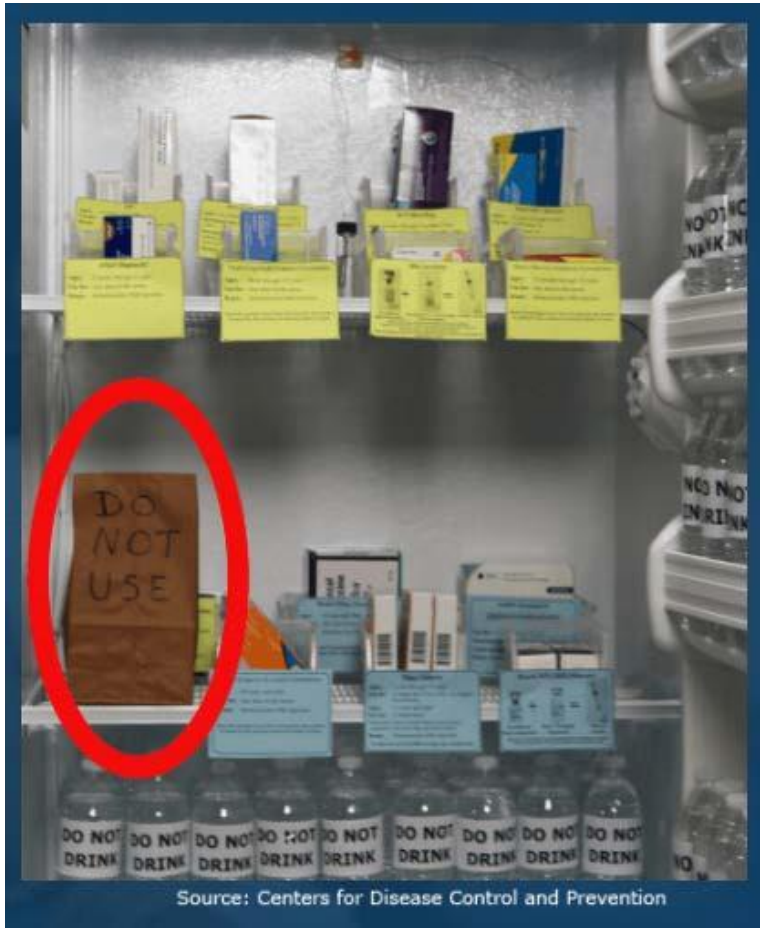
Temperature excursions or inappropriate conditions for any vaccine require immediate action. Any temperature reading outside ranges recommended in the manufacturers' package inserts is considered a temperature excursion.

In general, manufacturers analyze information about the magnitude of the temperature excursion and the total amount of time that temperatures were out of range, as well as information about the vaccine in question, to determine whether a vaccine is likely to still be viable.

Storage and Temperature Monitoring Equipment

If there is any question about whether vaccines may have been exposed to a temperature excursion because the unit became too cold or too hot, CDC recommends the following steps:

1. Any staff member who hears an alarm or notices a temperature excursion on the DDL should notify the primary or alternate vaccine coordinator immediately or report the problem to their supervisor.
2. Label exposed vaccines “DO NOT USE” and isolate them from other vaccines in the storage unit (do not discard these vaccines).



Source: Centers for Disease Control and Prevention

Storage and Temperature Monitoring Equipment

3. The vaccine coordinator, supervisor, or if necessary, the person reporting the problem should begin to document the event with the following information:

- Date and time of the temperature excursion
- Storage unit temperature and room temperature, if available (including minimum/maximum temperatures during the time of the event, if available)
- Name of the person completing the report
- Description of the event, including: a general description of what happened, the length of time vaccine may have been affected (if using a DDL), an inventory of affected vaccines, items in the unit (including water bottles) other than vaccines, any problems with the storage unit and/or affected vaccines before the event, and other relevant information

4. Implement your facility SOPs to adjust unit temperature to the appropriate range. At a minimum, check the temperature monitoring device to make sure it is appropriately placed in the center of the vaccines.

Storage and Temperature Monitoring Equipment

5. Contact the vaccine manufacturer(s) for further guidance on whether to use affected vaccines and for information about whether patients will need to be recalled for re-vaccination. Be prepared to provide documentation of the event (e.g., temperature log data) to ensure you receive the best guidance.

6.Complete your documentation of the event, including:

- Action taken (what you did with vaccine and the time, whom you contacted and instructions received, and what you did to prevent a similar future event)
- Results (what happened to affected vaccines and other comments)

7. If any vaccines are determined to be non-viable, contact the Maine Immunization Program to request a return authorization form.

Never allow vaccines to remain in a nonfunctioning unit for an extended period of time. If you believe the unit has failed, begin to implement your emergency vaccine plan and SOPs.

Knowledge Check

Determine the correct answer.

Your facility uses digital data logger for temperature monitoring of your vaccine storage units. 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 VFC data and is required to be kept for 3 years.

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 alternative 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 alternate 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 and Temperature Monitoring Equipment

Storage units and temperature monitoring devices need regular maintenance to ensure proper operation, maintain required temperatures, and extend the useful life of the equipment. Check the manufacturer's product information for cleaning instructions and recommended maintenance schedules. Document maintenance tasks and repairs as indicated in your routine storage and handling plan and SOPs.

Storage and Temperature Monitoring Equipment

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 and Temperature Monitoring Equipment

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, 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 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

Because all temperature monitoring devices experience “drift” over time that affects their accuracy, calibration testing should be done every 1 to 2 years or according to the manufacturer’s suggested timeline.

If calibration testing indicates your temperature monitoring device is no longer accurate within +/-0.5° C (+/-1° F), it should be replaced. Adjustments to correct accuracy of the device are not recommended. You may prefer to replace the device rather than submitting it for calibration testing. Any new temperature data logger must have a current and valid Certificate of Calibration Testing (also known as Report of Calibration).

