Department of Nursing
POLICY AND PROCEDURE

POLICY NUMBER: 269
VERSION: 3

SUBJECT: VACCINE MANAGEMENT PLAN: STORAGE AND HANDLING

PURPOSE: To ensure proper storage and handling of biologics (vaccines).

POLICY: Clinic staff shall adhere to the guidelines regarding the proper storage and handling of vaccines to ensure that patients are administered potent vaccines.

PROCEDURE:

I. Vaccine Storage Units

A. Equipment

1. Only a Vaccine for Children (VFC) compliant refrigerator (s) and freezer (s) are to be used to store vaccines.
2. Storage units must be maintained at the recommended temperature ranges:
   a. Refrigerator: between 36º F- 46º F (2-8º C)
   b. Freezer: below 5º F (-15º C)
3. Storage units must have adequate capacity to store vaccine supply at all times, including during peak back-to-school and flu season.
4. Storage unit must be cleaned routinely and properly maintained.
5. All records of repairs are kept in Facilities and are available for review upon request.

B. Power Supply

1. Each unit is plugged directly into a wall outlet and is not controlled by a light switch, power strips, or surge protectors with an on/off switch.
2. Extension cords are never to be used to connect storage units to an outlet.
3. A plug guard must be used to prevent an inadvertent disruption in power.
4. The outlet it is plugged into must to be labeled with a “DO NOT UNPLUG” sign at each outlet to prevent a disruption in power to the unit.

C. Set-up

1. Storage units are set up according to VFC Program requirements.
2. Units are kept away from direct sunlight and away from walls to allow air circulation.
3. Vaccine is never stored in the doors, drawers, or bins. Unit drawers/deli crispers are removed.

4. To stabilize temperatures, water bottles are kept in the refrigerator where vaccines cannot be stored, for example, doors and areas where a bin was removed. Frozen cold packs are kept in the freezer for similar purpose.
5. VFC and private vaccine storage areas/shelves are marked “VFC” and “private” to clearly identify vaccine supplies.
6. Vaccines are organized in plastic mesh baskets and clearly labeled by type of vaccine supplies. Vaccines are grouped by pediatric, adolescent, and adult types.
7. The glycol-encased thermometer probe is placed in the center of the unit, near the vaccines. The thermometer’s display is securely attached to the outside of the storage unit.
8. Vaccines are stored in their original packaging until administered; vaccine supply is 2-3 inches away from walls, air vents, and floor to allow space for air circulation.
9. Food, beverages, and laboratory, specimens are not to be stored in units at any time.
10. When medications or culture medium are stored in the unit, they must be placed on a shelf below the vaccines.

II. Temperature Monitoring

A. Thermometers and Data Loggers

1. Each storage unit has a VFC- compliant thermometer accurate within +/-1^{o} F (+/- 0.5^{o} C).
2. Each thermometer has a current and valid Certificate of Calibration (also known as a Report of Calibration).
3. Each thermometer has a biosafe glycol-encased probe placed in the center of the storage unit in close proximity to the vaccine.
4. Each thermometer has a display of current, minimum, and maximum temperatures.
5. There is one back-up thermometer, meeting VFC requirements, for use when primary thermometers fail or are being recalibrated.
6. The probe for the thermometer is never to be placed in the unit’s doors, near or against unit’s walls, underneath air vents, or on the unit floor.
7. Thermometer batteries are replaced every six months.
8. HDHS Data loggers provide continuous monitoring of the vaccine refrigerator temperatures and are in place in addition to the thermometers. Involved staff must be able to access the system.

B. Annual Thermometer Calibration

1. Primary and back-up thermometers are calibrated annually (or every other year if the manufacturer’s recommendation is for a longer period).

2. The thermometer is calibrated by a laboratory with accreditation from an International Laboratory Accreditation Cooperation/Mutual Recognition Arrangement (ILAC/MRA) signatory body.
3. The valid certificate will contain the date of testing, thermometer model/serial number, measurement results, uncertainties, pass/fail statements, and statement that testing meets International Organization Standardization (ISO) standards.
4. Certificates of Calibration are filed in a readily accessible area, kept for three years and are presented to California Department of Public Health (CDPH) staff for review upon request.

