

This chapter provides an overview of best practice guidance for storage and handling. CDC's *Vaccine Storage and Handling Toolkit*, <http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf>, contains comprehensive information on best practices and recommendations. Manufacturers' product information and package inserts include the most current information about the storage and handling of specific vaccines. Refer to CDC's *Storage and Handling* webpage for links to these and other resources, <http://www.cdc.gov/vaccines/recs/storage/default.htm>. Participants in the Vaccines for Children (VFC) program or those who have any vaccines purchased with public funds should consult their state or local immunization program for specifics because some program requirements may differ from the information contained in the *Vaccine Storage and Handling Toolkit*.

## Vaccine Storage and Handling

There are few immunization issues more important than the appropriate storage and handling of vaccines. Vaccine-preventable disease rates have decreased in part because of proper storage and handling of vaccines. Exposure of vaccines to temperatures outside the recommended ranges can decrease their potency and reduce the effectiveness and protection they provide. Storage and handling errors can cost thousands of dollars in wasted vaccine and revaccination. Errors can also result in the loss of patient confidence when repeat doses are required. It is better to not vaccinate than to administer a dose of vaccine that has been mishandled. Vaccine management, including proper storage and handling procedures, is the basis on which good immunization practices are built.

Vaccines must be stored properly from the time they are manufactured until they are administered. Assuring vaccine quality and maintaining the cold chain is a shared responsibility among manufacturers, distributors, public health staff, and health-care providers. A proper cold chain is a temperature-controlled supply chain that includes all equipment and procedures used in the transport and storage and handling of vaccines from the time of manufacture to administration of the vaccine. By following a few simple steps and implementing best storage and handling practices, providers can ensure that patients will get the full benefit of vaccines they receive.

## Storage and Handling Plans

Every facility should have detailed written protocols for routine and emergency vaccine storage and handling and they should be updated annually. These policies and procedures should be available in writing as a reference for all staff members and easily accessible.

### Vaccine Storage and Handling

- Vaccine-preventable disease rates decreased in part because of proper storage and handling
- Storage and handling errors
  - decrease potency and reduce effectiveness and protection
  - cost thousands of dollars in wasted vaccine and revaccination
  - loss of patient confidence
- It is better to not vaccinate than to administer a dose of vaccine that has been mishandled

### Cold Chain (a temperature-controlled supply chain)

- Vaccines must be stored properly from the time they are manufactured until they are administered
- Shared responsibility among manufacturers, distributors, public health staff, and healthcare providers

## Vaccine Storage and Handling Plans

- Develop and maintain written ROUTINE plan for:
  - ordering and accepting vaccine deliveries
  - storing and handling vaccines
  - managing inventory
  - managing potentially compromised vaccines
- Develop and maintain written EMERGENCY vaccine retrieval and storage plan
  - back-up storage location with appropriate storage units, temperature monitoring capability, and back-up generator that can maintain power to the vaccine storage units
  - adequate supply of packing materials and portable refrigerators and freezers or qualified containers and packouts, or refrigerated truck

## Staff Training and Education

- Assign responsibilities to a primary vaccine coordinator
- Designate at least one alternate (back-up) vaccine coordinator

A routine storage and handling plan provides guidelines for daily activities, such as:

- Ordering and accepting vaccine deliveries
- Storing and handling vaccines
- Managing inventory
- Managing potentially compromised vaccines

Every facility should also have an emergency vaccine retrieval and storage plan. The plan should identify a back-up location where the vaccines can be stored. Considerations when choosing this site include appropriate storage units, temperature monitoring capability, and a back-up generator that can maintain power to the vaccine storage units. Potential back-up locations might include a local hospital, pharmacy, long-term care facility, or the Red Cross.

There should be an adequate supply of packing materials and portable refrigerators and freezers or qualified containers and packouts on hand to accommodate the facility's largest annual vaccine inventory (e.g., flu season). A refrigerated truck may be needed to move large inventories of vaccine.

Power outages or natural disasters are not the only events that can compromise vaccine. Forgotten vials of vaccine left out on the counter or doses of vaccine stored at improper temperatures due to a storage unit failure are other examples of how vaccines can be potentially compromised. Protocols after an event will vary depending on individual state or agency policies. Contact the local or state health department immunization program (hereafter referred to as "immunization program"), vaccine manufacturer(s), or both for appropriate actions or guidelines that should be followed for all potentially compromised vaccines. Do not discard vaccines unless directed to by the immunization program and/or the manufacturer.