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 to 2 years or according to the manufacturer’s suggested timeline.

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.

Please note: with a combination storage unit, adjustments to the freezer temperature can adversely affect the refrigerator compartment temperature, possibly resulting in frozen refrigerated vaccines.

Storage and Temperature Monitoring Equipment

Do not 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 and SOPs to identify an alternative unit with appropriate temperatures and sufficient storage space until the primary unit can be repaired or replaced.

Storage and Temperature Monitoring Equipment

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.

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 any other way, its accuracy should be checked against another calibrated temperature monitoring device. If there is any question about accuracy, the device should be sent for calibration testing or replaced.

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 calibration testing or replacement.

Inventory Management, Transport, and Preparation

Vaccines are expensive, so it's important to make sure they are unpacked and stored correctly, and to account for every dose received and used by your facility, whether administered, wasted, compromised, expired, or transferred. Keeping accurate records to assist you in ordering and rotating stock on a regular basis will ensure that your facility has available the vaccines your patients need.

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 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. If vaccines and diluents inside get too warm, they cannot be used. Be sure all staff members know that vaccine deliveries require immediate attention.

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.

When unpacking deliveries:

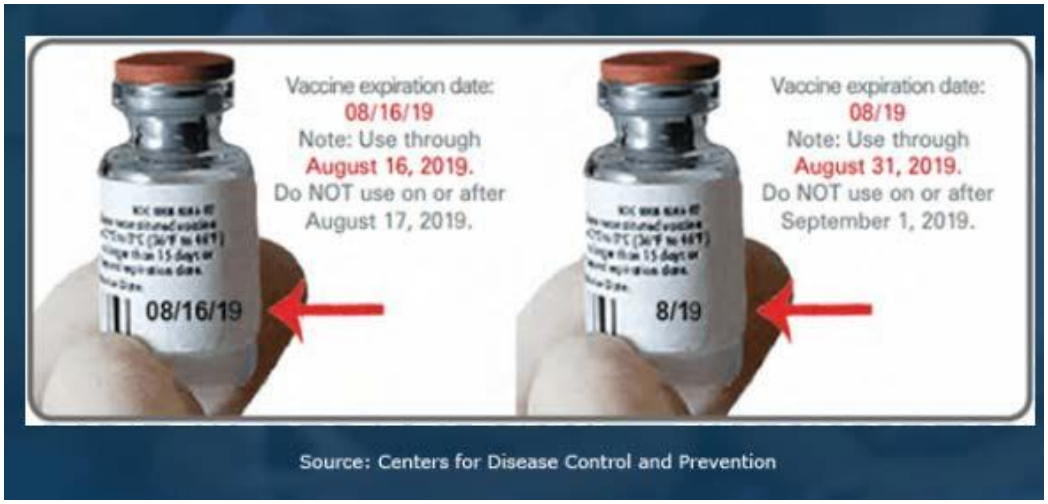
- Examine the shipping container and vaccines for signs of physical damage.
- Check the contents against the packing list to be sure they match.
- If the shipment includes lyophilized (freeze-dried) vaccines, make sure they came with the correct type and quantity of diluents.
- Check both the vaccine 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.

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

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 has only a month and year, the product may be used up to and including the last day of that month. If a day is included with the month 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, by an earlier date 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.
- Multidose vials might have a specified time frame for use once they have been entered with a needle. For example, the package insert may state that the vaccine must be discarded 28 days after it is entered.

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.

Knowledge Check

Determine the correct answer.

Today is 10/19 and the date on the single-dose vaccine vial you are about to give is also 10/19 of the current year. Can this vial of vaccine be used?

YES 

NO

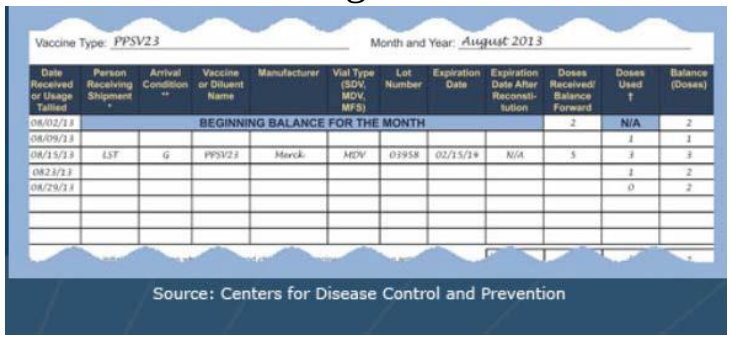
Vaccines can be used until the end of the expiration date listed. This vaccine can be used today, but would be invalid if used tomorrow (10/20).

Inventory Management, Transport, and Preparation

A stock record helps you keep track of your vaccine inventory. These records can be in paper or electronic form, or part of an immunization information system (IIS) with the capacity to manage vaccine inventory. The stock record should be updated weekly.

You should account for and document every dose of vaccine on a stock record, including:

- Date of delivery (and initials of the person who unpacked the delivery)
- Vaccine and diluent name and manufacturer
- Number and expiration date for each lot (including expiration dates based on beyond use date guidance in the product information)
- Number of doses received
- Condition of each vaccine and diluent upon arrival
- Cold chain monitor (CCM) reading if CCM is included in the shipping container
- Number of doses used (i.e., administered, wasted, expired or transferred)
- Balance of remaining doses after subtracting the amount used



Vaccine Type: PPSV23 Month and Year: August 2013

Date Received or Usage Tallied	Person Receiving Shipment *	Arrival Condition **	Vaccine or Diluent Name	Manufacturer	Vial Type (SDV, MDV, MFS)	Lot Number	Expiration Date	Expiration Date After Reconstitution	Doses Received/ Balance Forward	Doses Used †	Balance (Doses)
08/02/13	BEGINNING BALANCE FOR THE MONTH								2	N/A	2
08/09/13										1	1
08/15/13	LST	G	PPSV23	Merck	MDV	03958	02/15/14	N/A	5	3	3
08/23/13										1	2
08/29/13										0	2

