Vaccine Storage and Handling Toolkit

Updated with COVID-19 and Mpox Vaccines Storage and Handling Information
Addendum added January, 2023

U.S. Department of
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The Vaccine Storage and Handling Toolkit has been updated with an addendum to address proper storage, handling, transport, and emergency handling of COVID-19 and mpox vaccines. The addendum will be updated as new vaccine products are approved and vaccination information evolves. Please check the CDC Vaccine Storage and Handling Toolkit website (www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html) regularly for the most current version of the toolkit. The addendum can be found starting on page 51.

Disclaimer: This document provides best practices and Centers for Disease Control and Prevention (CDC) recommendations on storage, handling, and transport of vaccines and diluents. It also provides information on vaccine storage and handling requirements related to the Vaccines for Children program. Use of trade names and commercial sources in this toolkit is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services (DHHS), the U.S. Public Health Service (PHS), or CDC.

Introduction

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

This toolkit provides information, recommendations, and resources to assist you in properly storing and handling your vaccine supply. The Centers for Disease Control and Prevention (CDC) *Vaccine Storage and Handling Toolkit* brings together best practices from the Advisory Committee on Immunization Practices (ACIP) General Best Practice Guidelines for Immunization,* product information from vaccine manufacturers, and results of scientific studies. Implementing these best practices and recommendations will help protect your patients, safeguard your vaccine supply, and avoid the unnecessary costs of revaccinating patients and replacing expensive vaccines.

For specific, detailed storage and handling protocols for individual vaccines, always refer to the manufacturers' product information and package inserts,* or contact the manufacturer directly.

Vaccines for Children Program

The Vaccines for Children (VFC) program provides vaccines at no cost to eligible children. VFC providers are important partners in making sure VFC-eligible children receive viable, properly handled vaccine.

This toolkit provides general background information on many of the VFC storage and handling requirements and illustrates best practices essential to safeguarding the public vaccine supply.

If you are a VFC provider or receive other vaccines purchased with public funds, consult your state or local immunization program (referred to throughout this document as "immunization program"*) to ensure you are meeting all mandatory storage and handling requirements that are specific or tailored to your jurisdiction.

You may see vendors use terms such as "VFC-compliant," "CDC-compliant," or "satisfies VFC requirements" in their marketing materials or on their websites. In this context, "compliance" and related terms may lead consumers to incorrectly believe that CDC or the VFC program has independently assessed and verified the quality of these products. CDC/VFC is not authorized to assess, validate, verify, or endorse the products or services of private companies. Should you encounter this type of language in vendor marketing materials, please keep in mind that neither CDC nor the VFC program has validated any product or service for compliance with CDC or VFC program requirements or standards.

COVID-19 and Mpox Vaccine Storage and Handling Addendum

At this time, all COVID-19 and mpox vaccines are available to enrolled providers through the CDC's COVID-19 and Mpox Vaccination Programs (COVID-19 vaccination provider and Mpox vaccination provider program). This addendum provides specific guidance regarding proper storage and handling practices for these vaccines. Carefully review the information for these vaccines and considerations when integrating them into existing storage and handling practices. If you are a VFC provider or receive other vaccines purchased with public funds, consult your state or local immunization program (referred to throughout this document as "immunization program"*) to ensure you are meeting all mandatory storage and handling requirements that are specific or tailored to your jurisdiction.

* ACIP recommendations: www.cdc.gov/vaccines/hcp/acip-recs/index.html
Manufacturers' package inserts: www.immunize.org/fda/
Immunization programs: www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html

Introduction

How to Use the Vaccine Storage and Handling Toolkit

This toolkit outlines CDC recommendations for vaccine storage and handling.

This list shows the icons you will see throughout the toolkit and their meanings:

ICON	DESCRIPTION
	CDC Recommendation – CDC recommends this as a minimal action to protect your vaccine supply.
	CDC Best Practice – CDC recommends best practices as additional actions, practices, and procedures to enhance protection of your vaccine supply.

Additional CDC vaccine storage and handling information is available at:

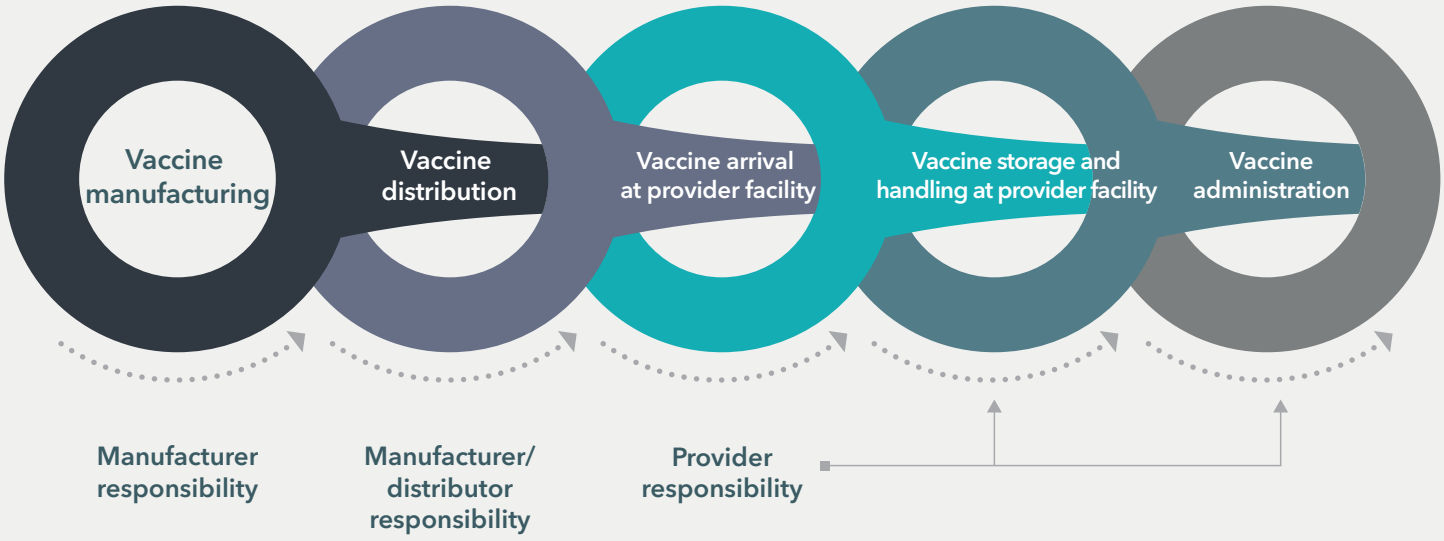
- Vaccine storage and handling home page:
  www.cdc.gov/vaccines/hcp/admin/storage-handling.html
  (sign up for notifications about updates)
- Educational webinars and continuing education for health care providers:
  www.cdc.gov/vaccines/ed/courses.html
- Contact information for state/local immunization programs:
  www.cdc.gov/vaccines/imz- managers/awardee-imz-websites.html
- E-mail specific questions to CDC: NIPInfo@cdc.gov

Proper vaccine storage and handling play critical roles in efforts to prevent vaccine-preventable diseases. Vaccines exposed to storage temperatures outside the recommended ranges may have reduced potency, creating limited protection and resulting in the revaccination of patients and thousands of dollars in wasted vaccine.

Proper storage and handling begin with an effective vaccine cold chain.

A cold chain is a temperature-controlled supply chain that includes all vaccine-related equipment and procedures. The cold chain begins with the cold storage unit at the manufacturing plant, extends to the transport and delivery of the vaccine and correct storage at the provider facility, and ends with administration of the vaccine to the patient.

Cold Chain Flowchart



If the cold chain is not properly maintained, vaccine potency may be lost, resulting in an unusable vaccine supply.

Vaccines must be stored properly from the time they are manufactured until they are administered. Potency is reduced every time a vaccine is exposed to an improper condition. This includes overexposure to heat, cold, or light at any step in the cold chain. Once lost, potency cannot be restored.

Exposure to any inappropriate conditions can affect potency of any refrigerated vaccine, but a single exposure to freezing temperatures (0° C [32° F] or colder) can actually destroy potency. Liquid vaccines containing an adjuvant can permanently lose potency when exposed to freezing temperatures.

When the cold chain fails

Ensuring vaccine quality and maintaining the cold chain are shared responsibilities among manufacturers, distributors, public health staff, and health care providers.

An effective cold chain relies on three main elements:

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

Results of a cold chain failure can be costly.[1,2,3] ACIP's *General Best Practice Guidelines for Immunization* states, "vaccine exposed to inappropriate temperatures that is inadvertently administered should generally be repeated."[4]

A break in the cold chain can mean extra doses for patients, increased costs for providers, and damage to public confidence in vaccines.

More importantly, patients refusing revaccination can remain unprotected from serious, vaccine-preventable diseases.

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.

By following a few simple steps and implementing CDC-recommended storage and handling practices, providers can ensure patients receive high-quality vaccine that has not been compromised.

1. Department of Health and Human Services, Office of Inspector General. Vaccines for Children Program: Vulnerabilities in Vaccine Management, June 2012, oig.hhs.gov/oei/reports/oei-04-10-00430.asp.
2. Gazmararian JA, Oster NV, Green DC, Schuessler L, Howell K, et al. Vaccine storage practices in primary care physician offices: assessment and intervention. *Am J Prev Med* 2002;23(4):246–53.
3. Bell KN, Hogue CJR, Manning C, Kendal AP. Risk factors for improper vaccine storage and handling in private provider offices. *Pediatrics* 2001;107(6):1–5.
4. Centers for Disease Control and Prevention. ACIP's *General Best Practice Guidelines for Immunization*, www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html.

Vaccine storage and handling practices are only as effective as the staff that implements them. Staff that is well-trained in general storage and handling principles and organization-specific storage and handling standard operating procedures (SOPs) is critical to ensuring vaccine supply potency and patient safety.

Staff Training

All staff members who receive vaccine deliveries as well as those who handle or administer vaccines should be trained in vaccine-related practices and be familiar with your facility's storage and handling SOPs. If you are a VFC provider or have vaccines purchased with public funds, contact your immunization program* for specific state requirements related to training, policies, and procedures.

Online Training Resources

CDC's *You Call the Shots*: Vaccine Storage and Handling† is a free, online training module focused on storage and handling requirements.

Check with your immunization program* and professional organizations to see what vaccine storage and handling training resources they offer.

† *You Call the Shots*: Vaccine Storage and Handling: www.cdc.gov/vaccines/ed/youcalltheshots.html

Storage and Handling SOPs

CDC recommends your facility develop and maintain clearly written, detailed, and up-to-date storage and handling standard operating procedures (SOPs). SOPs will help your facility stay organized, serve as a reference and training tool, and ensure proper vaccine management. SOPs help ensure proper procedures are followed and problems are identified, reported, and corrected. SOPs should also provide guidance for emergencies such as equipment malfunctions, power failures, or natural disasters.

Storage and handling plans and SOPs should contain plans and information for three major areas (see the **Vaccine Storage and Handling SOP Worksheet**):

- General information—include 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 SOPs—include information for all aspects of vaccine inventory management, from ordering to monitoring storage conditions
- Emergency vaccine storage, handling, and transport SOPs—outline steps to be taken in the event of equipment malfunctions, power failures, natural disasters, or other emergencies that might compromise vaccine storage conditions

Worksheets to assist you in developing your organization's routine and emergency SOPs are located in the resources section.

Train staff on routine vaccine storage and handling and emergency SOPs. Keep SOPs near vaccine storage units and make sure staff knows where to find them. Document all training completed with dates and participant names.

Storage and handling training should be completed:

- 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

* Immunization programs: www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html

Vaccine Coordinator Recommendations

Designate a primary vaccine coordinator. This person will be responsible for ensuring all vaccines are stored and handled correctly and should be an expert on your facility's storage and handling SOPs.

Coordinator responsibilities should 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 minimum/maximum temperatures at start of each workday*
- 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
- Removing expired vaccine from storage units
- Responding to temperature excursions (out-of-range temperatures)
- Maintaining all documentation, such as inventory and temperature logs
- Organizing vaccine-related training and ensuring staff completion of training
- Monitoring operation of vaccine storage equipment and systems
- Overseeing proper vaccine transport (when necessary) per SOPs
- Overseeing emergency preparations per SOPs:
  - Tracking inclement weather conditions†
  - Ensuring appropriate handling of vaccines during a disaster or power outage‡

Coordinator responsibilities may be completed by the coordinator or delegated to appropriate staff. Ensure the coordinator has trained the delegate(s) and documented competency for the specific tasks assigned.

Staff Training and SOP Best Practices

» Review and update SOPs annually.
» Appoint an alternate vaccine coordinator to act in the absence of the primary coordinator.
» The alternate coordinator, like the primary coordinator, should be an expert in routine and emergency SOPs.

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*This is a VFC provider requirement.

†The Federal Emergency Management Agency (FEMA) offers a wide range of information on disaster preparedness: www.fema.gov/. The Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA) offers information concerning the storage and use of temperature-sensitive biological products that have been involved in a temporary electrical power failure or flood conditions: www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/.

‡The National Oceanic and Atmospheric Administration (NOAA) provides up-to-date information on U.S. weather conditions:
www.weather.gov/
www.goes.noaa.gov/

SECTION THREE: Vaccine Storage and Temperature Monitoring Equipment

It is important your facility has proper storage and monitoring equipment that is set up correctly, maintained appropriately, and repaired as needed. This equipment protects patients from inadvertently receiving compromised vaccine and your facility against costs of revaccinating patients, replacing expensive vaccines, and losing patient confidence in your practice.

Vaccine Storage Units: Refrigerator and Freezer Recommendations

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

- **Use purpose-built or pharmaceutical-grade units designed to either refrigerate or freeze**. These units can be compact, under-the-counter style or large.

Purpose-built units, sometimes referred to as "pharmaceutical-grade," are designed specifically for storage of biologics, including vaccines. 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 promoting uniform temperature and fast temperature recovery from an out-of-range temperature.

Household-grade units can be an acceptable alternative to pharmaceutical-grade vaccine storage units. As the name implies, these units are primarily designed and marketed for home use. However, the freezer compartment of this type of unit is not recommended to store vaccines and there may be other areas of the refrigerated compartment that should be avoided as well. If your facility provides frozen vaccine, a separate freezer unit is necessary.

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 pose a significant risk of freezing vaccines, even when used for temporary storage. (Note: Not all small storage units are dormitory- or bar-style units. Compact, purpose-built units for biologics can be used to store vaccines.)

Storage unit doors

A door that is not sealed properly or left open unnecessarily not only affects the temperature in a unit, it also exposes vaccines to light, which can reduce potency of some vaccines. Consider using safeguards to ensure the doors of the unit remain closed—for example, self-closing door hinges, door alarms, or door locks.

Storage Unit Best Practices

To fully ensure the safety of vaccines, equipment should include a recommended unit with enough space to accommodate your maximum inventory without crowding.

Storage Unit Placement

Good air circulation around the outside of the storage unit is important. Place a storage unit 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. If not secured properly, unit doors pose a particular risk to maintaining appropriate internal temperatures of vaccine storage units. Studies find most units work best when placed in an area with standard indoor room temperatures, usually 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.

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Stabilizing Temperatures in New and Repaired Units

It may take 2 to 7 days to stabilize the temperature in a newly installed or repaired refrigerator and 2 to 3 days for a freezer.

Before using a unit for vaccine storage, check and record the minimum and maximum temperatures each workday for 2 to 7 days. If temperatures cannot be recorded digitally, check and record temperatures a minimum of two times each workday. Once you have 2 consecutive days of temperatures recorded within the recommended range, your unit is stable and ready for use.

Temperature Ranges

Refrigerators should maintain temperatures between 2° C and 8° C (36° F and 46° F)*. Freezers should maintain temperatures between -50° C and -15° C (-58° F and +5° F). Ultra-cold freezers should maintain temperatures between -90° C and -60° C (-130° F and -76° F) . Refrigerator or freezer thermostats should be set at the factory-set or midpoint temperature, which will decrease the likelihood of temperature excursions.

Consult the owner's manual for instructions on how to operate the thermostat. Thermostats are marked in various ways and, in general, show levels of coldness rather than temperatures. The only way to know the temperature where vaccines are stored is to measure and monitor it with a temperature monitoring device.

Temperature Monitoring Device (TMD)

Every vaccine storage unit must have a TMD. An accurate temperature history that reflects actual vaccine temperatures is critical for protecting your vaccines. Investing in a reliable device is less expensive than replacing vaccines wasted due to the loss of potency that comes from storage at out-of-range temperatures.

- **CDC recommends a specific type of TMD called a "digital data logger" (DDL).** A DDL provides 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"). Unlike a simple minimum/maximum thermometer, which only shows the coldest and warmest temperatures reached in a unit, a DDL provides 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 to reflect only air temperature. However, not all DDLs can measure ultra-cold temperatures. For accurate ultra-cold temperature monitoring, it is essential to use an air-probe or a probe designed specifically for ultra-cold temperatures.

Temperature data from a DDL can either be downloaded to a computer using special software or retrieved from a website. The software or website may also allow you to set the frequency of temperature readings. Reviewing DDL data is critical for vaccine viability, so it is important to decide whether independent software or a website program works best for your facility.

* Probes that are permanently embedded in a buffer are acceptable as long as the temperature monitoring system for the entire unit can be calibration-tested.

Keep the data for 3 years so they can be analyzed for long-term trends and/or recurring problems. Those receiving public vaccine may need to keep records longer as required by state regulations.

