

This chapter provides best practice guidance for storage and handling. Additional resources are available in Appendix C.

Vaccine Storage and Handling

There are few immunization issues more important than the appropriate storage and handling of vaccines. The success of efforts against vaccine-preventable diseases is attributable in part to proper storage and handling of vaccines. Vaccines exposed to temperatures outside the recommended ranges can have reduced potency and protection. 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. Proper maintenance of vaccines during transport is known as the cold chain. 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 manufacturer 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.

Vaccine Storage Temperatures

Vaccines are fragile. They must be maintained at the temperatures recommended by vaccine manufacturers and protected from light at every link in the cold chain. Most live virus vaccines tolerate freezing temperatures, but deteriorate rapidly after they are removed from storage. Inactivated vaccines can be damaged by exposure to temperature fluctuations (e.g., extreme heat or freezing temperatures). Potency can be adversely affected if vaccines are left out too long or exposed to multiple temperature excursions (out-of-range temperatures) that can have a cumulative negative effect. It is a good idea to post a sign on the front of the storage unit(s) indicating which vaccines should be stored in the freezer and which should be stored in the refrigerator.

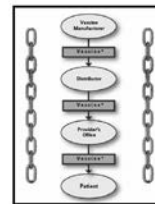
Freezer

All varicella-containing vaccines should be stored in a continuously frozen state at the manufacturer recom-

Vaccine Storage and Handling

- Success against vaccine-preventable diseases due in part to proper storage and handling
- Storage and handling errors
 - reduced potency and effectiveness
 - 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 to patients
 - manufacturer to distributor
 - distributor to office
 - office to patient

Vaccine Storage Temperatures

- Live vaccines
 - most tolerate freezing
 - deteriorate rapidly after removal from storage
- Inactivated vaccines
 - damaged by exposure to temperature fluctuations (extreme heat or freezing temperatures)
- Potency negatively affected by extended or multiple temperature excursions

Vaccine Storage and Handling

Recommended Temperatures

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

mended freezer temperature until administration. All varicella-containing vaccines (VAR, Varivax; ZOS, Zostavax; and MMRV, ProQuad) should be stored between between -58°F and +5°F (-50°C and -15°C).

The measles, mumps, rubella vaccine (MMR) can be stored either in the freezer or the refrigerator. Storing MMR in the freezer with MMRV may help prevent inadvertent storage of MMRV in the refrigerator.

Refrigerator

All inactivated vaccines require refrigerator storage temperatures between 35°F and 46°F (2°C and 8°C), with a desired average temperature of 40°F (5°C). The following live attenuated vaccines must also be kept at refrigerator temperature: influenza (LAIV, FluMist); rotavirus (RV1, Rotarix and RV5, RotaTaq); typhoid (Ty21-A, Vivotif); and yellow fever (YF-Vax). Review each manufacturer's instructions in the product information for vaccine specific storage temperatures.

Before reconstitution with diluent, all varicella-containing vaccines can be stored at refrigerator temperature between 35°F and 46°F (2°C and 8°C) for up to 72 continuous hours. Contact the vaccine manufacturer and/or your local or state immunization program for guidance before discarding any refrigerated varicella-containing vaccine that cannot be used within 72 hours.

Storage and Handling Plans

Written routine and emergency storage and handling plans should be developed and maintained.

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

- ordering and accepting vaccine deliveries;
- storing and handling vaccines;
- managing inventory; and,
- managing potentially compromised vaccines.

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

Vaccine Storage and Handling Plans

- Develop and maintain written routine plan for:
 - ordering and accepting vaccine deliveries;
 - storing and handling vaccines;
 - managing inventory; and,
 - managing potentially compromised vaccines
- Develop and maintain written emergency vaccine retrieval and storage plan
 - backup storage location with appropriate storage units, temperature monitoring capability, and backup generator
 - adequate coolers or refrigerated truck

An adequate supply of packing materials (e.g.; coolers, cold packs, barriers) to accommodate the facility's vaccine supply should be available to move vaccines if needed. Keep a copy of the most current emergency plan, guidelines for transporting vaccines. 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 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 vaccine. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

Personnel, Training and Education

A primary vaccine coordinator who is responsible for ensuring that vaccines are stored and handled correctly should be assigned at each facility. At least one backup vaccine coordinator who can perform these responsibilities in the absence of the primary coordinator should be designated. These responsibilities include, but are not limited to the following tasks:

- ordering vaccines;
- overseeing proper receipt and storage of vaccine shipments;
- organizing vaccines within the storage unit(s);
- temperature monitoring of the storage unit(s) at least twice daily;
- recording temperature readings on a log;
- daily physical inspection of the storage unit(s);
- rotating stock so that vaccine closest to its expiration date will be used first;
- monitoring expiration dates and ensuring that expired vaccine is removed from the storage unit(s) and not administered to patients;
- responding to potential temperature excursions;
- overseeing proper vaccine transport;

Personnel, Training and Education

- Assign responsibilities to a primary vaccine coordinator
- Designate at least one backup person
- Provide training and continuing education on vaccine storage and handling for staff

Vaccine Coordinator Responsibilities

- Ordering vaccines
- Overseeing proper receipt and storage of shipments
- Organizing vaccines within storage unit(s)
- Temperature monitoring of storage unit(s) at least twice daily
- Recording temperature readings on log
- Daily physical inspection of storage unit(s)
- Rotating stock so that vaccine closest to its expiration date will be used first

Vaccine Storage and Handling

Vaccine Coordinator Responsibilities

- Monitoring expiration dates and removing expired vaccine
- Responding to potential temperature excursions
- Overseeing proper vaccine transport
- Maintaining storage and handling documentation
- Maintaining storage equipment and records
- Maintaining VFC program documentation in participating clinics
- Ensuring adequate staff training

Training and Education

- Personnel 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 in storage and handling guidelines occur

Vaccine Storage Equipment

- Select carefully; use properly; maintain regularly; monitor consistently
- Consult immunization program for any specific requirements
- Keep an equipment logbook
 - equipment serial number
 - equipment installation date
 - dates of routine maintenance
 - dates of service/repairs and contact information on service provider
 - equipment instructions

- maintaining all appropriate vaccine storage and handling documentation, including temperature-excursion responses;
- maintaining storage equipment and records;
- maintaining proper documentation for the Vaccines for Children (VFC) program in participating facilities; and,
- ensuring that designated staff is adequately trained.

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. These policies and procedures should be available in writing as a reference for all staff members. 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. Immunization programs often have good resources for staff training.

Vaccine Storage Equipment

Vaccine storage equipment 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 general guidelines for vaccine storage equipment. Providers should consult their immunization program, particularly those who provide vaccines purchased with public funds, for any specific storage equipment requirements.

It is good practice to 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 servicing, and the name and contact information of the person or company performing each of these tasks should be recorded. A logbook is also an ideal place to keep the instructions that came with the equipment.

Freezers and Refrigerators

Using the correct freezer and/or refrigerator can help prevent costly vaccine losses and the inadvertent administration of compromised vaccines. Freezers and refrigerators

are available in many different sizes, types (e.g., stand-alone versus combination), and grades (e.g., household, commercial, and pharmaceutical). CDC strongly recommends stand-alone freezers and refrigerators without freezers. Studies have demonstrated they maintain the required temperatures better than combination units. An alternative to stand-alone units would be to use the refrigerator compartment of a combination refrigerator/freezer unit to store refrigerated vaccines. A separate stand-alone freezer would be used to store frozen vaccines. CDC has received multiple reports of incidences when refrigerated vaccines have been compromised by exposure to freezing temperatures in a combination unit. At a minimum, a combination refrigerator/freezer unit sold for home use with separate exterior doors and thermostat controls for each compartment is acceptable (but not recommended).

Any freezer or refrigerator used for vaccine storage should have its own exterior door that seals tightly and properly, as well as thermostat controls. It must be able to maintain the required temperature range throughout the year. The unit should be dedicated to the storage of biologics and it must be large enough to hold the year's largest vaccine inventory without crowding (including flu vaccine). A storage unit that is frost-free or has an automatic defrost cycle is preferred. If using a combination freezer-refrigerator unit to store vaccines, care must be taken to ensure that the freezer is not so cold that the refrigerator temperature drops below the recommended temperature range. There should be separate temperature controls (thermostats) for the freezer and refrigerator compartments.

Good air circulation around the vaccine storage unit is essential for proper heat exchange and cooling functions. The 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.

