



TEXAS DEPARTMENT OF STATE HEALTH SERVICES

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DAVID L. LAKEY, M.D.
COMMISSIONER

January 15, 2015

RE: Policy 0015-1 Routine and Emergency Vaccine Storage and Handling Plans

Dear Texas Vaccines for Children (TVFC) provider,

The Centers for Disease Control and Prevention (CDC) requires Vaccine for Children (VFC) providers to develop and implement feasible and appropriate plans for routine and emergency vaccine management. As such, the Texas Department of State Health Services (DSHS) Immunization Branch has developed Vaccine Management Plan Templates (E11-11190) as a resource available to all TVFC providers.

The Vaccine Management Plan Templates include templates for both the Routine Vaccine Storage and Handling Plan and the Emergency Vaccine Storage and Handling Plan. These templates capture all information required by the CDC.

Please note, TVFC providers are not required to use these templates, but they are valuable tools available to providers should they need assistance in developing the required vaccine management plans. If the templates are not used, providers must develop routine and emergency vaccine management plans that include all of the information included in the templates provided by the TVFC Program.

TVFC providers must review and update their Routine Storage and Handling Plan and the Emergency Vaccine Storage and Handling Plan annually or more frequently if there are any changes to the plan, changes in equipment used to store TVFC vaccine or changes to staff in charge of vaccine management. A review date is required on all plans in order to verify that they are current. All plans must include the signature, name, and title of the preparer of the documents.

TVFC providers will be asked to provide a copy of their routine and emergency vaccine storage and handling plans at VFC Compliance Visits. The plans must be posted on or near the refrigerator or freezer containing TVFC vaccine. Providers must ensure that all employees involved with vaccine management are aware of this plan.

The TVFC Program has updated the Emergency Vaccine Storage and Handling Plan Checklist (E-11-14497) for providers to use in the event of an emergency situation. This checklist provides guidance for the emergency transport of both refrigerated and frozen vaccines.

Further guidance regarding routine and emergency vaccine management and vaccine transport can be found in Chapter 3 – Vaccine Management of the TVFC Provider Manual. The TVFC Provider Manual is available online at: <http://www.dshs.state.tx.us/immunize/tvfc/ProviderResources.shtm>.

Thank you for your continued support of the TVFC Program. For any questions, please contact the appropriate DSHS Health Service Region (HSR) below.

DSHS Health Service Region Phone List

| Provider PINS Beginning With | Health Service Region | Phone Number |
|--|------------------------------|---------------------|
| 01 | HSR 1 | 806-783-6416 |
| 02 | HSR 2 | 325-795-5660 |
| 03 | HSR 3 | 817-264-4793 |
| 04 or 05 not in Hardin, Jefferson or Orange Counties | HSR 4/5N | 903-533-5310 |
| 05 in Hardin, Jefferson or Orange Counties or 06 or 25 | HSR 6/5S | 713-767-3410 |
| 07 | HSR 7 | 254-778-6744 |
| 08 or 00 | HSR 8 | 210-949-2067 |
| 09 | HSR 9 | 432-571-4132 |
| 10 | HSR 10 | 915-834-7924 |
| 11 | HSR 11 | 956-421-5552 |

Sincerely,



Monica Gamez
Director, Infectious Disease Control Unit



Vaccine Management Plan Templates

- Vaccine Coordinators and Resources
- Routine Vaccine Storage and Handling Plan
- Emergency Vaccine Storage and Handling Plan

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Contact List

| Vaccine Coordinators | | | |
|--|---|--|-----------------------|
| Vaccine Coordinators (Name/Title) | Telephone Number (home, cell, pager) | Alt. Telephone Number (home, cell, pager) | E-mail Address |
| Primary: | | | |
| Alternate (Back-up #1): | | | |
| Alternate (Back-up #2): | | | |
| Resources Contact List | | | |
| Resources | Telephone Number | E-mail Address | |
| Local Health Department (LHD) | | | |
| DSHS Health Service Region (HSR) | | | |
| DSHS Vaccine Call Center | 1-888-777-5320 | VacCallCenter@dshs.state.tx.us | |
| DSHS Pharmacy | 512-776-7500 | | |
| | | | |
| Additional Resources | Company/Entity Name | Telephone Number | E-mail Address |
| Electric Power Company | | | |
| Refrigerator Repair | | | |
| Freezer Repair | | | |
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Texas Vaccines for Children (TVFC) Program Routine Vaccine Storage and Handling Plan

Instructions for TVFC providers: All TVFC providers are responsible for proper routine management of their vaccine inventory. Once completed, this template can serve as the required Routine Vaccine Storage and Handling Plan.

