



**LOS ANGELES COUNTY DEPARTMENT OF HEALTH SERVICES
HARBOR-UCLA MEDICAL CENTER**

SUBJECT: VACCINE FOR CHILDREN IMMUNIZATION PROGRAM:
VACCINE MANAGEMENT GUIDELINES

POLICY NO. 313B

CATEGORY: Provision of Care	EFFECTIVE DATE: 5/16
POLICY CONTACT: Jennie Ung, PharmD	UPDATE/REVISION DATE:
REVIEWED BY COMMITTEE(S): Pharmacy and Therapeutics	

PURPOSE:

To establish methods to ensure 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 Vaccines for Children (VFC).

POLICY:

At Harbor-UCLA Medical Center, the VFC program helps families by providing free vaccines, to providers who serve eligible children 0 through 18 years of age. The VFC program is administered at the national level by the U.S. Centers for Disease Control and Prevention (CDC) through the National Center for Immunization and Respiratory Diseases. CDC contracts with vaccine manufacturers to purchase vaccines at reduced rates. Enrolled VFC providers are able to order vaccines through their State VFC Program and receive routine vaccines at no cost. This allows them to provide routine immunizations to eligible children without high out-of-pocket costs. In order to maintain eligibility for the program, strict adherence is required: yearly online job aid training for vaccines, meet with a California VFC representative who will conduct a site visit, Quality Assurance Review (QAR) to assess the provider’s compliance with the standards, and follow the VFC guidelines for vaccine storage.

The CDC has established minimum guidelines for vaccine storage and handling, detailing the steps (see Appendix A for website to toolkit).

PROCEDURE:

I. Storage

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 2-8°C, aim for 4°C.
3. Frozen vaccine must be stored at -15°C, no colder than -50°C, aim for -17°C.

REVISED: 5/19, 6/22

REVIEWED: 5/16, 5/19

APPROVED BY: _____

Anish Mahajan, MD
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4. 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 service these outlets.
5. A calibrated certified digital thermometer with a minimum and maximum reading capacity and the temperature probe in biosafe glycol-encased probe must be used for every unit storing VFC. The calibration and certification will need to be re-certified/re-calibrated as noted in the manufacturer’s instructions. All calibration/certifications must be kept on file for the period of certification.
6. The temperature of the refrigerator and freezer where the vaccines are stored must be checked and recorded on a temperature log twice daily (in the AM when clinic opens, and in the PM just before closing).
7. Vaccine temperature logs are signed by the clinic supervisor and kept for 3 years.
8. If there is a refrigerator or freezer malfunction or power outage, the time interval of the outage needs to be documented in the VFC temperature log as this is critical to determine the stability of the vaccines. The hospital is equipped with backup generators.
9. All members handling VFC will complete the online job aid training for vaccines annually (See Appendix A for website to online job aid training).
10. **Multi-dose vaccine vials** are exempted from discarding 28 days after first use requirement. The Joint Commission exempts all vaccines from the 28-day rule and announced: “The **CDC Immunization Program** states that **vaccines** are to be discarded per the manufacturer’s expiration date”.

II. Emergency and Power Outage

1. VFC providers must develop contingency plans to assure vaccine viability in the case of natural disasters, power outages, or other non-planned for emergencies. Such contingency plans might be a back-up generator or moving vaccines to another location which have a generator. Templates for routine storage, handling and emergency procedures are attached to this policy.
2. Any incident which may call into question the vaccine stability, including incidents of improper vaccine storage and handling, must be reported to the **Los Angeles County Immunization Program (LACIP) Customer Support Services at the time of the event** (see Appendix A for phone number). The report must include: the temperature of the refrigerator and freezer at the time of the incident. Be prepared to provide the following information to Customer Support:
 - Amount of vaccine in stock (type and # of doses)
 - Vaccine lot numbers and expiration dates
 - Date and time of last documented refrigerator/freezer temperatures
 - Maximum temperature of the unit and time the unit was out of range

During the power outage/failure, keep the refrigerator and freezer doors closed. This will help conserve the cold mass of the vaccines. 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 LACIP have been notified. Frozen vaccines are more sensitive to warm temperature just as refrigerated vaccine is most sensitive to cold temperature. For the short-term power outage, 1 to 2 hours: **DO NOT OPEN THE REFRIGERATOR OR FREEZER DOOR**. The 1- to 2-hour time frame depends on the room temperature. The hotter the room, the shorter the time when essentially no action is required. In the event of a long-term power outage, or high room temperature, the vaccines will have to be transported to a safe storage facility in a shorter time period. Vaccine may be moved to a back-up



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storage unit in the clinic that is functioning. The procedure below for packing vaccine will keep all vaccines (except varicella vaccine) within recommended temperatures for 12 hours during transport.

Requirements for transporting vaccines:

- Varivax & Proquad: You must have **ice packs** in an appropriate cooler to transport Varivax & Proquad vaccines.
- All other vaccines: Can be transported in an appropriate cooler with cold packs. They should be stored in your refrigerator.