## Staff Training and Education

Assign a primary vaccine coordinator who is responsible for ensuring that vaccines are stored and handled correctly at each facility. Designate at least one alternate (back-up) vaccine coordinator who can perform these responsibilities in the absence of the primary coordinator. These responsibilities include, but are not limited to, the following tasks:

- Ordering vaccines
- Overseeing proper receipt and storage of vaccine deliveries
- Organizing vaccines within the storage unit(s)

- Temperature monitoring of the storage unit(s) (i.e., current temperature at least 2 times each workday).
- Recording temperature readings on a log
- Daily physical inspection of the storage unit(s)
- Rotating stock so that vaccines closest to their expiration dates will be used first
- Monitoring expiration dates and ensuring that expired vaccines and diluents are removed from the storage unit(s) and not administered to patients
- Responding to potential temperature excursions
- Overseeing proper vaccine transport
- Maintaining all appropriate vaccine storage and handling documentation, including temperature-excursion responses
- Maintaining storage equipment and maintenance records
- Maintaining proper documentation for the VFC program in participating facilities
- Ensuring that designated staff is adequately trained

A physician partner or member of management should be directly involved with the clinical staff that is responsible for vaccine storage and handling. Management staff should have a clear understanding of the vaccine replacement costs and clinical implications of mismanaged vaccines.

All personnel who handle or administer vaccines should be familiar with the storage and handling policies and procedures for their facility. This includes not only those who administer vaccines, but also anyone who delivers or accepts vaccine shipments and anyone who has access to the unit(s) where vaccines are stored. Vaccine storage and handling training should be provided to all new personnel who handle or administer vaccines, including temporary staff. Continuing education for staff is essential when new vaccines are stocked and when there are any changes to the storage and handling guidelines for a particular vaccine. CDC has a free web-based storage and handling module as part of the online training tool, “*You Call the Shots*,” at <http://www.cdc.gov/vaccines/ed/youcalltheshots.htm>. Continuing education credit for a variety of healthcare professionals and a certificate of completion are available. Many immunization programs and professional organizations also offer vaccine storage and handling training programs.

## **Training and Education**

- Staff who
  - handle or administer vaccines
  - deliver or accept vaccine shipments
  - have access to vaccine storage unit(s)
- Provide training and continuing education when
  - new or temporary staff are oriented
  - new vaccines are stocked
  - changes to storage and handling guidelines occur

## Vaccine Deliveries

- Notify vaccine coordinator or alternate (back-up) coordinator when delivery arrives
- Avoid having people accept deliveries who may not understand the importance of storage at appropriate temperatures upon arrival
- Examine vaccine deliveries
  - container
  - contents
  - shipping temperature monitors/indicators
- If there are concerns, label vaccines “Do NOT Use,” store under appropriate conditions, separate from other vaccines
- Consult immunization program, distributor, and/or vaccine manufacturer for guidance

## Receiving and Unpacking Vaccine Deliveries

Proper vaccine storage and handling is important from the moment the vaccine arrives at the facility. All office staff should be trained to notify the vaccine coordinator or the alternate (back-up) coordinator when a vaccine delivery has arrived. This is extremely important for receptionists or other front desk staff since they may be the first to know that vaccines have been delivered. Avoid having other people accept deliveries who may not understand the importance of storage at appropriate temperatures. The vaccine coordinator should request delivery during office hours and update vaccine orders to reflect any period of time the office will be closed, such as holidays or scheduled vacation time.

Examine deliveries right away and store vaccines at the proper temperatures immediately upon arrival. Examine the shipping container and its contents for any evidence of damage during shipment. Cross check the contents with the packing slip to be sure they match. Check heat and cold temperature monitors/indicators if either are included in the shipping container following instructions on the monitors for reading and reporting. If a monitor indicates a possible temperature excursion during shipping, the monitor reading should be documented for future reference. Report the reading to the distributor within the required timeframe if VFC vaccines or other vaccines purchased with public funds are involved. Vaccines sent directly by the manufacturer are in specially designed boxes and may not contain heat or cold temperature monitors.

Allowable shipping time varies among distributors and manufacturers and is dependent on the type of container and packout. Determine if shipping time was within allowable limits noted on shipping insert or container. If the shipping time was more than the allowable limit or there are any discrepancies with the packing slip or concerns about the contents, immediately notify the primary vaccine coordinator (or the alternate [back-up] coordinator). If neither is available, notify a supervisor immediately. Label the vaccines “Do NOT Use” and store the vaccines under appropriate conditions separate from other vaccines. Then, according to your facility’s procedures, contact your immunization program, the distributor, and/or vaccine manufacturer(s) for guidance.

Record the contents of each container on an inventory log (stock record). This log should include the name of each vaccine, the number of doses for each vaccine received, the date it was received, the condition of the vaccines upon arrival, the names of the vaccine manufacturers, the lot numbers, the expiration dates for each vaccine, and any action taken regarding questionable vaccines.