Any vaccine storage in a dormitory-style refrigerator is not recommended by CDC. A dormitory-style refrigerator is defined as a small combination freezer/refrigerator unit that is outfitted with one exterior door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator. Based on research published in December 2009, the National Institute of Standards and Technology (NIST) concluded that "the dorm-style refrigerator is NOT recommended for vaccine storage under any circumstance." In performance testing, the dormitory-style refrigerator demonstrated consistently unacceptable performance, regardless of where the vaccine was placed inside the unit. This unit also exhibited large

Freezers and Refrigerators

- Stand alone freezers and refrigerators without freezers are strongly recommended (frost-free or automatic defrost units are preferred)
- Freezer and refrigerator compartments must each have own exterior door and thermostat controls
- 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)

Storage Unit Placement

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

Thermometers

- Use calibrated thermometers with a Certificate of Traceability and Calibration from an ISO 17025 accredited testing lab, NIST, or another internationally recognized standards agency
 - digital
 - bio-safe liquid
 - continuous graphic
 - minimum/maximum

Temperature Monitoring

- Temperatures in both the freezer and refrigerator units should be read and recorded twice each day
 - once in the morning and once before leaving at the end of the workday
- Post temperature log on the door of the storage unit
- Keep temperature logs for at least 3 years unless state statutes or rules require a longer period

spatial temperature gradients confirming that there is no “good” vaccine storage area in a dorm-style unit. Based on this research, CDC strongly recommends using a compact refrigerator without a freezer compartment rather than a dormitory-style combined refrigerator/freezer to reduce the risk of exposing vaccine to freezing temperatures, even for temporary storage of vaccines.

Thermometers

Thermometers are a critical part of good storage and handling practice. The freezer and the refrigerator unit or compartment should each have its own thermometer. There are a variety of types, including digital, bio-safe liquid, continuous graphic, and minimum/maximum thermometers. For measuring vaccine storage unit temperatures, CDC recommends using only calibrated thermometers with a Certificate of Traceability and Calibration. The traceability declaration is to confirm that the measurement standards and instruments used during calibration of the product are from an ISO 17025 (International Organization of Standardization) accredited testing laboratory, to NIST, or to another internationally recognized standards agency.

Because all thermometers are calibrated as part of the manufacturing process, this recommendation refers to a second calibration process that occurs after manufacturing but before marketing and is documented with a certificate that comes with the product. Periodic recalibration is necessary. Manufacturer guidelines should be consulted for specific information on recalibration. For many types of thermometers, purchasing a replacement thermometer may be less expensive than recalibration. Immunization programs are often excellent resources for information on calibrated thermometers.

Temperature Monitoring

Regular temperature monitoring is vital to proper cold chain management. Temperatures in both the freezer and refrigerator units should be read twice each day, once in the morning and once before leaving at the end of the workday. A temperature log should be posted on the door of the storage unit where the twice daily temperature readings are recorded. CDC recommends keeping these temperature logs for at least 3 years unless state statutes or rules require a longer period. 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.

Some providers have purchased alarmed, continuous, automatic, temperature monitoring devices. CDC’s recommenda-

tion is to continue manual temperature monitoring at least twice daily. Although they may help to minimize human error, the alarmed and continuous monitoring temperature devices have not proven fail safe. CDC continues to receive reports of automatic electronic monitoring system failures and undetected, unresolved vaccine temperature excursions using these systems as the sole equipment temperature monitor. Manually recording temperatures provides an opportunity to visually inspect the storage unit, reorganize the vaccine when necessary (e.g., moving vaccine away from walls or cold air vents), identify vaccines with short expiration dates, remove any expired vaccines, and provide a timely response to temperature excursions.

It is inevitable that manual temperature monitoring may not be accomplished when a provider's office is closed, however. In that case, the electronic monitoring system can provide a backup for assurance that storage temperatures remain within vaccine manufacturers' recommended ranges and that corrective action can be taken quickly if they 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.

Thermometer placement within the unit is just as important as thermometer selection. Prior to storing vaccines in a unit, the temperature should be allowed to stabilize and then be measured in various locations within the unit to document that a consistent temperature can be maintained. This can detect if there are any particular cold or hot spots where vaccine should not be placed, as well as determining where the most reliable, consistent thermometer reading can be obtained. New units may need 2 or more days of operation to establish a stable operating temperature.

If at any time it is discovered that stored vaccines have been exposed to temperatures outside the recommended ranges, these vaccines should remain properly stored, but segregated and marked "Do NOT Use" until guidance can be obtained. Protocols after an event will vary depending on individual state or agency policies. Contact the immunization program, vaccine manufacturer(s), or both for guidance.

