

Vaccine Management Policy

The Vaccines for Children (VFC) Program requires the Kansas Immunization Program (KIP) ensure that VFC provider vaccine management practices are consistent with sound immunization, fiscal, business and medical practices, and do not result in unnecessary costs to the program due to excessive wastage or unaccounted for VFC vaccines. The Centers for Disease Control and Prevention (CDC) have established minimum guidelines detailing the steps of proper vaccine storage and handling. This toolkit is found at:

<http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf>

Kansas VFC providers are diligent in their practices to ensure sound vaccine management practices. The Kansas Immunization Program appreciates these efforts. These vaccine management policies are designed to help assure continuation of the VFC program for Kansas children by:

- a. Assisting each provider clinic in quality improvements in VFC vaccine management practices
- b. Reducing wasted vaccines
- c. Ensuring vaccines are stored appropriately so they are stable
- d. Decreasing and/or eliminating unaccounted for vaccines

Clinic policies and procedures shall be updated annually with signature and date. Program staff will review each clinic's policies and procedures at the VFC compliance site visit and/or unannounced visits. VFC providers must have policies and procedures to address management of VFC vaccines in each of the following areas; Vaccine Storage and Handling and Vaccine Ordering.

Storage and Handling:

Appropriate vaccine storage ensures vaccines are stable and will protect against disease.

1. Vaccines must be handled and stored in accordance with the Food and Drug Administration (FDA) approved package insert that is shipped with each product.
2. Refrigerated vaccines must be stored between 35-46 degrees F (2-8 degrees C).
3. Frozen vaccine must be stored at 5 degrees or less F (-15 degrees C).
4. The storage units for any VFC vaccine may not be a "dorm-style/bar-style" unit.
5. Refrigerated units must be large enough to hold the year's largest inventory (i.e. back to school/FLU season).
6. Stand-alone pharmaceutical grade refrigerators and freezers are recommended.
7. Household type units currently in use are acceptable but must have separate doors for the refrigerator and freezer, and each unit must have separate temperature controls. Household units with a single door and/or single temperature control are not acceptable unless the unit is only used for refrigerated vaccine.
8. A "Do Not Unplug" warning sign must be placed next to the electrical outlets for each vaccine storage refrigerator and freezer and on the electrical breaker that services these outlets. Tamper proof plugs are also recommended.

9. Providers are required to monitor temperatures with a certified calibrated thermometer issued by an ILAC MRA-accredited laboratory or certification must contain measurements that meet ISO 17025 standards. Calibration certificates contain model and serial #, date of calibration; and measurement results that passed with uncertainty limits (recommended = +/-1•F (0.5•C). January 1,2015, VFC providers must also have a backup calibrated thermometer available that meet the standards mentioned above.
10. The data logger KIP provides meets these calibration certification specifications.
11. The temperature of the refrigerator and freezer where the vaccines are stored must be documented on the temperature log at least twice daily: in the AM when clinic opens and in the PM just before closing. Alarm systems are strongly recommended as back-up for notification of out of range temperatures. It is required that each temperature reading must be accompanied by (1) the time of reading (2) the name (or initials) of person who assessed and recorded the reading. If there is a refrigerator or freezer malfunction or power outage, the time interval of the outage needs to be determined as this is critical to determine the stability of the vaccines. Backup generators are strongly encouraged.
12. VFC providers must develop a Vaccine Emergency Response Plan to assure vaccine viability in the case of natural disasters, power outages, or other emergencies. Such contingency plans might be a back-up generator or moving vaccines to another location which has a generator. Templates are found on the website.
13. Any incident which may call into question the vaccine stability, including incidents of improper vaccine storage and handling, must be reported to KIP and the vaccine manufacturers. The report must include vaccine antigens and length of time and temperature at which vaccine was stored. Not all vaccines are non-viable if the temperature excursion and time factors were minimal. Mark vaccines DO NOT USE and leave refrigerated or frozen until the manufacturer and KIP have been notified. Frozen vaccines are more sensitive to warm temperatures just as refrigerated vaccine is most sensitive to cold temperatures.
14. Once the vaccines are determined to be non-viable, place them in a container and mark DO NOT USE. Complete the KIP Wasted Vaccine Form and document the wasted doses on the KSWebIZ inventory reconciliation. Fax the Wasted Vaccine form to KIP at 785-296-6510 each month with temperature logs.

Vaccine Ordering:

Vaccine ordering is more than placing the orders. It is an analysis of the number of children served and their insurance or eligibility status over a 12 month period that assist clinics in determining the vaccine manufacturer and presentation needed. Assessing vaccine storage capacity and having written vaccine storage and handling policies that are communicated to, and followed by staff is important.

1. Providers need to calculate their vaccine needs based on an analysis of children served in each age cohort and eligibility (fund) type. Contact one of our program nurse consultants for assistance. *Check your order! Be sure you order the correct vaccine and number of doses!*
2. Effective January 1, 2015, upon meeting validations, all VFC providers may order as needed. Providers should have a four week supply of vaccine on hand.
3. Vaccine management includes deciding which vaccine manufacturer and presentation to use. This helps improve staff knowledge of the vaccines administered, decreases errors in vaccine administration and streamlines inventory. This decreases wastage and unaccounted for vaccines.
4. Providers must close all VFC reconciliations monthly and within 7 days of any vaccine order. If discrepancies are found on your reconciliation, it is recommended that these counts be done more frequently to assist in identifying discrepancies in vaccine counts early.
5. Designate a primary and a backup person to be responsible for ensuring vaccine management.
6. Open shipments immediately and receive them into KSWebIZ. This will determine the length of time the vaccine was in transit.
7. Accept new inventory immediately by funding source. Store vaccine by funding source; 317, CHIP, Private, State and VFC.

8. Separate new vaccine shipments from those currently in stock. Use stock with the earliest expiration date first.
9. If a provider receives vaccines they did not order, contact Jackie Strecker immediately at 785-296-2199. Providers who order the wrong vaccine are responsible for those doses.
10. Excessive overstocking of vaccines result in waste. Order what is needed!
11. Providers may place excess doses on the KIP Redistribution List if the vaccine has a minimum of 90 days and a maximum of 365 days before the vaccine expiration date. The ordering provider is responsible for any doses which expire on the redistribution list that have not been accepted for transfer by another VFC provider. Providers accepting vaccine from the redistribution list are responsible for using the doses once they are transferred. KIP encourages providers to only accept doses they can administer before the expiration date. The transferring and receiving providers will document doses on their Reconciliation reports as transferred vaccines by the funding source. Vaccine funding sources will be included on the redistribution list.

Vaccine Storage Units:

There are several manufacturers of vaccine storage units. Samples of these are found on the KIP website at:

<http://www.kdheks.gov/immunize/storage.htm>

KIP does not endorse any product. The examples are only for demonstration purposes. Each provider is responsible for the terms and conditions of any purchase made.

Program specific documents and policies are found in the Immunization Program Manual at:

<http://www.kdheks.gov/immunize>