## Vaccine Storage and Temperature Monitoring Equipment

These items should be selected carefully, used properly, maintained regularly (including professionally serviced when needed), and monitored consistently to ensure the recommended temperatures are maintained. This chapter provides only general guidelines for equipment. Providers should consult their immunization program, particularly providers of VFC vaccines or other vaccines purchased with public funds, for any specific storage equipment requirements.

Keep a logbook for each piece of vaccine storage equipment. The serial number of each piece of equipment, the date each piece of equipment was installed, the dates of any routine maintenance tasks (such as cleaning), the dates of any repairs or service, and the contact information of the service provider should be recorded. A logbook is also an ideal place to keep the instructions that came with the equipment.

### Freezers and Refrigerators

Using proper vaccine storage units can help prevent costly vaccine losses and the inadvertent administration of compromised vaccines. CDC recommends stand-alone units, meaning self-contained units that either freeze or refrigerate, and are suitable for vaccine storage. These units can vary in size, from compact, counter-top or under-the-counter style to large, pharmaceutical grade units. Studies demonstrated that stand-alone units maintain the required temperatures better than combination units, particularly the freezer section of household, combination units.

If existing equipment is a household, combination refrigerator/freezer, CDC recommends using only the refrigerator compartment for refrigerated vaccines. Use a separate stand-alone freezer to store frozen vaccines. Research found that freezers in household combination units cannot hold proper storage temperatures for frozen vaccines particularly during defrost cycles. This applies to both temporary and long-term storage.

Any freezer or refrigerator used for vaccine storage must be able to maintain the required temperature range throughout the year. The unit should be dedicated to the storage of biologics and must be large enough to hold inventory a provider might have at the busiest point in the year without crowding (including flu vaccine). There should also be enough room to store water bottles in the refrigerator and frozen water bottles in the freezer to stabilize the temperatures and help maintain temperature longer in a power outage.

### Freezers and Refrigerators

- Stand-alone units that only freeze or refrigerate
  - can vary in size from compact, counter-top or under-the-counter to large, pharmaceutical grade
  - maintain required temperatures better than combination units, particularly the freezer section of these units
- If existing equipment is a household, combination refrigerator/freezer
  - only use refrigerator for vaccine storage
  - use a stand-alone freezer for frozen vaccines
  - applies to both temporary and long-term storage
- Able to maintain required temperature range throughout year
- Dedicated to storage of biologics
- Large enough to hold year's largest vaccine inventory without crowding (including flu vaccine)
- If stand-alone freezer is manual defrost, must defrost regularly and have another storage unit that maintains appropriate temperatures for temporary storage during defrosting
- Frost-free or automatic defrost cycle may be preferred

## Storage Unit Placement

- Promote good air circulation around storage unit
  - place in well-ventilated room
  - allow for space on all sides and top
  - allow at least 4 inches between storage unit and a wall
  - do not block motor cover
  - ensure unit stands level with at least 1 to 2 inches between bottom of unit and floor

## Dormitory-style Refrigerator

- Small combination freezer/refrigerator unit with one external door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator
- NOT recommended for vaccine storage under any circumstances, even temporarily
- Prohibited for storage of VFC vaccines or other vaccines purchased with public funds
- NOT recommended for vaccine storage under any circumstances, even temporarily

If your stand-alone freezer is manual defrost, you must defrost regularly and have another storage unit that maintains appropriate temperatures for temporary storage of the vaccine while defrosting. A frost-free unit with an automatic defrost cycle may be preferred if regular manual defrosting cannot be assured.

Good air circulation around a vaccine storage unit is essential for proper cooling functions. A storage unit should be in a well-ventilated room with space around the sides and top and at least 4 inches between the unit and a wall. Nothing should block the cover of the motor compartment and the unit should be level and stand firmly with at least 1 to 2 inches between the bottom of the unit and the floor.

CDC does not recommend storage of any vaccine in a dormitory-style or bar-style, combined refrigerator/freezer unit under any circumstances, even temporarily. A dormitory-style refrigerator is defined as a small combination freezer/refrigerator unit with one exterior door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment within the refrigerator. These units have exhibited severe temperature control and stability issues throughout the entire storage area. Dormitory-or bar-style units pose a significant risk of freezing vaccines, even when used for temporary storage. The use of this type of unit is prohibited for storage of VFC vaccines or other vaccines purchased with public funds.

## Temperature Monitoring Devices

Temperature Monitoring is a critical part of good storage and handling practice. CDC recommends using only a calibrated digital data logger with a current and valid certificate of calibration testing (also known as a Report of Calibration). This certificate informs the user of a temperature monitoring device's level of accuracy compared to a recognized standard. Calibrated temperature monitoring devices are required for providers who receive VFC vaccines or other vaccines purchased with public funds.

