

Health Services

Procedure Manual

Procedure Subject/Title: Management of Texas Vaccines For Children (TVFC)
Applicability: All BVCHC Clinic Sites
Purpose: To ensure uniform management of this resource throughout the agency.

NOTE: ALL SITES WILL COMPLY WITH THESE PROCEDURES. SOME SITES REPORT THROUGH AN AGENCY TVFC COORDINATOR.

Procedure:

- 1) Designated staff positions/persons will be responsible for management of the TVFC program, including shipments, inventory and daily logs at each clinic site.
- 2) At least two staff per site need to be identified as responsible for this program. Both staff will be trained and able to assume responsibility for the TVFC program/supplies.
- 3) When vaccines arrive:
 - A. Check expiration dates on all vaccines received.
 - B. Check for damage during shipping. If **damage or compromise suspected**, place vaccine in the refrigerator or freezer (specific to the vaccine) and identify it as having a possible problem and immediately notify the Texas Department of Health Pharmacy and then the Texas Vaccines for Children Program.
 - C. Upon arrival, vaccines must be **immediately** stored in the proper area, either refrigerator or freezer, and all inventory received is documented on the packing slip. Two staff will unpack, inventory and sign that this has been completed and that both staff concur on the packing slip. For specific information on handling and storage refer to IMMTrac Vaccine Management Sheet – Recommendations for Handling and Storage of Selected Biologicals.
- 4) Each site will maintain a TVFC Notebook. All documentation related to this program will be maintained in the notebook in date order, i.e. packing slips, temperature logs, inventory counts, administration logs, biological order forms (C-33 & C-68 forms), Vaccine Loss Reports (C-69 forms) and transfer forms when applicable.

- 5) Regulation of refrigerator temperature:
 - A. Temperature readings are documented upon arrival in the morning and one hour before leaving the clinic.
 - B. The temperature is recorded on the approved TVFC temperature log.
 - C. If a temperature is found to be outside of the acceptable range the procedure on TVFC Refrigerator Temperature is followed. Immediately contact the Texas Department of Health Pharmacy for further directions.
- 6) Log maintenance:
 - A. As vaccinations are prepared for administration the log is completely filled out for that patient. The vaccines are **then** administered to the patient.
- 7) All logs are submitted to the TVFC coordinator on the first day of each month by fax. Originals are stored in the TVFC notebook at each site.
- 8) IMMTrac process:
 - A. Information from the logs is entered into the IMMTrac system daily. The TVFC coordinator will work with other staff to facilitate the entry of this data into the IMMTrac system when requested to do so. NOTE: This does not require clinical staff and can be accomplished by other trained office staff when they have demonstrated competence in this data entry. Competence in this skill should be documented and placed in their personnel file.

ATTACHMENTS:

Vaccine Management – Recommendations for Handling and Storage of Selected Biologicals

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Procedure Subject/Title: Texas Vaccines For Children (TVFC) Refrigerator Temperature
Applicability: All BVCHC Clinic Sites
Purpose: To ensure that vaccines are maintained per manufacturers' guidelines.

NOTE: ALL SITES WILL COMPLY WITH THESE PROCEDURES. SOME SITES REPORT THROUGH AN AGENCY TVFC COORDINATOR.

Procedure:

- 1) If a refrigerator temperature is found to be outside of the acceptable parameters the TVFC Coordinator should be contacted **immediately**. If this position is not available that position's supervisor and the Texas Department of Health Pharmacy should be contacted **immediately**.
- 2) If refrigerator/freezer temperature is out of range document action taken at the bottom of the Temperature Recordings Form on the front of the appliance.
- 3) Initiate an Occurrence Report and submit to the Performance Improvement Department.
- 4) Temperatures will be recorded every 30 minutes until the temperature is within the acceptable range. This documentation will be maintained in the TVFC notebook at each site.
- 5) The temperature should be monitored for a period of two (2) hours after it reaches the correct temperature to ensure that the temperature is stable after making adjustments to the refrigerator/freezer.
- 6) Notify the TVFC Coordinator when the temperature is stabilized.

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Procedure Subject/Title: Texas Vaccines For Children (TVFC) Packing Slips
Applicability: All BVCHC Clinic Sites
Purpose: To ensure that packing slips are maintained for documentation of receipt of vaccines.

NOTE: ALL SITES WILL COMPLY WITH THESE PROCEDURES. SOME SITES REPORT THROUGH AN AGENCY TVFC COORDINATOR.