Vaccine Placement and Labeling

A storage unit should be big enough so that vaccines can be placed away from the walls, coils, and vents in the part of the unit best able to maintain the constant, required temperature. Vaccines should be kept in their original packaging with the lids in place until ready for administration and stacked in rows with vaccine of the same type. Bins, baskets, or some other type of uncovered containers that allow for air circulation can be used to organize the vaccines within the storage unit. There should be space between the

Vaccine Placement and Labeling

- Store vaccine away from unit walls, coils, and vents
- Keep vaccines in original packaging
- Stack in rows with same type of vaccine
- Use uncovered storage containers
- Use labels with vaccine names and age indications or color coding
- Protect vaccine from light

Vaccine Storage and Handling

vaccine stacks or containers. These measures will help to avoid confusion between vaccines, provide for air circulation around and through vaccine 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. The manufacturer's product information indicates if the vaccine must be protected from light.

Vaccines that must be reconstituted are shipped with diluent specific to that vaccine. Vaccine diluents are not all the same, some contain vaccine antigen. As with vaccines, diluents should be stored according to the guidelines in the manufacturer's product information. When feasible, diluents that require refrigeration should be stored with their corresponding vaccines. Never store any diluent in the freezer because the vials are not designed for freezer storage and could crack. (See job aid in Appendix C)

Diluent Storage

- Diluent is shipped with the corresponding vaccine
- Store diluent as directed in manufacturer's product information
- Store refrigerated diluent with corresponding vaccine (these diluents may contain vaccine antigen)
- Do not freeze diluents
- Label diluent to avoid inadvertent use of the wrong diluent when reconstituting a vaccine

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 sitting or by placing labels on the containers. It may be helpful to use color coding (e.g., one color for pediatric and another for adult) or include the age indications for each vaccine type on the labels. 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.

Vaccine Storage Troubleshooting

To maintain the proper temperature ranges, the freezer and refrigerator 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.

Storage units should be plugged directly into wall outlets; multi-strip outlets should not be used. Plug guards or safety-lock plugs should be put in place 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. The circuit breakers can also be labeled to alert janitors 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 the storage unit, and at the circuit breaker box. The warning sign should include emergency contact information.

Containers of water, labeled “Do NOT Drink,” can be placed in the refrigerator to help stabilize the temperature in the unit. If the refrigerator unit has vegetable/fruit bins, these should be removed. If there is a shelf holding the vegetable/fruit bins in place, it should also be removed. The water containers can then be put in place of the vegetable/fruit bins. Deli drawers should also be removed. The same principle applies to the freezer. Extra frozen packs or blue ice can be stored in the freezer. These measures will help keep the temperature stable with frequent opening and closing of the doors.

Vaccines should never be stored in the door of the freezer or refrigerator. The temperatures in these areas are not stable. The door of the freezer can be used to store extra frozen packs or blue ice and the door of the refrigerator can be used to store extra water containers or diluents that do not contain vaccine antigen. Frozen packs and water bottles stored in the doors should be placed securely so that they cannot dislodge and prevent the door from closing. In addition, caution must be taken to avoid weighing down the doors so much that the seals are compromised when the doors are closed.

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

- Are the vaccines placed properly in the unit?
- Are the vaccines in their original boxes?
- Are vaccines being stored away from the walls, coils, and vent and not being stored in the doors?

During a work day 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. Vaccine purchased with public funds should be identified and stored separately from vaccines purchased with private funds.

CDC recommends that vaccines be kept in storage units dedicated only to vaccines. If other biologic specimens must be stored in the same unit as vaccines, specimens should be stored on a lower shelf than the vaccines. This is to ensure that if a specimen leaks, the vaccine 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. It is

Preventive Measures

- Plug unit directly into wall; do NOT use multi-strip outlet
- Use a plug guard or safety-lock plug
- Install a temperature alarm
- Label circuit breakers
- Use water bottles in the refrigerator and ice packs in the freezer to maintain temperature

Preventive Measures

- Do NOT store vaccine in vegetable/fruit bins, deli drawers, or doors
- 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 Inventory Control

- Conduct a monthly vaccine and diluent inventory
- Order vaccine responsibly based on
 - projected demand
 - storage capacity
 - current supply
- Request delivery during office hours

Expiration Dates

- Monitor vaccine and diluent expiration dates closely
- Rotate stock so that vaccine and diluent with shortest 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., 12/15/2012 – use through 12/15/2012)
 - through end of month indicated if expiration date is mm/yyyy (e.g., 12/2012 – use through 12/31/2012)

Expiration Dates

- Multidose vials
 - can be used through expiration date on label unless otherwise stated in manufacturer's product information
 - mark with date first opened
- Reconstituted vaccine
 - once reconstituted use within timeframe indicated by manufacturer or discard
- Never use expired vaccine or diluent

very important that staff know whom to contact in case of a malfunction or disaster.