All temperature monitoring devices, through normal use, drift over time, which affects their accuracy. Because of this, temperature monitoring devices should undergo periodic calibration testing. Testing should be performed every 1 to 2 years from the last testing date or according to the manufacturer's suggested timeline. CDC recommends that testing meets standards defined in the *Vaccine Storage and Handling Toolkit*. If calibration testing indicates that your temperature monitoring device is no longer accurate, it should be replaced. Immunization programs are often excellent resources for information on temperature monitoring devices.



Several types of temperature monitoring devices are available. CDC recommends digital data loggers with the following characteristics: a digital display easily readable from outside the unit; a detachable probe in a buffered material, which more closely reflects vaccine temperatures rather than air temperature in the unit; an alarm for out-of-range temperatures; current and minimum and maximum temperature accuracy within  $\pm 1^{\circ}\text{F}$  ( $\pm .5^{\circ}\text{C}$ ); a low battery indicator; memory that stores at least 4000 readings; and user programmable logging interval. CDC recommends a back-up digital data logger for each vaccine storage unit. Staff should be trained and understand how to set up, read and analyze temperature data provided by the data logger.

Temperature monitoring device placement within the unit is just as important as device selection. Place the buffered probe with the vaccines. This should be in the middle, center of the storage unit away from walls, ceiling, cooling vents, door, floor, and back of the unit. Prior to storing vaccines in a unit, allow the unit temperature to stabilize for a week before placing vaccines in the unit. CDC recommends using a digital data logger to monitor the temperature in the storage unit prior to storage of vaccines.

## Temperature Monitoring

Regular temperature monitoring is key to proper cold chain management. Store frozen vaccines (Varicella, MMRV, and Zoster) in a freezer between  $-58^{\circ}\text{F}$  and  $+5^{\circ}\text{F}$  ( $-50^{\circ}\text{C}$  and  $-15^{\circ}\text{C}$ ). Store all other routinely recommended vaccines in a refrigerator between  $35^{\circ}\text{F}$  and  $46^{\circ}\text{F}$  ( $2^{\circ}\text{C}$  and  $8^{\circ}\text{C}$ ). The desired average refrigerator vaccine storage temperature is  $40^{\circ}\text{F}$  ( $5^{\circ}\text{C}$ ). Exposure to temperatures outside these ranges may result in reduced vaccine potency and increased risk of vaccine-preventable diseases.

CDC recommends reviewing and recording temperatures in both the freezer and refrigerator units at least 2 times each workday, in the morning and before leaving at the end of the workday.

This best practice recommendation applies to all vaccine storage units, regardless of whether or not there is a temperature alarm, or a digital data logger that continuously records temperatures in the unit. These readings will provide a better indication of any problems with the storage unit's function.

Reviewing and recording temperatures also provides an opportunity to visually inspect the storage unit, reorganize the vaccines when necessary (e.g., moving vaccine away

### Temperature Monitoring Devices

- Use only calibrated temperature monitoring devices with a certificate of calibration testing (Report of Calibration) from an accredited laboratory
  - required for providers who receive VFC vaccines or vaccines purchased with public funds
- Calibration testing every 1 to 2 years from last calibration testing date or according to the manufacturer's suggested timeline

### Digital Data Logger Characteristics

- Digital temperature display outside storage unit
- Detachable probe in a buffered material
- Alarm
- Current and minimum and maximum temperatures
- Accuracy within  $\pm 1^{\circ}\text{F}$  ( $\pm .5^{\circ}\text{C}$ )
- Low battery indicator
- Measures current and daily minimum and maximum temperatures in the unit
- Memory for storing at least 4,000 readings
- Uses programmable logging interval

## Recommended Temperatures

- Freezer
  - between -58°F and +5°F (between -50°C and -15°C)
- Refrigerator
  - between 35°F and 46°F (between 2°C and 8°C)
  - average: 40°F (5°C)

## Temperature Monitoring

- Review and record temperatures in both freezer and refrigerator units 2 times each day, once in the morning and once before leaving at the end of the workday
- Post temperature log on the door of each storage unit
- If using a continuous temperature monitor, download temperature data and review weekly
- Keep temperature logs (hard copies and downloaded data) 3 years or according to individual state record retention requirements

## Temperature Excursion

- If stored vaccines have been exposed to temperatures outside recommended ranges
  - store the vaccines properly
  - separate from other vaccine supplies
  - mark “Do NOT Use”
  - contact immunization program, vaccine manufacturer(s), or both for guidance

from walls or cold air vents), identify vaccines and diluents with short expiration dates, remove any expired vaccines and diluents, and provide a timely response to temperature excursions.