TVFC providers must review and update this plan **annually** or more frequently if there are any changes to the plan, changes in equipment used to store TVFC vaccine, or changes to staff responsible for vaccine management, storage and handling. The most current Routine Vaccine Storage and Handling Plan will be reviewed during TVFC Compliance Site Visits and Unannounced Storage and Handling Visits.

A copy of this plan, along with the Emergency Vaccine Storage and Handling Plan, must be posted on or near any refrigerator or freezer used to store TVFC vaccine.

| | |
|---|---|
| Practice Name: | Clinic Address: |
| TVFC PIN#: | E-mail Address: |
| Telephone Number: () - | Fax Number: () - |
| Name of Managing Physician or Equivalent: | TVFC Contact: |
| Primary Vaccine Coordinator: | Back-up Vaccine Coordinator(s): |
| Person Responsible for Receiving Vaccine Shipments: | Person Responsible for Vaccine Inventory & Ordering: |
| Person Responsible for Rotating Vaccine Inventory: | Person Responsible for Completing Vaccine Loss Reports: |

Routine Vaccine Storage and Handling Plan reviewed and updated by:

| | |
|------------|----------------------|
| Name: | Title: |
| Signature: | Date of Last Review: |

Procedures for Proper Storage and Handling of Vaccine

For guidance, refer to Chapter 3 of the TVFC Provider Manual.

Temperature Monitoring

- _____ is responsible for monitoring and recording temperatures of all vaccine storage units. In their absence, _____ is the responsible back-up for monitoring and recording temperatures.
- A Temperature Recording Form (C-105) must be posted on or near all units storing TVFC vaccine.
- Freezer/refrigerator temperatures must be recorded twice daily on the Temperature Recording Form (C-105).
- Providers are required to record min/max temperatures at least once daily, preferably in the morning.
- Results of each temperature check must be documented on the Temperature Recording Form (C-105). The time and the initials of the staff member monitoring/recording must be documented on the form.
- If an out-of-range temperature is observed, immediately contact your responsible entity (DSHS HSR or LHD) and complete the Vaccine Storage Troubleshooting Record attached to the Temperature Recording Form.

Vaccine Storage

- Providers are required to have appropriate equipment that can store vaccine and maintain proper conditions.
- Refrigerator/freezer units must be large enough to hold the year's largest inventory without crowding.
- Two types of storage units are acceptable for storage: a refrigerator that has a separate freezer compartment with a separate exterior door and separate thermostat controls for the refrigerator and freezer compartments or stand-alone, single-purpose refrigerators and freezers.
- Small combination refrigerator-freezer units outfitted with a single external door and dorm-style refrigerators are never allowed for the storage of TVFC vaccine.
- The refrigerator compartment must maintain temperatures between 35°F and 46°F (2°C and 8°C) for vaccine viability.
- The freezer compartment must maintain temperatures between -58°F and +5°F (-50°C and -15°C).
- Place water bottles (labeled "Not for consumption") on the top shelf by the cold air vent, floor, and in door racks of the refrigerator.
- Place frozen coolant packs along walls, back, and bottom of freezer and inside the door racks.
- Diluents that are not packaged with vaccine may be stored in the door of the refrigerator and can provide extra insulation much like bottles of water.

Vaccine Storage (continued)

- It is never acceptable to store food or drinks in the same refrigerator or freezer as vaccine.
- Refrigerators and freezers storing vaccine must be plugged directly into a wall outlet with a plug guard. Multi-strip outlets must not be used.

