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MODULE 6 – Vaccine Management

http://www2a.cdc.gov/nip/isd/shtoolkit/splash.html

Overview

This module consolidates and standardizes information on all elements of vaccine management to help immunization grantees and their VFC providers improve the quality of their vaccine management from distribution to administration. It specifies the responsibilities at the various levels of vaccine management and provides general guidelines for effective vaccine management and correct vaccine storage and handling.

The module describes the required policies of the VFC program, which are based on guidance from the *Vaccine Storage and Handling Toolkit* (referenced above) and other relevant resource materials developed for proper vaccine management. Specific topics covered are:

- Vaccine Distribution
- Elements of Vaccine Management
- Grantee Vaccine Management Requirements
- Provider Vaccine Management Requirements
- Provider Vaccine Management Recommendations
- Vaccine Transfers

Specific recommendations for vaccine storage and handling procedures may vary among grantee immunization programs. This module outlines the minimum vaccine management requirements for the VFC program. Grantees may add additional vaccine management requirements to their provider enrollment requirements; however, the process to add additional requirements described in Module 3 must be followed.

Vaccine Distribution

Historically, the management, distribution and ordering of federally purchased vaccines was handled individually by each of the 64 immunization grantees. Grantees had their own storage facilities and developed processes or systems to support distribution of vaccines from the manufacturer to providers. Some grantees outsourced the ordering and/or distribution of vaccines to a third-party distributor, and others used in-house resources for these functions.

In order to improve efficiencies and achieve cost savings, CDC initiated the Vaccine Management Business Improvement Project (VMBIP). This initiative recommended several changes designed to enhance operating efficiency, improve vaccine inventory visibility and reduce operating expenses.

One of these significant program changes calls for the implementation of a new model for distribution and funds management. In the early stages of the new centralized distribution process, ordering at the provider level will occur largely as it does today, with providers ordering their vaccines directly from the grantees. Orders will then be shipped directly from a CDC-contracted distributor to providers.

The implementation of centralized vaccine distribution is occurring in three phases: 1) pilot sites, 2) grantees with existing third-party distribution, and 3) grantees with existing in-house distribution. The first phase of centralized distribution was a focused pilot of four grantees. Lessons learned from the early phases will help make the transition to overall centralized distribution smoother for the grantees that follow.

There are some differences in vaccine management responsibilities between grantees that have transitioned to centralized vaccine distribution and those grantees that have not yet transitioned. The most significant of these differences are shown in Table 1 below.

Table 1. Responsibilities of grantees before and after centralized vaccine distribution

Responsibility	Pre-Centralized Vaccine Distribution	Centralized Vaccine Distribution
Distribution System Management	Managed by grantee (in-house, third-party contract)	Managed by CDC
Grantee Vaccine Inventory Management	Managed by grantee	CDC manages inventory for federal contract vaccines; grantee manages inventory of any non-federal contract vaccines
Bulk Orders	Placed with VFC, 317, and grantee funds	CDC places VFC and 317 orders, grantees will only place order using grantee funds
VACMAN	VACMAN 3.1 – transmits bulk orders and direct-ship orders only	VACMAN 4.1 – transmits bulk orders and all provider orders (direct-ship and non-direct-ship)

Elements of Vaccine Management

The management of publicly purchased vaccine is one of the most important activities conducted by an immunization grantee. Vaccines must be maintained properly to protect their viability prior to administration. Adhering to proper storage and handling procedures will minimize vaccine loss and wastage. The following paragraphs describe the key elements of vaccine management for immunization programs. Grantees are advised to consult CDC's *Vaccine Storage and Handling Toolkit*, available on the Vaccines website at http://www.cdc.gov/vaccines/ for detailed procedures, and to access other CDC resources

regarding vaccine storage and handling at
http://www.cdc.gov/vaccines/recs/storage/default.htm

The Cold Chain

Storage and handling errors in which vaccines are compromised can be costly in money and time. Vaccines must be stored properly from the time they are manufactured until the time they are administered. Excess heat or cold will reduce their potency and increase the risk that recipients will not be protected. The system used to maintain and distribute vaccines in optimal condition is called the "cold chain." The cold chain has three main components:

- Transport and storage equipment
- Trained personnel
- Efficient management procedures

All three components are needed to ensure safe vaccine transport and storage.

The cold chain begins with the refrigerator or freezer at the vaccine manufacturing plant, extends through the transfer of vaccine to the distributor and then to the provider's office, and ends with the administration of the vaccine to the patient. Proper storage temperatures must be maintained at every link in the chain. At the transport link (from manufacturer to distributor to provider), vaccine is transported in a refrigerated or frozen state, as appropriate (refrigerator 35°–46°F [2°–8°C]; freezer 5°F [-15°C] or colder), using an insulated container or a refrigerated truck. During storage, vaccines must also be appropriately stored at the recommended temperature ranges shown above.