Post a temperature log on each storage unit door or nearby in a readily accessible and visible location. In addition, if using a device that enables download of temperature data, review and store data at least once every week and reset the device before returning to storage unit monitoring.

CDC recommends maintaining an ongoing file of temperature data, including hard copies and downloaded data for at least 3 years or according to individual state record retention requirements. As the storage unit ages, recurring temperature variances or problems can be tracked and documented. This data can be important when evaluating the need for a new storage unit or if there is a potential need to recall and revaccinate patients because of improperly stored vaccine.

Twice daily temperature monitoring may not be accomplished when a provider’s office is closed. A digital data logger that stores data and/or can be accessed remotely can provide information on storage temperatures while the office is closed and help assure that timely corrective action can be taken if temperatures go out of range. Providers should determine how they are to be notified in the event of an emergency (e.g., a power outage) during hours when the facility is not open.

Equally important to temperature monitoring is taking timely corrective action when there is a temperature excursion. If it is discovered that stored vaccines have been exposed to temperatures outside the recommended ranges, these vaccines should remain properly stored, but separated from other vaccine supplies and marked “Do NOT Use” until guidance can be obtained. Protocols after an event will vary depending on individual state or agency policies. Contact your immunization program, vaccine manufacturer(s), or both for guidance.

## Vaccine and Diluent Placement and Labeling

Vaccines should be stored in the center of the unit as this is the area where appropriate temperatures are typically most stable. A storage unit should be big enough so that vaccines can be placed in the part of the unit best able to maintain the constant, required temperature away from the walls, coils, cooling vents, ceiling, door, floor and back of the unit. Vaccines and diluents should be kept in their original packaging with the lids on until ready for administration and stacked in rows with vaccine and diluent of the same



type. Trays or uncovered containers/bins that allow for air circulation can be used to organize the vaccines and diluents within the storage unit. Do not store vaccines in unit doors or in deli, vegetable, or fruit crisper drawers. Avoid storing vaccines on the refrigerator top shelf. If the top shelf must be used, place water bottles close to the vent and only store vaccines not sensitive to coldest temperatures (e.g., MMR).

Some diluents must be refrigerated and others may be stored in the refrigerator or at room temperature. Always follow the manufacturer's guidance in the product information/package inserts. If possible, store diluent next to the corresponding vaccine. Some of these diluents may contain vaccine antigen. Never store diluents in the freezer.

There should be space between the vaccine and diluent stacks or containers. This will help to avoid confusion between products, provide for air circulation around and through stacks for even cooling, and protect vaccines from unnecessary light exposure. Not only live attenuated vaccines, but also some inactivated vaccines must be protected from light. Information on light sensitivity can be found in the manufacturer's product information/package insert.

Each vaccine and diluent stack or container should be clearly labeled. This can be accomplished by attaching labels directly to the shelves on which vaccines and diluents are stored or by placing labels on the containers. Store pediatric and adult vaccines on different shelves. Use color coded labels that include the vaccine type, as well as age and gender indications, if applicable. Having each vaccine and diluent stack or container labeled helps decrease the chance that someone will inadvertently administer the wrong vaccine or use the wrong diluent to reconstitute a vaccine. Vaccines that sound or look alike should not be stored next to each other, e.g., DTaP and Tdap. VFC vaccines and other vaccines purchased with public funds should be identified and stored separately from vaccines purchased with private funds.

## Vaccine Storage Troubleshooting

To maintain the proper temperature ranges, the freezer and refrigerator units must be in good working condition and they must have power at all times. There are several things that can be done to prevent problems.

Plug storage units directly into wall outlets. Do not use power outlets with built-in circuit switches (they have little red reset buttons), outlets that can be activated by a wall switch, or multi-outlet power strips. These can be tripped or switched off, resulting in loss of electricity to the storage

### Vaccine and Diluent Placement and Labeling

- Store vaccines away from walls, coils, cooling vents, top shelf, ceiling, door, floor, and back of unit
- Keep vaccines and diluents in original packaging with lids on to protect from light
- Stack in rows with same type of vaccine and diluent
- Use uncovered storage containers to organize vaccines and diluents
- Do not store vaccines in storage unit doors, on the top shelf, on the floor, or in deli, vegetable or fruit crisper drawers
- Store pediatric and adult vaccines on different shelves
- Use labels with vaccine type, age, and gender indications or color coding
- Do not store sound-alike and look-alike vaccines next to each other
- VFC vaccines and other vaccines purchased with public funds should be identified and stored separately from vaccines purchased with private funds

## Diluent Storage

- Store diluent as directed in manufacturer’s product information
- Store refrigerated diluent with corresponding vaccine (these diluents may contain vaccine antigen)
- Never store diluents in the freezer
- Label diluent to avoid inadvertent use of the wrong diluent when reconstituting a vaccine

unit. Plug only one storage unit into an outlet. This will help to prevent a safety switch from being triggered to turn off power and reduce the risk of overloading the outlet which could be a fire hazard.