   Certificate must include:

   - Name and address of lab conducting the test
   - Name of device-optional
   - Model number of device (enables product identification)
   - Serial number (enables product identification)
   - Date of calibration (report or issue
   - Measurement results for the device
5. The thermometer will be replaced when no longer accurate within +/-1^{o} F (+/-0.5^{o} C), based on calibration results.

C. Safeguarding Vaccines, Handling and Reporting Out-of-Range Temperatures

1. When an out-of-range temperature is identified, immediate action is taken to assess the situation and to prevent vaccine spoilage.
2. The VFC Program is contacted to report the incident and to file a storage and handling incident report.
3. Vaccine that is expired or spoiled must be labeled as “DO NOT USE”.
4. Staff must follow the Emergency Vaccine Management plan in the case of power outage, appliance malfunction, weather conditions, or human error that may affect vaccine viability.
5. When necessary to transport vaccine to another storage unit or to a predetermined site, the procedure must be in adherence with the VFC Program guidelines.
6. Document actions taken on my VFCVaccines.org.

D. Temperature Monitoring and Documentation

1. Place VFC-supplied temperature logs on the storage unit door or nearby in an accessible location.
2. The refrigerator temperature must be read and recorded twice a day, when the clinic opens and at closing.

   The CURRENT, MIN., and MAX. refrigerator and freezer temperatures must be read and recorded twice a day.

The first temperature (AM) obtained in the morning should be before the storage unit has been opened.

The second temperature should be read and recorded at the end of the day, allowing time for corrective actions in the event of out-of-range unit temperatures.

The MIN and MAX should be reset after each reading.

3. The person documenting the storage unit temperature initials the log.
4. Temperatures are documented on VFC Program temperature logs only. This is also required where the continuously recording/graphing thermometer system is in place.
5. The temperature logs are posted on the storage unit door or nearby in an easily accessible location.
6. The temperature logs must be retained for three years and will be made available to the VFC representatives upon request.
7. After completion of the temperature log, a supervisor needs to review the log acknowledging that the temperatures recorded are correct and that any out of range temperatures have been properly addressed.
8. Maintain the completed logs for three years and make them available to VFC Representatives upon request for review.

E. <u>Inventory Management</u>

1. A physical vaccine inventory is conducted at least once a month and before ordering vaccines.
2. The practice must have enough vaccine supply to meet the needs of its VFC-eligible patients.
3. Two weeks of additional supply may be on hand to mitigate shortages and shipment delays.
4. The practice uses an inventory control system, CAIR, usage log which documents each patient, vaccine type, lot number, and date of administration.
5. The practice maintains accurate records, including purchase invoices, for privately purchased vaccines and makes them available upon request to VFC Representatives.
6. Vaccine that is drawn up and not used is disposed of properly.
7. When diluent is packaged with the vaccine, the practice stores them together. When diluent is not packaged with its vaccine, the diluent is clearly labeled and stored where it can be easily identified.

F. <u>Stock Rotation, Returns, and Transfers</u>

1. The practice organizes vaccines so those with earliest expiration dates are used first.
2. The practice may return expired/spoiled vaccine to McKesson for excise tax credit within three months of expiration/spoilage.
3. For vaccine due to expire within three months and it will not be used:
   a. Notify the VFC Program about the vaccine;

   b. Request a transfer approval from the VFC program through MyVFCVaccines and;
   c. Identify VFC providers in the area to contact and inquire if they may be able to use the soon-to-expire vaccines.