Vaccine Shipping and Receiving Procedures

- _____ is responsible for receiving vaccine orders. In their absence, _____ is responsible to receiving vaccine orders.
- Providers must always accept vaccine shipments. Never refuse or return vaccine shipments without specific instructions from DSHS or your responsible entity.
- Providers must ensure that the accurate shipping address and delivery hours are entered into the Electronic Vaccine Inventory (EVI) system.
- TVFC requires all providers to have a protocol to ensure the vaccine is stored immediately and appropriately upon arrival. The following steps should be taken when a vaccine shipment arrives:
 1. Check the vaccine received against packing list to verify all vaccines have been received.
 2. Verify the packing list against the order placed in EVI to ensure all ordered vaccines were received.
 3. Ensure adequate diluent is included for vaccines requiring reconstitution.
 4. IMMEDIATELY contact your responsible entity if vaccine (or diluent) ordered is not received.
 5. Place vaccine in appropriate storage immediately.
 6. Make sure to place those vaccines with longer expiration dates behind shorter-dated vaccines. This ensures short-dated vaccine is used first.
- If the temperature monitoring strip indicates, or if staff suspects, that the cold chain has been compromised, staff should immediately:
 - Segregate questionable vaccine in a bag labeled “Do Not Use” and place in proper storage until viability can be determined. Do not write on the vaccine itself.
 - Contact the DSHS Pharmacy or manufacturer immediately to determine the viability of the vaccine.
 - Contact responsible entity to inform them of the determination of the viability of the vaccine.
- TVFC providers must call their responsible entity immediately upon receipt of vaccine(s) received in error.

Vaccine Ordering Procedures

- _____ is responsible for ordering vaccine.
- All vaccine orders will be placed in EVI unless internet access is unavailable.

Vaccine Ordering Procedures (continued)

- Providers are required to enter into EVI all vaccine received, doses transferred, doses administered, expired/wasted vaccine and a physical count for all TVFC vaccines in their inventory each month regardless of whether an order is placed.
- Temperature Recording Forms (C-105) must be completed and submitted monthly to their responsible entity.
- Providers should abide by their established maximum stock levels (MSL) and tiered ordering frequency (TOF) when ordering vaccine. Providers are allowed to request quantities exceeding their MSL; however, a justification is required.
- Providers are responsible for entering accurate provider information into EVI, including shipping address, days and hours available to receive vaccine shipments, and primary and back-up contact information.

Inventory Control (e.g., Stock Rotation)

- _____ is responsible for controlling TVFC inventory.
- _____ is responsible for reporting vaccine received, doses administered, vaccine transferred, vaccine loss, and physical count in EVI each month.
- Vaccine with the shortest expiration date must be used first.
- Providers are required to notify their responsible entity 90 days prior to the vaccine expiration date.

Vaccine Loss (Expired, Spoiled, and Wasted Vaccine)

- Providers are required to follow the procedures listed below when vaccine loss occurs:
 - _____ is responsible for completing and submitting the Vaccine Loss Reports.
 - Remove expired/spoiled vaccine from the vaccine storage unit immediately.
 - Contact your responsible entity immediately with the antigen, lot number, expiration date and reason for expiration/loss.
 - Report every dose of vaccine that is lost (wasted, spoiled or expired) to the TVFC Program on a Vaccine Loss Report electronically generated in EVI within four days of the date of the loss.
 - The completed Vaccine Loss Report must be signed by the medical provider who signed the VFC Program Provider Agreement.
- Providers should follow the procedures listed below for returning nonviable vaccine (if applicable):
 - _____ is responsible for returning nonviable vaccine.
 - Complete the Vaccine Loss Report as indicated above and submit to the responsible entity.

Vaccine Loss (Expired, Spoiled, and Wasted Vaccine) (continued)

- Once the Vaccine Loss Report is processed, TVFC providers will receive a shipping label from McKesson.
- Providers must ensure that all and only vaccines listed on that Vaccine Loss Report are included in the box for return.
- If more than one box will be used, mark the boxes with “Box 1 of 2,” “Box 2 of 2,” etc.
- A copy of the Vaccine Loss Report should be included in each box when returning the non-viable vaccine.
- Providers must indicate on the Vaccine Loss Report the number of the box in which the vaccine is being shipped (e.g., “Box 1 of 2,” “Box 2 of 2,” etc.).
- Any wasted vaccine listed on the Vaccine Loss Report (opened multi-dose vials, dropped or broken vials/syringes) should be marked through with a single line.
- NEVER include broken vials/syringes or exposed syringe needles in the box for return.
- Providers must wait until UPS returns to their office with the next delivery to return the box with the nonviable vaccines.

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Texas Vaccines for Children (TVFC) Program Emergency Vaccine Storage and Handling Plan

Instructions for TVFC providers: All TVFC providers are responsible for proper management of their vaccine inventory in the event of an emergency. Once completed, this template can serve as the required Emergency Vaccine Storage and Handling Plan.

TVFC providers must review and update this plan **annually** or more frequently if there are any changes to the plan or changes in staff responsible for vaccine management, storage and handling. The most current Emergency Vaccine Storage and Handling Plan will be reviewed during TVFC Compliance Site Visits and Unannounced Storage and Handling Visits.