Procedure:

- 1) When vaccines are delivered to a clinic site two staff persons will initial on the packing slip each item unpacked/received. On the bottom of each packing slip staff will write the statement, "All vaccine accounted for." Both staff will sign this statement.

If the quantity received is different than what is documented on the packing slip this will be clearly documented on the packing slip. Both staff inventorying the shipment will sign a statement on the bottom of the packing slip that lists the discrepancy. The TVFC Coordinator or the site manager will contact agency's pharmacist and the TVFC designated contact person and notify them of the discrepancy.

- 2) All packing slips are placed in the TVFC notebook when step #1 is completed.
- 3) On the last working day of each month (no later than the morning of the first day of each month) the TVFC paperwork is completed at each site and must be faxed to the TVFC Coordinator's office by 5 p.m. Faxed items will include:
 - A. Log of patients who received vaccines that month.
 - B. Vaccine inventory for the month.
 - C. Temperature log for the month.
 - D. All packing slips for any vaccines received during that month.
 - E. Transfer forms from other clinics.

- 4) The TVFC Coordinator will compile all the data. If discrepancies are found the individual clinic manager/designated staff will be notified and this will be resolved by the 3rd of each month.
- 5) The TVFC Coordinator will submit all data and orders to the TVFC Program by the designated due date for each site. The TVFC Coordinator will communicate with sites that submit independently to determine if their process is on time and without problems.

RECOMMENDATIONS RE: EQUIPMENT INVOLVED WITH STORAGE OF VACCINES

- 1) Do not connect these refrigerators to an outlet with a ground-fault interrupter or one activated by a wall switch. The Texas Vaccine for Children program requires a “Do Not Unplug” sign on the refrigerator and/or freezer.
- 2) Use plug guards to prevent accidental dislodging of the wall plug.
- 3) Place a thermometer located at the center of the storage compartment. This thermometer should be of the constant recording type with graphed readings.
- 4) Equip refrigerator with several bottles of chilled water and freezer with several ice trays or ice packs to fill empty space to minimize temperature fluctuations in the event of a brief electrical or mechanical failure occurrence. These items may be placed in the door of the refrigerator/freezer.

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Procedure Subject/Title: Expiration of Texas Vaccines For Children (TVFC) Products
Applicability: All BVCHC Clinic Sites
Purpose: To ensure that vaccines are used prudently.

NOTE: ALL SITES WILL COMPLY WITH THESE PROCEDURES. SOME SITES REPORT THROUGH AN AGENCY TVFC COORDINATOR.

Procedure:

1. Expiration dates of all vaccines should be checked monthly.
2. Notify other clinics in our clinic system when vaccines are **within 90 days** of expiration so that a decision on how to efficiently use them and prevent wasting them can be made. If a viable plan cannot be developed and carried out by our Agency notify the Texas Vaccines for Children program contact person of the situation. Document all communication with the TVFC Program and maintain it in the TVFC Notebook.
3. When there is a vaccine that is expired:
 - A. Remove it from the refrigerator/freezer and bag the product separately and label it as "EXPIRED – Do NOT USE" and return it to the refrigerator/freezer.
 - B. A designated staff person will complete a Vaccine Loss Report (C-69) and follow directions for submission to the Texas Department of Health Pharmacy.

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Procedure Subject/Title: Handling of Vaccine
Applicability: All BVCHC Clinic Sites
Purpose: To ensure that vaccines are maintained and used per manufacturers' guidelines.

NOTE: ALL SITES WILL COMPLY WITH THESE PROCEDURES. SOME SITES REPORT THROUGH AN AGENCY TVFC COORDINATOR.

Procedure:

1. When a multi-dose vial is first opened and/or reconstituted place the date and time that this occurred on the label of the vial and your initials.
2. Discard reconstituted, live-virus and other vaccines if they are not used within the interval specified in the package insert.
 - A. Examples of time frames: Varicella vaccine should be discarded after 30 minutes; measles-mumps-rubella (MMR) should be discarded after 8 hours.
3. Do not open more than one vial of a particular vaccine at a time.
4. Store vaccines only in the central storage area of the refrigerator/freezer – not in the door.
5. Never place food in the refrigerator/freezer where vaccines are stored.
6. Orient and keep staff informed of all procedures related to vaccine handling and storage.
7. Orient and keep staff informed of any violation of handling protocols or any accidental storage problem (i.e. electrical failure) and contact Texas Department of Health Pharmacy regarding the handling of the affected vaccine.