Use a DDL or other appropriate TMD for:

- Each vaccine storage unit
- Each transport unit (emergency or non-emergency)

Have at least one backup TMD in case a primary device breaks or malfunctions.

Use 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 temperatures at least every 30 minutes

Use DDLs with a current and valid Certificate of Calibration Testing.

Certificate of Calibration Testing

Calibration testing is done to ensure the accuracy of a temperature monitoring device's readings against nationally accepted standards.

A DDL's Certificate of Calibration Testing should include:

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

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
- 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 or higher
- Refers to another acceptable accuracy validation method, such as comparison to other traceable reference standards or tests at thermometric fixed points

Calibration testing should be done every 2 to 3 years or according to the manufacturer's suggested timeline. TMDs can experience a "drift" over time, affecting their accuracy. This testing ensures the accuracy of the device continues to conform to nationally accepted standards.

Mishandling a TMD can affect its accuracy. If a TMD is dropped, hit against the side of a storage unit, or is potentially damaged in any way, its accuracy should be checked against another calibrated TMD. If there is any question about accuracy, the device should be replaced or sent for calibration testing.

* Since these devices are typically battery-operated, you should have a supply of extra batteries on hand. If you are storing ultra-cold vaccine, make sure your DDL is appropriate for ultra-cold monitoring. See the COVID-19 Vaccine Storage and Handling Addendum for more information.

† Battery changes may affect temperature accuracy and may warrant checking against a known, calibrated TMD. Check with the device's manufacturer for specific information on battery changes.

Monitoring Vaccine Temperature and Vaccine Equipment

Monitoring vaccine storage equipment and temperatures are daily responsibilities to ensure the viability of your vaccine supply and the safety of your patients. Implementing routine monitoring activities can help you identify temperature excursions quickly and take immediate action to correct them, preventing loss of vaccines and the potential need for revaccination of patients.

Power Supply

Even with appropriate equipment and temperature monitoring practices in place, power disruption can result in destruction of the entire vaccine supply. Precautions should always be taken 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 turns the power off.**
- **Use a safety-lock plug or an outlet cover to prevent the unit from being unplugged.**
- **Post "DO NOT UNPLUG" warning signs at outlets and on storage units to alert staff, custodians, electricians, and other workers not to unplug units.**
- **Label fuses and circuit breakers to alert people not to turn off power to a storage unit.**
- **Use caution when using power outlets that can be tripped or switched off and avoid using:**
  - Built-in circuit switches (may have reset buttons)
  - Outlets that can be activated by a wall switch
  - Multi-outlet power strips

If built-in circuit switches, Uninterruptible Power Supply (UPS) unit, or power strip surge protection must be used, make sure the device is rated to carry the maximum current as specified by the manufacturer of the refrigerator or freezer. Additionally, consider how the device manages when the power is restored. Whether the device automatically restarts and allows the equipment to run or has to be manually switched on should be considered and represented in Emergency Plans and SOPs. Contact the unit manufacturer for any additional questions or guidance regarding circuit switches, power strips, UPI, or surge protection.

If the entire storage unit is affected by a temperature excursion because of a power supply issue or unit malfunction, refer to your facility's emergency SOPs.

Certain types of TMDs 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.

CDC does not recommend the following TMDs:

- Alcohol or mercury thermometers, even if placed in a fluid-filled, biosafe, liquid vial
- Bimetal stem TMDs
- TMDs used for food
- Chart recorders
- Infrared TMDs
- TMDs that do not have a current and valid Certificate of Calibration Testing

Please note: Some devices sold in hardware and appliance stores are designed to monitor temperatures 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 vaccines.

Organizing and Storing Vaccine

Correctly organizing and placing vaccines in a storage unit helps prevent conditions that could reduce vaccine potency or cause vaccine failure.

- **Store vaccines in their original packaging with lids closed until ready for administration.** Vials and manufacturer-filled syringes should always be stored in their original packaging. Loose vials or syringes may be exposed to unnecessary light, potentially reducing potency, and may be more difficult to track for expiration dates. They may also impact inventory management and increase the risk of administration errors because they may be confused with other vaccines. For certain purpose-built units, it is recommended that vaccine be stored outside of the packaging. If this is the case, follow the manufacturer's guidance for vaccine storage.

- **Check and record storage unit minimum and maximum temperatures at the start of each workday.** If your TMD does not read minimum/maximum temperatures, then check and record the current temperature a minimum of two times per workday (at the start and end of the workday).

  Record:

  - Minimum/maximum temperature
  - Date
  - Time
  - Name of person who checked and recorded the temperature
  - Any actions taken if a temperature excursion occurred

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

Food and beverages should never be stored in the unit with vaccines. If other biologics are stored in the unit, vaccines should be stored on the shelf above them.

Temperature Monitoring

Regular checks provide an opportunity to inspect the storage unit, reorganize any misplaced vaccines, and remove any expired vaccines. Check the temperature each time vaccines are accessed in the unit.

Review storage unit temperature readings and review continuous DDL software or website information weekly for changes in temperature trends that might require action.

If there appears to be any fluctuation in temperature, troubleshoot the problem based on additional information provided in this toolkit, manufacturer manuals, and/or your office storage and handling SOPs.

How to Store Vaccines

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.

Water bottles are not recommended for use with certain pharmaceutical-grade and purpose-built units. For such units, follow the manufacturer's guidance.

Organizing and Storing Vaccine

To confirm vaccines are stored correctly and to minimize the risk of administration errors, implement the following practices:

» Store each type of vaccine or diluent in its original packaging and in a separate container.

» Position vaccines and diluents 2 to 3 inches from the unit walls, ceiling, floor, and door. If using a household-grade unit, avoid storing vaccines and diluents in any part of the unit that may not provide stable temperatures or sufficient air flow, such as directly under cooling vents; in deli, fruit, or vegetable drawers; or on refrigerator door shelves. The instability of temperatures and air flow in these areas may expose vaccines to inappropriate storage temperatures.

» Label shelves and containers to clearly identify where each type of vaccine and diluent is stored.

» Store vaccines and diluents with similar packaging or names or with pediatric and adult formulations on different shelves.

» Whenever possible, store diluent with the corresponding refrigerated vaccine. Never store diluent in a freezer.

» Avoid placing or storing any items other than vaccines, diluents, and water bottles inside storage units.

- If other medications and biological products must be stored in the same unit as vaccines, they must be clearly marked and stored in separate containers or bins from vaccines.
  - —Potentially contaminated items (e.g., blood, urine, stool) should be properly contained and stored below vaccines due to risk of contamination from drips or leaks.
  - —The freezer of a household-grade unit may be used for non-vaccine, medical storage, so long as the use does not compromise the temperature range within the refrigerator compartment where vaccine is stored.

» Arrange vaccines and diluents in rows and allow space between them to promote air circulation.

» Place vaccines and diluents with the earliest expiration dates in front of those with later expiration dates.

Temperature Excursions

Temperature excursions or inappropriate storage conditions for any vaccine require immediate action. Any temperature reading outside the recommended ranges 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.

CDC recommends the following steps in the event of a temperature excursion:

1. Any staff 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. Notify staff by labeling exposed vaccines "DO NOT USE" and placing them in a separate container apart from other vaccines (do not discard these vaccines).
3. The vaccine coordinator, supervisor, or if necessary, the person reporting the problem, should begin to document the event with the following information†:
   a. Date and time of the temperature excursion
   b. Storage unit temperature as well as room temperature, if available (including minimum/maximum temperatures during the time of the event, if available)
   c. Name of the person completing the report and description of the event‡:
      — General description of what happened
      — The length of time vaccine may have been affected, if using a DDL
      — Inventory of affected vaccines
      — List of items in the unit (including water bottles) other than vaccines
      — Any problems with the storage unit and/or affected vaccines before the event
      — Other relevant information
4. Implement your facility SOPs to adjust unit temperature to the appropriate range. At a minimum, check the TMD to make sure it is appropriately placed in the center of the vaccines.
5. Contact your immunization program and/or vaccine manufacturers per your SOPs for further guidance on whether to use affected vaccines and for information about whether patients will need to be recalled for revaccination. 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:
   a. Action taken
      — What you did with vaccine and how long it took to take action
      — Whom you contacted and instructions received
      — What you did to prevent a similar future event
   b. Results
      — Final disposition of affected vaccines (e.g., shortened expiration date per manufacturer, discarded, or returned)
      — Other comments

* Manufacturers' vaccine package inserts: www.immunize.org/fda/. Vaccines under an Emergency Use Authorization (EUA) will provide an EUA Fact Sheet for Healthcare Providers with this information.

† The Immunization Action Coalition has developed a Temperature Monitoring Log and a Vaccine Storage Troubleshooting Record to support these activities.

‡ Responses from vaccine manufacturers to events depend on information given by the provider to the manufacturer. If different information about the same event is provided to the same manufacturer, this can lead to different recommendations on whether vaccine can be used or whether patients need to be revaccinated. In addition, each event is unique, and manufacturer recommendations based on existing stability data cannot be applied to future events that may appear to be similar.

Regular Maintenance of Vaccine Storage Units and Temperature Monitoring Devices

Storage units and TMDs need regular maintenance to ensure proper operation.

Never allow vaccines to remain in a malfunctioning unit for an extended period of time. If you believe your unit has failed, implement your emergency SOPs.

Conduct routine maintenance for all vaccine storage units and related equipment so that your equipment functions at maximum efficiency.

- Check seals and door hinges.
- Clean coils and other components per manufacturer direction.
- Defrost manual-defrost freezers when the frost exceeds either 1 cm or the manufacturer's suggested limit. Follow the manufacturer's instructions. While defrosting, store vaccines temporarily in another unit with appropriate freezer temperatures.
- Clean the interior of each unit to discourage bacterial and fungal growth. Do so quickly to minimize the risk of a temperature excursion.
- Test any backup generator quarterly and have it serviced annually.

Troubleshooting Equipment Problems

Adjusting Storage Unit Temperatures

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

Temperature adjustments should be:

- Made by the primary or alternate vaccine coordinator, based on information from the TMD and temperature monitoring log
- Performed at a time that is not during a busy workday when the unit door is being frequently opened and closed

Remember that temperatures within any storage unit will vary slightly, even with normal use. Therefore, before making any 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, to allow the temperature to stabilize and then check it again to determine if the thermostat should be adjusted.

If you believe there could be an issue with your TMD, use your backup device to confirm the temperature.

If you confirm that an adjustment is needed:

1. Refer to the owner's manual for detailed instructions.
2. Make a small adjustment toward a warmer or colder setting by turning the thermostat knob slowly to avoid going outside the correct temperature range.
3. Once the adjustment is made, allow the temperature inside the unit to stabilize for 30 minutes without opening the door.
4. Recheck the temperature.

5. Repeat these steps as needed until the temperature has stabilized
   - between 2° C and 8° C (36° F and 46° F) for a refrigerator,
   - between -50° C and -15° C (-58° F and +5° F) for a freezer, and
   - between -90° C and -60° C (-130° F and -76° F) for an ultra-cold freezer.
6. Consider placing additional water bottles in the unit to help improve temperature stability.

Do not leave vaccines in a storage unit that does not maintain temperatures 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 SOPs to identify an alternative unit with appropriate temperatures and sufficient storage space until the primary unit can be repaired or replaced.

If you are using a combination storage unit, note that adjustments to the freezer temperature can adversely affect the refrigerator compartment temperature, possibly resulting in frozen vaccines in the refrigerator.

Repeated Alarm Alerts

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 settings. If the alarm continues to trigger or the temperature remains out of range, transfer vaccines to a backup unit as directed by your SOPs. A repair technician should check your equipment to determine the need for repair or replacement.

SECTION FOUR: Vaccine Inventory Management

Proper vaccine inventory management is essential for appropriate vaccine ordering and stock rotation, and ensures your facility has the vaccines your patients need. Vaccines are expensive, so making sure they are unpacked, stored, prepared, administered, and transported correctly is critical.

Vaccine Delivery

Scheduling and Receiving Deliveries

Maintaining the cold chain is the first step in vaccine inventory management. Staff members who might accept vaccine deliveries should be trained to immediately notify the vaccine coordinator or alternate coordinator when deliveries arrive. Vaccines must always be immediately checked and stored properly upon arrival.

Unpacking Deliveries

Vaccines and diluents must be carefully unpacked, stored at recommended temperatures, and documented immediately after they arrive. Do not place an unopened and/or unpacked shipment box in a vaccine storage unit because the cool packs shipped with the vaccine may make the packaged vaccine too cold if placed inside the storage unit.

Never leave a vaccine shipping container unpacked and unattended. If vaccines and diluents get too warm, they cannot be used. Be sure all staff knows that vaccine deliveries require immediate attention.

Immediately examine shipments for signs of damage and to guarantee receipt of the appropriate vaccine types and quantities.

- Examine the shipping container and vaccines for signs of physical damage.
- Check the contents against the packing list to be sure they match.
  - For frozen vaccines, the packing list will show the maximum time vaccines can be in transit based on shipment date.
- If the shipment includes lyophilized (freeze-dried) vaccines, make sure they came with the correct type and quantity of diluents.
- Immediately check both vaccine and diluent expiration dates to ensure you have not received any expired or soon-to-expire products.
- Immediately check the cold chain monitor (CCM), a device used to monitor vaccine temperatures during transport (if one was included) for any indication of a temperature excursion during transit.

Vaccine Inventory Accounting

Stock Counts

Stock records are used to determine the type and amount of vaccines your facility should stock to meet the needs of your patients. At least once a month and before placing any vaccine order, count all vaccine and diluent doses to make sure the number of doses in the storage unit matches the number of doses documented in the stock record. Always check expiration dates while counting stock and remove any expired doses immediately. **Tally Sheets**

Stock Records

BEST PRACTICES

Use a stock record to account for and document every dose of vaccine. This record will help you keep track of your inventory and can be in either paper or electronic form. This record should be updated weekly and include the vaccine delivery information below:

- Date of delivery and initials of the person who unpacked the box
- Vaccine and diluent name and manufacturer
- Number and expiration date for each lot
- Number of doses received
- Condition of each vaccine and diluent upon arrival
- CCM reading if included in the shipping container
- Number of doses used
- Balance of remaining doses after subtracting the amount used

Note: State and local programs that have an immunization information system (IIS) with vaccine inventory accounting functions will require VFC providers to use the IIS to track their inventory.

Tally sheets can help keep stock records 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.

If the numbers in the storage unit do not match the doses documented in the stock record, enter the correct number based on your count on a separate line below the old balance on your stock record. Make a note next to the new entry indicating that your count confirmed the new balance and sign it. Use the corrected balance for calculating stock quantities in the future.

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.

If there are discrepancies between the contents and the packing list or other concerns about the contents, immediately notify the vaccine manufacturer. If you are a VFC provider or receive vaccines purchased with public funds, contact your immunization program.*

Diluents should be documented on a separate stock record and should equal quantities of corresponding vaccines.

At the end of each month, determine the total number of vaccine and diluent doses used that month and the amount of stock still available. At the end of each year, use your stock record to determine the number of doses received for the year and add up your monthly dose counts to get a total number of doses used. This information will help you determine your facility's needs and guide you in ordering so you can minimize future waste and reduce the need for transfer and transport of vaccines. It will also help to make sure you have a sufficient supply to meet your patients' needs.

Vaccine Ordering

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 (e.g., due to mechanical failure of a storage unit).

Most facilities should also reorder based on patient needs after checking stock count. Vaccine orders usually arrive within 1 to 2 weeks, but there can be delays. When possible, avoid placing last-minute or rush orders to lessen the risk of running out of vaccines.

Stock Rotation and Removal

Vaccine stock should be rotated and checked for expired doses regularly. Any expired vaccines and diluents should be removed immediately to avoid inadvertently administering them. Arrange stock for each vaccine type so that doses with the earliest expiration dates are placed in front of those with later expiration dates.

Contact your immunization program* to find out if expired vaccines purchased with public funds can be returned.

Arranging Your Stock

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 delivery. This will ensure that vaccines expiring sooner are used first.

* Contact your immunization program for details about specific state or local regulations impacting this activity.
† An adequate supply of vaccine varies for most providers, facilities, or immunization programs. It is recommended that reordering is done when stock has been reduced to a 4-week inventory.

Understanding Expiration Dates

All vaccine products, like other medications, have an expiration date, sometimes referred to as the expiry date. The expiration date is determined by the **manufacturer**.

The expiration date is **the final day that the vaccine can be administered**. Vaccines past the expiration date should NEVER be used.

Determining when a vaccine or diluent expires is a critical step in maintaining proper storage and handling. Understanding vaccine expiration dates can help save your practice time and money.

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.

In some instances, such as the examples for beyond-use date (BUD) below, vaccines must be used before the expiration date on the label.

Expiration Dates

The vaccine coordinator (or other designated person) should remove expired vaccine and diluent immediately from the inventory.

Beyond-Use Dates

Some vaccines have a beyond-use date/time. **The Beyond-use date** is different from expiration date. The beyond-use date, or BUD, is the last date or time that a vaccine can be safely used after it has been moved from one storage state to another (e.g., frozen to refrigerated) or prepared for patient use. It is a new deadline after which the product should not be used. The BUD varies by product and type of transition. This is sometimes also called a beyond-use time if it falls on the same day at a different time of day.

Unlike the expiration date that is determined by the manufacturer, the BUD is determined by the health care provider using guidance provided by the manufacturer. The BUD replaces the manufacturer's expiration date but never extends it. Always use the earlier date between the two.