Use plug guards or safety-lock plugs to prevent someone from inadvertently unplugging the unit. A temperature alarm system that will alert staff to after-hour temperature excursions, particularly if large vaccine inventories are maintained, may be helpful in assuring a timely response to storage problems. Label circuit breakers to alert custodians and electricians not to unplug vaccine storage units or turn off the power. This can be done by posting a warning sign near the electrical outlet, on storage units, and at the circuit breaker box. Warning signs should include emergency contact information.

Place containers of water, labeled “Do NOT Drink,” in the refrigerator to help stabilize the temperature in the unit. Place water bottles where vaccines are not stored, such as the door, top shelf, and on the floor of the storage unit. The same principle applies to the freezer. Store frozen water bottles in the freezer and the freezer door. Be careful that the water bottles do not weigh down doors so much that the seals are compromised and the doors do not close properly. These measures will help keep the temperature stable with frequent opening and closing of the storage unit.

In addition to temperature monitoring, a physical inspection of storage units should be performed daily. An inspection should include the following:

- Are the vaccines placed properly in the unit?
- Are the vaccines in their original packaging?
- Are vaccines being stored away from the walls, coils, cooling vents, ceiling, and floor and not in the doors?

During a workday it is easy for vaccines to be shifted into an area of the storage unit where the temperature may not be appropriate or stable, such as against a wall, under a cold air vent, or in the door. CDC recommends that vaccines be kept in storage units dedicated only to vaccines. If other biologic specimens, such as blood or urine, must be stored in the same unit as vaccines, specimens should be stored on a lower shelf. This is to ensure that if a specimen leaks, the vaccines will not be contaminated. Food and beverages should not be stored in a vaccine storage unit because frequent opening of the unit can lead to temperature instability.

While it is important to take measures to prevent problems, equally important is taking immediate corrective action when a problem does exist, for example, when the storage

unit temperature falls outside the recommended range. Staff should know who to contact in case of a malfunction or disaster.

If you experience a power outage, immediately begin to implement your emergency plan. Depending on room temperature, storage temperatures may be maintained for only a very short period of time. If there is an extended period of time before the situation can be corrected and there are no other storage units available on site, move the vaccines to the back-up storage facility using the guidelines in the emergency plan.

## Vaccine and Diluent Inventory Control

Conduct a vaccine inventory monthly to ensure adequate supplies to meet demand. Include vaccine diluents in the inventory. Determining factors for the amount of vaccine and diluent ordered include: projected demand, storage capacity, and current vaccine supply. Avoid overstocking vaccine supplies, which could lead to vaccine wastage or having outdated vaccine on hand.

Check vaccine and diluent expiration dates a minimum of weekly. Rotate stock so that vaccines and diluents with the soonest expiration dates are used first to avoid waste from expiration. If the date on the label has a specific month, day, and year, the vaccine can be used through the end of that day. If the expiration date on the label is a month and year, the vaccine can be used through the last day of that month. A multidose vial of vaccine that has been stored and handled properly and is normal in appearance can be used through the expiration date printed on the vial unless otherwise stated in the manufacturer's product information. Some vaccines should be used within a certain time frame after the first time a needle is inserted (e.g., multidose vials), after the vaccine is reconstituted (e.g., vaccines requiring reconstitution), or if the manufacturer deems it is necessary to shorten the expiration date. This time frame is called the "beyond use date" or BUD. The BUD is the date or time after which the vaccine should not be used. It may not be the same as the expiration date printed on the vial by the manufacturer. The BUD varies among vaccines and can be found in the package insert. Check the package insert to determine if the vaccine has a BUD, and for the correct time frame (e.g., days, hours) the vaccine can be stored once the vial has been entered or has been reconstituted. Calculate the BUD using the time interval found in the vaccine's package insert. Label the vaccine with the correct beyond use date/time and your initials. Refer to the CDC's *Vaccine Inventory Management* for specific vaccine product information, including the beyond use dates at <http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling->

### Preventive Measures

- Plug unit directly into wall; do NOT use multi-outlet power strip
- Do NOT use power outlets with built-in circuit switchers
- Do NOT use power outlets that can be activated by a wall switch
- Plug only one unit into an outlet
- Use a plug guard or safety-lock plug
- Install a temperature alarm
- Label circuit breakers and electrical outlets
- Post warning signs that include emergency contact information
- Use water bottles in refrigerator and frozen water bottles in freezer to maintain temperature
- Perform daily inspection of storage unit(s)
- If other biologics must be stored in the same unit, store them BELOW the vaccines to avoid contamination
- Never store food and beverages in the same unit with vaccines
- Take immediate corrective action when there is a problem