If there is suspicion of a cold chain failure or evidence that vaccine has been exposed to temperatures outside the recommended temperature range, providers should immediately notify the state, city or territorial immunization program. Vaccine should be marked "DO NOT USE" so that the vaccine is not used until a response indicating that the vaccine is still potent has been received. Providers should not discard any vaccine unless directed to do so by the immunization program.

The manufacturer's package insert describes the required storage conditions for a vaccine. Manufacturers also have access to internal (unpublished) thermostability data concerning the impact of exposures to inappropriate temperatures. Grantees should contact manufacturers for guidance in the event of such exposure.

Prevention of Vaccine Loss and Wastage

Immunization program staff and healthcare providers and staff are responsible for maintaining vaccine quality from the time a shipment arrives until the moment a dose is administered. Maintaining the quality of vaccines and other biological products is the shared responsibility of manufacturers, vaccine handlers, and all healthcare professionals involved in immunization delivery.

Vaccine wastage is both costly and preventable. There are many reasons for vaccine wastage including heat exposure, freezing, breakage of vials and syringes, poor reconstitution practices, contamination and suspected contamination, discarding doses at the conclusion of outreach sessions, missing inventory, and theft. However, the most significant causes of vaccine wastage are attributed to poor vaccine management, i.e., loss due to expiration and loss due to cold chain failures.

Vaccine loss due to expiration is frequently a consequence of over ordering and/or poor inventory management. To reduce the risk of expiration loss, avoid stockpiling vaccine or building up more inventory than can be used before the expiration date. Grantees should advise providers against stockpiling vaccine and review provider orders to prevent excessive inventory build-up.

Inventory management

Public and private providers enrolled in the VFC program are responsible for the proper maintenance of their vaccine inventories and for ordering vaccine in the appropriate amounts. In preparation for the transition to the new Vaccine Ordering and Distribution System software (VODS), CDC recommends that grantees implement tiered-ordering practices that link order frequency to provider size and usage. In general, the largest providers would be expected to order monthly. Medium-size providers would order every 2 months, and small providers would order quarterly. Storage capacity may also be a consideration in order frequency.

Providers should order all vaccines at one time. To avoid shortages, always encourage providers to order replenishment vaccine at least 15 days in advance of their actual need.

Grantees should require providers to submit a vaccine inventory with each order. This provides a check against possible stockpiling or inventory build-up and may also prompt the provider to order all vaccines at the same time.

When providers do have excess inventory, steps may be taken to prevent vaccine loss. Providers should be required to review their inventories regularly for short-dated vaccine and to report short-dated vaccine to the immunization program. Where practical, and as long as the cold chain can be maintained, short-dated vaccine may be transferred to another provider so that it may be used prior to expiration. The grantee must actively coordinate the transfer of vaccine between the providers.

In addition to loss or wastage due to mismanagement, vaccine can be lost because it is unaccounted for. If grantees observe that unaccounted for vaccine is becoming a problem, they should begin to look at their accountability policies and provider reporting requirements to determine if data are available to identify providers with large volumes of unaccounted for vaccine. Optimally, inventory, wastage reports, and doses administered reports can be used to determine the number of unaccounted for doses for each provider. The following formula should be used:

(Vaccine inventory at start of month + doses received) - (doses administered + wastage + vaccine transferred to another location) = expected ending inventory.
Expected ending inventory - actual ending inventory = unaccounted for vaccine.

If grantees decide to monitor for unaccounted vaccine, the process must be reflected in their accountability policies.

Grantee Vaccine Management Requirements

Before Transition to Centralized Distribution

All grantee staff working on VFC activities should receive initial formal training and periodic review of the grantee's responsibilities for VFC vaccine management. The content and date of the training for each staff member should be documented and kept as part of the staff member's training/orientation record. All staff should have a copy of the responsibilities and should know how to do the following:

- Provide training on appropriate vaccine ordering, handling, storage, accounting and wastage reporting to enrolled VFC providers and their staff involved in the public vaccine distribution system. The initial training should occur at time of enrollment into the VFC program. The training should include offering providers a simple generic storage and handling plan that they may implement to meet the storage and handling plan requirements. Follow-up training should occur in any of the following situations: provider request, site visit findings or program changes.
- Maintain records of training of VFC providers and other attendees responsible for storage and handling of vaccine.
- Maintain an efficient system to distribute public vaccines.
- Ensure that vaccines are delivered to providers in a timely manner.
- Ensure vaccine is available to fulfill provider orders.
- Ensure that vaccines within the distribution system are handled, stored and shipped so as to preserve vaccine viability.
- Provide guidance to providers on vaccine storage and handling issues.
- Review, approve and process orders from VFC-enrolled providers in a timely manner.
- Order vaccine in accordance with the annual vaccine spending plan that outlines population-based vaccine needs, funding sources and purchase schedules for each antigen.
- Ensure that vaccines remain effective (potent) by developing, reviewing regularly, and, as necessary, updating written standard operating procedures (SOPs) for vaccine ordering, receiving, storage, handling, shipping, tracking and disposal.
- Review vaccine storage and handling practices to update all VFC providers on the latest storage and handling policies.
- Request that VFC providers notify the program of any vaccine doses that will expire before they will be able to administer them. When feasible and if the cold chain can be ensured, redistribute short-dated vaccines to high-volume providers who are able to administer them before they expire.

- Document expired and wasted doses of publicly provided vaccine by developing and implementing written procedures for providers to report and respond to losses resulting from vaccine expiration, wastage, and compromised cold chain.
- Require providers to return wasted and expired vaccines to facilitate collection of excise tax credit.
- Request federal excise tax credit from manufacturers for outdated or unusable vaccine. Policies and procedures for returning vaccine and requesting credit for federal excise tax can be found on the Vaccines web site: http://www.cdc.gov/vaccines/programs/vfc/forms/excise-tax.htm
  Track grantee vaccine inventory and reorder vaccine as providers deplete inventory.
- Ensure vaccine purchase amounts are in line with the grantee-submitted spending plans.
  -Apportion costs for bulk orders
  -Apportion costs for direct-ship vaccine orders
- Forward orders to CDC via VACMAN

After Transition to Centralized Distribution

All grantee staff working on VFC activities should receive initial training and periodic review in a formal setting on the grantee's responsibilities for VFC vaccine management. The content and date of the training for each staff member should be documented and kept as part of the staff member's training /orientation record. All staff should have a copy of the responsibilities and should know how to do the following:

- Provide training on appropriate vaccine ordering, handling, storage accounting and wastage reporting to enrolled VFC providers and their staff involved in the public vaccine distribution system. The initial training should occur at time of enrollment into the VFC program. The training should include offering providers a simple generic storage and handling plan that they may implement to meet the storage and handling plan requirements. Follow-up training should occur in any of the following situations: provider request, site visit findings or program changes.
- Maintain records of training of VFC providers and other attendees responsible for storage and handling of vaccine.
- Review, approve and process orders from VFC-enrolled providers in a timely manner.
- Order grantee-funded vaccine in accordance with the annual vaccine spending plan that outlines population-based vaccine needs, funding sources and purchase schedules for each antigen.
- Ensure that vaccines remain effective (potent) by developing, reviewing regularly, and, as necessary, updating written standard operating procedures (SOPs) for vaccine ordering, receiving, storage, handling, tracking and disposal.
- Urban grantees and local health departments must develop written SOPs for storage and handling.
- Review vaccine storage and handling practices to update all VFC providers on the latest storage and handling policies.
- Request that VFC providers notify the program of any vaccine doses that will expire before they will be able to administer them. When feasible and if the cold chain can

be ensured, redistribute short-dated vaccines to high-volume providers who are able to administer them before they expire.

- Document expired and wasted doses of publicly provided vaccine by developing and implementing written procedures for providers to report and respond to losses resulting from vaccine expiration, wastage, and compromised cold chain.
- Require providers to return wasted and expired vaccines to the distributor to facilitate collection of excise tax credit.
- Track inventory and reorder vaccine as providers deplete inventory of non-federal contract vaccines.
- Ensure vaccine purchase amounts are in line with the grantee-submitted spending plans.
  - Apportion costs for bulk orders
  - Apportion costs for direct-ship vaccine orders
- Forward orders to CDC via VACMAN or VODS when it becomes available (bulk and all provider orders—non-direct ship and direct ship).