Not all vaccine products have a BUD. The package insert or Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers will specify if there is a BUD and how to calculate it. Always review this informational material to determine if a BUD applies. Examples of BUD include:

Reconstituted vaccines have a limited period for use once the vaccine is mixed with a diluent.

Multidose vials might have a specified period for use once they have been punctured with a needle. For example, the package insert may state that the vaccine must be discarded 28 days after the first puncture with a needle. If the vial is first punctured on 06/01/2023, the BUD is 06/29/2023. The vaccine should not be used after the BUD.

Manufacturer-shortened expiration dates may apply when vaccine is exposed to inappropriate storage conditions. The manufacturer might determine the vaccine can still be used, but will expire on an earlier date than the date on the label. The BUD should be noted on the vial label along with the initials of the person making the calculation.

Vaccine Disposal

General vaccine disposal guidelines for:

- **Expired or compromised vaccine**—sometimes unused vaccine and diluent doses, unopened vials, expired vials, and potentially compromised vaccine may be returned for credit, even if they must be discarded. Contact your immunization program* and/or the vaccine manufacturer for vaccine-specific information.
- **Open and broken vials and syringes, manufacturer-filled syringes that have been activated, and vaccine predrawn by providers**—these cannot be returned and should be discarded according to your state requirements.
- **Empty vaccine vials**—most are not considered hazardous or pharmaceutical waste and do not require disposal in a biomedical waste container.† However, check and comply with your state requirements for disposal.

Medical waste disposal requirements may vary from state to state because they are set by state environmental agencies. Contact your immunization program* or state environmental agency for guidance to ensure your facility's vaccine disposal procedures comply with state and federal regulations.

* Contact your immunization program for details about specific state or local regulations impacting this activity.
† While vials are not usually considered hazardous or pharmaceutical waste, an empty RV dispensing tube or oral applicator is considered medical waste and should be disposed of in a medical waste container.

Preparing Vaccine for Administration

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

Vaccine Preparation

- Prepare vaccines in a designated area away from any space where potentially contaminated items are placed.
- Only prepare vaccines when you are ready to administer them.
- Before preparing the vaccine, always check the:
  - Vial to ensure it is the correct vaccine
  - Expiration date or beyond-use date/time to ensure it has not passed
- 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.

Different types of vaccine vials

Single-Dose Vials

A single-dose vial (SDV) contains one dose and should be used one time for one patient. SDVs do not contain preservatives to help prevent microorganism growth. Never combine leftover vaccine from one SDV with another to obtain a dose.

Only open an SDV when 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.

Multidose Vials

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 indicated 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 vaccine or 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 BUD noted in the package insert.

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

Based on safe injection practices, CDC does NOT recommend the use of vial adapters, spikes, or other vial access devices when withdrawing vaccine from a multidose vial. Leaving a vial access device inserted into a vial septum provides a direct route for microorganisms to enter the vial and contaminate the fluid.

Manufacturer-Filled Syringes

A manufacturer-filled syringe (MFS) is prepared and sealed under sterile conditions by the manufacturer. **Activate an MFS (i.e., remove the syringe cap or attach the needle) only when ready to use.**

An MFS does 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 by the end of the workday.

SECTION FIVE: Vaccine Preparation

Reconstitution of Vaccine

Lyophilized (freeze-dried) vaccines are in either powder or pellet form and must be mixed with a liquid (diluent) in a process known as "reconstitution" before being administered.

Diluents vary in volume and composition and are specifically designed to meet volume, pH balance, and the chemical requirements of their corresponding vaccines. Refer to the manufacturer's package insert for guidance on storage and handling.

Diluents are not interchangeable unless specified by the manufacturer.

- Some diluents contain an antigen or an adjuvant needed for vaccine effectiveness. Even if the diluent is composed of sterile water or saline, use only the diluent supplied with the vaccine to reconstitute it.

Never use a stock vial of sterile water or normal saline to reconstitute vaccines.

Never administer vaccine reconstituted with the wrong diluent.

- If an incorrectly reconstituted vaccine has already been administered, contact your immunization program* or the vaccine manufacturer for revaccination guidance.

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

†If you are a VFC provider or have other vaccines purchased with public funds and must transfer vaccine to another facility so it can be used before it expires, contact your immunization program* for guidance on vaccine transport.

* Immunization programs: www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html

Predrawing Vaccine

Predrawing vaccines can result in waste if more are drawn up than needed.

- **Draw up vaccines only at the time of administration.** The practice of prefilling syringes is discouraged for several reasons. However, there may be rare instances when the only option is to predraw vaccine.

If vaccines must be predrawn, adhere to the following best practices:

- Set up a separate administration station for each vaccine type to prevent medication errors.
- Draw up vaccines only after arriving at the clinic site or mass vaccination event. Drawing up doses days or even hours before administering them is not a best practice because general-use syringes are not designed for storage.
- Each person administering vaccines should draw up no more than one MDV or 10 doses at one time.
- Once each predrawn dose is prepared, label the syringe with the vaccine name and dosage, the beyond-use date and time, lot number, and the preparer's initials. Additional pertinent information can be added, such as age range or primary or booster dose, as needed.
- Monitor patient flow to avoid drawing up unnecessary doses.
- Predraw reconstituted vaccine into a syringe only when you are ready to administer it. If a predrawn vaccine is not used within 30 minutes of being reconstituted, follow manufacturer guidance for storage conditions and time limits. A manufacturer may specify that an unused reconstituted vaccine can only be stored in the vial for a specified amount of time.
- Predrawn syringes must be stored at the manufacturer-recommended temperatures throughout the clinic day.
- Discard any remaining vaccine in predrawn syringes at the end of the workday.

Never transfer predrawn reconstituted vaccine back into a vial for storage.

As an alternative to predrawing vaccines, use manufacturer-filled syringes for large vaccination clinics.

Instructions for transport of some COVID-19 vaccine products may be different from those for other vaccines. Carefully review this section as well as the COVID-19 vaccine storage and handling addendum for information on specific COVID-19 vaccine products to ensure the vaccine is transported safely and the vaccine cold chain is maintained.

Transport, as described in this section, involves the movement of vaccine between providers or other locations over a short distance and time frame and is appropriate for events such as an emergency or off-site clinic or to ensure vaccines that are about to expire can be used rather than wasted.

Vaccine Transport Situations

Vaccine transport to off-site or satellite facilities is different from both shipping and emergency transport. Shipping usually involves a professional carrier and a longer distance and time frame for moving vaccines between locations. Emergency transport usually involves relocating vaccines to protect them when a facility's ability to store vaccines is compromised (e.g., because of power loss). Depending on the situation, some transport recommendations may be the same, but there are also some differences.

Vaccine Transport

Vaccines from your supply should not be routinely transported. In instances where the transport of vaccine from your supply is necessary, take appropriate precautions to protect your supply. Vaccines should only be transported using appropriate packing materials that provide the maximum protection.

Protecting Your Vaccine Supply

- Vaccine that will be used at an off-site or satellite facility should be delivered directly to that facility.
- If delivery to the specific site is not possible, then vaccine can be transported in a stable storage unit and monitored with a TMD. If the facility doesn't have the capacity to refrigerate the vaccines, then a portable vaccine storage unit or qualified container and packout may be used with a DDL.
- Develop an emergency plan or SOPs for transporting vaccines and include procedures and protocols for packing and transport.

Partially used vials cannot be transferred between providers OR across state lines.**

* Contact your immunization program for details about specific state or local regulations impacting this activity.

- **The total time for transport alone or transport plus clinic workday should be a maximum of 8 hours† (e.g., if transport to an off-site clinic is 1 hour each way, the clinic may run for up to 6 hours), unless guidance from the manufacturer differs.**
- **Use a transport temperature monitoring log to document temperatures and how long the vaccine is in the portable storage container.**
- **Transport diluents with their corresponding vaccines to ensure there are always equal amounts of vaccines and diluents for reconstitution.**
- **Your facility should have a sufficient supply of materials needed for vaccine transport of your largest annual inventory. Appropriate materials include:**
  - Portable vaccine refrigerator/freezer/ultra-cold freezer units (preferred option)
  - Qualified containers and packouts
  - Hard-sided insulated containers or Styrofoam™ (Use in conjunction with the *Packing Vaccines for Transport during Emergencies*‡ tool. This system is only to be used in an emergency.)
  - Coolant materials such as phase change materials (PCMs) or frozen water bottles that can be conditioned between 4° C and 5° C (39° F and 41° F)
  - Insulating materials such as bubble wrap and corrugated cardboard—enough to form two layers per container
  - TMDs for each container

†COVID-19 vaccine transport times may be different. Refer to COVID-19 vaccine product specific information in the COVID-19 Vaccine Addendum.
‡Packing Vaccines for Transport during Emergencies: www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf

Soft-sided containers specifically engineered for vaccine transport are acceptable. Do not use commercially available soft-sided food or beverage coolers because most are poorly insulated and likely to be affected by room or outdoor temperatures.

The same shipping materials the vaccines were initially shipped in should rarely, if ever, be used as they are not meant for reuse. This could put the cold chain and, ultimately, the viability of the vaccine, at risk.

Transport of Vaccines

It is always safest to have vaccines delivered directly to a facility with a vaccine storage unit ready to receive the shipment, but this is not always possible. If necessary, vaccines may be transported using a portable vaccine refrigerator with a temperature monitoring device placed with the vaccines. If a portable vaccine refrigerator is not available, qualified containers and packouts with a TMD in each container can be used. For transport to an off-site clinic, bring only what is needed for the workday.

Transport System Recommendations

	Emergency Transport	Transport for Off-Site Clinic, Satellite Facility, or Relocation of Stock
Portable Vaccine Refrigerator or Freezer	Yes	Yes
Qualified Container and Packout	Yes	Yes
Conditioned Water Bottle Transport System*	Yes	No
Manufacturer's Original Shipping Container	Yes (last resort only)	No
Food/Beverage Coolers	No	No

Coolants for Transport

PCMs between 4° C and 5° C (39° F and 41° F) can also be purchased to maintain proper temperatures. Follow the manufacturer's instructions† for use to reduce the risk of freezing vaccines during transport.

Do not use frozen gel packs or coolant packs from original vaccine shipments to pack refrigerated vaccines. They can still freeze vaccines even if they are conditioned or appear to be "sweating."

In emergency situations, a system using conditioned water bottles can be used. Manufacturers' original shipping containers may also be used as a last resort in an emergency situation.

The *Packing Vaccines for Transport during Emergencies** tool describes a system in which properly conditioned frozen water bottles can be used as a coolant when transporting vaccine during emergency situations.

Transport Planning and Preparation

Improper packing for transport is as risky for vaccines as a failed storage unit.

Include vaccine packing and transport protocols in your routine and emergency storage and handling SOPs. At a minimum, include the following procedures and protocols:

For all staff-facilitated transport:

- Identify trained staff to pack vaccines as well as primary and backup vehicles and drivers for transport in advance.
- Consider renting a refrigerated truck if you have a large quantity of vaccines or need to transport vaccines an extended distance.
- Take an inventory of your vaccines and record actions to protect the vaccines during transport.
- Open unit doors only when necessary and only after completing all preparation for packing and moving vaccines.
- If using a company or personal vehicle, only transport vaccines inside the passenger compartment (not in the trunk or bed of a truck, which may be too hot or too cold).
- Move transport containers directly to a vehicle that is already at a comfortable temperature, neither too hot nor too cold.
- 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 your immunization program‡ for additional guidance and resources on emergency transport of vaccines, particularly in major emergencies.

* Packing Vaccines for Transport during Emergencies: www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf
† Manufacturers' vaccine package inserts: www.immunize.org/fda/
‡ Immunization programs: www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html

Transporting Opened Multidose Vials

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.**

Transporting Predrawn Syringes

CDC recommends transporting vaccine in vials. However, there may be instances when the only option is to transport predrawn vaccine in a syringe. U.S. Pharmacopeia includes guidance for transporting predrawn vaccine in syringes in the USP COVID-19 Vaccine Toolkit: Operational Considerations for Healthcare Practitioners.

Transporting Diluents

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

If diluents stored at room temperature (20° C to 25° C [68° F to 77° F]) are going to be transported with refrigerated vaccines, they should be refrigerated in advance for as long as possible so they do not raise the container temperature when placed with refrigerated vaccines.

Never freeze diluents—not even during transport.

Place an insulating barrier like bubble wrap between the diluents and conditioned water bottles or phase change materials.

Transporting Frozen Vaccines

If frozen vaccines must be transported, use a portable vaccine freezer unit or qualified container and packout that maintains temperatures between -50° C and -15° C (-58° F and +5° F) or -90° C and -60° C (-130° F and -76° F) for ultra-cold transport.

Follow these steps for transporting frozen vaccines:

- Place a TMD (preferably with a buffered probe) in the container as close as possible to the vaccines.
- Immediately upon arrival at the destination, unpack the vaccines and place them in a freezer at a temperature range between -50° C and -15° C (-58° F and +5° F) or -90° C and -60° C (-130° F and -76° F) for ultra-cold freezer storage. Any stand-alone freezer that maintains these temperatures is acceptable.
- Record the time that vaccines are removed from the storage unit and placed in the transport container, the temperature during transport, and the time at the end of transport when vaccines are placed in a stable storage unit.

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

Temperature Monitoring During Transport

Use a continuous TMD, preferably a DDL with the capability to measure minimum/maximum temperatures, for monitoring and recording temperatures while transporting vaccines:

- The TMD should have an accuracy of +/-0.5° C (+/-1° F).
- Place buffered probe material in a sealed vial directly with the vaccines.
- Keep the TMD display on top of vaccines so you can easily see the temperature.
- Record the time and minimum/maximum temperature at the beginning of transport.

* Manufacturers' vaccine package inserts: www.immunize.org/fda/

† The only exception to this is for transport of COVID-19 Vaccine (Pfizer) which can be transported at ultra-cold temperatures using dry ice. See the COVID-19 Vaccine Storage and Handling Addendum for more information.

Temperature Monitoring after Transport

Immediately upon arrival at the destination, vaccines should be stored in an appropriate storage unit with a TMD. Be sure to follow these guidelines for monitoring and recording storage unit temperature:

- If the device displays minimum/maximum temperatures, this information should be checked and recorded.
- If the device does not display minimum/maximum temperatures, then the current temperature should be checked and recorded a minimum of two 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 storage unit using the following guidance:

- If using a DDL that records minimum/maximum temperatures, only check and record temperatures each time the portable vaccine storage unit is opened. If the TMD measures current temperatures only, place the probe as close as possible to the vaccines, and check and record temperatures hourly.
- Keep the container closed as much as possible.
- For off-site clinic use, remove only one multidose vial or 10 doses at a time for preparation and administration by each person administering vaccines.

SECTION SEVEN: Emergency Vaccine Storage and Handling

Instructions for handling some COVID-19 vaccine products during an emergency may be different from those for other vaccines. Carefully review this section as well as the COVID-19 vaccine storage and handling addendum for information on specific COVID-19 vaccine products to ensure the vaccine cold chain is maintained during an emergency.

Emergencies like equipment failures, power outages, severe weather conditions, or natural disasters usually happen without warning and may compromise vaccine storage conditions. In addition to vaccine transport planning, you should make plans to prepare for emergencies.*

Emergency Equipment Backup Options

Alternative Storage Facility

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.

- **Establish a working agreement with at least one alternative storage facility even if you have a generator as backup equipment.** Make sure you have 24-hour access to this facility. 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.

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 unit fails.

Accessing Your Building after Hours

Emergency situations can arise outside of normal business hours, so maintain a relationship with your facility's building manager and/or security staff. Ensure all staff members are familiar with emergency SOPs, including after-hours roles and responsibilities. **Your facility's storage and handling SOPs should include instructions for accessing your vaccine storage units when the building is closed, with a building map/diagram and locations of:**

- Spare batteries
- Flashlights
- Keys
- Locks
- Circuit breakers
- Emergency transport equipment and materials

Keep information on after-hours building access and security procedures with SOPs and with building management and security staff, if appropriate, and also make sure relevant staff has copies of this information available at home.

* The Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA) offers information concerning the storage and use of temperature-sensitive biological products that have been involved in a temporary electrical power failure or flood conditions: www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ProductSecurity/ucm147243.htm.

Vaccines may remain inside a nonfunctioning unit as long as appropriate temperatures are maintained. Monitor your DDL to determine when additional action should be taken.

Generators and backup battery power sources

Having an on-site generator prevents the need to transport vaccines 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 generator should be tested quarterly and serviced annually.

A backup battery power source can be used in lieu of a generator.

- Backup battery power sources should be tested quarterly and serviced annually.
- Check the manufacturer's guide for testing

If an alternative vaccine storage facility is not available

If you cannot find an alternative vaccine storage facility within a reasonable distance, or if you cannot reach your alternative facility, you can use portable vaccine refrigerator/freezer units (if power source is available), qualified containers and packouts, or a hard-sided insulated container or Strofoam™ using the *Packing Vaccines for Transport during Emergencies* tool. Always place a TMD with the vaccines and carefully monitor the TMD to ensure vaccines remain within the appropriate temperature range. Temporary storage containers should remain closed, and vaccines can only be stored safely for as long as the containers are validated to maintain proper storage temperatures.

Power Outages

Monitoring Unit Temperature during a Power Outage

If your storage unit has an external temperature monitoring display that you can check without opening the unit 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.
- Temperature excursions should be avoided, if possible, by using emergency plans and SOPs for transport and alternative storage. However, if temperatures have fallen outside of the recommended range, follow your procedures for temperature excursions.