### Vaccine and Diluent Inventory Control

- Conduct a monthly vaccine and diluent inventory
- Order vaccine based on
  - projected demand
  - storage capacity
  - current supply
- Avoid overstocking

## Expiration Dates

- Monitor vaccine and diluent expiration dates at minimum, weekly
- Rotate stock so that vaccine and diluent with soonest expiration dates are used first
- If normal in appearance and stored and handled properly, product can be used
  - through end of day indicated if expiration date is mm/dd/yyyy (e.g., 12/15/2015 – use through 12/15/2015)
  - through end of month indicated if expiration date is mm/yyyy (e.g., 12/2015 – use through 12/31/2015)
- Multidose vials
  - can be used through expiration date on vial unless otherwise stated in manufacturer’s product information
- Reconstituted vaccine
  - expiration date/time might change once opened or reconstituted. This is referred to as the Beyond Use Date (BUD) and is provided in the manufacturer’s product information
- Note any change in expiration date/time on vial
- Never use expired vaccine or diluent

toolkit.pdf. Note on a vial any change from the original expiration date/time printed on it, along with your initials. Never use expired vaccine or diluent and immediately remove them from the storage unit.

## Emergency or Off-Site/ Satellite Facility Transport

General guidance regarding transport is provided here and in CDC’s *Vaccine Storage and Handling Toolkit*. Providers should also contact vaccine manufacturers and/or their immunization program for guidance. Some immunization programs may have vaccine packing and transport practices and procedures for maintaining the cold chain in the field that are specific to their area.

Vaccine manufacturers do not generally recommend or provide guidance for transport of vaccines and CDC discourages regular transport. If possible, have vaccines delivered directly to the off-site/satellite facility. Each transport increases the risk that vaccines will be exposed to inappropriate storage conditions.

Plan for emergencies by ensuring that you have proper equipment to maintain the cold chain during transport. CDC recommends that if emergency transport of vaccines is necessary, it should be done using a qualified container and pack-out or portable refrigerator/freezer. Vaccine manufacturers do not recommend re-use of shipping containers and packing material for routine transport.

If vaccines must be transported to an off-site/satellite facility, the amount of vaccines transported should be limited to the amount needed for that workday, including transport and work time (maximum 8 hours). CDC recommends using a digital data logger with a current and valid certificate of calibration testing. CDC does not recommend cold chain monitors (CCMs) since they do not provide adequate data on excursions that may occur during transport.

The facility’s standard operating procedure (SOP) should specify that:

- Vaccines are attended at all times during transport to maintain the cold chain
- Vaccines are not placed in the vehicle trunk
- Vaccines are delivered directly to the facility
- Vaccines are promptly unpacked and placed in appropriate storage units on arrival

A digital data logger with a current and valid certificate of calibration testing is placed with the vaccines during transport.

Diluents should be transported with their corresponding vaccines to ensure that there are always equal numbers of vaccine and diluent for reconstitution. Follow manufacturer guidance for specific temperature requirements. Diluents that contain antigen (e.g., DTaP-IPV diluent used with Hib lyophilized vaccine) should be transported with their corresponding vaccines at refrigerator temperature. NEVER transport any diluents at freezer temperature. Refer to CDC's *Vaccine Storage and Handling Toolkit*, or your immunization program for guidance on vaccine and diluent transport.

### Transporting Varicella-Containing Vaccines to Off-Site/Satellite Facilities

The vaccine manufacturer does not recommend transporting varicella-containing vaccines to off-site/satellite facilities. Varicella-containing vaccines are fragile. If these vaccines must be transported to an off-site/satellite facility, CDC recommends transport with a portable freezer unit that maintains the temperature between -58°F and +5°F (-50°C and -15°C). Portable freezers may be available for rent in some places. If varicella-containing vaccines must be transported and a portable freezer unit is not available, do not use dry ice.

Varicella-containing vaccines may also be transported at refrigerator temperature between 35°F and 46°F, (2°C and 8°C) for up to 72 continuous hours prior to reconstitution using the guidelines in CDC's *Vaccine Storage and Handling Toolkit*.

Having a patient pick up a dose of vaccine (e.g., zoster vaccine) at a pharmacy and transporting it in a bag to a clinic for administration is not an acceptable transport method for zoster vaccine or any other vaccine.