A copy of this plan, along with the Routine Vaccine Storage and Handling Plan, must be posted on or near any refrigerator or freezer used to store TVFC vaccine.

| | |
|---|---------------------------------|
| Practice Name: | Clinic Address: |
| TVFC PIN#: | E-mail Address: |
| Telephone Number: () - | Fax Number: () - |
| Name of Managing Physician or Equivalent: | TVFC Contact: |
| Primary Vaccine Coordinator: | Back-up Vaccine Coordinator(s): |

Location vaccines will be transferred to in case of emergency:

| | |
|---|---------------------------------------|
| Location Name: | Contact Person at Receiving Location: |
| Address: | Telephone Number: |
| Is there a generator? <input type="checkbox"/> Yes <input type="checkbox"/> No | Date of Agreement: |

Emergency Vaccine Storage and Handling Plan reviewed and updated by:

| | |
|------------|----------------------|
| Name: | Title: |
| Signature: | Date of Last Review: |

Procedures for Proper Emergency Storage and Handling of Vaccine

- Identify a responsible person and a responsible back-up person to enact the Emergency Vaccine Storage and Handling Plan. Be sure to include contact information such as home, office, and cell phone numbers for each.

The person responsible for enacting the Emergency Vaccine Storage and Handling Plan is: _____ . The back-up person responsible for enacting the Emergency Storage and Handling Plan is: _____ .

- Identify an emergency storage location to take the TVFC provided vaccine for storage. The emergency storage location must have appropriate vaccine storage equipment capable of maintaining temperatures within the accepted ranges, as well as adequate space to accommodate the largest vaccine inventory without crowding. Temperatures for storage units are required to be monitored and recorded per CDC guidelines. A location with a power generator or other alternate source of power such as a hospital, pharmacy or grocery store is preferable. (Note the emergency location on the first page of the Emergency Vaccine Storage and Handling Plan.)
- Be sure to contact the emergency storage location for their approval before including them on your plan and list their contact person(s) and phone number(s) on your plan. You might consider locating a back-up location in case your primary alternative location is unavailable or unable to store your vaccine inventory for any reason.
- Specify the steps to transport vaccine to the alternate location. Steps should include:
 1. Noting the time the emergency situation/power outage occurs.
 2. Noting the temperature of the refrigerator and freezer before removing any vaccine for transportation.
 3. Indicating what containers will be used and how the refrigerated vaccine should be packed for transportation.
 4. Taking an inventory of the vaccine as you move it into the transport container being careful to indicate the number of doses of each vaccine and the expiration dates. Use the Vaccine Transfer Authorization Form (EC-67).
 5. Keeping a certified and calibrated thermometer in the transport container next to the vaccines and noting the time and temperature when you place the vaccine in the alternate storage. This information reveals how long the vaccine was at less- than-ideal temperature and may be needed in the event a determination of viability is required once the vaccines are returned to your facility.

The Emergency Vaccine Storage and Handling Plan Checklist (E11-14497) is available for documenting this process in the event of an emergency.

Providers must use a Vaccine Transfer Authorization Form (EC-67) when transferring vaccines in the event of an emergency. For detailed guidance regarding transfer of vaccines and cold chain management, refer to: Chapter 3 of the Provider Manual.

In the table below, please provide where to obtain the items required for emergency transport of vaccine and the appropriate contact information.

| Where to obtain: | Phone number: |
|-----------------------------------|---------------|
| Portable Refrigerator: (Optional) | () - |
| Portable Freezer: (Optional) | () - |
| Cooler: | () - |
| Cold Packs: | () - |
| | () - |
| | () - |

In the event of a city-wide evacuation, contact your responsible entity for evacuation plan.