Source: Centers for Disease Control and Prevention

Inventory Management, Transport, and Preparation

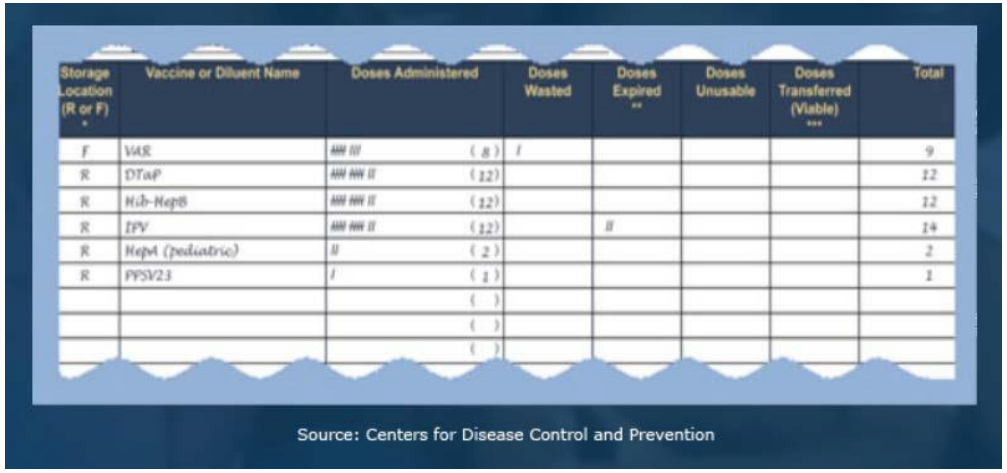
If you receive multiple doses of the same vaccine in the same presentation from the same lot with the same expiration date, you can document these doses as one entry on the stock record. Indicate the total number of doses received, regardless of how many vials or syringes the doses came in. For example, if you receive 10 single-dose vials of the same vaccine with the same lot number and expiration date, you can make a single entry on the stock record, noting that 10 doses were received.

Doses of diluents that come with lyophilized (freeze-dried) vaccines should be documented on a separate stock record. Quantities of vaccines and their corresponding diluents should be equal at all times.

Inventory Management, Transport, and Preparation

Use tally sheets to help you keep your stock record up to date. Place tally sheets outside the storage unit door (or another easily accessible location), and have staff use tick marks to keep a count of every dose removed from the unit (with columns for those administered, wasted, compromised, expired, or transferred).

At least weekly, add up the dose counts on the tally sheet and transfer that information to the stock record.



Storage Location (R or F) *	Vaccine or Diluent Name	Doses Administered	Doses Wasted	Doses Expired **	Doses Unusable	Doses Transferred (Viable) ***	Total
F	VAR	𝍸 III (8)	1				9
R	DTaP	𝍸 𝍸 II (12)					12
R	Hib-HepB	𝍸 𝍸 II (12)					12
R	IPV	𝍸 𝍸 II (12)		II			14
R	HepA (pediatric)	II (2)					2
R	PPSV23	I (1)					1
		( )					
		( )					
		( )					

Source: Centers for Disease Control and Prevention

Inventory Management, Transport, and Preparation

Vaccine stock should be rotated and checked for expired doses regularly.

The vaccine coordinator (or other designated person) should rotate vaccine and diluent stock at least once a week, as well as each time your facility receives a vaccine deliver. Arrange stock in the storage unit so that for each vaccine type, doses with the earliest expiration dates are placed in front of those with later expiration dates.

Check expiration dates on vaccines and diluents at least once a week, and immediately remove any expired vaccines and diluents to avoid inadvertently administering them.

Be sure to document expired doses on the tally sheet and stock record. Maine Immunization Program expired vaccine must be reconciled out of inventory and returned using a return authorization form that can be obtained by calling the program.

Inventory Management, Transport, and Preparation

The information in your stock record will help you determine the type and amount of vaccine your facility should stock to meet the needs of your patients. Make sure you are only ordering the vaccines and presentations that are appropriate for the ages and types of patients your facility serves.

CDC recommends provider should order and stock only enough vaccine to meet patient needs. Storing a larger volume than your facility needs can increase the risk of wasting vaccines if they expire before they can be used or they are compromised in some way.

Most facilities should also reorder based on patient needs after doing a stock count. Vaccine orders usually arrive within 1 to 2 weeks, but keep in mind there could be delays. If possible, avoid placing a last-minute or rush orders to prevent the risk of running out of 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

"Transport" has a different meaning than "shipping" which usually involves a professional carrier and a longer distance and time period for moving vaccines between locations. Transport involves the movement of vaccine over a short time frame and distance between providers. The time needed to transport should be fewer than 8 hours and vaccine should be placed in a stable storage unit as quickly as possible.

CDC does not recommend any shipment of vaccines from your vaccine supply or any routine transport of vaccines.

Vaccines should only be transported when absolutely necessary (e.g., for a mass immunization clinic, in an emergency, or to ensure vaccines that are about to expire can be used rather than wasted). Frozen vaccines should never be transported except in an emergency.

CDC does not recommend reshipping vaccines after receiving them from a commercial distributor or manufacturer because doing so would put the cold chain, and ultimately, the viability of the vaccines, at risk.

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.

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 temperature monitoring device. If the device displays min/max temperatures, they should be checked and recorded. If the device does not display min/max temperatures, then the current temperature should be checked and recorded a minimum of 2 times (at the start and end of the workday).

