

# Oklahoma Vaccines for Children Program

## Vaccine Management Guidelines and Plan: Ordering, Storage, Accountability, Administration, and Vaccine Storage Accident or Emergency Procedures

### Remember – Vaccines are Expensive!

Vaccines stored outside of the proper temperature range are very expensive in many ways:

- Cost for replacement of vaccines
- Cost for the employee's time researching who was affected and what vaccines need to be repeated, time frame, notifying the clients, scheduling recall appointments, etc.
- Loss of clients' confidence in the medical profession
- Bad publicity
- Possible inability to re-bill clients' insurance coverage

### SUMMARY OF REQUIREMENTS

Maintain written procedures for vaccine management (see the following guidelines).

Train all staff in the proper handling and storage of vaccine from the time it is received until it is administered.

Store vaccines appropriately in a refrigerator with the temperature maintained at 35° to 46°F or, for varicella vaccine, in a freezer with a temperature maintained at 5°F or colder.

Store varicella and MMRV vaccine only in freezers or refrigerator/freezers with separate doors and compartments for the freezer.

Dormitory style refrigerators are not acceptable for varicella and MMRV vaccine storage.

Any mishandled vaccine should not be administered until viability is determined.

Properly store vaccines immediately upon delivery.

Assign one person to check and record refrigerator and freezer temperatures twice daily, and one back-up person.

Refrigerator and freezer temperature must be checked and recorded twice daily – upon arrival in the morning and immediately before leaving for the evening.

Take immediate action if refrigerator or freezer temperature is “out-of-range”.

Both refrigerator and freezer should have their own thermometers.

Thermometers should be placed in the center of the unit, away from coils, walls, floor and fans to get a true reading of the temperature.

## VACCINE ORDERING

### SUPPLY, DATA ENTRY, AND REPORTING

The distribution system is a time-based system. Large providers will receive shipments monthly, mid-size providers will receive vaccine bi-monthly and small providers will receive shipments quarterly.

Providers utilizing the Oklahoma State Immunization Information System (OSIIS) will receive shipments of vaccine automatically according to their shipping frequency. **Pre-set levels will be based on past vaccine usage as recorded in OSIIS.** When a clinic's inventory, as recorded in OSIIS decreases, a replacement supply will be automatically sent to bring the inventory for each vaccine up to the maximum supply level. If data entry of vaccines administered is not up-to-date in OSIIS, an order will not be generated. Data entry into OSIIS must be up-to-date. Record the names of personnel responsible for OSIIS data entry on the *Vaccine Management Procedures* worksheet for your clinic.

Force orders will need to be ordered before it is time for a provider's next shipment. (Depending on a providers shipping frequency-monthly, bi-monthly or quarterly) Forcing an order will not guarantee faster shipment.

An order that is "forced" in OSIIS represents additional vaccine above the usual supply. A "forced" order is one that you place in OSIIS manually. "Forced" orders exceeding the vaccine supply may be approved for the following reasons:

- Back-to-school rush,
- Special clinics such as clinics at schools, childcare facilities, health fairs, disease outbreak control, etc.,
- Replacement of vaccine due to power outages or refrigerator/freezer failure.

If vaccine that is "force ordered" is needed before a provider's next shipping frequency, please contact the Immunization Service at (405) 271-4073.

Providers not utilizing OSIIS may place orders by calling the Immunization Service at (405) 271-4073 or by faxing orders using the *Vaccine Order Form* to the Immunization Service at (405) 271-6133.

Providers not utilizing OSIIS will receive shipments of vaccine automatically according to their shipping frequency (Monthly, Bi-Monthly or Quarterly). Vaccine needs should be carefully and thoroughly planned in order to limit vaccine waste through expiration and mechanical failure or power outage. **Failure to complete *Doses Administered Reports* can lead to delay in vaccine shipment or possible removal from the VFC program.**

### VACCINES AVAILABLE THROUGH THE VFC PROGRAM

Vaccines available include DTaP, Pediatric DT (single doses only), DTaP-Hib, Td, Hib, Tdap, IPV, MMR, hepatitis B, hepatitis A, Human Papillomavirus (HPV), influenza, 23-valent

pneumococcal polysaccharide (PPV), 7-valent pneumococcal conjugate (PCV), MMRV, meningococcal, rotavirus, and varicella.

