Policy & Procedure Title: Storage and Handling-Vaccine Management

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Policy & Procedure Summary

All personnel who handle or administer vaccines should be familiar with the routine and emergency vaccine management plans for their facility. Provider vaccine storage and handling plans must include the signature, name, and title of the preparer of the documents. Those trained on these plans include 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. The vaccine management plan as well as the Immunization Division policies and procedures should be available in writing as a reference for all staff members.

Policy Statement

All VFC providers must comply with the program requirements for vaccine management, including the storage of vaccine under proper conditions at all times. Routine and emergency vaccine storage and handling plans should be developed and maintained to provide guidance for daily activities, such as ordering and accepting vaccine deliveries; storing and handling vaccines; managing inventory; and managing potentially compromised vaccines.

Annual training must be conducted for all staff members in each facility enrolled in the VFC program. This training must include a review of the location’s routine and emergency vaccine management plans, and the content of these plans. This annual training must be documented with a log of all attendees. VFC providers need to maintain documentation of this training that will be presented during a site visit with an Immunization Field Representative.

In addition, vaccines 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 changes to the storage and handling guidelines for a particular vaccine. The Indiana Immunization Division offers training on vaccines specific topics for all facilities.

Vaccine Ordering and Inventory Control

Vaccine coordinators should order vaccines to maintain an adequate amount to meet the needs of the facility’s patients. The amount of vaccine needed can vary throughout the year. Anticipate peak periods such as back-to-school appointments or influenza season and order accordingly. Order the vaccines and presentations that are appropriate for the ages and types of patients the facility serves.

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. It is also important to avoid overstocking vaccine supplies which could lead to vaccine wastage or having outdated vaccine on hand.

Vaccine coordinators should request delivery during regular office hours. Vaccine shipments should be delivered when staff is available to unpack and store the vaccine properly. Shipment times should be updated at the time each vaccine order is submitted and should reflect any period of time the office will be closed, such as holidays, scheduled vacation, change in hours of operation and/or lunch hour. Providers must be on site with appropriate staff available to receive vaccine at least one day a week other than Monday, and for at least four consecutive hours during that day.

Vaccine Inventory Management

- Vaccine and diluent expiration dates should be closely monitored.
  - Expired vaccine and diluent should never be used and should be promptly removed from the storage unit.
• 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 (mm/dd/yyyy), the vaccine can be used through the end of that day.

• If the expiration date on the label is a month and year (mm/yyyy), the vaccine can be used through the end of that month.

• **Opened vials of multi-doses vaccines should NOT be wasted before the manufacturer's expiration date.** Multi-dose vials of vaccines have different storage and handling requirements than multi-dose vials of medications.
  
  o **Multi-dose vials should not be discarded 28 or 30 days after opening.** Providers who discard open multi-dose vials after 28 or 30 days may be required to replace the wasted vaccines, according to the Vaccine Loss and Replacement Policy. Some flu vaccines should be disposed after 28 days; information will be provided each flu season.

• 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.

• Keep vaccines in their original packaging with the lids in place until ready for administration and stacked in rows with vaccine of the same type. This prevents exposure to light and prevents mixing of lot numbers and expiration dates.

**Vaccine Storage Units**

Refrigerator and freezer vaccine storage units must meet all recommendations and requirements. These program requirements are defined in policy “Storage and Handling – Storage Unit Requirements”. Please refer to this policy for complete requirements.

**Vaccine Temperature Monitoring**

Temperature monitoring and equipment must meet program requirements. The temperatures in storage units must be monitored and documented appropriately as defined in the policy “Storage and Handling – Temperature Requirements”. Please refer to this policy for complete requirements.

**Managing Potentially Compromised Vaccines**

If vaccine and/or diluent has expired or has been exposed to a temperature excursion, the Vaccine Coordinator should identify and isolate all potentially compromised vaccines and store separately in an alternate storage unit within the recommended temperature range. Label these as “DO NOT USE”.

Contact the Indiana Immunization Division and the vaccine manufacturers for appropriate actions that should be followed for all potentially compromised vaccines and diluents.

Educate staff administering vaccines on correct handling and preparation procedures to decrease the likelihood of vaccines and diluents inadvertently being compromised.

**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. Educate all facility staff about proper vaccine storage.
This is extremely important for receptionists or other front desk staff since they are often the first to know that vaccines have been delivered.

Orders should also be received in VOMS as soon as the shipment arrives to ensure proper inventory management. **Providers should not manually enter inventory in VOMS when receiving an order.** Failure to follow procedures for receiving vaccine orders may result in providers having large discrepancies in vaccine inventory, and may result in suspension from the program.

Vaccines must be kept in their original packaging with the lids in place until ready for administration to protect them from sunlight and fluorescent light. Storing vaccines outside of their packaging leads to administration errors when staff is confused about vaccines, and makes managing inventory and tracking expiration dates more difficult. Also vaccines not in the original packaging cannot be transferred to another facility.

**Note:** NEVER refuse a vaccine shipment of publicly funded vaccine. **If there is a problem with the shipment, place the vaccine in the appropriate storage unit and contact the Immunization Division immediately.**

Vaccines should be stored at proper temperatures IMMEDIATELY upon arrival.