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

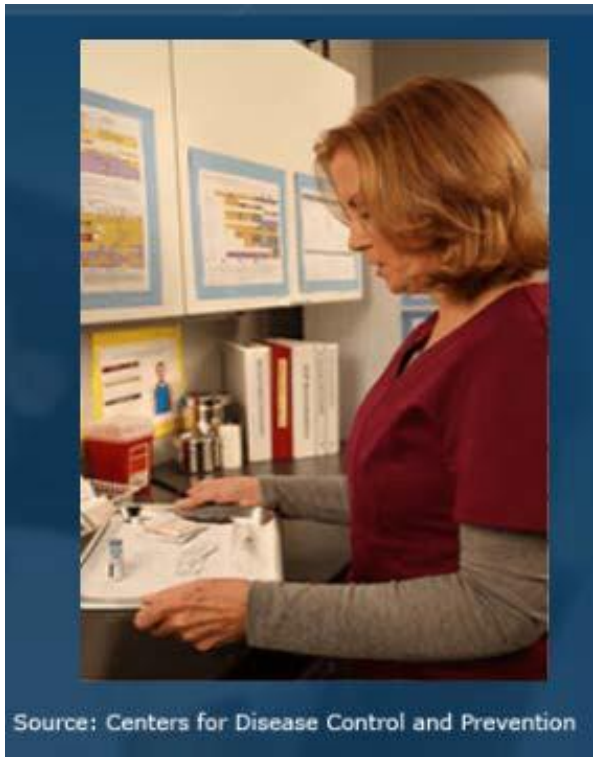
Transport diluents with their corresponding vaccines to ensure there are always equal amounts of vaccine and diluents for reconstitution. Follow the manufacturer's guidance for specific temperature requirements.

If diluents that are stored at room temperature (68°F to 77°F or 20°C to 25°C) 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 or 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 manufacturer(s) for guidance. Do not discard the vaccines or diluents unless directed to do so by the immunization program or manufacturer.

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.


Source: Centers for Disease Control and Prevention

- 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. 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) 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.

Single-dose vials do not contain a preservative to help prevent the growth of microorganisms. There have been outbreaks of infections caused by pooling contents and/or storing contents for future use.

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. 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

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 or 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.

Inventory Management, Transport, and Preparation

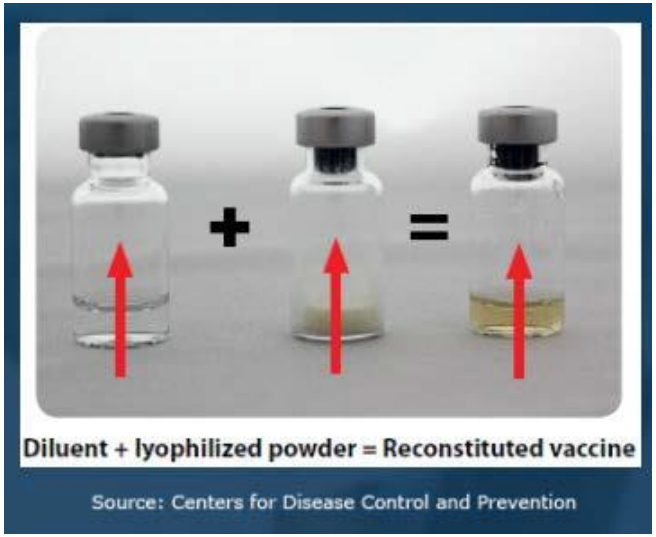
A manufacturer-filled syringe (MFS) is prepared and sealed under sterile conditions by the manufacturer.

Do not active an MFS (i.e., remove the syringe cap or attach the needle) until ready to use. MMFs 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.

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 it.
- 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).

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

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

Inventory Management, Transport, and Preparation

CDC recommends drawing 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. Predrawing 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 predrawn 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 predrawing 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 predrawing vaccines, CDC recommends using manufacturer-filled syringes for large immunization clinics.

Inventory Management, Transport, and Preparation

If vaccine must be predrawn:

- Set up a separate administration station for each vaccine type to prevent medication errors.
- Do not draw up vaccines before arriving at the clinic site.
- Each person administering vaccines should draw up no more than one MDV, or 10 doses, at a time.
- Monitor patient flow to avoid drawing up unnecessary doses.
- Discard any remaining vaccine in predrawn syringes at the end of the workday.
- Do not predraw reconstituted vaccine into a syringe until you are ready to administer it.
- If not used within 30 minutes of being reconstituted, follow manufacturer guidance for storage conditions and time limits.
- Never transfer predrawn reconstituted vaccine back into a vial for storage.

Knowledge Check

Is the statement below true or false?

In general, open mutidose 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) is it better to use manufacturer-filled syringes as opposed to predrawing vaccine from vials.

TRUE 

FALSE

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

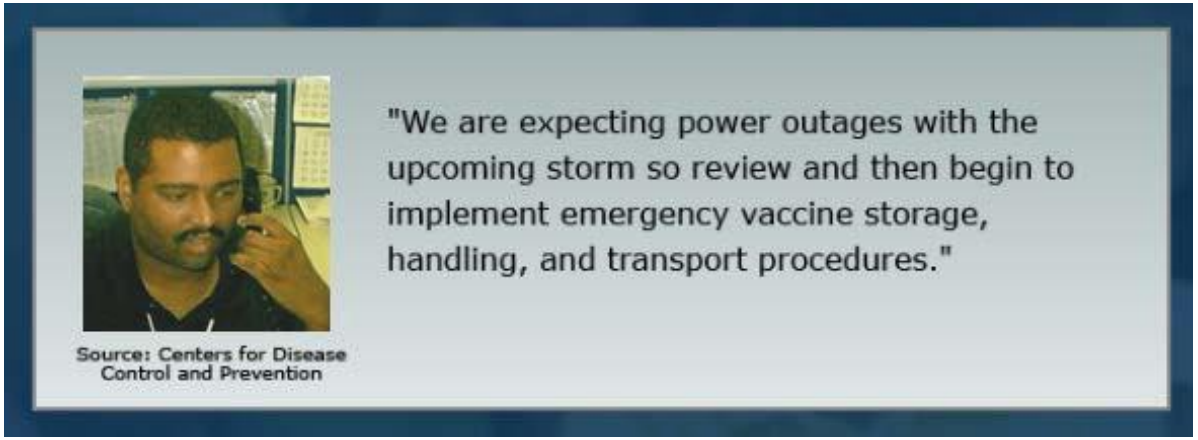
Emergency Preparations

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 nonfunctioning unit for an extended period of time. Therefore, making preparations in advance to retrieve and/or protect vaccines as quickly as possible during a potentially compromising situation could save your facility costly vaccine loss.