If the problem is short-term (usually 2 hours or less) and depending on outside ambient temperature, the storage unit temperature can probably be maintained with the water containers in the refrigerator, with frozen packs or blue ice in the freezer, and by keeping the unit doors closed. If there is an extended period of time before the situation can be corrected and there are no other storage units available on site, the vaccine should be moved to the backup storage facility using the guidelines in the emergency plan.

Vaccine Inventory Control

A vaccine inventory should be conducted monthly to ensure adequate supply to meet demand. Vaccine diluents should also be included in the inventory to ensure adequate supplies are available. Determining factors for the amount of vaccine and diluent ordered include: projected demand, storage capacity, and current vaccine supply. Vaccine coordinators should request delivery during office hours. Each vaccine order should be updated to reflect any period of time the office will be closed, such as holidays or scheduled vacation time.

It is also important to avoid overstocking vaccine supplies which could lead to vaccine wastage or having outdated vaccine on hand. Vaccine and diluent expiration dates should be closely monitored. Rotate stock so that vaccine and diluent with the shortest expiration date 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 end 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. Mark a multidose vial with the date it is first opened. Mark reconstituted vaccine with the date and time it is reconstituted. The expiration date or time might change once the vaccine is opened or reconstituted. This information is provided in the manufacturer's product information. Expired vaccine and diluent should never be used and should be promptly removed from the storage unit.

Receiving and Unpacking Vaccine Shipments

Proper vaccine storage and handling is important from the moment the vaccine arrives at the facility. All office staff should be informed of who to notify when a vaccine delivery has arrived. This is extremely important for receptionists or

other front desk staff since they are often the first to know that vaccines have been delivered. Vaccine shipments should be inspected on arrival. Vaccines should be stored at the proper temperature immediately upon arrival. The shipping container and its contents should be examined for any evidence of damage during transport. The contents should be cross checked with the packing slip to be sure they match. Both heat and cold temperature monitors/indicators should be checked upon delivery following instructions on the monitors for reading and reporting. If a monitor indicates possible adverse temperature excursion during shipping, the monitor reading should be documented for future reference and reported to the distributor within the required timeframe if VFC vaccine is involved. Shipments sent directly by the vaccine manufacturer are in specially designed boxes and may not contain heat or cold temperature monitors.

The shipment date should be checked to determine how long the package was in transit. If the interval between shipment from the distributor and arrival of the product at the facility was more than 48 hours, this could mean the vaccine has been exposed to excessive heat or cold that might alter its integrity. If there are any discrepancies with the packing slip or concerns about the vaccine shipment, the vaccines should be stored in proper conditions, but segregated and marked “Do NOT Use” until the integrity of the vaccines is determined. Contact either the immunization program or the vaccine manufacturer, depending on who shipped the vaccine and the state or agency policy.

The contents of each shipment should be recorded 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 name of the vaccine manufacturer, the lot numbers, the expiration dates for each vaccine, and any action taken as a result of a question of vaccine integrity.

Vaccine Transport to Off-Site Clinics

The number of times vaccines are handled and transported should be minimized. If vaccine transportation to another location is required, it is critical that vaccine potency is protected by maintaining the cold chain at all times. Some immunization programs may recommend or require different vaccine transport practices and procedures. Providers should contact their immunization program for details on how to pack vaccine and diluent for transport and procedures for maintaining the cold chain in the field.

When a multidose vial is used, Food and Drug Administration (FDA) regulations require that it be used only by the provider’s office where it was first opened. A partially used

Vaccine Shipments

- Inspect vaccine shipments
 - container
 - contents
 - shipping temperature monitors/indicators
- If there are concerns, store vaccines properly, but segregate from other vaccines and mark “Do NOT Use”
- Consult immunization program or vaccine manufacturer for guidance

Vaccine Transport to Off-Site Clinics

- Maintain cold chain at all times
- Contact immunization program for specific policies regarding vaccine transport
- Diluent should travel with its corresponding vaccine
- Monitor temperature hourly if vaccine kept in cooler during off-site clinic
- Patient transport of vaccine (e.g., zoster) from pharmacy to clinic for administration is not an acceptable transport method for any vaccine

Transport of Varicella-Containing Vaccine to Off-Site Clinics

- CDC and manufacturer do not recommend transporting varicella-containing vaccine to off-site clinics
- 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 transported at refrigerator temperature between 36°F and 46°F, (2°C and 8°C) for up to 72 continuous hours prior to reconstitution
- Must use the guideline in the Vaccine Storage and Handling Guide

vial may be transported to or from off-site clinics operated by the same provider as long as the cold chain is properly maintained. However, such a vial may not be transferred to another provider or transported across state lines. While there is no defined limit to the number of times vaccine may be transported to different clinic sites, each transport increases the risk that vaccine will be exposed to inappropriate storage conditions.