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Procedure Subject/Title: Vaccine Storage Emergency Protocol
Applicability: All BVCHC Clinic Sites
Purpose: To ensure that vaccines are maintained safely at all times.

NOTE: ALL SITES WILL COMPLY WITH THESE PROCEDURES. SOME SITES REPORT THROUGH AN AGENCY TVFC COORDINATOR.

Procedure:

1. Vaccines are to be transferred as soon as possible to the designated emergency storage site in the event of:
 - A. Extended power outage with unstable temperature regulation.
 - B. Construction/repairs of clinic that might involve interruption of power.
 - C. Any other planned or unplanned event that could compromise maintenance of temperature parameters for vaccines.
2. Any staff member with a concern regarding the safe storage of vaccines should contact their immediate supervisor.
3. When notification occurs all management staff of the clinic and the administrator responsible for the site should be notified of the concern and consulted regarding the plan of action.
4. The Texas Department of Health in the county where the clinic is located will be contacted to notify them of our emergency situation and the need for temporary storage of our vaccine supply. If we are unable to reach the Texas Department of Health the nearest hospital facility or other public agency equipped with a generator (i.e. law enforcement/ambulance offices/dispatch facilities) will be contacted and arrangements made to transfer vaccines for storage.
5. Before transporting vaccines the following actions must occur:
 - A. Do not discard any vaccine.
 - B. Record the refrigerator/freezer temperature(s) and the time the temperature reading was obtained.

- C. Keep the doors to the units closed as much as possible.
 - D. Be sure that the location where the vaccines are being transported to have been notified of your approximate time of arrival with the vaccines.
6. To transport the vaccines:
- A. Note the time and the temperature of the refrigerator/freezer and remove the vaccine for transportation.
 - B. Move the vaccine directly from the refrigerator/freezer into the appropriate transfer container.
 - i. Document the number of doses of each vaccine being transported on Form C-33. Make a copy of this form and place the original in your TVFC Notebook. Take the copy with you to the transfer site and provide it to the facility who is storing your vaccine. Document the name of the person who assumed responsibility for your vaccine.
 - ii. Preparation of refrigerated vaccines:
 - a. These vaccines must be packed and stored to maintain an internal temperature between 35 degrees and 46 degrees Fahrenheit. Place a thermometer in the container that you are packing your vaccines in.
 - b. Place each type of vaccine in a labeled baggie. Label should include name of our clinic, name of contact person and the contact person's telephone number.
 - c. Pack with ice packs. Vaccines must be separated from the ice packs with plastic or foam.
 - d. Document the temperature inside the container just before closing the container.

- iii. Preparation of frozen vaccines:
 - a. Frozen vaccines must be packed in dry ice to maintain an internal temperature at or below + 5 degrees Fahrenheit. An estimate of dry ice is 1 pound for every 10 doses of vaccine. Place a thermometer in the container that you are packing your vaccines in.
 - b. If dry ice is not available and cannot be obtained in a reasonable amount of time, contact the Local Health Department to which you are transporting the vaccine.
 - c. Place the frozen vaccine in a baggie and label it with the name of our clinic, name of contact person and the contact person's telephone number.
 - d. Document the temperature inside the container just before closing the container.
 - e. **Varicella must not be allowed to thaw. Should thawing occur contact the manufacturer and/or TVFC for further instructions. Do not discard the vaccine. TVFC will provide instructions on next steps.**

******Be careful to ensure that frozen vaccine is placed in the container with dry ice and that refrigerated vaccines are not placed in the dry ice.**

- C. Transport the vaccines to the accepting storage facility.
- D. Document temperature in transfer containers when the container is opened. Remove all vaccines and place in a refrigerator or freezer, as appropriate. Maintain them in the baggies with the facility name and contact person's name and phone number on them.

7. To return vaccines to our clinic site:
 - A. Be certain that our facility's refrigerator/freezer has been maintaining the correct temperature range for a period of at least two hours.
 - B. Follow the same procedures as documented in #6 above to retrieve and transport the vaccines back to our clinic site.
 - C. If there is concern about the efficacy of the vaccines do not administer them until the Local Health Department has been contacted re: your concerns and instructions received and this is documented.

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Procedure Subject/Title: Vaccine Loss Protocol
Applicability: All BVCHC Clinic Sites
Purpose: To ensure vaccines that become compromised are handled properly.

NOTE: ALL SITES WILL COMPLY WITH THESE PROCEDURES. SOME SITES REPORT THROUGH AN AGENCY TVFC COORDINATOR.