Emergency Preparations

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 flood a facility. This will help ensure the vaccine supply is protected and available for use.



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 temperature monitoring device(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.

Emergency Preparations

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 should 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:

- Sever 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.

Emergency Preparations

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.

Always place a temperature monitoring device 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

An emergency situation can arise outside of business hours, and having a relationship with your facility's building manager and/or security staff can be essential to protecting your vaccines. Meet with the manager and/or security personnel regularly and always introduce them to new staff members. Your storage and handling SOPs should have written instructions for accessing your vaccine storage units when the building is closed.

Provide anyone who needs access to vaccine storage units during an emergency with written instructions, a building diagram/map, and locations of:

- Spare batteries
- Flashlights
- Keys
- Locks
- Circuit breakers
- Packing materials

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. If you can monitor the temperature of the storage unit from the outside without opening the door, take the following steps:

- Record room temperature (if possible) and the temperature inside 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 you cannot monitor the temperature inside the unit without opening the door, wait until the power is restored, then take the following steps:

- Record room temperature (if possible) and the temperature inside the unit.
- If using a digital data logger, document the length of time power was off and the minimum and maximum temperatures during that period.
- If necessary, follow your procedures for temperature excursions (out-of-range temperatures).

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

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

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 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.

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

Emergency Preparations

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, at a minimum, the procedures and protocols outlined on the following pages.

Emergency Preparations

Packing

- 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 absolutely 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, available on the Maine Immunization Program website.

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 truck).
- 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.

Emergency Preparations

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 or 20°C to 25°C) 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, not even during transport.

Emergency Preparations

The manufacturer does not recommend transporting frozen vaccines (VAR, ZVL, MMRV). If these vaccines must be transported during an emergency, CDC recommends using a portable vaccine freezer unit or qualified container and pack-out that maintains temperatures between -50°C and -15°C (-58°F and 5°F).

Follow these steps for transporting frozen vaccines:

- Place a calibrated temperature monitoring device in the container as close as possible to the vaccines.
- Record the time vaccines are removed from the storage unit and placed in the container, the temperature during transport, and the time at the end of transport when the vaccines are placed in a stable storage unit.
- Immediately upon arrival at the destination, place vaccines in a freezer at a temperature range between -50°C and -15°C (-58°F and 5°F).

Do not use dry ice, even for temporary storage. Dry ice might expose the vaccines to temperatures colder than -50°C (-58°F).

If necessary, frozen varicella-containing vaccines that have not been reconstituted may be transported at refrigerator temperatures between 2°C and 8°C (36°F and 46°F). Frozen varicella-containing vaccines can be refrigerated for up to 72 continuous hours before reconstitution. Transported frozen varicella-containing vaccines cannot be put back in the freezer. They must be used or discarded.

Emergency Preparations

Transport of Multidose Vials (MDVs)

- If absolutely necessary, a partially used vial may be transported to or from an off-site/satellite facility operated by the same provider, as long as the cold chain is properly maintained.
- However, a partially used vial cannot be transferred from one provider to another or across state lines.

Emergency Preparations

Use a continuous temperature monitoring device, preferably a digital data logger, for monitoring and recording while transporting vaccines:

- The continuous temperature monitoring device should have an accuracy of +/- 0.5°C (+/- -1°F).
- Place liquid or solid buffered probe material in a sealed vial directly with the vaccines.
- Keep the continuous temperature monitoring device display on top of vaccines so you can easily see the temperatures.
- CDC does not recommend using cold chain monitors during transport since they provide limited data on temperature excursions that may occur.

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 refrigerated conditions (set apart from other vaccines). Immediately contact the vaccine manufacturer(s) for guidance. Do not discard the vaccines.

Knowledge Check

Is the statement below true or false?

Emergency storage and handling plans and SOPs 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. Making preparations 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 and SOPs. 
- Move vaccine inventory into temporary storage containers.
- Take a count of existing vaccine inventory.

The emergency storage and handling plan and SOPs 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 as long as 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 and SOPs

Clearly written, detailed, and up-to-date storage and handling plans and standard operating procedures (SOPs) will help your facility stay organized, serve as a reference and training tool, and assure proper vaccine management. Without SOPs, there is no way to be sure proper procedures will be followed or that problems will be identified, reported, or corrected.

SOPs should also provide guidance for emergency situations such as equipment malfunctions, power failures, or natural disasters. SOPs are a critical component in protecting your vaccine supply and, ultimately, your patients.

If you have multiple facilities, the details of your SOPs may differ depending on local policies.

Storage and Handling Plans and SOPs

Storage and handling plans and SOPs 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

Storage and Handling Plans and SOPs

General information in the SOPs should include:

- Contact information for:
  - Primary and alternate vaccine coordinators and additional staff to assist in emergencies
  - Maine Immunization Program
  - Vaccine manufacturers
  - Refrigerator and freezer maintenance and repair companies
  - Temperature monitoring device companies
  - Utility/power company
  - Vaccine storage unit alarm company (if applicable)
  - Generator repair company (if applicable)
  - Sources for qualified containers and pack-outs
- Descriptions of roles and responsibilities of primary and alternate vaccine coordinators
- Information for each storage unit, including serial number, links to equipment websites, installation dates, and routine maintenance and repair records
- Samples of all vaccine-related forms used in your facility
- Protocols for staff education and training

Storage and Handling Plans and SOPs

Routine storage and handling SOPs should include information about:

- Ordering and accepting vaccine deliveries
- Receiving and unpacking deliveries
- Managing inventory
- Storage requirements for each vaccine and diluent in your inventory (package inserts)
- Placing vaccines and diluents in storage units
- Handling vaccines prior to administration
- Disposing of vaccines and supplies
- Monitoring storage unit and temperatures
- Maintaining storage equipment and temperature monitoring devices
- Responding to storage and handling problems
- Transporting vaccines to off-site/satellite facilities

Storage and Handling Plans and SOPs

Because emergencies can happen at any time, it is important that in addition to facility staff, custodians, security officers, and/or building managers are aware of he emergency plan and know how to notify appropriate staff about any problems with vaccine storage equipment or power outages.