Diluent should travel with its corresponding vaccine to ensure that there are always equal numbers of vaccine vials and diluent vials for reconstitution. Diluent should be transported at room temperature or inside the same insulated cooled container as the corresponding vaccine, according to manufacturer guidelines for each diluent. If transported inside cooled containers, diluent must not be in direct contact with frozen or cold packs because of the potential for freezing. If any diluents that have been stored at room temperature are going to be carried in the insulated transport container, refrigerate the diluents in advance so they do not raise the temperature of the refrigerated vaccines.

Transporting Varicella-Containing Vaccines to Off-Site Clinics

CDC and the vaccine manufacturer do not recommend transporting varicella-containing vaccines to off-site clinics. Varicella-containing vaccines are fragile. If these vaccines must be transported to an off-site clinic, 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 be transported at refrigerator temperature between 36°F and 46°F, (2°C and 8°C) for up to 72 continuous hours prior to reconstitution using the guidelines in the Vaccine Storage and Handling Guide (<http://www.cdc.gov/vaccines/recs/storage/guide/vaccine-storage-handling.pdf>, p. 72).

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**.

Temperature Monitoring During Off-Site Clinics

Vaccines should be stored at the recommended temperatures immediately upon arrival at the facility. (Vaccine Storage and Handling Guide, <http://www.cdc.gov/vaccines/recs/storage/guide/vaccine-storage-handling.pdf>). Record storage unit temperatures twice daily. If vaccine must be

kept in an insulated cooler, keep the cooler closed as much as possible. At a minimum, record the cooler temperature hourly.

Vaccine Preparation

Vaccine should be drawn from the vial into the syringe at the time of administration. CDC strongly discourages providers from filling syringes in advance, for a number of reasons. 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 and possible bacterial growth in vaccines that do not contain a preservative, such as vaccines supplied in single-dose vials.

Syringes other than those filled by the manufacturer are designed for immediate administration and not for vaccine storage. If for some reason 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. Any syringes prefilled by the provider must be stored at the recommended temperature range and used or discarded by the end of the clinic day.

As an alternative to prefilling syringes, CDC recommends use of manufacturer-supplied prefilled syringes for large immunization events, such as community influenza clinics. These syringes are designed for both storage and administration. Once a manufacturer prefilled syringe is activated (i.e., syringe cap removed or needle attached), the sterile seal is broken. The syringe should be used that day or discarded at the end of the clinic day.

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 unopened vials, expired vials, unused doses, doses drawn but not administered, and potentially compromised vaccine due to inappropriate storage conditions. If these vials or doses are publicly purchased, contact the immunization program for instructions on returning doses for excise tax credit. Vaccine that has been prefilled by the provider staff and unused should never be returned to the manufacturer or distribution center. If the immunization program or the manufacturer advises discarding the vials or syringes, this should be done using the medical waste disposal procedures outlined in individual immunization program guidelines.

Do Not Prefill Syringes

- Increases the risk for administration errors
- Wasted vaccine
- Possible bacterial growth in vaccines that do not contain a preservative
- Administration syringes not designed for storage
- Any syringes prefilled by the provider must be stored at the recommended temperature range and used that day or discarded at the end of the clinic day

Prefilling Syringes

- Consider using manufacturer-supplied prefilled syringes for large immunization events because they are designed for both storage and administration
- Do not “activate” (remove syringe cap or attach needle) until ready to administer the vaccine; “activation” breaks the sterile seal
- Any unused activated syringe should be discarded at end of clinic day

Vaccine Disposal

- Consult immunization program or vaccine manufacturer regarding returnable vaccines
- Vaccines that are not returnable should be discarded as medical waste according to state guidelines

Additional resources/job aids are available in Appendix C and more detail on vaccine storage and handling topics is available in CDC's Storage and Handling Toolkit.

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