If you cannot monitor the temperature inside the unit without opening the door and you do not have an alternative facility with power where the vaccines can be stored or other emergency vaccine storage SOPs, wait until power is restored and then take the following steps:

- Record the room temperature (if possible) and the temperature inside the unit.
- If using a DDL, document the length of time the power was off and the minimum and maximum temperatures during that period.
- If temperatures inside the unit have already fallen outside of the recommended range, follow your procedures for temperature excursions. Even if an excursion has occurred, move your vaccines to an alternative storage unit or location where they can be stored at appropriate temperatures, if possible. Make sure to separate and mark these vaccines "Do NOT Use" until a decision can be made about whether the vaccines can still be used.

During a power outage, only open the storage unit door if:

» Power is restored.

» It is determined that the vaccines need to be packed in separate storage containers and/or transported to an alternative storage facility.

Buffered temperature probe	Temperature probe designed to prevent false readings by protecting the thermometer from sudden changes in temperature that can occur when opening a refrigerator door. A probe is "buffered" by immersing it in a vial filled with liquid (e.g., glycol, ethanol, glycerin), loose media (e.g., sand, glass beads), or a solid block of material (e.g., Teflon®, aluminum).
Beyond-use date (BUD)	The date or time after which a vaccine should not be administered, stored, or transported. The BUD should never exceed the manufacturer's original expiration date.
Calibration	Professional measurement of the accuracy of a temperature monitoring device's readings against nationally accepted standards.
Cold chain monitor (CCM)	Generally, a single-use device that monitors the temperature inside a vaccine shipping container. CCMs should be thrown away after being checked. CCMs are stored in a separate compartment of the shipping container (a CCM may not be included when vaccines are shipped directly from the manufacturer).
Conditioned water bottles	Frozen water bottles that have been submerged under lukewarm water until the ice block inside can spin freely.
Digital data logger (DDL)	An electronic device that records data digitally over time or in relation to location either with a built-in or external instrument or sensor.
Diluent	A diluting agent (e.g., a liquid) added to reconstitute lyophilized vaccine before administration. Manufacturers of these vaccines also supply the matching diluent.
Dormitory-style (bar-style) storage unit	A combination refrigerator/freezer unit with one exterior door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator. These units have been shown to pose a significant risk of freezing vaccines, even when used for temporary storage.
Fan-forced air circulation	Technology using powerful fans or multiple cool air vents inside the unit that promote uniform temperature and fast temperature recovery.
Household-grade storage unit	A storage unit that is primarily sold for home use.
Lyophilized	Freeze-dried; usually referring to a vaccine that is freeze-dried into a powder or wafer.
Minimum/maximum temperature	A vaccine storage unit's coldest and warmest temperature readings during a set period of time.

Phase change materials (PCMs)	Engineered packing supplies that help control container temperatures during vaccine transport or shipping.
Portable vaccine storage unit	A type of powered refrigerator or freezer unit specifically designed for use during vaccine transport. These are passive units that require a power source to function. Please note that some active units are "qualified" to maintain desired temperatures for a set amount of time in the event of a power loss.
Potency	A vaccine's strength or effectiveness; in the context of this toolkit, potency refers to a vaccine's response to environmental conditions.
Presentation	Type of packaging for a vaccine (e.g., single-dose vial, multidose vial, manufacturer-filled syringe, etc.).
Purpose-built /pharmaceutical-grade unit	Unit that are specifically designed to store vaccines.
Qualified container and packout	A type of container and supplies specifically designed for use when packing vaccines for transport. They are passive containers that do not require a power source and are "qualified" through laboratory testing under controlled conditions to ensure they achieve and maintain desired temperatures for a set amount of time.
Standard operating procedures (SOPs)	A set of step-by-step instructions compiled by an organization to help workers carry out complex routine or emergency operations. SOPs aim to achieve efficiency, quality output, and uniformity of performance, while reducing miscommunication and preventing failure to comply with industry regulations and best practices.
Stand-alone storage unit	A storage unit that operates independently of any other device or system for its desired function (i.e., a refrigerator that only functions as a refrigerator or a freezer that only functions as a freezer).
Temperature excursion	Any temperature reading that is outside the recommended range for vaccine storage as defined in the manufacturer's package insert.
Tolerance	Compliance with nationally accepted standards for the calibration limits of temperature monitoring equipment. The equipment can either be considered "in" or "out" of tolerance.
Traceability	An unbroken chain of measurements and associated uncertainties.
Uncertainty	The quantification of the doubt about the measurement result.

REFERENCE: Purpose-Built Vaccine Storage Units

Numerous vaccine storage units have entered the market that are designed specifically for the storage of vaccines. These units can take many physical forms. Some look like traditional stand-alone units, while others can take the form of dispensing or vending units, either with or without doors. Although these units may be similar to pharmaceutical-grade or medical-grade units, they are unique in that they are designed and tested to keep vaccines in appropriate storage conditions. If you are a VFC provider, your immunization program determines which purpose-built units meet VFC program requirements. Always check with your immunization program before purchasing any unit that will be used to store VFC vaccines. Features and considerations related to these types of units include the following:

VFC vaccine management

» Purpose-built units must have the ability to allow the user to separate public and private vaccine stock physically or virtually.

» If stock is separated virtually, an inventory printout† must be accessible upon request.

» If unable to physically remove expired vaccine from a purpose-built unit immediately, the unit must be able to make expired vaccine inaccessible.

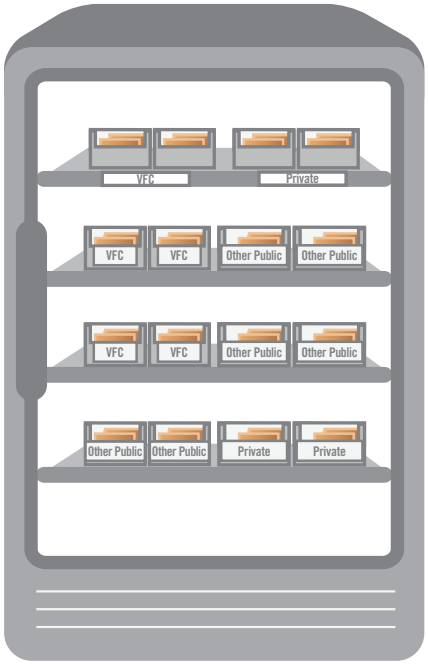
†The inventory printout should be used to answer storage and handling and inventory sections of the site visit reviewers guide.

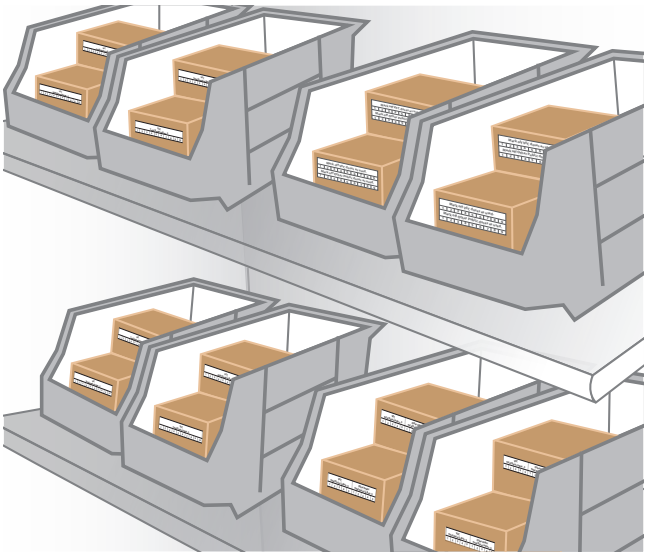
Temperature Monitoring

- Many purpose-built units have multiple temperature probes or sensors. It is important that these probes or sensors have current Certificates of Calibration.
- Many of the purpose-built closed or doorless units may utilize air sensors (non-buffered probes). Since these units have very limited exposure to ambient air, the use of a buffered probe is not essential.
- Many purpose-built units will have built-in digital data loggers with electronic interfaces that will allow you to track the continuous temperatures and/or provide min/max temperatures. If you are a VFC provider, always check to make sure that these satisfy the VFC program data logger requirements.

Vaccine Storage

- Many purpose-built units have undergone testing and temperature mapping so that the probe is in the most appropriate location.
- Although purpose-built units can have multiple temperature probes, a backup DDL is still needed for transport to a backup facility in an emergency.
- Many purpose-built units do not need water bottles to serve as thermal ballast.





WORKSHEET: Vaccine Storage and Handling SOPs

Complete the following checklist and forms and store this information in an easily accessible area near the vaccine storage unit.

CHECKLIST OF GENERAL INFORMATION

» Up-to-date contact information
- Primary vaccine coordinator
- Alternate vaccine coordinator
- Additional staff to assist in emergencies
- Immunization program
- Vaccine manufacturers
- Refrigerator and freezer maintenance and repair companies
- Temperature monitoring device (TMD) companies
- Utility/power company
- Vaccine storage unit alarm company (if applicable)
- Generator repair company (if applicable)
- Sources for qualified containers and packouts

» Descriptions of the roles and responsibilities of the 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

CHECKLIST FOR ROUTINE STORAGE AND HANDLING

» Protocols for:
- Ordering and accepting vaccine deliveries
- Unpacking deliveries
- Managing inventory
- Storing each vaccine and diluent
- Placing vaccines and diluents in storage units
- Handling vaccines prior to administration
- Disposing of vaccines and supplies
- Monitoring storage unit and temperature
- Maintaining storage equipment and TMDs
- Responding to storage and handling problems
- Transporting vaccines to off-site/satellite facilities

CHECKLIST FOR EMERGENCY VACCINE STORAGE, HANDLING, AND TRANSPORT

» All contact information in Checklist for General Information as well as up-to-date contact information for:
- Alternative vaccine storage facility (one or more)
- Transportation of vaccines

» Vaccine storage unit specifications (type, brand, model number, serial number)

» Diagram of facility showing important elements, including doors, flashlights, packing materials, batteries, circuit breakers

» Keep a copy of emergency SOPs with emergency supplies and at multiple off-site locations such as homes of vaccine coordinator and alternate coordinator and with building manager, security staff, and alternative storage facility.

» 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

WORKSHEET: Vaccine Storage and Handling SOPs

Store emergency information with emergency supplies.

STAFF CONTACT LIST			
Name	Title	Telephone Numbers home/cell/other	E-mail Address
	Primary Vaccine Coordinator		
	Alternate Vaccine Coordinator		

EMERGENCY STAFF CONTACT LIST			
Name	Title	Telephone Numbers home/cell/other	E-mail Address
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			
13.			
14.			
15.			

List contacts in order of preference. Determine whether all or certain persons on the list should be contacted or if the first person reached is sufficient.

WORKSHEET: Vaccine Storage and Handling SOPs

GENERAL RESOURCES CONTACT LIST

Resources	Contact Person Name/Title	Telephone Numbers home/cell/other	E-mail Address
Local Health Department Immunization Program			
State Health Department Immunization Program			
Vaccine Manufacturers			
Refrigerator Repair Company			
Freezer Repair Company			
Utility/Power Company			
Temperature Monitoring Device Company			
Vaccine Storage Unit Alarm Company (if applicable)			
Generator Repair Company (if applicable)			

ALTERNATIVE VACCINE STORAGE FACILITIES

Alternative Vaccine Storage Facility Name/Address	Contact Person Name/Title	Telephone Numbers home/cell/other	E-mail Address
1.			
2.			
3.			
4.			

TRANSPORTATION TO ALTERNATIVE VACCINE STORAGE FACILITIES

Emergency Resources Name/Address	Contact Person Name/Title	Telephone Numbers home/cell/other	E-mail Address
Refrigeration Company			
Refrigeration Company (alternative)			
Private Vehicle			
Private Vehicle (alternative)			

WORKSHEET: Vaccine Storage and Handling SOPs

PACKING MATERIAL SUPPLIERS CONTACT LIST

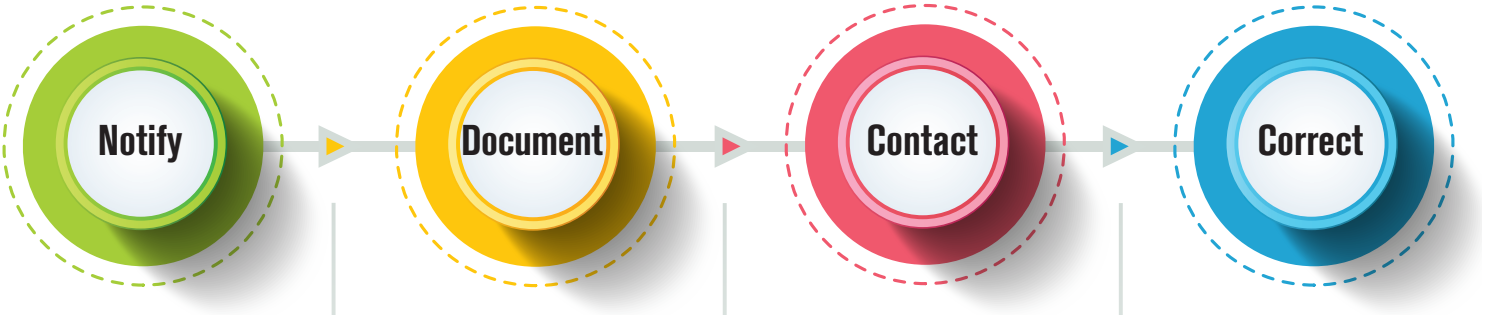
Emergency Resources	Company Name	Contact Person Name/Title	Telephone Numbers home/cell/other	E-mail Address
Portable vaccine refrigerator/freezer units				
Qualified containers and packout materials				
Qualified containers and packout materials (alternative)				
Packing materials				
Packing materials (alternative)				

VACCINE STORAGE UNIT SPECIFICATIONS

Type of Unit (Refrigerator or Freezer)	Brand	Model Number	Serial Number
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

Handling a Temperature Excursion in Your Vaccine Storage Unit

Any temperature reading outside ranges recommended in the manufacturers' package inserts is considered a temperature excursion. Identify temperature excursions quickly and take immediate action to correct them. This can prevent vaccine waste and the potential need to revaccinate patients.



Notify

» Notify the primary or alternate vaccine coordinator immediately or report the problem to a supervisor.

» Notify staff by labeling exposed vaccines, "DO NOT USE," and placing them in a separate container apart from other vaccines in the storage unit. Do not discard these vaccines.

Document

» Document details of the temperature excursion:

- Date and time
- Storage unit temperature (including minimum/maximum temperatures during the time of the event, if available)
- Room temperature, if available
- Name of the person completing the report
- General description of the event (i.e., what happened)
- If using a digital data logger (DDL), determine the length of time vaccine may have been affected
- Inventory of affected vaccines
- List of items in the unit other than vaccines (including water bottles)
- Any problems with the storage unit and/or affected vaccines before the event
- Other relevant information

Contact

» Contact your immunization program and/or vaccine manufacturer(s) for guidance per your standard operating procedures (SOPs).

» Be prepared to provide the immunization program or manufacturer with documentation and DDL data so they can offer you the best guidance.

Contact manufacturer for excursions:	
Dynavax	1-844-375-4728
GlaxoSmithKline	1-888-825-5249
Massachusetts Biological Labs	1-888-825-5249
MedImmune	1-877-633-4411
Merck	1-800-672-6372
Pfizer	1-800-438-1985
Sanofi Pasteur	1-800-822-2463
Seqirus	1-855- 358-8966

Correct

» If the temperature alarm goes off repeatedly, do not disconnect the alarm until you have determined and addressed the cause.

» Check the basics, including:

- Power supply
- Unit door(s)
- Thermostat settings

» If the excursion was the result of a temperature fluctuation, refer to the section, "Vaccine Storage and Temperature Monitoring Equipment," in CDC's *Vaccine Storage and Handling Toolkit* for detailed guidance on adjusting storage unit temperature to the appropriate range.