Copies of the emergency SOPs should be stored with the emergency supplies, kept with vaccine coordinator staff at their homes, and shared with others as appropriate, such as security officers or building managers.

Storage and Handling Plans and SOPs

Emergency storage and handling SOPs should include the following information:

- Name and address of alternative vaccine storage facility, names and numbers of contact persons, and 24-hour access information for facility
- Names and numbers for companies or private drivers to transport vaccines to alternative vaccine storage facilities
- Sources of qualified containers and pack-outs and calibrated temperature monitoring devices
- Vaccine storage unit specifications, including brand name, model number, serial number, and maintenance and repair company contact information
- A facility floor diagram showing the locations of important elements, including doors, flashlights, spare batteries, keys, locks, circuit breakers, and packing materials
- Protocols for:
  - Monitoring vaccines during a power outage
  - Packing vaccines and diluents for emergency transport
  - Transporting vaccines to and from an alternative vaccine storage facility
  - Assessing whether vaccine can be used after an emergency
  - Accessing your building and facility after hours.

Knowledge Check

Is the statement below true or false?

The only staff member who must be familiar with the emergency storage and handling plan and SOPs is the person in charge of vaccine storage and handling.

TRUE

FALSE 

Because emergencies can happen at any time, it is important that in addition to facility staff, custodians, security officers, and/or building managers are aware of the emergency storage an handling plan and SOPs and know how to notify appropriate staff about any problems with vaccine storage equipment or power outages.

Post Test and Education Credit

This completes the Maine Immunization Program Vaccine Storage and Handling online training presentation.

To receive credit for the training you MUST complete a post test.

Once you have completed and submitted the test the Maine Immunization Program will be notified and you will be awarded credit for this training. You will also receive notification by email of completion for your records.

Please have your PIN # and email ready before beginning the test. They will be required.

LINK TO TEST

As always, thank you for helping to keep Maine's children free from vaccine-preventable disease.

Storage and Handling

VFC Vaccine Storage Unit Recommendations

It is essential to ensure vaccines are stored under proper conditions so that they protect the children that receive them. The VFC program recommends the following types of storage units:

- Pharmaceutical-grade stand-alone or combination units
- Household/commercial stand-alone units
- Household/commercial combination using the refrigerator section only

Storage and Handling

VFC Vaccine Storage Unit Requirements

Appropriate storage units must:

- Have enough space to store the largest inventory a provider might have at the busiest point in the year without crowding
- Maintain appropriate temperatures for the vaccines stored within the unit at all times
- Be protected from disconnection from the power source

VFC providers must not use dormitory style refrigerator/freezer units for vaccine storage at ANY time, including for temporary vaccine storage.

- Studies by the National Institute of Standards and Technology (NIST) concluded that dormitory-style or bar-style combination units pose a significant risk of freezing vaccines, even when used for temporary storage.

Storage and Handling

VFC Temperature Monitoring Equipment Requirements

Routine review of and access to temperature data are critical for determining whether vaccine has been properly stored and for assessing usability of vaccine that was involved in a temperature excursion. All VFC providers must use continuous temperature monitoring devices (data loggers) within storage unity that store vaccines that will be administered to VFC-eligible children.

To meet VFC program requirements, the device must be equipped with:

- A temperature probe (one that best reflects the temperature of the vaccine, such as one that uses a buffering material, is recommended)
- An active temperature display that can be easily read from outside the unit
- The ability to continuously monitor and record data that can be routinely downloaded

Storage and Handling

VFC Temperature Monitoring Equipment Requirements (continued)

The following are additional characteristics for these devices that are required by the Maine Immunization Program:

- Alarm for out-of-range temperatures
- Current, minimum, and maximum temperature indicator
- Low-battery indicator
- Accuracy of +/- 0.5° C (+/- 1° F)
- Memory storage for at least 4,000 readings
- Recommended maximum logging interval (or reading rate) of every 30 minutes that can be programmed by the user

Storage and Handling

Temperature Monitoring Device Calibration Testing

VFC providers must have a working, calibrated, continuous monitoring and temperature recording device with a current and valid Certificate of Calibration Testing issued by an appropriate entity. If you need to determine if a Certificate of Calibration Testing or Report of Calibration was issued by an appropriate entity, check to see if the certificate indicates one or more of the following items about calibration testing:

- Conforms to International Organization for Standardization (ISO/International Electrotechnical Commission (IEC) 17025 international standards for calibration testing and traceability
- Performed by a laboratory accredited by International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatory body – a list of ILAC/MRA signatories may be found atAC.org/ILAC-MRA-and-signatories/
- Traceable to the standards maintained by the National Institute of Standards and Technology (NIST)
- Meets specifications and testing requirements for the American Society for Testing and Materials (ASTM) Standard E2877 Tolerance Class F (< +/-0.5° C or < +/-1° F) or better
- Refers to another acceptable accuracy validation method, such as comparison to other traceable reference standards or tests at thermometric fixed points

Storage and Handling

Temperature Monitoring and Documentation

The VFC vaccine coordinator and backup vaccine coordinator are responsible for temperature monitoring and documentation for vaccine storage units. Any additional staff that is responsible must be trained in appropriate temperature monitoring and documentation.