- Vaccine shipments should be inspected on arrival.
  - The shipping container and its contents should be examined for any evidence of damage during transport.
  - 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 Immunization Division within 2 hours of receipt of the shipment.
    - Shipments sent directly by the vaccine manufacturer are in specially designed boxes and may not contain heat or cold temperature monitors.
  - Determine the length of time the vaccine was in transit by looking at the packing list.
    - 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.
  - The contents should be cross checked with the packing slip to be sure they match.
  - Diluents should be stored according to the manufacturers’ instructions. Diluents should be clearly labeled, whether they are stored at room temperature or in the refrigerator. Label the packages of corresponding vaccines and diluents from the same manufacturer so that they will be used together. This avoids confusion and helps to ensure that you use only the specific diluent provided by the manufacturer for each type of lyophilized (freeze-dried) vaccine.
    - Immediately store at the appropriate temperatures.

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. Any discrepancies or concerns should be reported immediately to the Indiana Immunization Division at (800) 701-0704 within 2 hours of receipt of shipment.
The contents of each shipment should be received within the Vaccine Ordering Management System (VOMS) immediately upon receipt. Lack of receipt of the vaccines could potentially result in errors in inventory and result in suspension.

Receiving Direct Ship Vaccines

All varicella-containing vaccines are shipped separately from other vaccines and are shipped directly from the manufacturer, Merck. The vaccine shipping containers are packed according to Merck guidelines that take into account the maximum temperature to which the container will be exposed, the time in transit, and the need to keep the vaccine at the appropriate temperature during shipping.

- Varicella-containing vaccine should be stored at proper temperatures IMMEDIATELY upon arrival.
  - To maintain potency the vaccine must be stored frozen between -58°F and +5°F (-50°C to -15°C).
  - The manufacturer recommends that the vaccine NOT be stored on dry ice. Use of dry ice may subject the product to temperatures colder then -58°F (-50°C).

- Varicella-containing vaccine shipments should be inspected on arrival.
  - The shipping container and its contents should be examined for any evidence of damage during transport.
    - Varicella-containing shipments contain refrigerant packs to protect product on all sides to keep it stable and cold. This practice replaces the use of dry ice during shipment.
  - Determine the length of time the vaccine was in transit by looking at the packing list.
    - Adequate refrigerant (frozen gel packs) are placed to maintain proper temperatures for three days from the shipment date located on the packing slip. If the container is received after this time period, contact Merck Order Management Center immediately for replacement instructions at (800) 637-2579. The Immunization Division should also be contacted in this event.
  - Shipments sent directly by the vaccine manufacturer are in specially designed boxes and may not contain heat or cold temperature monitors.

- Invoice and packing slips are separate from product.

- Diluent is conveniently located in the top compartment of the shipping box underneath the cardboard cap. Store the diluent upon arrival in a refrigerator (2°C to 8°C/36°F to 46°F) or at room temperature (20°C to 25°C/68°F to 77°F).

- Immediately store at frozen temperatures.

Vaccine Preparation

Vaccine should be drawn from the vial into the syringe at the time of administration. An individual should only administer a vaccine he or she has prepared and drawn up.

Syringes other than those filled by the manufacturer are designed for immediate administration and not for vaccine storage. Do not predraw doses before they are needed. Predrawing vaccine into syringes is a quality control and patient safety issue for many reasons. Filling a syringe before it is needed increases the risk for administration errors. Once in the syringe, vaccines are difficult to tell apart, and there is no stability data available for vaccines stored in plastic syringes. 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.
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.

Vaccines that must be reconstituted are supplied with diluent specific to that vaccine. Vaccine diluents are not all the same, some contain vaccine antigen. Some are packaged within the same carton and others are packed separately.

For specific information for individual vaccine preparation, see the CDC’s Vaccine Storage and Handling Guide found in References & Resources section of this policy.

**Vaccine Disposal**

Any wasted or expired vaccine should be reported to the Indiana Immunization Division by creating a Vaccine Return in VOMS, when it is available. In the interim, providers must submit paper Vaccine Return forms (State Form 54052). These vaccines are returned to McKesson Specialty Distribution, the vaccine distributor, for excise tax credits. Program requirements for the completion of vaccine returns are defined in policy “Provider Vaccine Returns”.

Contact the Indiana Immunization Division at (800) 701-0704 regarding the disposition of unopened vials, expired vials, unused doses, doses drawn but not administered, and potentially compromised vaccine due to inappropriate storage conditions. **No publicly funded vaccines should be disposed of without first contacting the Immunization Division.** Vaccine that has been prefilled by the provider staff and unused should never be returned to the manufacturer or distribution center. If the Immunization Division advises discarding the vials or syringes, this should be done using the medical waste disposal procedures outlined in individual immunization program guidelines.

**Procedure Details**

**Step 1)** The provider should assign at least two staff members to serve as the primary vaccine coordinator and the backup coordinator to ensure proper storage and handling of all publicly funded vaccine. See the Vaccine Coordinator policy for detailed responsibilities for these roles.

**Step 2)** The provider should develop routine and emergency storage and handling plans to provide guidance for daily activities.

**Step 3)** The provider should offer orientation and ongoing training to all staff who handle or administer vaccines.

**References & Resources**


**Refrigerator/Freezer Temperature Log**

**Revision History**

- 07/17/2012, Created
- 03/01/2014, Revised
- 11/19/2014, Revised
- 02/16/2016, Revised
- 04/01/2017, Revised