Procedure:

1. Vaccine loss must be reported immediately to the Local Health Department and Texas Vaccines For Children (TVFC) representative.
 - A. If the loss of vaccine is due to power failure, improper refrigeration or vaccine left out of the refrigerator or freezer:
 - i. Obtain the current temperature recording form and record the current temperature of the refrigerator/freezer and have it available during the telephone call.
 - ii. Be prepared to provide them with information concerning the temperature of the vaccine, the amount of vaccine involved, the expiration dates of the involved vaccines, and how long the vaccine was exposed to inappropriate temperatures.
 - iii. Fill out column 1 on Form C-33 listing the exact number of doses by vaccine type.
 - iv. Complete and submit to the TVFC Program/Local Health Department the Vaccine Loss Report (Form C-69).
2. Do not discard or remove your vaccine from the refrigerator or freezer until instructed to do so by the Local Health Department or TVFC program.

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Procedure Subject/Title: Transfer of Texas Vaccine For Children Vaccines to Another Brazos Valley Community Health Center Site
Applicability: All BVCHC Clinic Sites
Purpose: To ensure that vaccines are safely transferred internally prior to seeking other sources of vaccines to borrow.

NOTE: ALL SITES WILL COMPLY WITH THESE PROCEDURES. SOME SITES REPORT THROUGH AN AGENCY TVFC COORDINATOR. CONTACT BRAZOS VALLEY COMMUNITY HEALTH CLINICS FOR VACCINE TRANSFERS. IF WE ARE UNABLE TO TRANSFER VACCINE IN-HOUSE THEN THE LOCAL HEALTH DEPARTMENT (LHD) SHOULD BE CONTACTED FOR A POSSIBLE VACCINE TRANSFER.

Procedure:

TRANSFERRING FROM ONE CLINIC TO ANOTHER CLINIC WITHIN THE BRAZOS VALLEY COMMUNITY HEALTH CENTER SYSTEM:

1. Contact the vaccine coordinator at the site that would like to borrow from to ensure that the clinic is able to spare the vaccines needed.
2. When there is verbal agreement between two clinics to transfer vaccines, the site who is transferring vaccines will complete the Vaccine Transfer Form (including the lot number, expiration date of the vaccine and number of doses being transferred).
3. The Vaccine Transfer Form is signed by the person at the transferring site **and** the person responsible for actually physically transferring the vaccines to a receiving clinic.
4. A copy of the Vaccine Transfer Form stays with the originating clinic and the original form stays in the cooler with the vaccines being transferred until they arrive at the receiving clinic.
5. On arrival at the receiving clinic the original Vaccine Transfer Form is completed and all signatures obtained and it stays at the receiving clinic. A copy is made and mailed to that clinic's vaccine coordinator so that monthly inventory counts can be documented.

6. All original forms are maintained in the clinic's binder that houses all documentation of vaccine information.

VACCINE TRANSFER CRITERIA:

1. All vaccines must be transferred in an enclosed cooler along with several ice packs within the cooler with a thermometer to document temperatures during transport.

***NOTE:** Never place a vaccine vial directly against an ice pack. Wrap the vial in paper towels or place inside a small box to maintain a constant stable temperature.

2. Varicella and Zoster vaccines are frozen live viruses that **must be** transferred in a special box packed with dry ice or special ice packs to maintain a constant temperature of 32 degrees during the entire transport period.

***NOTE:** Local health departments may have these special transport boxes that the clinic system may borrow and then immediately return to the local health department.

3. All vaccines must be delivered immediately and placed in the refrigerator or freezer immediately upon arrival at the receiving clinic site.
4. Notify staff at the receiving clinic of the new arrival of transferred vaccines and document who was notified.

TRANSFERRING FROM A LOCAL HEALTH DEPARTMENT (LHD) TO A CLINIC WITHIN THE BRAZOS VALLEY COMMUNITY HEALTH CENTER SYSTEM:

1. The vaccine coordinator at the clinic needing the vaccine will contact their local health department and request a transfer and negotiate how the transfer will occur. This conversation and plan should be documented and placed in the clinic's binder that houses all documentation of vaccine information.
2. The local health department will deliver the requested vaccine by their preferred method. The delivered vaccine will have a Vaccine Transfer Form that will require completion when the vaccines are received.
3. After the Vaccine Transfer Form is signed by the receiving clinic, send a copy to the vaccine coordinator for your clinic. Maintain the original in your notebook.