### Monitoring Temperatures at Off-Site/Satellite Facility

Vaccines should be placed in an appropriate storage unit(s) at the recommended temperature range(s) immediately upon arrival at the alternate facility. CDC recommends placing a digital data logger in the storage unit(s) with the vaccines. Read and document temperatures 2 times during the workday. CDC does not recommend keeping vaccines in a transport container unless it is a portable refrigerator or freezer unit. If vaccines must be kept in transport containers during an off-site clinic:

#### Transport to Off-Site/Satellite Facilities

- Not recommended by vaccine manufacturers
- If possible, have vaccines delivered directly to the off-site/satellite facility
- Plan for emergencies by ensuring you have proper equipment to maintain cold chain during transport
- If transport is necessary, use a qualified container and pack-out or portable refrigerator/freezer
- Vaccine manufacturers do not recommend re-use of shipping containers and packing material for routine transport

#### Transport of Varicella-containing Vaccines to Off-Site/Satellite Facilities

- The manufacturer does not recommend transporting varicella-containing vaccines to off-site facilities
- If vaccine must be transported, use a portable freezer that maintains the temperature between -58°F and +5°F (-50°C and -15°C)
- Do NOT use dry ice
- Varicella-containing vaccines may be also transported at refrigerator temperature between 35°F and 46°F (2°C and 8°C), for up to 72 continuous hours prior to reconstitution
- Must use the guideline in CDC's *Vaccine Storage and Handling Toolkit*
- Patient transport of vaccine (e.g. zoster) from pharmacy to a clinic for administration is not an acceptable transport method for any vaccine

## Vaccine Preparation

- Once the protective cap is removed, vaccine in single-dose vial should be used or discarded at end of workday
- Once manufacturer-filled syringe is activated (remove needle cap or attach needle) sterile seal is broken and should be used or discarded at end of workday
- Do not predraw vaccine
  - increases risk for administration errors
  - wasted vaccine
  - possible bacterial growth in vaccines that do not contain a preservative
  - administration syringes not designed for storage
- Consider using manufacturer-filled syringes for large immunization events because they are designed for both storage and administration

- Container(s) should remain closed as much as possible.
- Calibrated temperature monitoring device(s) (preferably with a buffered probe) should be placed as close as possible to vaccines.
- The temperature(s) inside the containers(s) should be read and documented at least hourly.
- Only the amount of vaccine needed at one time (no more than 1 multidose vial or 10 doses) should be removed for preparation and administration by each vaccinator.

## Vaccine Preparation

Most vaccines are supplied in single-dose vials or manufacturer-filled syringes. These preparations do not contain a bacteriostatic (preservative) agent. Once a single-dose vial is opened, meaning that the protective cap has been removed, it should be discarded at the end of the workday if not used. The same is true for an activated manufacturer-filled syringe. Removing the needle cap or attaching a needle activates a manufacturer-filled syringe and breaks the sterile seal. Multidose vials contain a bacteriostatic (preservative) agent. Once opened, a multidose vial may be used through the expiration date unless contaminated or the manufacturer's product information specifies a different timeframe (BUD).

CDC recommends that providers draw up vaccine only at the time of administration and not predraw vaccines. Filling a syringe before it is needed increases the risk for administration errors. Once in the syringe, vaccines are difficult to tell apart. Other problems associated with this practice are wasted vaccine, the risk of inappropriate temperature conditions, resulting in potentially reduced vaccine potency, and possible bacterial contamination in vaccines that do not contain a preservative, such as single-dose vials.

Syringes other than those filled by the manufacturer should be used only for immediate administration and not for vaccine storage. If for some reason, like a large flu clinic, more than one dose of a particular vaccine must be predrawn, draw up only a few syringes at one time (no more than 10 doses or the contents of a single multidose vial). In accordance with best practice standards, these syringes should be administered by the person who filled them.

As an alternative to predrawing vaccine, CDC recommends using manufacturer-filled syringes for large immunization events, such as community influenza clinics. These syringes are designed for both storage and administration.



## Vaccine Disposal

Unused vaccine and diluent doses may be returnable under certain circumstances. Contact the vaccine supplier, which may be the immunization program or the vaccine manufacturer, for specific policies regarding the disposition of returnable vaccine, unopened vials, expired vials, unused doses, and potentially compromised vaccine due to inappropriate storage conditions.

In general, most empty vaccine vials are not considered hazardous or pharmaceutical waste and do not require disposal in a biomedical waste container. However, requirements for medical waste disposal are regulated by state environmental agencies so you should contact your immunization program or state environmental agency to ensure that your disposal procedures are in compliance with state and federal regulations.

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Immunization Action Coalition Storage and Handling Handouts: <http://www.immunize.org/clinic/storage-handling.asp>

### Vaccine Disposal

- Consult immunization program or vaccine manufacturer regarding returnable vaccines
- Refer to CDC's *Vaccine Storage and Handling Toolkit* for comprehensive storage and handling guidance.

# Storage and Handling

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