Provider Vaccine Management Requirements

All VFC-enrolled providers do not have the same level of expertise regarding vaccine management. An important responsibility of the grantee to the VFC program is to work with providers to develop and implement accurate but simple plans for routine and emergency vaccine management. Grantees must be able to provide templates to providers on key vaccine management requirements. Please see Appendix 5 for a sample emergency storage and handling plan. All providers must be able to meet the following requirements in order to participate in the VFC program:

Vaccine Personnel

- Designate one staff member to be the primary vaccine coordinator and at least one back-up vaccine coordinator who is able to perform the same responsibilities as the primary vaccine coordinator in the event that the primary person is unavailable. These positions will be responsible for some key requirements and will provide oversight for all vaccine management within the office.
- The designated vaccine coordinator and backup must be responsible for the following vaccine management activities:
  - -Adjusting the temperature of a vaccine storage unit;
  - -Documenting the temperature on the temperature logs for each storage unit;
  - -The primary vaccine coordinator should review temperature logs weekly if daily monitoring is being conducted by a backup person to ensure proper temperature recording. The backup staff should monitor the temperature logs if the primary coordinator is recording the daily temperatures.
- The primary and backup vaccine coordinators are responsible for training other staff who are responsible for administering vaccines or who may be required to transport vaccine in an emergency situation, following the office's vaccine storage and handling plan. A simple log sheet with the staff member's name and date of training should be kept as documentation.

- Unless otherwise noted, the vaccine coordinator and/or backup should be the VFC contacts for the office.

Storage and Handling Plans

Providers may develop their own written routine and emergency storage and handling plans or use the grantee-supplied storage and handling templates and customize the templates to reflect their office practice. Both the routine and the emergency plans should be simple, and the processes outlined in the plan should be presented in a clear and concise manner. Both plans should be reviewed and updated as necessary.

- The routine vaccine storage and handling plan should include guidance on the following aspects of routine vaccine management:
  - -ordering vaccines
  - -controlling inventory
  - -storing vaccines and monitoring storage conditions
  - -minimizing vaccine wastage
  - -vaccine shipping, including receiving, packing and transporting
- The emergency vaccine storage and handling plan should include guidance on what to do in the event of refrigerator or freezer malfunctions, power failures, natural disasters, or other emergencies that might compromise appropriate vaccine storage conditions The emergency plan should include the following:
  - -person(s) responsible for preparing and transporting vaccine, including contact information
  - -how this person will be notified that vaccine needs to be moved
  - -location that will receive vaccine
  - -how receiving location will be notified of transport
  - -how to pack vaccine for transport
  - -worksheet to document vaccine involved in power or equipment failure

  At a minimum the emergency plan must be reviewed and updated annually (or as necessary) or when there is a change in staff who have responsibilities specified in the emergency plan.

Vaccine Storage Equipment

Providers must have appropriate equipment that can store vaccine and maintain proper conditions. If a provider does not have the appropriate storage units, the grantee must work with the provider to obtain storage units that are acceptable.

Two types of storage units are acceptable: 1) a refrigerator that has a separate freezer compartment with a separate exterior door, or 2) stand-alone refrigerators and freezers.

Refrigerators or freezers used for vaccine storage must comply with the following requirements:

- Be able to maintain required vaccine storage temperatures year-round;
- Be large enough to hold the year's largest inventory;

- Have a working thermometer certified in accordance with National Institute of Standards and Technology (NIST) or the American Society for Testing and Materials (ASTM) standards placed in a central area inside each storage compartment;
- Be dedicated to the storage of vaccines. (Food and beverages must not be stored in a vaccine storage unit because this practice results in frequent opening of the door and destabilization of the temperature.)

Vaccine Storage Practices

The vaccine storage practices listed below can be the responsibility of the vaccine coordinator or can be delegated to another staff member. If the practices are delegated, the vaccine coordinator should monitor the activity periodically.

- Rotate vaccine stock by placing vaccines with shorter expiration dates in front of those with longer expiration dates; check for short-dated vaccine.
- Notify the immunization program of any vaccine doses that will expire before they can be administered. Only with the approval and direct guidance of the immunization program and only if the cold chain can be ensured, redistribute short-dated vaccines to high-volume providers who are able to administer it before it expires.
- Store vaccines that require refrigeration in the middle of the refrigerator compartment away from the coils, walls, floor, and cold air vent.
- Store vaccines that require freezer storage in the middle of the freezer compartment, away from the walls, coils, and peripheral areas.
- Space stored vaccine to allow for cold air circulation around the vaccine.
- Do not store vaccines in the door of the storage unit.

Temperature Monitoring

Temperature monitoring should be the primary responsibility of the vaccine coordinator and backup. If other staff must monitor temperatures, those persons must be trained on how to respond to and document actions taken when temperatures are outside the appropriate range.