If the vaccine will be stored in refrigerators after transport, be sure those refrigerators have maintained temperatures between 2-8°C for at least 3 to 5 days.

Guidelines for vaccine transport and short-term storage:

- Cooler: Use a hard-plastic Igloo-type cooler. Attach a "Vaccines: Do Not Freeze" label to the cooler
 - "Conditioned" cold packs: Condition frozen gel packs by leaving them at room temperature for 1 to 2 hours until the edges have defrosted, and packs look like they've been "sweating." Cold packs that are not conditioned can freeze the vaccine.
 - Thermometer: Prepare the thermometer by placing it in the refrigerator at least 2 hours before you pack the vaccine.
 - Packing material: Use two 2-inch layers of bubble wrap. Not using enough bubble wrap can cause the vaccine to freeze.
 - Place the thermometer's digital display and the Return or Transfer of Vaccines Report form on top
3. Once the vaccines are determined to be non-viable, place them in a container and mark **DO NOT USE**. Complete the VFC Wasted Vaccine Form; document the wasted doses on the Monthly Immunization Report or eziz.com reconciliation. Fax the wasted form to VFC (see Appendix A for fax number) each month with the Monthly Immunization Report and request a vaccine return shipping label.

III. Vaccine Ordering

Vaccine ordering has to be accurate and concise. It is analysis of the numbers of children served over what time frame, determining the vaccine manufacturer and presentation the clinic will use, assessing storage capacity and having written vaccine storage and handling policies that are communicated to and followed by staff.

1. Vaccine ordering is submitted by designated staff and indicating the appropriate amount of each vaccine at the correct interval is an important component of vaccine accountability.
2. Providers need to calculate their vaccine needs based on the numbers of children served in each age cohort. Contact one of our program nurse consultants for assistance. *Check your order! Be sure you order the correct vaccine!*
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 the inventory. These factors decrease wastage and unaccounted for vaccines.
4. VFC providers must count all VFC vaccine inventory at least monthly and within 7 days of any vaccine order.
5. A Routine Vaccine Storage and Handling Plan Worksheet will assist in documenting and training staff on the importance of vaccine management.



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6. Examine the content of the vaccines immediately upon receipt. Check the temperature monitor in the package as well as the ice/gel packs to ensure vaccines have not been exposed to high temperatures and then store appropriately.
7. Enter new inventory information immediately.
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 VFC at once (see **Appendix A** for phone number).
10. Excessive overstocking of vaccines results in waste and is avoidable.
11. Providers may place the excess doses on the LACIP Re-distribution list if:
 - a. The vaccine has a minimum of 180 days and a maximum of 365 days before the vaccine's expiration date;
 - b. 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;
 - c. Providers accepting vaccine from the redistribution list are responsible for using the doses once they are transferred. LACIP encourages providers to accept only doses they can administer before the expiration date;
 - d. The transferring and receiving provider will document these doses on their monthly reconciliation reports as transferred vaccines.

IV. Roles and responsibilities of key practice staff

1. Clinic Supervisor - Nurse:
 - Ensures that all clinic taskforce members and staff utilizing VFC vaccines receive certification training.
 - Ensures that the guidelines for storing and administering VFC vaccines are upheld within the clinic.
 - Responsible for adhering to the action plan.
2. Clinic Vaccine Coordinator - Nurse:
 - Responsible for ensuring that all nursing staff that administer VFC vaccines complete on-line training.
 - Ensures twice a day temperature recording of the clinic refrigerator/freezer temperature
 - Ensures proper storage of vaccines inside the clinic
 - Contacts VFC Pharmacist for assistance with vaccine storage if needed
 - Maintains records for vaccine invoices (except for vaccine pharmacy receive, pharmacy maintains records of invoices)
3. VFC Pharmacist: works in collaboration with the Clinic Vaccine Coordinator in Specialty Pediatric Clinic:
 - Completes on-line training
 - Monitors vaccine expiration dates monthly
 - Reviews 8 month expiration date log posted on the refrigerator/freezer with the vaccines inside the refrigerator/freezer to ensure that the log is updated and correct.
 - Identifies vaccines in stock at 8 months of expiration date
 - Rotates vaccine stock placing earliest to expire vaccine in front
 - Identifies overstock vaccines and assist Clinic Vaccine Coordinator to order additional vaccine doses
 - Maintains records for vaccine invoices



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- Ensures temperature logs (refrigerator/freezer) are filled out twice daily in the Pharmacy for VFC vaccine overstock.

Reviewed and approved by:
Medical Executive Committee 6/2022

A handwritten signature in cursive script that reads "Beverley A. Petrie".

Beverley A. Petrie, M.D.
President, Professional Staff Association

Appendix A: Websites and Phone Numbers

1. The CDC has established minimum guidelines for vaccine storage and handling, detailing the steps of good vaccine storage and handling. This toolkit is found at: <http://www.cdc.gov/vaccines/recs/storage>
2. Online job aid training for vaccines annually at <http://eziz.org/myvfcvaccines/>.
3. Los Angeles County Immunization Program (LACIP) Customer Support Service phone number (877) 243-8832.
4. VFC fax number (877) 329-9832