Temperature monitoring and documentation requirements include the following:

- Designated staff must review and record minimum and maximum temperatures for each vaccine storage unit at the beginning of each clinic day before resetting the minimum and maximum temperature readings on the device. This helps to ensure temperature excursions are identified quickly and corrections are made to prevent vaccine loss and to ensure vaccine is viable before use.
- This review must be documented with the date, time, and name and/or initials of the person assessing the temperatures, along with any actions taken if the temperature readings are out of acceptable range:
  - Between 2° C and 8° C (36° F and 46° F) for refrigerators
  - Between -50° C and -15° C (-58° F and 5° F) for freezers

Storage and Handling

Handling Expired Vaccines

When possible Expired vaccines and diluents must be removed from vaccine storage units to prevent inadvertent administration of expired vaccine. If it is not possible to immediately remove the expired vaccine, segregate expired vaccines within the unit preventing them from being administered.

- Expired vaccines must be placed in a container or bag and clearly labeled “DO NOTUSE.”
- Return expired vaccines within six months of expiration and as directed by the Maine Immunization Program. Note: all expired vaccines must be returned to the federal program even if more than six months have passed since expiration.

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 CANNOT be used to store vaccine at ANY time.

Knowledge Check

Determine the correct answer.

What is the recommended temperature range for refrigerators?

- Between 0° C and 5° C (32° F and 41° F)
- Between 2° C and 8° C (36° F and 46° F) 
- Between 8° C and 12° C (46° F and 54° F)
- Between 10° C and 20° C (50° F and 68° F)

The recommended temperature range for refrigerators is between 2° C and 8° C (36° F and 46° F)

Knowledge Check

Determine the correct answer.

What is the recommended temperature range for freezers?

- Between -75° C and -50° C (-103° F and -58° F)
- Between -60° C and -35° C (-76° F and -31° F)
- Between -50° C and -15° C (-58° F and +5° F) 
- Between -30° C and 5° C (-22° F and 41° F)

The recommended temperature range for freezers is between -50° C and -15° C (-58° F and +5° F)

Knowledge Check

Is the statement below true or false?

CDC recommends the use of stand-alone refrigerators and stand-alone freezer units.

TRUE 

FALSE

Studies by the National Institute of Standards and Technology (NIST) show that household, single-condenser, combination refrigerator/freezer units are less capable of simultaneously maintaining proper storage temperatures. In addition, NIST studies of combination refrigerator/freezer units demonstrated that the freezer section was incapable of consistently maintaining frozen vaccine storage temperatures.

Knowledge Check

Is the statement below true or false?

Minimum and maximum temperatures should be checked and recorded at least once a day.

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 VFC 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 of these requirements to safeguard vaccines.

Vaccine Management

Vaccine Inventory Management

VFC providers are expected to maintain an adequate inventory of vaccine for both the VFC and non-VFC-eligible patients they serve.

Proper inventory management practices help to ensure VFC vaccine is used only for VFC-eligible children.

Vaccine Management

Vaccine Storage and Handling

The system used to maintain and distribute vaccines in optimal condition is called the "cold chain." The cold chain begins with the cold storage unit at the vaccine manufacturing plant, extends through the transfer of vaccine to the distributor and then to the provider's office, and ends with the administration of the vaccine to the patient.

Proper storage temperatures must be maintained at every link in the chain.

Vaccine Management

If a cold chain failure is suspected or there is evidence that vaccine has been exposed to temperatures outside the recommended ranges, providers must immediately:

- Quarantine and label vaccines, “Do Not Use.”
- Store vaccines in a unit under proper conditions.
- Contact the appropriate vaccine manufacturer(s) to obtain documentation confirming whether the vaccine can be used.
- Contact the Maine Immunization Program if vaccine needs to be wasted.

All actions taken when responding to temperature excursions must be documented.

The vaccines should not be administered until a response has been received from the manufacturers indicating the vaccine is acceptable for use. Providers should not discard any vaccines unless directed to do so by the Maine Immunization Program.

Vaccine Management

When receiving vaccine shipments, providers must:

- Open vaccine packages immediately.
- Inspect the vaccines and packaging for damage.
- Compare the vaccines received with the vaccine products shown on the packing list.
- Immediately store vaccines at appropriate temperatures.
- Check the cold chain monitor (CCM) readings if a CCM is included with the shipment.

For frozen vaccines, providers should determine the length of time the vaccine was in transit. It is important to check the shipper insert supplied in the box. This insert will let the provider know the acceptable transit time based on the shipment date shown on the packing list.

If the provider believes that a vaccine shipment has been compromised, temperature monitors are out of range, or a warm indicator has been activated, they should contact the customer service center for centralized distribution immediately at 1-877-TEMP123. This telephone number is printed on any temperature monitor that might be placed in a vaccine shipment.

Vaccine Management

VFC Provider Staff

VFC providers must designate one staff member to be the primary VFC vaccine coordinator. This individual may also be referred to as the VFC vaccine manager or primary VFC contact. VFC providers must also designate at least one backup coordinator in the even that the primary coordinator is unavailable.

The VFC vaccine coordinator and backup coordinator are responsible for implementing and overseeing all VFC program requirements in the facility.

Any changes in key staff must be communicated to the Maine Immunization Program as soon as possible.

Vaccine Management

Vaccine Storage and Handling Standard Operating Procedures

Providers must develop, maintain, and implement plans for routine and emergency vaccine management. These plans should contain clearly written, detailed, and up-to-date storage and handling standard operating procedures (SOPs). These SOPs will help your facility stay organized, serve as a reference and training tool, and assure proper vaccine management. SOPs should also provide guidance for emergency situations such as equipment malfunctions, power failures, or natural disasters. SOPs are a critical component in protecting your vaccine supply and, ultimately, your patients.