4. All vaccines being transferred or transported will be in adherence with the VFC Program guidelines, and the appropriate forms will be used, (Refrigerated Vaccine Transport Log IMM-1132, Frozen Vaccine Transport Log, IMM-1116).
5. If vaccine becomes spoiled or expires, staff must remove them immediately from the storage unit, report it to the VFC Program, and complete the appropriate documentation. (Return or Transfer of VFC Vaccines Report IMM-986, 7/2013)
6. The practice may return unused vials/prefilled syringes to McKesson if unopened and in original packaging.
7. Certain vaccine supplies should not be returned:
   a. Used syringes with or without needles
   b. Syringes with vaccine drawn up and not used
   c. Broken or damaged vaccine vials
   d. Multi-dose vials that have already been withdrawn
8. Vaccine that is spoiled or expired must be reported to the VFC Program before a new order can be submitted.

G. Vaccine Ordering

1. As a large-sized VFC provider (use more than 2000 vaccines/month), the clinic may order monthly and more frequently if indicated by usage.
2. Orders are submitted on MyVFCVaccines and are placed according to clinic-based eligibility data, assigned order frequency, vaccine usage, and take into account the inventory in stock.
3. When vaccine is offered by two or more manufacturers, the practice orders one brand to mitigate administration errors.
4. A physical inventory must be completed before any placing an order.
5. This practice orders all the vaccines it needs before the next assigned order.
6. A summary of on-hand inventory is included with each order.
7. Orders are placed with sufficient inventory on hand to allow time for order processing and vaccine delivery.
8. An accurate report of all VFC vaccine doses administered is maintained on the Daily Usage Log, for each vaccine-ordering period.
9. Every VFC dose is accounted for. Vaccine doses not accounted for or lost due to negligence will be replaced at the expense of the Provider of Record for the site.
10. The practice verifies it’s operation hours in MyVFCVaccines before submitting each order. Any changes to the practice’s hours are reported to the VFC program to avoid receiving vaccine shipments when the clinic is closed or the staff is not available.

H. Receiving and Inspecting of Vaccine Shipments

1. Staff familiar with procedures for accepting vaccine shipments as outlined on the Vaccine Receiving Log and Checklist.
2. Inspect the shipment immediately upon arrival to confirm that it was not opened, broken, torn, or tampered with and that it is addressed to your clinic.
3. Open the package immediately to read the monitor (should be shipped with a thermometer) and to determine if the vaccine was exposed to an out-of-range temperature.
4. Check the shipping date to determine how long the vaccine was in transit. If there is anything questionable call the VFC program immediately.
5. Varicella is not shipped with a thermometer. This shipment also needs to be inspected for the date it was sent, and the package integrity.
6. If the vaccine arrives more than 4 days after the shipping date, call the VFC program immediately.
7. Compare the contents of the package to the packing slip.
8. Cross reference box contents with approved doses on VFC's order confirmation. Check that the correct amount of diluent is included. Varicella and MMRV are shipped separately and will not be included with other vaccines in your shipment.
9. Any missing or extra doses are to be recorded on the Vaccine Receiving Log. Fax a copy of the completed log and the packing slip to the VFC program immediately.
10. Check vaccine for expiration dates to verify vaccines do not have short-dated expiration dates.
11. Report immediately to the VFC program, all shipment discrepancies and vaccines exposed to out-of-range temperatures.
12. Never reject vaccine shipments. The practice assumes responsibility for all VFC vaccine shipped to its site.

REFERENCES:

www.eziz.org :

IMM-962-Preparing Refrigerators for Vaccine Storage, 12/16

IMM-963-Refrigerator Setup for Vaccine Storage, 1/18

IMM-965-Preparing Freezers for Vaccine Storage, 12/16

IMM-966-Freezer Setup for Vaccine Storage, 11/16

IMM-983-Transporting Refrigerated Vaccine, 1/2018

IMM-986-Return or Transfer of VFC Vaccines Report, 7/2013

IMM-1116-Frozen Vaccine Transport Log, 12/2017

IMM-1119-Certificate of Calibration Quick Guide 10/16

IMM-1122-Vaccine Management Plan, 4/18

IMM-1123-Emergency Vaccine Plan, 12/2014

IMM-1130-Transporting Frozen Vaccines, 1/2017

IMM-1132-Refrigerated Vaccine Transport Log, 11/2016

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