» If you believe the storage unit has failed, implement your emergency vaccine storage and handling SOPs. Never allow vaccines to remain in a nonfunctioning unit following a temperature excursion.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Fahrenheit to Celsius and Celsius to Fahrenheit Conversion

°F	°C	°F	°C	°F	°C
-22	-30	**21**	-6.1	**64**	17.8
-21	-29.4	**22**	-5.6	**65**	18.3
-20	-28.9	**23**	-5	**66**	18.9
-19	-28.3	**24**	-4.4	**67**	19.4
-18	-27.8	**25**	-3.9	**68**	20
-17	-27.2	**26**	-3.3	**69**	20.6
-16	-26.7	**27**	-2.8	**70**	21.1
-15	-26.1	**28**	-2.2	**71**	21.7
-14	-25.6	**29**	-1.7	**72**	22.2
-13	-25	**30**	-1.1	**73**	22.8
-12	-24.4	**31**	-0.6	**74**	23.3
-11	-23.9	**32**	0	**75**	23.9
-10	-23.3	**33**	0.6	**76**	24.4
-9	-22.8	**34**	1.1	**77**	25
-8	-22.2	**35**	1.7	**78**	25.6
-7	-21.7	**36**	2.2	**79**	26.1
-6	-21.1	**37**	2.8	**80**	26.7
-5	-20.6	**38**	3.3	**81**	27.2
-4	-20	**39**	3.9	**82**	27.8
-3	-19.4	**40**	4.4	**83**	28.3
-2	-18.9	**41**	5	**84**	28.9
-1	-18.3	**42**	5.6	**85**	29.4
0	-17.8	**43**	6.1	**86**	30
1	-17.2	**44**	6.7	**87**	30.6
2	-16.7	**45**	7.2	**88**	31.1
3	-16.1	**46**	7.8	**89**	31.7
4	-15.6	**47**	8.3	**90**	32.2
5	-15	**48**	8.9	**91**	32.8
6	-14.4	**49**	9.4	**92**	33.3
7	-13.9	**50**	10	**93**	33.9
8	-13.3	**51**	10.6	**94**	34.4
9	-12.8	**52**	11.1	**95**	35
10	-12.2	**53**	11.7	**96**	35.6
11	-11.7	**54**	12.2	**97**	36.1
12	-11.1	**55**	12.8	**98**	36.7
13	-10.6	**56**	13.3	**99**	37.2
14	-10	**57**	13.9	**100**	37.8
15	-9.4	**58**	14.4	**101**	38.3
16	-8.9	**59**	15	**102**	38.9
17	-8.3	**60**	15.6	**103**	39.4
18	-7.8	**61**	16.1	**104**	40
19	-7.2	**62**	16.7		
20	-6.7	**63**	17.2		

°C	°F	°C	°F
-30	**-22**	13	**55.4**
-29	**-20.2**	14	**57.2**
-28	**-18.4**	15	**59**
-27	**-16.6**	16	**60.8**
-26	**-14.8**	17	**62.6**
-25	**-13**	18	**64.4**
-24	**-11.2**	19	**66.2**
-23	**-9.4**	20	**68**
-22	**-7.6**	21	**69.8**
-21	**-5.8**	22	**71.6**
-20	**-4**	23	**73.4**
-19	**-2.2**	24	**75.2**
-18	**-0.4**	25	**77**
-17	**1.4**	26	**78.8**
-16	**3.2**	27	**80.6**
-15	**5**	28	**82.4**
-14	**6.8**	29	**84.2**
-13	**8.6**	30	**86**
-12	**10.4**	31	**87.8**
-11	**12.2**	32	**89.6**
-10	**14**	33	**91.4**
-9	**15.8**	34	**93.2**
-8	**17.6**	35	**95**
-7	**19.4**	36	**96.8**
-6	**21.2**	37	**98.6**
-5	**23**	38	**100.4**
-4	**24.8**	39	**102.2**
-3	**26.6**	40	**104**
-2	**28.4**		
-1	**30.2**		
0	**32**		
1	**33.8**		
2	**35.6**		
3	**37.4**		
4	**39.2**		
5	**41**		
6	**42.8**		
7	**44.6**		
8	**46.4**		
9	**48.2**		
10	**50**		
11	**51.8**		
12	**53.6**		

SAMPLE: Stock Record and Tally Sheet

STOCK RECORD

Instructions: Use the monthly stock record to document inventory from new vaccine/diluent shipments and track weekly accounts of doses used. At the end of each month, count inventory in storage unit(s) and compare with recorded balance. If physical count and recorded balance are different, record the actual (physical count) balance next to the previous recorded balance. Note the cause of the discrepancy or if it is unknown. Start a new stock record every month, listing at the top the previous month's balance as the new month's starting balance.

Vaccine Type: PPSV23 Month and Year: August 2023

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)††
08/02/23	BEGINNING BALANCE FOR THE MONTH								2	N/A	2
08/09/23										1	1
08/15/23	LST	G	PPSV23	Merck	MDV	03958	02/15/24	N/A	5	3	3
08/23/23										1	2
08/29/23										0	2

* The initials of the person who unpacked and checked the vaccines/diluents upon arrival
** G = Vaccines/diluents arrived in good condition
? = Condition of vaccines/diluents questionable and state and local health department immunization program and vaccine manufacturer(s) contacted. Document details/outcome on reverse side of stock record.
*** SDV = Single-dose vial
MDV = Multidose vial
MFS = Manufacturer-filled syringe
† Includes number of doses administered, wasted, unusable, expired, or transferred.
†† Enter the sum of "Total Doses Received/Balance Forward" minus "Total Doses Used."

Vaccine Totals	7	5	2

Physical Stock Check (In Doses)	2
Difference ("Balance" minus Physical Stock)	0
Balance Carried Forward (In Doses)	2

Some state or local health department immunization programs have developed their own stock record for immunization providers. Contact program staff for information. If stock records are not available from your state or local health department or an immunization information system (IIS), this stock record may be used.

TALLY SHEET

Instructions: Place a copy of this sheet on or near the refrigerator and freezer doors. Record the week (by date or week number). Write the vaccine/diluent names and indicate the storage location (refrigerator = R, freezer = F). Make a tick mark in the appropriate box for each dose of vaccine/diluent removed from the unit (i.e., each dose administered, wasted, unusable, expired, or transferred). At the end of the week, add the tick marks for each vaccine/diluent and update the totals on the appropriate stock record. File the completed tally sheet and replace with a new sheet.

Week: August 19—23, 2023 (Week 3)

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)					8
R	DTaP	𝍸 𝍸 II (12)					12
R	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

* R = Refrigerator F = Freezer
** Some unusable doses (VFC vaccines or other vaccines purchased with public funds) may need to be returned to your state or local health department immunization program.
*** Viable vaccine doses transferred to your state or local health department immunization program or another facility.

Some state or local health department immunization programs have developed their own tally sheets for immunization providers. Contact program staff for information. If tally sheets are not available from your state or local health department immunization program or an immunization information system (IIS), this tally sheet may be used.

Instructions: Use the monthly stock record to document inventory from new vaccine/diluent shipments and track weekly accounts of doses used. At the end of each month, count inventory in storage unit(s) and compare with recorded balance. If physical count and recorded balance are different, record the actual (physical count) balance next to the previous recorded balance. Note the cause of the discrepancy or if it is unknown. Start a new stock record every month, listing at the top the previous month's balance as the new month's starting balance.

Vaccine Type: _____ Month and Year: _____

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)††
	BEGINNING BALANCE FOR THE MONTH									**N/A**	

* The initials of the person who unpacked and checked the vaccines/diluents upon arrival

** G = Vaccines/diluents arrived in good condition
? = Condition of vaccines/diluents questionable and state and local health department immunization program and vaccine manufacturer(s) contacted. Document details/outcome on reverse side of stock record.

*** SDV = Single-dose vial
MDV = Multidose vial
MFS = Manufacturer-filled syringe

† Includes number of doses administered, wasted, unusable, expired, or transferred.

†† Enter the sum of "Total Doses Received/Balance Forward" minus "Total Doses Used."

Vaccine Totals	
Physical Stock Check (In Doses)	
Difference ("Balance" minus Physical Stock)	
Balance Carried Forward (In Doses)	

Some state or local health department immunization programs have developed their own stock record for immunization providers. Contact program staff for information. If stock records are not available from your state or local health department or an immunization information system (IIS), this stock record may be used.

Tally Sheet

Instructions: Place a copy of this sheet on or near the refrigerator and freezer doors. Record the week (by date or week number). Write the vaccine/diluent names and indicate the storage location (refrigerator = R, freezer = F). Make a tick mark in the appropriate box for each dose of vaccine/diluent removed from the unit (i.e., each dose administered, wasted, unusable, expired, or transferred). At the end of the week, add the tick marks for each vaccine/diluent and update the totals on the appropriate stock record. File the completed tally sheet and replace with a new sheet.

Week: _____

Storage Location (R or F)*	Vaccine or Diluent Name	Doses Administered	Doses Wasted	Doses Expired	Doses Unusable**	Doses Transferred (Viable)***	Total

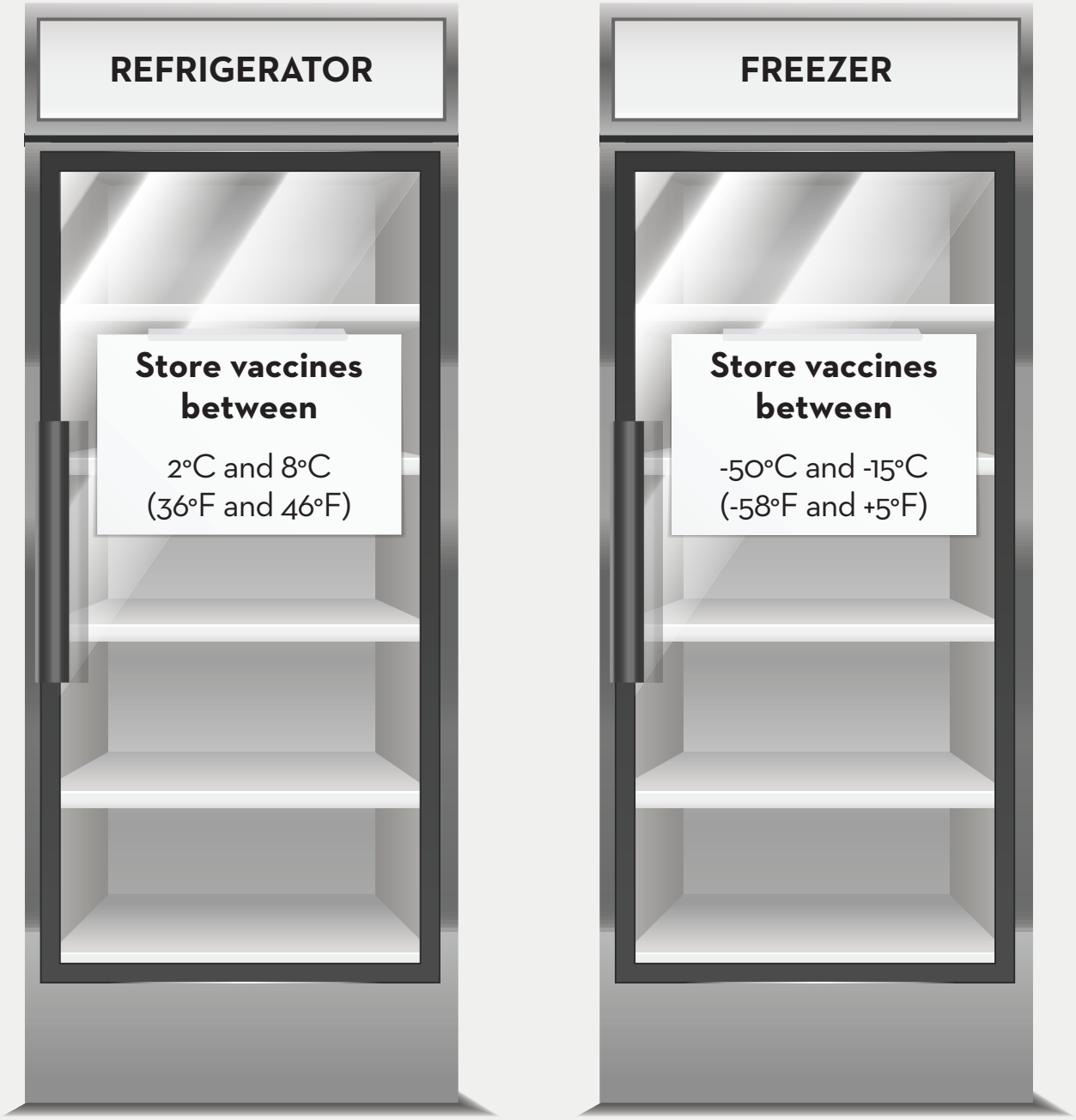
* R = Refrigerator F = Freezer

** Some unusable doses (VFC vaccines or other vaccines purchased with public funds) may need to be returned to your state or local health department immunization program.

*** Viable vaccine doses transferred to your state or local health department immunization program or another facility.

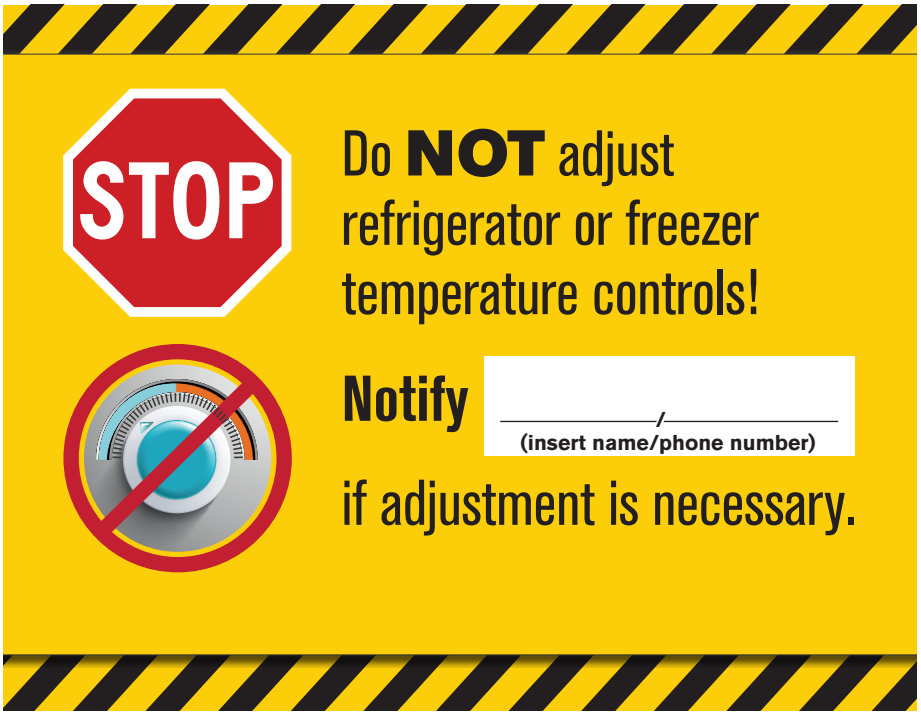
Some state or local health department immunization programs have developed their own tally sheets for immunization providers. Contact program staff for information. If tally sheets are not available from your state or local health department immunization program or an immunization information system (IIS), this tally sheet may be used.

HANDLE WITH CARE: Protect Your Vaccine | Protect Your Patients

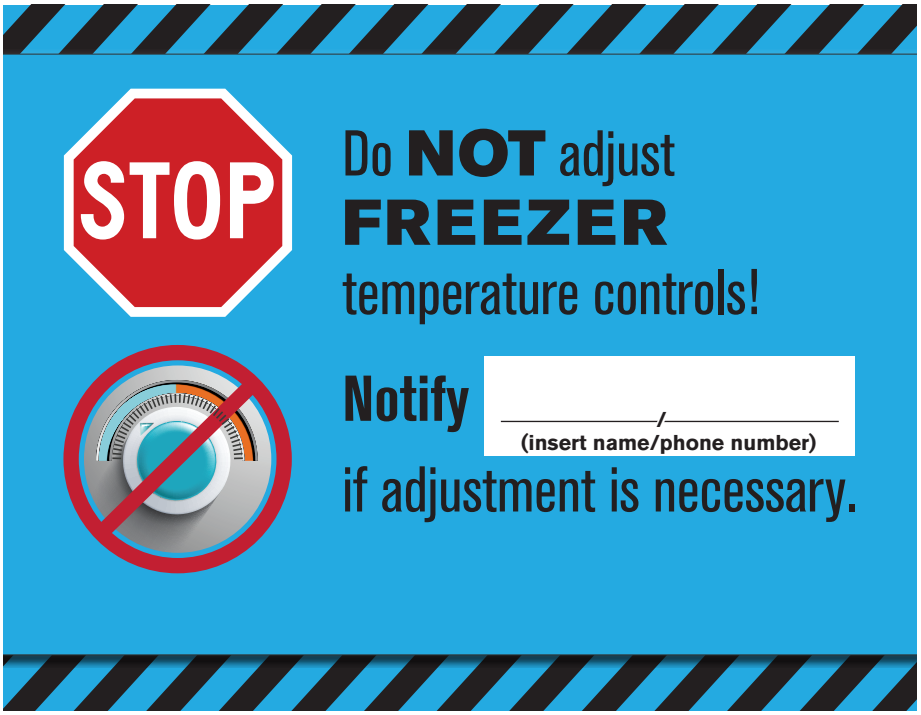


- Keep your storage units and vaccines within the appropriate temperature ranges.
- Check and record storage unit min/max temperatures at start of each workday. If your device does not display min/max temperatures, then check and record current temperature a minimum of 2 times (at start and end of workday). Also check current temperature before accessing and administering vaccine.
- Take immediate action if temperatures are out of range.
- Keep vaccines in their original packages.
- Many vaccines should be protected from light (consult manufacturer's product information).
- Check expiration dates and rotate your vaccine stock to keep most recent expiration dates at the front.