As new vaccines are licensed and approved by ACIP the OSDH Immunization Service will contact you about their availability.

## **BRAND PREFERENCE**

Every effort is made to allow brand preferences, but this is not always an option. Specific brands of DTaP, Hib, Tdap, hepatitis B, and hepatitis A vaccines will be provided depending on availability.

## **VARICELLA and MMRV VACCINE ORDERS**

Merck Vaccines, Inc. will ship orders for varicella and MMRV vaccine to providers with a *Refrigerator Certification Form for Varicella Vaccine Storage* on file with the Immunization Service. Varicella and MMRV should remain frozen at all times. Varicella and MMRV vaccine should be stored in the freezer compartment of a frost-free, kitchen-size or larger refrigerator which can maintain an average temperature of -15°C or 5°F. **Dormitory style refrigerators are not acceptable for varicella and MMRV vaccine storage.**

## **RECEIVING VACCINE DELIVERIES**

**Designate personnel and back-up personnel to be responsible for accepting vaccine deliveries and ensure that vaccines are refrigerated and/or placed in the freezer immediately after arrival.** Document the designated staff responsible for receiving vaccine deliveries and reporting problems with vaccine shipments to the Immunization Service on the *Vaccine Management Procedures* worksheet for your clinic and *Routine Vaccine Storage Plan* worksheet.

The duties of the designated staff are:

- 1. Open vaccine shipments immediately upon arrival to ensure that the cold chain has been maintained.**
2. Check order against invoice to ensure the vaccine amounts and lot numbers match the invoice.
3. Do not place unopened shipments of vaccine in the refrigerator or freezer.
- 4. If your clinic uses OSIIS, receive the vaccine into OSIIS within 24 hours of accepting the delivery.** However, if you did not receive the vaccines listed in OSIIS, do not receive them in OSIIS; call the Immunization Service to have the OSIIS inventory corrected.
- 5. Report any problems with vaccine shipments immediately to the Immunization Service at (405) 271-4073.**
6. Maintain all vaccine invoices for three years.

Vaccine is shipped by contract courier on Mondays, Tuesdays, and Wednesdays and should be received within 24 hours of shipping, except MMRV and varicella vaccine, which is shipped by Merck Vaccine Division.

## VACCINE ACCOUNTABILITY

### RECORD-KEEPING

All providers should keep a record of vaccinations, including date, vaccine type, manufacturer, lot number, dose number and name of the person administering the vaccine. Records should be kept in OSIS or the client's chart or both. Eligibility for VFC vaccine should also be recorded in OSIS or the client's chart. The client's immunization record should be updated at each visit.

### REPORTING

All VFC vaccine should be accounted for in OSIS or on monthly *Doses Administered Reports*. *Doses Administered Reports* should be submitted to the Immunization Service no later than the 5<sup>th</sup> working day of the following month. Providers must account for all VFC vaccine shipped to them. Failure to complete *Doses Administered Reports* or to properly use OSIS can lead to delay in vaccine shipment or possible removal from the VFC program.

### PROVIDER SITE VISITS

Immunization Service staff routinely conducts site visits with VFC providers. Site visits include auditing records, reviewing vaccine storage and handling procedures, and assuring compliance with the VFC Program guidelines. VFC providers not in compliance with the VFC Program guidelines may be removed from the program.

## INVENTORY CONTROL

**Designate personnel to be responsible for weekly stock rotation and monthly physical inventory of vaccine.** Document the name of the designated staff person below and on the Vaccine Storage Emergency Response Plan.

The duties of the designated staff are:

- Ensure that vaccines with the most current expiration dates are used first and are kept in front of vaccines with longer expiration dates.
- Check your vaccine stock weekly and rotate as necessary. Notify the Immunization Service at (405) 271-4073 if vaccine will expire within the next 3 to 6 months and you will not be able to use it within that time period.
- Conduct a physical inventory monthly and reconcile with OSIS. Please consult your Immunization Representative for instructions on reconciling the inventory in the refrigerator/freezer with OSIS.
- Return expired vaccine to the Immunization Service.