At a minimum, the overall vaccine management plan must be reviewed and updated at least annually and include a review date and provider signature. Plans must also be updated when there is a change in the SOPs or in staff that has responsibilities specified in the plan.

Vaccine Management

Vaccine Storage and Handling Management Plan

The vaccine storage and handling plan must contain standard operating procedures (SOPs) for vaccine management processes and practices and include the following components at a minimum:

- Names of current primary VFC vaccine coordinator and at least one backup VFC vaccine coordinator
- SOPs for vaccine storage and handling practices
  - Receiving vaccine shipments
  - Ordering vaccines
  - Managing inventory (e.g., rotating stock, ordering vaccines, and maintaining appropriate amounts of vaccines at all times)
  - Preventing and reporting vaccine wastage and vaccine returns
  - Documenting staff training on vaccine management and storage and handling
  - Responding to emergency vaccine storage and handling situations

Vaccine Management

Vaccine Storage and Handling Management Plan (continued)

As part of the overall plan, SOPs must address management of vaccine in an emergency.

The SOPs must include guidance on what to do in the event of:

- Refrigerator or freezer malfunctions
- Power failures affecting vaccine storage units
- Natural disasters or other emergencies that might compromise appropriate vaccine storage conditions

In addition, the SOPs must contain guidance for maintaining the vaccine cold chain during transport to and from and storage at emergency storage locations.

Emergency SOP's should be tested annually, or more frequently as needed, to ensure the emergency system in place will maintain the proper cold chain.

Knowledge Check

Is the statement below true or false?

The vaccine cold chain begins at the vaccine manufacturing plant and ends when vaccine is delivered to the provider's office.

TRUE

FALSE 

The cold chain begins with the cold storage unit at the vaccine manufacturing plant, extends through the transfer of vaccine to the distributor and then to the provider's office, and ends with the administration of the vaccine to the patient. Proper storage temperatures must be maintained at every link in the chain.

Knowledge Check

Is the statement below true or false?

All changes in key staff must be communicated to the Maine Immunization Program one time a year with annual enrollment.

TRUE

FALSE 

All changes in key staff must be communicated to the Maine Immunization Program as soon as they occur.

Knowledge Check

Determine the correct answer.

When should vaccine storage and handling SOPs be updated?

- At minimum, plans should be reviewed once a year
- When one or more standard operating procedures change
- When there is a change in staff that has responsibilities specified in the plan
- All of the above 

At minimum, the overall vaccine management plan must be reviewed, dated and signed annually. Plans must also be updated when there is a change in standard operating procedures or in staff that has responsibilities specified in the plan.

Knowledge Check

Is the statement below true or false?

VFC providers must notify the Maine Immunization Program when a vaccine cold chain failure has occurred and vaccine needs to be wasted.

TRUE 

FALSE

If a cold chain failure is suspected or there is evidence that vaccine has been exposed to temperatures outside the recommended temperature ranges, providers should immediately contact the manufacturers to determine whether the vaccine may be used. If vaccine needs to be wasted, the Maine Immunization Program should be notified as soon as possible.

VFC Site Visits and Provider Education

VFC Site Visits

A VFC site visit is an opportunity for Maine Immunization Program staff to educate and support VFC providers who vaccinate VFC-eligible children using federally purchased vaccines. The purpose of these visits is to assess a provider's understanding and implementation of each VFC program 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 VFC provider will receive a VFC visit at least every 24months.

VFC Site Visits and Provider Education

What Happens During a VFC Site Visit?

VFC program staff will contact the provider's facility to schedule a VFC site visit. During the visit, VFC program staff will evaluate a provider's understanding and implementation of VFC program 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 VFC program requirements.

Site visits are also opportunities for providers to ask questions and for VFC program staff to offer resources to support providers' efforts in vaccinating children.

VFC Site Visits and Provider Education

Practices Not Meeting VFC Requirements

Overall, VFC site visit results confirm that VFC providers understand and are successfully implementing the program in their practices. However, on occasion, some issues and educational needs are identified and require additional follow-up and communication with VFC program staff to ensure the provider's success with the program.

VFC program staff will work with the provider to develop a follow-up plan that outlines specific actions that need to be taken to address issues identified during the visit.

VFC Site Visits and Provider Education

Unannounced Vaccine Storage and Handling Visits

Some VFC providers 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, thereby ensuring all VFC-eligible children are receiving viable vaccine that protects them from vaccine-preventable diseases.

VFC Site Visits and Provider Education

VFC Provider Education

Vaccine coordinators and back-up coordinators are required to complete training covering all VFC requirements every 12 months.

New primary and secondary coordinators must complete the following:

- Maine Immunization Program online training – Vaccines for Children
- Maine Immunization Program online training – Storage and Handling

Primary and secondary vaccine coordinators who have completed both trainings in the previous year will only need to do one of the following:

- Complete the Maine Immunization Program online training – Storage and Handling
- Attend a VFC regional training presented by the Maine Immunization Program
- Participate in a VFC Compliance Site Visit

Knowledge Check

Is the statement below true or false?

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

TRUE

FALSE 

Each VFC provider will receive a VFC 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 provide all of the above ensuring that all VFC-eligible children are receiving viable vaccine and are protected against vaccine-preventable diseases.

Knowledge Check

Is the statement below true or false?

VFC providers must complete training covering all VFC requirements every 24 months.

TRUE

FALSE 

All primary and secondary vaccine coordinators must complete training covering all VFC requirements every 12 months.

Post Test and Education Credit

This completes the Maine Immunization Program Vaccines for Children (VFC) online training presentation.

To receive credit for the training you MUST complete a post-test.

Once you have completed and submitted the test the Maine Immunization Program will be notified and you will be awarded credit for this training. You will also receive notification by email of completion for your records.

Please have your PIN # and email ready before beginning the test. They will be required.

As always, thank you for helping to keep Maine's children free from vaccine-preventable disease.