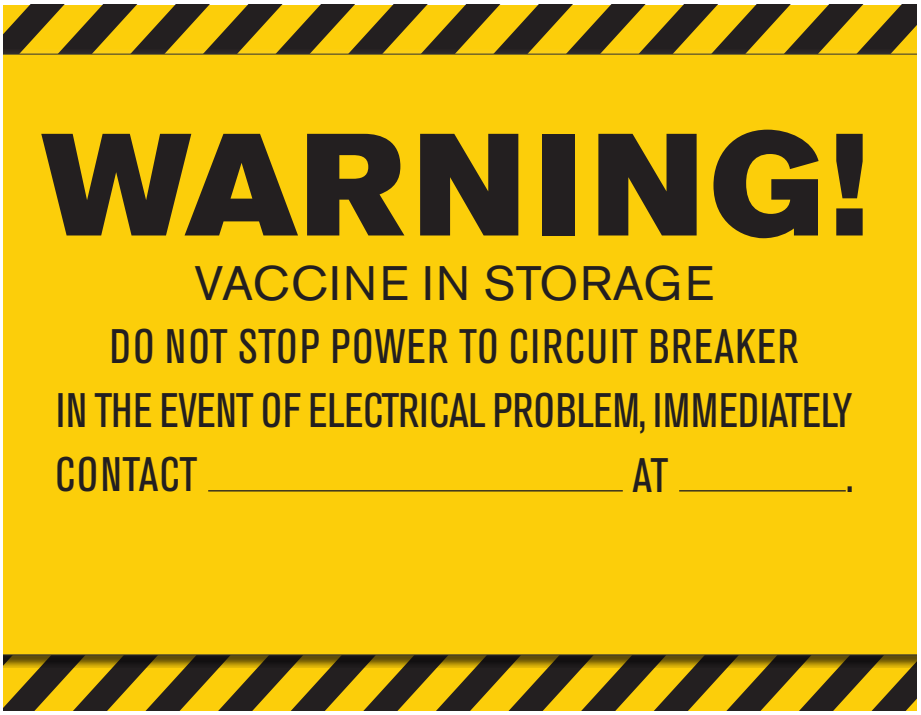
WARNING LABELS: Do Not Adjust Refrigerator Controls



WARNING LABELS: Do Not Adjust Freezer Controls



WARNING LABELS: Warning! Do Not Stop Power to Circuit Breaker



WARNING LABELS: Warning! Do Not Unplug Refrigerator

WARNING!

DO **NOT** UNPLUG THE **REFRIGERATOR** OR BREAK CIRCUIT.

VACCINE IN STORAGE.

IN THE EVENT OF ELECTRICAL PROBLEM, IMMEDIATELY CONTACT: _____/_____.

(insert name/phone number)

¡AVISO!

NO DESCONECTE EL **REFRIGERADOR** NI CORTE EL CIRCUITO.

¡CONTIENE VACUNAS!

SI HAY UN PROBLEMA CON LA ELECTRICIDAD, COMUNIQUESE INMEDIATAMENTE CON:

_____/_____.

(inserte nombre y número de teléfono aqui)

WARNING LABELS: Warning! Do Not Unplug Freezer

WARNING!

DO **NOT** UNPLUG THE **FREEZER** OR BREAK CIRCUIT.

VACCINE IN STORAGE.

IN THE EVENT OF ELECTRICAL PROBLEM, IMMEDIATELY CONTACT: _____/_____.

(insert name/phone number)

¡AVISO!

NO DESCONECTE EL **CONGELADOR** NI CORTE EL CIRCUITO.

¡CONTIENE VACUNAS!

SI HAY UN PROBLEMA CON LA ELECTRICIDAD, COMUNIQUESE INMEDIATAMENTE CON:

_____/_____.

(inserte nombre y número de teléfono aqui)

TRANSPORT LABELS: Refrigerate/Freeze Upon Arrival

TRANSPORT LABELS: Open Immediately: Refrigerate/Freeze Upon Receipt

TRANSPORT LABELS: Fragile: Handle with Care

TRANSPORT LABELS: Perishable: Rush

COVID-19 AND MPOX VACCINES STORAGE AND HANDLING

This addendum to the *Vaccine Storage and Handling Toolkit* (January, 2023) provides information, recommendations, and resources to assist COVID-19 and mpox vaccination providers in properly storing and handling COVID-19 vaccines to meet the requirements of the Vaccination Program Provider Agreement. The toolkit brings together best practices from the Advisory Committee on Immunization Practices (ACIP) General Best Practice Guidelines for Immunization, product information from vaccine manufacturers, and results of scientific studies. Implementing the toolkit best practices and recommendations will help to safeguard the vaccine supply and ensure patients receive safe and effective vaccines.

This addendum provides information on storage and handling best practices for COVID-19 vaccines and mpox vaccines. This addendum will be updated with specific storage and handling information for each vaccine product as it is authorized under an Emergency Use Authorization or approved by the Food and Drug Administration (FDA).

Vaccination Provider Requirements

All COVID-19 and mpox vaccination providers participating in the U.S. COVID-19 Vaccination Program and U.S. Monkeypox Vaccination Program are required to sign a Vaccination Program Provider Agreement to receive delivery of any COVID-19 or mpox vaccine from the distributor or a vaccine manufacturer. The agreement must be completed by all public and private providers, provider organizations, and government-affiliated federal, state, territorial, and local providers.

As part of the agreement, providers are required to:

- Store and handle vaccines under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with an EUA or vaccine package insert, manufacturer guidance, and CDC guidance in this toolkit.
- Monitor storage unit temperatures at all times, using equipment and practices that comply with guidance in this toolkit.
- Comply with immunization program guidance for handling temperature excursions.
- Monitor and comply with vaccine expiration dates and beyond-use dates/times.
- Preserve all records related to vaccine management for a minimum of three years.
- Comply with federal instructions and timelines for disposing of vaccine and diluent (if applicable), including unused doses.

Emergency Use Authorization Storage and Handling Information

Specific, detailed storage and handling protocols for individual vaccines are provided in manufacturer package inserts for vaccines licensed by the Food and Drug Administration (FDA). However, some vaccines are currently authorized for use under an EUA so vaccination providers should refer to the Fact Sheet for Healthcare Providers Administering Vaccine and manufacturer information for detailed storage and handling information for each vaccine.

Vaccine Cold Chain

Vaccines require a temperature-controlled environment. A cold chain is a temperature-controlled supply chain that includes all vaccine-related equipment and procedures. It begins with vaccine manufacturing and ends with vaccine administration. Vaccines must be stored properly from the time they are manufactured until they are administered. Potency is reduced every time a vaccine is exposed to an improper condition. This includes overexposure to heat, cold, or light at any step in the cold chain. Once lost, potency cannot be restored.

An effective cold chain relies on three main elements:

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

Vaccine appearance is not a reliable indicator that vaccines have been stored in appropriate conditions.

COVID-19 AND MPOX VACCINES STORAGE AND HANDLING

Staff and Training

All staff members who receive vaccine deliveries as well as those who handle or administer vaccines should be trained in vaccine-related practices and procedures. As a resource for staff, this toolkit highlights storage and handling best practices to help protect the vaccine supply. In addition, CDC's *You Call the Shots*: Vaccine Storage and Handling is a free, online training module focused on storage and handling requirements. Jurisdictions may also have specific requirements for storage and handling training, policies, and procedures.

All facilities must designate a primary vaccine coordinator and an alternate (backup) coordinator who will be responsible for ensuring all vaccines are stored and handled correctly. The primary and alternate vaccine coordinators should be experts on your facility's storage and handling procedures.

See Section Two, "Staff and Training," in the toolkit for more detailed information.

Vaccine Storage and Temperature Monitoring Equipment

COVID-19 and mpox vaccination providers must have proper storage and temperature monitoring equipment to meet the specific needs of the vaccine product(s) in their inventory. This includes the correct vaccine storage unit(s), whether a refrigerator, regular freezer, or ultra-cold freezer. Purpose-built, also referred to as "pharmaceutical-grade," units are preferred and designed specifically for storage of biologics, including vaccines. However, household-grade units can be an acceptable alternative in some situations. Most standard freezer units do not meet ultra-cold freezer requirements for storing vaccine between -60° C and -90° C (-76° F and -130° F).

It is essential that each vaccine storage unit has a temperature monitoring device (TMD) to ensure that vaccines are stored within the correct temperature range. CDC requires a specific type of TMD called a "digital data logger" (DDL) to monitor COVID-19 and mpox vaccines. A DDL provides the most accurate storage unit temperature information. Additionally, in the event of a temperature excursion (temperatures outside the correct range), a DDL can indicate how long and the temperatures the vaccine has been exposed to. This information is needed to determine the viability of the vaccine.

Always use a DDL that can continously monitor storage unit temperatures and has a:

- Buffered temperature probe
- Current and valid certificate of Calibration Testing

CDC recommends developing and maintaining clearly written, detailed, and up-to-date storage and handling standard operating procedures (SOPs). SOPs help ensure proper procedures are followed and problems are identified, reported, and corrected. SOPs should also provide direction for handling emergencies such as equipment malfunctions, power failures, or natural disasters.

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 pose a significant risk of freezing vaccines, even when used for temporary storage. (Note: Not all small storage units are dormitory- or bar-style units. Compact, purpose-built units for biologics can be used to store vaccines.)

Diluents

Vaccines often need to be mixed with a liquid product before administration. A diluent may be a normal saline product or may contain an adjuvant for vaccine effectiveness. Always follow the vaccine manufacturer's guidance for use of the diluent. Diluents are not interchangeable and can only be used with the product for which they are provided.

DDLs for Ultra-Cold Temperatures

DDLs using a buffered temperature probe provide the most accurate measurement of vaccine temperatures. However, many manufacturers use pure propylene glycol (freezing point -59° C (-74° F)) or a glycol mixture with a warmer freezing point. For accurate ultra-cold temperature monitoring, it is essential to use an air-probe or a probe designed specifically for ultra-cold temperatures with the DDL.

COVID-19 AND MPOX VACCINES STORAGE AND HANDLING

Temperature Monitoring Requirements

Staff must check and record temperatures at the beginning of each workday to determine if any excursions have occurred since the last temperature check.* Monitor and record storage unit temperatures following one of these options.

When recording include:

- Minimum/maximum temperature†
- Date
- Time
- Name of person checking and recording temperature
- Actions taken if a temperature excursion occurred

Food and beverages should never be stored in the unit with vaccines. If other biologics are stored in the unit, vaccines should be stored on the shelf above them.

CDC has temperature logs can that can be used for recording this information. Temperature records must be kept for a minimum of three years, or longer if required by your jurisdiction.

Storing vaccines correctly in a vaccine storage unit is also critical to protect the vaccine and reduce the chance of vaccine administration errors if COVID-19 or mpox vaccine are stored with other vaccines. Best practices include:

- Place water bottles on the top shelf, floor, and in the door racks of vaccine storage units to help maintain stable temperatures that might be disrupted by frequently opening and closing unit doors. (Note: Water bottles are not recommended for use in in ultra-cold freezers or in all purpose-built or pharmaceutical-grade units—see manufacturer guidance.)
- Avoid placing or storing any items other than vaccines, refrigerated diluents, and water bottles inside storage units.
- Store vaccines and diluents in original packaging.
- Position vaccines and diluents two to three inches from the storage unit walls, ceiling, floor, and door. If using a household-grade unit, avoid storing vaccines and diluents in any part of the unit that may not provide stable temperatures or sufficient air flow.
- Arrange vaccines and diluents in rows and allow space between them to promote air circulation.

Place vaccines and diluents with the earliest expiration dates in front of those with later expiration dates. Of note, EUA vaccine labels may not include expiration dates. To help providers track expiration dates and beyond-use dates (BUDs), CDC has a COVID-19 Vaccine Expiration Date Tracking Tool on its website available. Also note that expiration dates may change as additional stability data become available. In addition, mpox vaccine and some COVID-19 vaccines must be used within a certain time frame (beyond-use date) if moved from one state to another (e.g., frozen to refrigerated). Providers should monitor/track the BUD to ensure vaccine is not used after the BUD has been reached.

See Section Three, "Vaccine Storage and Temperature Monitoring Equipment," for more detailed information about storage units, temperature monitoring equipment, and vaccine placement in vaccine storage units.

"Temperature Excursions"

Any temperature reading outside the range recommended by the manufacturer is considered a temperature excursion and requires immediate action. To determine whether a vaccine is likely to still be viable, vaccine manufacturers will analyze information about the magnitude of the temperature excursion, including the total amount of time that temperatures were out of range. To provide the manufacturer with sufficient information to determine vaccine viability, CDC requires taking the following steps after a temperature excursion:

- Label the vaccine "Do Not Use" and store at the recommended temperature range until you receive manufacturer guidance. If it is a frozen vaccine that has been thawed, store in the refrigerator between 2° C and 8° C (36° F and 46° F) until you receive manufacturer guidance, as refreezing the vaccine may damage it.
- Document the date and length of time of the excursion, the storage unit temperature (minimum/maximum, if available), and inventory affected.
- Record any other relevant information.
- Contact the manufacturer and/or immunization program for guidance on whether to use affected vaccines and whether patients need to be recalled for revaccination.
- Document the event and actions taken for record-keeping requirements.

* Monitoring requirements may vary if you are using the manufacturer-provided shipping container for storage.
† If the DDL cannot display the minimum/maximum temperatures, record the current temperature at the beginning and end of each work day.

COVID-19 AND MPOX VACCINES STORAGE AND HANDLING

It is important to note that vaccine manufacturer responses to temperature excursion reports are dependent on information given by the provider to the manufacturer. Different information about the same event can lead to different recommendations on whether vaccine can be used or whether patients need to be revaccinated. In addition, each event is unique, and manufacturer recommendations cannot be applied to future events that may appear similar to past events. For manufacturer contact information for vaccine- and temperature-related questions, see the COVID-19 or mpox vaccines specific product information page in this addendum.

See Section Three, "Vaccine Storage and Temperature Monitoring Equipment," for more additional information about recording and reporting temperature excursions.

Vaccine Deliveries and Vaccine Inventory Management

Proper vaccine inventory management is essential for appropriate vaccine ordering and stock rotation and ensures your facility has the vaccines your patients need.

Maintaining the cold chain is the first step in vaccine inventory management. Vaccine deliveries must only be scheduled at times when staff is guaranteed to be present because vaccines can never be left unattended. To support efficient distribution of vaccine, full-day receiving hours should be available. When that is not possible, locations receiving vaccine and ancillary supply shipments must be available during a four-hour window on a weekday other than Monday. All COVID-19 vaccine and ancillary kit deliveries will require a signature. Deliveries of mpox vaccine do not require a signature.

Upon arrival, all shipments of vaccine must be immediately examined for signs of damage, for indication of a temperature excursion during transit, and to confirm receipt of the appropriate vaccine types and quantities. Before opening a vaccine shipment, ensure the vaccine and any diluent, if applicable, is immediately:

- Stored at recommended storage conditions.
- Documented using your facility's vaccine inventory management process.

Vaccine inventory accounting includes keeping stock records to determine the type and amount of COVID-19 and mpox vaccines your facility should stock to meet the needs of your patients. It also involves checking expiration dates regularly and rotating stock so that doses with the earliest expiration dates are placed in front of those with later dates.

COVID-19 Vaccine Ancillary Supplies

COVID-19 vaccine shipments will include ancillary supplies:

- Needles (various sizes for the population served)
- Syringes
- Alcohol prep pads
- Surgical masks and face shields for vaccinators
- COVID-19 vaccination record cards for vaccine recipients
- Vaccine needle and length guide
- Diluent and mixing supplies (based on vaccine product)

Mpox vaccine shipments do **NOT** include ancillary supplies.

Never leave a vaccine shipping container unpacked and unattended. If vaccines and diluents get too warm, they cannot be used. Be sure all staff knows that vaccine deliveries require immediate attention.

See Section Four, "Vaccine Inventory Management," for additional information about vaccine inventory accounting measures.

Expired Vaccine

Determining when a vaccine or diluent expires is a critical step in proper storage and handling.

Expired vaccines and diluents must be removed immediately from storage units to avoid inadvertently administering them. Manufacturers may have specific guidance on how to handle expired or compromised vaccines. However, open or broken vials and vaccine predrawn by providers cannot be returned and must be discarded according to your jurisdiction's requirements.

To help vaccination providers track expiration dates and beyond-use dates (BUDs), CDC has developed product specific tracking tools and labels:

- COVID-19 Vaccine
- Mpox Vaccine

COVID-19 AND MPOX VACCINES STORAGE AND HANDLING

Vaccine Disposal

Medical waste disposal requirements are set by state environmental agencies and may vary from state to state. Your jurisdiction's immunization program or environmental agency can provide guidance to ensure your facility's vaccine disposal procedures comply with state and federal regulations. Vaccine manufacturers should also provide guidance about proper disposal of their products, including any unused vaccine. In some instances, unused vaccine may be returned to the manufacturer. Empty vaccine vials are usually not considered hazardous or pharmaceutical waste and do not require disposal in a biomedical waste container. However, check and comply with your jurisdiction's requirements for disposal.

Vaccine Preparation

Preparing vaccine properly is critical to maintaining the integrity of the vaccine during transfer from the manufacturer's vial to the syringe and, ultimately, to the patient. CDC recommends preparing and drawing up vaccines just before administration. It is important to follow vaccine preparation instructions provided in the vaccine product's Fact Sheet for Vaccination Providers or the manufacturer package insert.

Vaccine products may have different preparation requirements. Some should not be shaken, or the vaccine will be compromised and cannot be used. Carefully follow the manufacturer's vaccine preparation guidance. Diluents, if applicable, are not interchangeable unless specified by the manufacturer. Vaccine mixed with the wrong diluent should never be administered.

See Section Five, "Vaccine Preparation," for detailed information about vaccine preparation.

Vaccine Preparation Best Practices

- Prepare vaccines in a designated area away from any space where potentially contaminated items are placed.
- Always follow the manufacturer's instructions for preparing vaccine.
- Only prepare vaccines when you are ready to administer them.
- Always check expiration dates. If your facility stocks multiple vaccine products, always confirm 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.

Predrawing vaccine can result in waste when more is drawn up than needed. In the rare instances when it is necessary to predraw vaccines, it is important to follow recommended guidance to avoid compromising and wasting vaccine and to maintain the cold chain. Carefully follow the toolkit best practices for predrawing vaccine as well as any manufacturer guidance.