### EXPIRED VACCINE

Every effort should be made to use vaccine before it expires. No more than an eight-week supply of vaccine should be on hand in order to reduce the amount of vaccine wasted due to

expiration or mechanical failure/power outages. Vaccine that will expire in 30 days or less is highlighted in orange on your *Current Inventory* screen in OSIS.

## **VACCINE ADMINISTRATION**

- Health care professionals or others who administer vaccines should be trained and knowledgeable.
- Vaccine should be administered following appropriate guidelines.
- All vaccines should be administered using appropriate needle size and gauge.
- IM injections should be given in the *vastus lateralis* or the *deltoid*.
- SQ injections can be given in the upper arm or the thigh. MMR and varicella should be administered SQ. IPV can be administered either IM or SQ.
- **Vaccine should never be administered in the buttocks.**
- Vaccines should never be mixed in the same syringe, unless they are licensed for combination, such as DTaP/Hib.
- Syringes should **never** be pre-filled.
- Vaccines should be given following an appropriate schedule.
- Vaccines should not be given at less than the minimum ages or intervals between doses as recommended by the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics, and the Academy of Family Physicians.
- MMR and varicella vaccine should not be given prior to the first birthday.
- Hepatitis A vaccine should not be given prior to the first birthday.

## **VACCINE STORAGE AND HANDLING**

**Designate primary and secondary persons to be responsible for:**

- Routine vaccine storage procedures
- Temperature monitoring
- Staff training
- Handling vaccine storage emergencies

Document the names of personnel responsible for routine vaccine storage on the *Vaccine Management Procedures* worksheet and *Routine Vaccine Storage Plan* worksheet.

The duties of the designated staff are:

### **REFRIGERATOR**

- 1. Maintain refrigerator temperatures at 35° to 46°F (2° - 8°C).**
2. Never allow vaccine to be frozen.
3. Store vaccine on the shelves of the refrigerator, not in the door or bins.
4. Arrange vaccine so that air is allowed to circulate freely.
- 5. Store all vaccines in the original box. MMR, MMRV, and varicella vaccine should be protected from light at all times.**
6. Do not allow food, beverages, or biologicals to be stored in the same unit with vaccine.
7. Post vaccine storage/handling chart and temperature log on outside of unit.
8. Place “DO NOT UNPLUG” signs near the outlet for each unit in which vaccines are stored and “DO NOT DISCONNECT” signs on the circuit breakers.
9. Assure that maintenance and cleaning personnel will be advised not to unplug storage units.

### **FREEZER**

The combination immunization of MMRV, MMR and varicella are to be stored and handled the same.

- 1. Store varicella vaccine at 5°F (-15°C) or colder.**
2. Do not store varicella vaccine in dormitory-style refrigerators.
3. Place “DO NOT UNPLUG” signs near the outlet for each unit in which vaccines are stored and “DO NOT DISCONNECT” signs on the circuit breakers
4. Assure that maintenance and cleaning personnel will be advised not to unplug storage units.
5. Post vaccine storage/handling chart and temperature log on outside of unit.
6. Do not allow food and beverages to be stored in the same unit with vaccine.

### **THERMOMETERS & TEMPERATURE MONITORING**

1. Place thermometers in both the refrigerator and the freezer and check and record temperatures twice daily, once in the morning and once before leaving the clinic for the night. Please note: If the temperature is a few degrees out-of-range, the unit may be in a defrost cycle. Check the temperature again in an hour. Most defrost cycles last less than an hour and the temperature returns to normal.
2. If the refrigerator or freezer temperatures are near the lower limits of the acceptable temperature ranges, take steps to ensure the temperature does not drop further. Conversely, if the refrigerator or freezer temperature is approaching the upper limit of the acceptable range, take immediate steps to ensure that it stays within range. This may be as simple as adjusting the thermostat or checking the temperature with a different thermometer to check the accuracy of the original reading.
3. Check storage units at the end of each day to ensure they are closed and, if possible, locked.
4. Make sure vaccines are not left on the counter before leaving for the day.

**TIP – Water bottles in the refrigeration unit and ice packs in the freezer will help maintain a constant temperature, especially if the power supply is disrupted.**

## STAFF TRAINING

All staff who handle or administer vaccines should be trained on proper vaccine storage and handling. In addition, all staff in the clinic should be informed of procedures for vaccine storage in the event of a disruption in power supply.