- Post a temperature log on the vaccine storage unit door or nearby in a readily accessible place.
- Record refrigerator and freezer temperatures twice each day (beginning and end) ensuring that refrigerator temperatures are between 35° and 46° F (2° and 8°C). The freezer temperature should be 5°F or lower (-15°C or lower); Twice-daily temperature monitoring and recording is required even if a continuous graphing/recording thermometer or a digital data logger is used.
- Take immediate action to correct improper vaccine storage conditions, including inappropriate exposure to light and inappropriate exposure to storage temperatures outside the recommended ranges. Document actions taken on the temperature log.
- Maintain an ongoing file of temperature logs, and store completed logs for 3 years (unless state statutes or rules require retention for a longer period).

Vaccine Shipments

- Immediately check vaccine cold chain monitors[1] and document the temperature inside the transport unit when vaccine arrives at office or clinic.
- Take proper action if cold chain monitor was activated.
- Develop a policy, complete with protocols and procedures, for maintaining the vaccine cold chain during transport to off-site clinics or emergency storage locations. See guidelines: *Maintaining the Cold Chain During Transport* (http://www.immunize.org/catg.d/p3049.pdf).

Vaccine Wastage

- Notify the immunization program of vaccine cold chain failure/wastage incidents involving publicly funded vaccines promptly after discovery of the incident. Follow the guidance of the grantee on how to document and report the incident.
- Implement written procedures for reporting and responding to losses resulting from vaccine expiration, wastage, and compromised cold chain.
- Remove wasted/expired vaccine from storage containers with viable vaccine to prevent inadvertent administration.
- Return, as directed by the grantee, all spoiled or expired publicly purchased vaccines for excise tax credit.

***Please note*:** *Prior to transition to centralized distribution, providers should return spoiled/expired vaccine to the grantee.*
Following transition to centralized distribution, providers should return vaccine to the centralized distributor.

Vaccine Preparation

It is not acceptable clinical practice to pre-draw vaccines into syringes. Providers should draw vaccine only at the time of administration to ensure that the cold chain is maintained and the vaccine is not inappropriately exposed to light.

Vaccine Ordering and Inventory Management

- Order vaccine in accordance with actual vaccine need; avoid stockpiling or build-up of excess vaccine inventory.
- Develop and maintain complete, accurate and separate stock records for both public and private vaccines. The requirement to keep separate records does not necessitate having separate storage units for public and private vaccines. Providers must be able to distinguish between their public and private vaccine stock.

Vaccine Security and Equipment Maintenance

Post warning notices at both the electrical outlet and the circuit breaker to prevent power from being disconnected.

[1] Cold Chain Monitors (CCMs) - These single-use devices come in three basic types: those that indicate whether packages have reached temperatures that are too warm, those that indicate whether packages have reached temperatures that are too cold, and those that continuously record the temperature. These types of monitors are designed to be irreversible indicators of inappropriate temperatures.

Additional Recommendations for Providers

Grantees may encourage providers to implement all or some of the following vaccine management activities, as applicable to the individual practice.

Vaccine Personnel

The primary and backup vaccine coordinators should train other staff to be responsible for vaccine storage and handling requirements in case of emergency.

Vaccine Storage Practices

- Remove vegetable bins from the refrigerator; replace with cold water bottles.
- Store all opened and unopened vials of vaccine in their boxes inside the appropriate storage unit so that their contents and expiration dates are easily visible.
- Stabilize refrigerator and freezer temperatures with proper placement and use of water bottles and frozen packs.
- Keep vaccines organized. Place opened vials of vaccine in a tray, so that they are readily identifiable. Indicate on the label of each vaccine vial the date and time it was reconstituted or first opened.
- Open only one vial, or box, of a particular vaccine at a time to control vaccine usage and allow easier inventory control.
- Store vaccine products that have similar packaging in different locations to avoid confusion and medication errors.

Temperature Monitoring

- Monitor vaccine storage temperatures by using a minimum/maximum thermometer or continuous recording thermometer in the refrigerator and freezer.
- Follow manufacturer's recommended schedule for recalibration of the certified thermometers.

Vaccine Inventory Management

Until transition to centralized distribution, conduct a monthly inventory to monitor vaccine use, anticipate needs and remove expired vaccines.

Vaccine Security and Equipment Maintenance

- Limit access to the vaccine supply to authorized personnel only.
- Install locks on refrigerators and, if possible, the electrical plug.
- Safeguard public vaccines by providing facility security, such as temperature alarms and restricted access to vaccine storage and handling areas.
- In larger clinics, provide a source of backup power (generators) and a security system to alert appropriate personnel in the event of a power outage.
- If applicable, test backup generators quarterly and maintain backup generators at least annually (check manufacturer specifications for test procedures and maintenance schedules).

Vaccine Transfers

Vaccine transfers between providers can occur only after receiving approval from the grantee. The grantee must actively coordinate the transfer of vaccine between providers.