COVID-19 Vaccine Transport

In most instances, vaccine will be delivered directly to the facility where it will be administered to maintain the vaccine cold chain. However, there may be circumstances where vaccine needs to be redistributed or transported. This can occur if:

- A CDC Supplemental COVID-19 Vaccine Redistribution Agreement is in place for vaccine to be redistributed beyond the identified primary CDC ship-to site (i.e., for larger organizations whose vaccine is shipped to a central depot and requires redistribution to additional clinic locations).
- A jurisdiction immunization program or commercial partner needs to redistribute vaccine within the jurisdiction based on need or to keep vaccine from being wasted.
- Vaccine needs to be transported for satellite, temporary, or off-site clinics, including programs at long-term care facilities, or for administration to patients such as those in a home healthcare program.

Mpox Vaccine Transport

Mpox vaccine is shipped from Strategic National Stockpile (SNS) sites to vaccine depots. Before storing vaccine,

- Examine the shipment for signs of damage.
- Check TempTale temperature monitoring device or DDL for temperature excursions.

If vaccine needs to be further transported (i.e., from vaccine depots to health departments or clinics), unpack vaccine from Credo Crates and repackage into an appropriate transport system as outlined in the Transport guidance here. Expiration date should be recorded when vials are separated from original packaging.

COVID-19 AND MPOX VACCINES STORAGE AND HANDLING

In these instances, appropriate precautions must be taken to protect the vaccine. Vaccine must only be transported using appropriate packing materials that provide maximum protection. Follow specific jurisdiction and federal direction for transporting vaccine products.

Transporting vaccine requires planning and preparation to ensure the cold chain is maintained. As a vaccination provider, you should carefully review Section Six, "Vaccine Transport," to ensure your facility has the appropriate procedures and supplies in place to safely transport vaccine. Transport guidance may vary based on the specific vaccine product.

The chart below shows general transport recommendations to maintain the vaccine cold chain in two situations: emergency transport and transport for use at off-site clinics or satellite facilities or for relocation of stock. Recommendations vary based on the situation. Some vaccine products may have specific transport guidance to ensure the cold chain is maintained and vaccine is protected. Refer to the relevant vaccine product information in this addendum for additional information.

COVID-19 Vaccine Transport Requirements

- Vaccine must be transported in a stable storage unit and monitored with a DDL. Record the time and minimum/maximum temperature at the beginning of transport. In most instances, packing materials that vaccines were initially shipped in are not meant for reuse (the most common exception is ultra-cold vaccine shipping materials).
- Transport equal amounts of vaccines, diluent (if needed), and supplies needed to administer and document vaccines.
- Immediately upon arrival at the destination, the time and minimum/maximum temperature must be recorded. Vaccines should be stored in an appropriate storage unit with a DDL. If this is not possible, vaccines should be kept in the portable storage unit and the unit temperature recorded every time the portable unit is opened.

CDC recommends transporting vaccine in vials. However, there may be instances when the only option is to transport vaccine in a predrawn syringe prepared by the provider. This should only occur when vaccine is in a multidose vial. U.S. Pharmacopeia includes guidance for transporting predrawn vaccine in syringes in the USP COVID-19 Vaccine Toolkit: Operational Considerations for Healthcare Practitioners.

A partially used vial cannot be transferred from one provider to another or across state lines.

General Transport System Recommendations	Emergency Transport	Transport for Off-Site Clinic, Satellite Facility, or Relocation of Stock
Portable Vaccine Refrigerator, Freezer, or Ultra-cold Freezer	Yes	Yes
Qualified Container and Packout	Yes	Yes
Conditioned Water Bottle Transport System	Yes	**No**
Manufacturer's Original Shipping Container	Yes (last resort only)	No
Food/Beverage Coolers	No	No

Emergency Storage and Handling

Emergencies such as equipment failures, power outages, severe weather conditions, or natural disasters usually happen without warning and may compromise storage conditions. It is critical that vaccination providers have plans in place for emergency situations. Some key issues to remember include:

- Vaccines may remain inside a nonfunctioning unit as long as appropriate temperatures are maintained. Monitor your DDL to determine when additional action should be taken.
- Having an on-site generator(s) prevents the need to transport vaccines to an alternative storage facility during a power outage.
- Emergency situations can arise outside of normal business hours, so your office staff as well your facility's building manager and/or security staff, if appropriate, must understand how to implement your emergency operation plans or access your facility if necessary.
- Ensure your facility has the resources on hand to safely pack vaccines for transport during emergencies.

See Section Seven, "Emergency Vaccine Storage and Handling," for additional information about monitoring and handling vaccine during an emergency.

COVID-19 AND MPOX VACCINES STORAGE AND HANDLING

Additional Resources

- ACIP's *General Best Practice Guidelines for Immunization*: www.cdc.gov/vaccines/hcp/ acip-recs/general-recs/index.html
- Educational webinars and continuing education for healthcare providers: www.cdc.gov/vaccines/ed/courses.html
- Emergency Use Authorization: www.youtube.com/watch?v=iGkwaESsGBQ&feature=youtu.be
- *Epidemiology and Prevention of Vaccine-Preventable Diseases*: www.cdc.gov/vaccines/pubs/pinkbook/index.html
- FDA Center for Biologics Evaluation and Research (CBER) information concerning the storage and use of temperature-sensitive biological products that have been involved in a temporary electrical power failure or flood conditions: www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/
- Federal Emergency Management Agency (FEMA) information on disaster preparedness: www.fema.gov/
- Immunization Action Coalition Refrigerator and Freezer Temperature Log Sheets and Vaccine Troubleshooting Record: www.immunize.org/va/va52_temperature-logs-iac.pdf
- Jurisdiction immunization programs: www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html
- Packing Vaccines for Transport during Emergencies: www.cdc.gov/vaccines/recs/storage/downloads/emergency-transport.pdf
- *You Call the Shots*: Vaccine Administration: www2.cdc.gov/vaccines/ed/vaxadmin/va/ce.asp
- *You Call the Shots*: Vaccine Storage and Handling: www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp
- Vaccine Administration home page: www.cdc.gov/vaccines/hcp/admin/admin-protocols.html
- Vaccine Storage and Handling home page: www.cdc.gov/vaccines/recs/storage/default.htm (sign up for notifications about updates)
- *Vaccine Storage and Handling Toolkit* web page: www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html

Disclaimer: *Use of trade names and commercial sources in the addendum is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services (DHHS), the U.S. Public Health Service (PHS), or the Centers for Disease Control and Prevention (CDC). You may see vendors use terms such as "CDC-compliant," or "satisfies federal COVID-19 vaccine response requirements" in their marketing materials or on their websites. In this context, "compliance" and related terms may lead consumers to incorrectly believe that CDC has independently assessed and verified the quality of these products. CDC is not authorized to assess, validate, verify, or endorse the products or services of private companies. Should you encounter this type of language in vendor marketing materials, please keep in mind that CDC has not validated any product or service for compliance with vaccination provider requirements or standards as outlined in the COVID-19 and Mpox Vaccination Provider Agreement.*

COVID-19 Vaccine (Pfizer-BioNTech)

Products: Pfizer-BioNTech COVID-19 Vaccine (Monovalent/Bivalent Gray cap Age 12 and Older), (Monovalent/Bivalent Orange Cap Ages 5 through 11), (Monovalent/Bivalent Maroon Cap Ages 6 months through 4 years)

Manufacturer Website: www.cvdvaccine.com

Manufacturer Phone Number: 1-877-829-2619 (1-877-VAX-CO19)

CDC Clinical Guidance for Pfizer-BioNTech COVID-19 Vaccine: www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html

Ages: 6 months through 4 years
(Maroon capped vial and bordered label)

MONOVALENT Primary Series (Dose 1 & 2)

BIVALENT Primary Series (Dose 3)

Ages: 5 through 11 years
(Orange capped vial and bordered label)

MONOVALENT Primary Series

BIVALENT Booster Dose

Ages: 12 and older
(Gray capped vial and bordered label)

MONOVALENT Primary Series

BIVALENT Booster Dose Single-dose and Multidose Vials

Vaccine Temperature Ranges:

- Ultra-cold: -90°C and -60°C (-130°F and -76°F) until the expiration date
- Refrigerated: 2°C and 8°C (36°F and 46°F) for up to 10 weeks

Vaccine Storage Unit(s):

- Ultra-cold freezer
- Refrigerator

Temperature Monitoring Device: For accurate temperature monitoring, use a digital data logger (DDL) able to measure minimum and maximum temperatures..

- **Ultra-cold freezer**: Use a DDL with an air-probe or a probe designed specifically for ultra-cold temperatures.
- **Refrigerator:** Use a DDL with a detachable probe that best reflects vaccine temperatures (e.g., probe buffered with glycol, glass beads, or Teflon®).

Delivery:

- Vaccine arrives in a thermal shipping container at temperatures between -90°C and -60°C (-130°F and -76°F) with dry ice or between -25°C and -15°C (-13°F and 5°F).
- Ancillary supplies kit(s), including diluent if needed, will arrive in a separate shipment from the the vaccine. Each kit includes the number of supplies needed to support the number of doses ordered. Vaccine for ages:
  - » 6 months through 4 years requires diluent
  - » 5 through 11 years requires diluent
  - » 12 years and older does NOT require diluent
- Follow the manufacturer's guidance for unpacking the vaccine and returning the temperature monitoring device and container, if indicated. (www.cvdvaccine-us.com/5-11-yearsold/storage-and-handling).
- Dispose of the single-use thermal shipping container. Do **NOT** use the thermal shipping container for storage.
- Ancillary supply kits will be delivered separately from the vaccine and have been reconfigured to support the number of doses ordered. **Note:** There are no ancillary supplies for Pfizer-BioNTech vaccine for persons 12 years of age and older (gray-capped vial)

COVID-19 Vaccine (Pfizer-BioNTech)

Storage Information: Vaccine can be stored in an ultra-cold freezer or a refrigerator following routine storage and handling best practices. Do **NOT** store in the thermal shipping container or a freezer.

Ultra-Cold Freezer

Store unpunctured vials between -90°C and -60°C (-130°F and -76°F) until the expiration date.

» Store vials upright in the tray or box protected from light
» Use Pfizer-BioNTech's expiration date tool at lotexpiry.cvdvaccine.com

Refrigerator

Store unpunctured vials between 2°C and 8°C (36°F and 46°F) for up to 10 weeks

» Store the vaccine vials upright.
» Protect from light.
» Do **NOT** refreeze thawed vaccine.
» Use CDC's beyond-use date labels for Pfizer-BioNTech COVID-19 Vaccine.

Temperature Monitoring:

Ultra-cold freezer or refrigerator:

Storage unit temperatures must be monitored regularly, checked, and recorded to determine if any temperature excursions have occurred since the last temperature check. For accurate temperature monitoring, use a digital data logger (DDL) with a detachable probe that best reflects vaccine temperatures.

» Most digital data loggers display the minimum maximum (min/max) temperatures. Check and record the min/max temperature at the start of each workday. (preferred method)
» If the digital data logger is unable to display min/max temperatures, check and record the current temperature at the start and end of each workday.

Transport:

CDC does not recommend routine transport of vaccines. Ideally, vaccines should be delivered directly to the facility where they will be used. If vaccines must be transported, follow:

- Manufacturer's guidance
- CDC Pfizer-BioNTech COVID-19 Transport Summary
- Routine vaccine storage and handling transport guidance outlined in this toolkit.

CDC recommends transporting vaccine in vials. However, there may be instances when the only option is to transport vaccine in a predrawn syringe. U.S. Pharmacopeia includes guidance for transporting predrawn vaccine in syringes in the USP COVID-19 Vaccine Toolkit: Operational Considerations for Healthcare Practitioners.

COVID-19 Vaccine (Pfizer-BioNTech)

Vaccine Preparation and Administration:

Use the correct product based on the age of the recipient.

Vial cap color	 Monovalent Maroon Cap	 Bivalent Maroon Cap	 Monovalent Orange Cap	 Bivalent Orange Cap	 Monovalent Gray Cap	 Bivalent Gray Cap
Ages	**6 months through 4 years**		**5 through 11 years**		**12 years and older**	
Supplied in:	MDV*: 10 doses per vial **Requires diluent**	MDV*: 10 doses per vial **Requires diluent**	MDV*: 10 doses per vial **Requires diluent**	MDV*: 10 doses per vial **Requires diluent**	MDV*: 6 doses per vial **No diluent**	MDV*: 6 doses per vial SDV*: 1 dose **No diluent**

* MDV=multidose vial; SDV=single-dose vial

- Frozen vaccine must be thawed prior to use.
- Thaw vaccine between 2°C and 8°C (36°F and 46°F) or between 8° C and 25° C (46° F and 77° F). The amount of time needed to thaw vaccine varies based on the temperature and number of vials.
  - » **Unpunctured vials** may be held between 8° C and 25° C (46° F and 77° F) for a total of 12 hours.
- Single-dose vials contain 1 dose of vaccine. Use a new vial for each recipient.
- Mix vaccine with diluent if indicated. Use a new vial of diluent for each vial.

Diluent	Maroon capped vial 6 months through 4 years		Orange capped vial 5 through 11 years		Gray capped vial 12 years and older	
0.9% sodium chloride; preservative free diluent	Monovalent	Bivalent	Monovalent	Bivalent	Monovalent	Bivalent SDV and MDV
	2.2 mL	2.2mL	1.3 mL	1.3 mL	NONE	NONE

- During vaccine preparation, gently swirl after thawing and between each withdrawal from a multidose vial. Do not shake the vial. If shaken, contact the manufacturer.
- Administer by intramuscular (IM) injection using a new needle and syringe for each injection.
  - » **Punctured vials** maybe be kept between 2°C and 25°C (35°F to 77°F) for up to 12 hours. Discard the vial and any remaining vaccine after 12 hours.
- Discard vials (multidose or single dose) when there is not enough vaccine to obtain a complete dose. Do NOT combine residual vaccine from multiple vials to obtain a dose.

Special Considerations:

- To determine the expiration date use Pfizer-BioNTech's expiration date tool at lotexpiry.cvdvaccine.com.
- If unable to access the tracking tool, count out 12 months using the month printed on the vial as month 1. The vaccine expires on the last day of the 12th month. For example, the vial has January 2023 printed on it. December 2022 would be the 12th month and the vaccine would be expired December 31, 2023.
- Expired vaccine or vaccine past the BUD, should NEVER be administered. To prevent this, use CDC expiration date and BUD tracking tools.

COVID-19 Vaccine (Moderna)

Products: Moderna COVID-19 Vaccine (Monovalent primary series 6 months through 5 years, Monovalent primary series 6 through 11 years, Monovalent primary series12 years and older, Bivalent booster doses 6 months through 5 years of age and Bivalent booster doses 6 years and older)

Manufacturer Website: www.modernatx.com/covid19vaccine

Manufacturer Phone Number: 1-866-MODERNA (1-866-663-3762)

CDC Clinical Guidance for Moderna COVID-19 Vaccine: www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html

Ages: 6 months through 5 years
MONOVALENT
(blue capped vial with magenta-bordered label)

Ages: 6 months through 5 years
BIVALENT
(pink capped vial with yellow-bordered label)

Ages: 6 through 11 years
MONOVALENT
(blue capped vial with purple-bordered label)

Ages: 12 years and older
MONOVALENT
(red capped vial with blue-bordered label)

Ages: 6 years and older
BIVALENT
(blue capped vial with gray-bordered label)

Vaccine Temperature Ranges:

Unpunctured vials may be stored:

- Frozen: -50°C and -15°C (-58°F and 5°F) until the expiration date
- Refrigerated: 2°C and 8°C (36°F and 46°F) up to 30 days

Vaccine Storage Unit(s):

Unpunctured vials may be stored in the:

- Freezer
- Refrigerator

Temperature Monitoring Device: For accurate temperature monitoring, use a digital data logger (DDL) with a detachable probe that best reflects vaccine temperatures (e.g., probe buffered with glycol, glass beads, or Teflon®) able to measure minimum and maximum temperatures.

Delivery:

- Vaccine arrives frozen between -50°C and -15°C (-58°F and 5°F). Examine the shipment for signs of damage.
- Ancillary supplies kit(s), including diluent if needed, will arrive in a separate shipment from the the vaccine. Each kit includes the number of supplies needed to support the number of doses ordered.
- Follow the manufacturer's guidance for unpacking the vaccine. Each box has a TagAlert temperature monitoring device that should be checked.

COVID-19 Vaccine (Moderna)

Storage Information: Vaccine can be stored in a freezer or refrigerator following routine storage and handling best practices.

Freezer

Store unpunctured vials between -50°C and -15°C (-58°F and 5°F) until the expiration date.*

- » Store vials upright in the tray or box protected from light
- » Do not store with dry ice or below -50°C (-58°F)
- » Determine the expiration date by scanning the QR code on the outer carton or go to modernacovid19global.com/vial-lookup

Refrigerator

Store unpunctured vials between 2°C and 8°C (36°F and 46°F).

- » Do NOT refreeze thawed vaccine.
- » Store vials upright in the tray or box protected from light.
- » Use tracking labels to monitor the beyond-use date.

Punctured vials may be stored between 2°F and 25°C (36°F and 77°F) for up to 12 hours.

Transport:

CDC does not recommend routine transport of vaccines. Ideally, vaccines should be delivered directly to the facility where they will be used. If vaccines must be transported, follow:

- Manufacturer's guidance
- CDC Moderna COVID-19 Transport Summary
- Routine vaccine storage and handling transport guidance outlined in this toolkit
- CDC recommends transporting vaccine in vials. However, there may be instances when the only option is to transport vaccine in a predrawn syringe. U.S. Pharmacopeia includes guidance for transporting predrawn vaccine in syringes in the *USP COVID-19 Vaccine Toolkit: Operational Considerations for Healthcare Practitioners*.