Duties of the designated staff person are:

1. Train staff designated to monitor temperatures in how to properly read thermometers.
2. Review the attached documents entitled *Checklist for Safe Vaccine Handling and Storage*.
3. Review the storage and handling procedures specific to each type of vaccine in the CDC's *Recommendations for Handling and Storage of Vaccines* with all new staff.
4. Periodically review the current guidelines for vaccine handling of individual vaccines with staff. Package inserts should always be your primary reference source. Understand package inserts for new vaccines before using.
5. Ensure that all staff know the steps to take in the event of a vaccine storage accident or emergency.

## VACCINE STORAGE EMERGENCY RESPONSE PLAN

Every clinic should have a plan to deal with vaccine storage accidents and emergencies that describe the steps to be taken if vaccine is stored improperly. Examples of such situations range from easily corrected problems such as the refrigerator door being left open overnight, to serious situations such as power outages.

The plan should cover vaccine storage accidents and emergencies. Vaccine accidents such as leaving the refrigerator door open overnight are seemingly minor events that can seriously compromise vaccines. Usually these accidents can be easily corrected. Vaccine emergencies are serious uncommon events such as power outages that necessitate moving the vaccine to another storage unit.

The worksheets at the end of this section will help you to prepare and respond to both vaccine accidents and emergencies. The worksheets should be posted on all vaccine storage units and all staff should be familiar with the procedures. Record the names of staff designated for each duty in the appropriate areas below and on the worksheets.

## VACCINE ACCIDENT PLAN

Staff members designated for routine vaccine storage will take the following steps:

1. Correct the situation; close the door and/or plug in the refrigerator/freezer, place vaccine in refrigeration.
2. Record the current temperature of the refrigerator/freezer on the worksheet.
3. Store the vaccines at appropriate temperatures. Make sure that the refrigerator/freezer is working properly or move the vaccines to a unit that is. **Do not automatically throw out the affected vaccine. Mark the potentially compromised vaccine so that it will not be used until its status is determined and so it can be easily identified.**

4. Collect essential data on the worksheet.
5. Call the Immunization Service at (405) 271-4073.
6. You may be asked to contact the manufacture of each vaccine. Be prepared to share lot number, expiration date, and storage information. You, the VFC provider, will make a determination about the vaccine's status for use based on the manufacture's information.
7. Send completed Vaccine Storage Incident Report to the Immunization Service.

## **VACCINE EMERGENCY RECOVERY PLAN**

Document the names of the staff persons responsible for handling vaccine storage emergencies on the *Vaccine Storage Emergency Response Plan*.

Duties of the designated personnel are:

1. Develop an emergency plan to follow in the case of mechanical failure or power outage and have it prominently posted near storage units.
2. Set up and maintain a monitoring /notification system during times of inclement weather or other conditions that would create a loss of power. The designated person(s) should track weather conditions. *Hospitals and other large offices and clinics should consider an alarm system to monitor refrigerator/freezer temperatures and a notification system so that the designated person(s) can be notified of problems. For the majority of offices and clinics that do not have an alarm system, a designated person should perform a manual check during possible conditions for power outages.*
3. Assure appropriate handling of vaccines during power outages.
4. If you do not have a back-up generator, identify a location with one. This may be the local hospital, retirement home, fire station, or an employee's home.
5. Make arrangements with the site to store your vaccines there when weather predictions call for inclement conditions (tornadoes, hurricanes, ice, snow, lightning, windstorms, etc.) and when your vaccine storage equipment cannot be fixed or the power cannot be restored within six (6) hours. Record the names of your alternate storage locations on the *Vaccine Management Procedures* and *Vaccine Storage Emergency Response Plan*.
6. Inventory vaccine before moving it.
7. Before moving your vaccines, call the location to ensure that their back-up generator is working.
8. In situations where a location with a back-up generator cannot be identified within a reasonable distance, preparations should be made to have coolers, frozen ice packs, and/or dry ice available to temporarily and safely store your vaccines.
9. If the location is accessible within 30 minutes, package the vaccines in a well-insulated container with coolants. Remember that varicella vaccines must be kept at or below  $-15^{\circ}\text{C}$  ( $5^{\circ}\text{F}$ ).