Vaccine Preparation and Administration:

Use the correct product based on the age of the recipient.

Vial cap color	Monovalent Blue capped vials with magenta-bordered label	Bivalent Pink capped vials with yellow-bordered label	Monovalent Blue capped vial with purple-bordered label	Monovalent Red capped vial with blue-bordered label	Bivalent Dark blue capped vial with gray-bordered label
Supplied in multidose vial	10 doses per vial	**2 doses per vial** **These vials should not be confused with single dose vials.** Once 2 doses have been removed, discard the vial.	5 doses per vial	10 primary doses	**6 through11 years of age:** 10 doses per vial **12 years of age and older:** 5 doses per vial

* These temperatures are within the appropriate range for routinely recommended vaccines BUT the temperature range for this vaccine is tighter. If storing the vaccine in a freezer with routinely recommended vaccines, carefully adjust the freezer temperature to the correct temperature range for this vaccine.

COVID-19 Vaccine (Moderna)

- Frozen vaccine must be thawed prior to use.
- Thaw vaccine between 2°C and 8°C (36°F and 46°F) or between 8° C and 25° C (46° F and 77° F). The amount of time needed to thaw vaccine varies based on the temperature and number of vials.
- Unpunctured vials may be held between 8°C and 25°C (46°F and 77°F) for a total of 24 hours.
- Do **NOT** dilute.
- During vaccine preparation, gently swirl after thawing and between each withdrawal from a multidose vial. DO not shake the vial. If shaken, contact the manufacturer.
- Administer by intramuscular (IM) injection using a new needle and syringe for each injection.
- Punctured vials maybe be kept between 8°C and 25°C (46°F and 77°F) for up to 12 hours. Discard the vial and any remaining vaccine after 12 hours.
- Discard the multidose vial when there is not enough vaccine to obtain a complete dose. Do NOT combine residual vaccine from multiple vials to obtain a dose.

Special Considerations:

- To determine the expiration date of a vial, scan the QR code located on the vial or carton. The QR code will bring up a website. Choose the lookup option, enter the lot number, and the expiration date will be displayed. You can also access the website directly: www.modernatx.com/covid19vaccine-eua.

COVID-19 Vaccine (Janssen)

Product: Janssen COVID-19 Vaccine (Johnson & Johnson)
Manufacturer Website: www.janssencovid19vaccine.com
Manufacturer Phone Number: 1-800-565-4008
CDC Clinical Guidance for Janssen COVID-19 Vaccine: www.cdc.gov/vaccines/covid-19/info-by-product/janssen/index.html

Vaccine Temperature Range:

- Refrigerated: 2°C and 8°C (36°F and 46°F) until the expiration date*

Vaccine Storage Unit:

- Refrigerator

Temperature Monitoring Device: For accurate temperature monitoring, use a digital data logger (DDL) with a detachable probe that best reflects vaccine temperatures (e.g., probe buffered with glycol, glass beads, or Teflon®).

Delivery:

- Vaccine arrives refrigerated between 2°C and 8°C (36°F and 46°F). Examine the shipment for signs of damage. Shipments have two cartons; each carton contains 10 multidose vials (50 doses), 100 doses total.
- Each box has two temperature monitoring devices (WarmMark monitor and FreezeMark indicator) that should be checked following the manufacturer's guidance.
- Ancillary kits will be delivered separately from the vaccine and include enough supplies to administer 100 doses of vaccine.

Storage Information: Vaccine can be stored in a refrigerator following routine storage and handling best practices.

Refrigerator

Store between 2°C and 8°C (36°F and 46°F)

» Unpunctured vaccine vials should be stored until the expiration date.
» The expiration date may be extended as more stability data become available. Contact the manufacturer to determine if the expiration date has been extended prior to discarding vaccine. Use CDC's expiration date tracking tool to document expiration date changes.
» Punctured vaccine vials may be stored in the refrigerator for up to 6 hours.
» Protect vaccine from light.
» **DO NOT FREEZE.**

* These temperatures are within the appropriate range for routinely recommended vaccines BUT the temperature range for this vaccine is tighter. If storing the vaccine in a refrigerator with routinely recommended vaccines, carefully adjust the refrigerator temperature to the correct temperature range for this vaccine.

COVID-19 Vaccine (Janssen)

Transport:

CDC does not recommend routine transport of vaccines. Ideally, vaccines should be delivered directly to the facility where they will be used. If vaccines must be transported, follow routine vaccine storage and handling transport guidance outlined in this toolkit. Use CDC's transport temperature log to record temperatures and time in transport. Adhere to the following transport requirements:

Refrigerated transport (2° C to 8° C; 36° F to 46° F):

- Vaccine must be transported in insulated containers qualified to maintain a temperature range of 2°C to 8°C (36°F to 46°F) for the duration of transport.
- Take care to ensure vaccine does not freeze during transport.
- CDC recommends the total time for transport alone or transport plus clinic workday should be a maximum of 8 hours.
- Punctured vials can be transported at refrigerated temperatures. Once punctured, the refrigerated vials must be used within 6 hours. Transport time counts as part of the 6-hour time limit.
- Vaccine vials may be transported more than once.
- When transport is complete, vaccine should immediately be placed in a vaccine storage unit between 2°C and 8°C (36°F and 46°F).
- CDC recommends transporting vaccine in vials. However, there may be instances when the only option is to transport predrawn vaccine in a syringe. U.S. Pharmacopeia includes guidance for transporting predrawn vaccine in syringes in the *USP COVID-19 Vaccine Toolkit: Operational Considerations for Healthcare Practitioners*.
- Transportation guidance and considerations are outlined in CDC's Transportation Summary for this product.

Vaccine Preparation and Administration:

- After puncturing the multidose vial stopper, store vaccine in the refrigerator for up to 6 hours (2°C to 8°C [36°F to 46°F]) or at room temperature for up to 2 hours (maximally 25°C [77°F]).
  - » Discard the vaccine if not used during this time.
- Each multidose vial contains 5 doses.
- Do NOT mix vaccine with diluent.
- During vaccine preparation, gently swirl before first puncture and between each withdrawal. Do NOT shake the vial. If the vial is shaken, contact the manufacturer.
- Discard vial when there is not enough vaccine to obtain a complete dose. Do NOT combine residual vaccine from multiple vials to obtain a dose.
- Administer by IM injection

Special Considerations:

- The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date:
  - » Scan the QR code on the outer carton, or
  - » Call 1-800-565-4008, or
  - » Visit www.vaxcheck.jnj.
- Write the expiration date on the carton. Use CDC's expiration date tracking tool to document expiration date changes.

COVID-19 Vaccine (Novavax)

Product: Novavax COVID-19 Vaccine (recombinant, adjuvanted), 12 years and older (Royal blue cap primary and booster series)
Manufacturer Website: www.novavaxcovidvaccine.com
Manufacturer Phone Number: 1-844-NOVAVAX (1-844-668-2829)
CDC Clinical Guidance for Novavax COVID-19 Vaccine: www.cdc.gov/vaccines/covid-19/info-by-product/novavax/index.html

Vaccine Temperature Range:

- Refrigerated: 2°C and 8°C (36°F and 46°F) until the expiration date

Vaccine Storage Unit:

- Refrigerator

Temperature Monitoring Device: For accurate temperature monitoring, use a digital data logger (DDL).

- **Refrigerator:** Use a DDL with a detachable probe that best reflects vaccine temperatures (e.g., probe buffered with glycol, glass beads, and or Teflon®).

Delivery:

- Vaccine arrives in a qualified shipping container at temperatures between 2°C and 8°C (36°F and 46°F). The vial has a royal blue cap and royal blue border on the label.
- Unpack vaccine immediately upon arrival at clinic and check the cold chain monitor (CCM) for any indication of a temperature excursion during transit.
- Check expiration date by scanning the QR on the outer carton or go to www.novavaxcovidvaccine.com
- Ancillary supplies including needles, syringes, and vaccination record cards will arrive separately from the vaccine.

Storage Information: Vaccine can be stored in a refrigerator following routine storage and handling best practices.

Refrigerator

Store between 2°C and 8°C (36°F and 46°F) until the expiration date.

- Store vaccine in the original packaging.
- Protect from light.
- Use storage labels to help staff easily identify the vaccine within the storage unit.
- Once punctured, Novavax COVID-19 Vaccine must be used within 6 hours.
  - Note when (time) the vial is first punctured and use within 6 hours.
  - Discard vial and any remaining vaccine after 6 hours.

COVID-19 Vaccine (Novavax)

Transport:

CDC does not recommend routine transport of vaccines. Ideally, vaccines should be delivered directly to the facility where they will be used. If vaccines must be transported, follow routine vaccine storage and handling transport guidance outlined in this toolkit. Use CDC's transport temperature log to record temperatures and time in transport. Adhere to the following transport requirements:

Refrigerated transport (2° C to 8° C; 36° F to 46° F):

- Vaccine must be transported in insulated containers qualified to maintain a temperature range of 2°C to 8°C (36°F to 46°F) for the duration of transport.
- Take care to ensure vaccine does not freeze during transport.
- CDC recommends the total time for transport alone or transport plus clinic workday should be a maximum of 8 hours.
- Punctured vials can be transported at refrigerated temperatures. Once punctured, the refrigerated vials must be used within 6 hours. Transport time counts as part of the 6-hour time limit.
- Vaccine vials may be transported more than once.
- When transport is complete, vaccine should immediately be placed in a vaccine storage unit between 2°C and 8°C (36°F and 46°F).
- CDC recommends transporting vaccine in vials. However, there may be instances when the only option is to transport predrawn vaccine in a syringe. U.S. Pharmacopeia includes guidance for transporting predrawn vaccine in syringes in the *USP COVID-19 Vaccine Toolkit: Operational Considerations for Healthcare Practitioners*.
- Transportation guidance and considerations are outlined in CDC's Transportation Summary for this product.

Vaccine Preparation and Administration:

- After puncturing the multidose vial stopper, store vaccine in refrigerator for up to 6 hours (2°C to 25°C (35°F to 77°F).
  - » Discard the vaccine if not used during this time.
- Each multidose vial contains 10 doses.
- Do NOT mix vaccine with diluent.
- During vaccine preparation, gently swirl before first puncture and between each withdrawal. Do NOT shake the vial. If the vial is shaken, contact the manufacturer.
- Discard vial when there is not enough vaccine to obtain a complete dose. Do NOT combine residual vaccine from multiple vials to obtain a dose.
- Administer by IM injection.

Special Considerations:

- The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date, visit www.novavaxcovidvaccine.com.
- Write the expiration date on the carton. Use CDC's expiration date tracking tool to document expiration date changes.

MPOX Vaccine (JYNNEOS)

Product: JYNNEOS (Smallpox and Monkeypox Vaccine, Live, Nonreplicating)
Manufacturer Website: jynneos.com
Manufacturer Phone Number: 1-844-422-8274
CDC Clinical Guidance for Mpox Vaccine: www.cdc.gov/poxvirus/monkeypox/clinicians/vaccines/vaccine-considerations.html

Vaccine Temperature Range:

Unpunctured vials may be stored:

- Frozen: Between -25°C and -15°C (-13°F and 5°F) until the expiration date
- Refrigerated: Between 2°C and 8°C (36°F and 46°F) for up to 8 weeks

Punctured vials may be stored:

- Refrigerated between 2°C and 8°C (36°F and 46°F) for up to 8 hours

Temperature Monitoring Device: For accurate temperature monitoring, use a digital data logger (DDL) with a detachable probe that best reflects vaccine temperatures (e.g., probe buffered with glycol, glass beads, or Teflon®).

Delivery:

- Vaccine is shipped from Strategic National Stockpile (SNS) sites to vaccine depots.
- Vaccine arrives frozen between -25°C and -15°C (between -13°F and 5°F)
- Examine the shipment for signs of damage. Each box contains 20 vials.
- Each box has a TempTale temperature monitoring device or DDL that should be checked following SNS guidance.
- If vaccine needs to be further transported (i.e., from vaccine depots to health departments or clinics), unpack vaccine from Credo Crates and repackage into an appropriate transport system as outlined in the Transport guidance below. Expiration date should be recorded when vials are separated from original packaging.

Storage Information: Vaccine can be stored in a freezer or refrigerator following routine storage and handling best practices. Individual guidance for each storage unit is as follows:

Freezer

Unpunctured vials may be stored frozen between -25°C and -15°C (-13°F and 5°F) until the expiration date.*

- » The expiration date may be extended as more stability data become available. As the expiration date approaches, contact the manufacturer to determine if the expiration date has been extended prior to discarding vaccine.
- » Store vaccine vials upright in the original package when possible.
- » Protect vaccine from light.

* These temperatures are within the appropriate range for routinely recommended vaccines BUT the temperature range for this vaccine is narrower. If storing the vaccine in a freezer with routinely recommended vaccines, carefully adjust the freezer temperature to the correct temperature range for this vaccine.

MPOX Vaccine (JYNNEOS)

Refrigerator

Unpunctured vials may be stored in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to 8 weeks from thawing. This updated information has been provided by the vaccine manufacturer based on available supportive stability data. Please note that this differs from the package insert, which states that the vaccine may be kept at 2°C to 8°C (36°F to 46°F) for 12 hours (Section 2.2 Preparation and Administration and 16.2 Storage Conditions).

- Once thawed, vaccine cannot be refrozen.
- Use CDC's JYNNEOS beyond-use date (BUD) labels to track how long the vaccine has been in the refrigerator.
  - If the expiration date shown on the carton is earlier than the 8 weeks after vial was first thawed, write the expiration date on the box or container holding the vaccine vials.
  - As the 8-week deadline approaches, contact the manufacturer to determine if the expiration date has been extended prior to discarding vaccine.
- Store vaccine vials upright.
- Protect vaccine from light.
- Use vaccine vials stored in the refrigerator before removing additional vials from the freezer.

Punctured vials should be stored at refrigerated temperatures (between 2°C and 8°C) for up to 8 hours. Place the vial back in the refrigerator after drawing up each dose. Do NOT leave vaccine vial out at room temperatures in between doses.

Transport:

Frozen transport is preferred if vaccine must be transported.

Frozen transport:

JYNNEOS vaccine may be transported frozen between -25°C and -15°C (-13°F and 5°F) for 72 cumulative hours (e.g., vaccine transported for 2 hours today has 70 hours of transport time remaining).

- Transport using a portable freezer or qualified container to maintain between -25°C and -15°C (-13°F and 5°F) with DDLs.
- When you have completed the vaccine transport for the day, remove any remaining vials from the transport container, and place vials immediately in freezer.
- Complete the information on the bottom portion of the label indicating the time in transport and hours remaining for transport.
- Store vaccine upright in the freezer between -25°C and -15°C (-13°F and 5°F) until the expiration date, if freezer capacity is available, or in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to 8 weeks from thawing.

Refrigerated transport:

JYNNEOS vaccine may be transported between 2°C and 8°C (36°F and 46°F) for 12 cumulative hours (e.g., vaccine transported for 2 hours today has 10 hours of transport time remaining).

- Transport using a portable refrigerator or qualified container to maintain between 2°C and 8°C (36°F and 46°F) with digital data loggers.
- When you have completed vaccine transport for the day, remove any remaining vials from the transport container and then place vials immediately in refrigerator.
- Complete the information on the bottom portion of the label indicating the time in transport and hours remaining for transport.
- Store vaccine upright in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to 8 weeks.

MPOX Vaccine (JYNNEOS)

Vaccine Preparation and Administration:

- Each vial contains one subcutaneous dose or approximately five intradermal doses.
- Discard vial when there is not enough vaccine to obtain a complete dose. Do NOT combine residual vaccine from multiple vials to obtain a dose.
- Frozen vaccine must be thawed at room temperature for 10 minutes before using.
- Do **NOT** refreeze thawed vaccine.
- With the vial upright, gently swirl the vaccine for 30 seconds.
- Examine the vaccine. It should be a milky light yellow to pale white colored suspension. Do not use if liquid contains other particulate matter or is discolored.
- Once punctured, the vaccine must be stored in the refrigerator and used within 8 hours.
- Administer by subcutaneous or intradermal injection.

Special Considerations:

- Unpunctured vials may be held at room temperature for up to 6 cumulative hours. No additional stability data at room temperature is available.

Predrawn vaccine

Predrawing vaccines can result in waste if more are drawn up than needed. In addition, once vaccines are drawn into syringes, it is difficult to tell them apart, which can lead to administration errors, and such errors must be reported to the Vaccine Adverse Event Reporting System. However, there may be rare instances when the only option is to predraw JYNNEOS vaccine. If vaccines must be predrawn:

- » Predrawn vaccine must be labeled with vaccine name, lot number, date and time prepared, preparer's initials, and MUST BE refrigerated.
- » Predrawn syringes must be stored at the manufacturer-recommended refrigerated temperatures throughout the clinic day.
- » A separate clean administration station for each vaccine type should be set up to prevent medication errors.
- » Vaccines should be drawn up into syringes only after arriving at the clinic site, or mass vaccination event. Drawing up doses days or even hours before administering them is not a best practice because general-use syringes are not designed for storage.
- » Each person administering vaccines should draw up no more than 10 doses at one time.
- » Patient flow should be monitored to avoid drawing up unnecessary doses.
- » If a predrawn vaccine is not used within 8 hours of being drawn, the dose should be discarded.
- » Predrawn vaccine should never be transferred back into a vial for storage.