Emergency Vaccine Storage and Handling Plan Checklist

| | |
|--|---|
| Contact with responsible entity made prior to transport by: | |
| Date: / / | Time: : AM <input type="checkbox"/> PM <input type="checkbox"/> |
| Person Transporting Vaccine: | |
| Transport of REFRIGERATED vaccine | |
| <input type="checkbox"/> | <p>Assemble packing supplies.</p> <p>Container used to transport refrigerated vaccines:</p> <p style="padding-left: 20px;"><input type="checkbox"/> Portable refrigerator <input type="checkbox"/> Cooler</p> <p>Other supplies:</p> <p style="padding-left: 20px;"><input type="checkbox"/> Conditioned cold packs* <input type="checkbox"/> Certified and calibrated thermometer</p> <p style="padding-left: 20px;"><input type="checkbox"/> Packing material</p> <p style="font-size: small; margin-top: 10px;">* To “condition” cold packs, remove them from the freezer and leave them at room temperature for 1 to 2 hours until edges have defrosted and packs look like they have been “sweating.” Frozen coolant packs that are not “conditioned” can freeze vaccines.</p> |
| <input type="checkbox"/> | Spread a layer of conditioned cold packs (at least 2 inches) at the bottom of the cooler. Cover the conditioned cold packs with a 2-inch layer of bubble wrap/crumpled paper. |
| <input type="checkbox"/> | Stack vaccine boxes on the bubble wrap/crumpled paper. Vaccines must not touch the cold packs in the cooler. |
| <input type="checkbox"/> | Place the thermometer/probe next to vaccines on top of the bubble wrap. |
| <input type="checkbox"/> | Cover vaccine with 2-inch layer of bubble wrap/crumpled paper. Spread conditioned cold packs to cover the bubble wrap/crumpled paper. |
| <input type="checkbox"/> | Fill the cooler to the top with bubble wrap/crumpled paper. |
| <input type="checkbox"/> | Place the thermometer’s digital display on top of the bubble wrap/crumpled paper. |
| <input type="checkbox"/> | Include a list of the vaccines that are stored in the container. Use a Vaccine Transfer Authorization Form (EC-67). |
| <input type="checkbox"/> | <p>Record temperatures on a Temperature Recording Form (C-105) prior to transport.</p> <p style="padding-left: 20px;">Temperature of storage unit at the time the vaccines are removed: _____</p> <p style="padding-left: 20px;">Time vaccines were removed from storage unit: _____ AM / PM</p> <p style="padding-left: 20px;">Temperature of the transport container when vaccines were placed inside: _____</p> |
| <input type="checkbox"/> | <p>Record temperatures on a Temperature Recording Form (C-105) upon arrival at the emergency storage location.</p> <p style="padding-left: 20px;">Temperature of transport container at the time the vaccines are removed: _____</p> <p style="padding-left: 20px;">Time vaccines were removed from transport container: _____ AM / PM</p> <p style="padding-left: 20px;">Temperature of the storage unit at the time vaccines were placed inside: _____</p> |

Emergency Vaccine Storage and Handling Plan Checklist

| | |
|--|---|
| Contact with responsible entity made prior to transport by: | |
| Date: / / | Time: : AM <input type="checkbox"/> PM <input type="checkbox"/> |
| Person Transporting Vaccine: | |
| Transport of FROZEN vaccine | |
| <input type="checkbox"/> | Assemble packing supplies. Container used to transport frozen vaccines: <input type="checkbox"/> Portable freezer <input type="checkbox"/> Cooler <input type="checkbox"/> VaxiPac Other supplies: <input type="checkbox"/> Frozen cold packs <input type="checkbox"/> Certified and calibrated thermometer <input type="checkbox"/> Packing material <input type="checkbox"/> VaxiPac PXC coolant packs |
| If cooler is used: | |
| <input type="checkbox"/> | Spread a layer of frozen cold packs (at least 2 inches) at the bottom of the cooler. Cover the frozen cold packs with a 2-inch layer of bubble wrap/crumpled paper. |
| <input type="checkbox"/> | Stack vaccine boxes on the bubble wrap/crumpled paper. Vaccines must not touch the cold packs. |
| <input type="checkbox"/> | Place the thermometer/probe next to vaccines on top of the bubble wrap. |
| <input type="checkbox"/> | Cover vaccine with 2-inch layer of bubble wrap/crumpled paper. Spread frozen cold packs to cover the bubble wrap/crumpled paper. |
| <input type="checkbox"/> | Fill the cooler to the top with bubble wrap/crumpled paper. |
| <input type="checkbox"/> | Place the thermometer's digital display on top of the bubble wrap/crumpled paper. |
| If VaxiPac is used: | |
| <input type="checkbox"/> | Pack vaccine in accordance with manufacturer instructions. |
| <input type="checkbox"/> | Include thermometer probe with vaccines. The digital display will remain on the outside of the VaxiPac. |
| For all transport of frozen vaccine: | |
| <input type="checkbox"/> | Include a list of the vaccines that are stored in the container. Use a Vaccine Transfer Authorization Form (EC-67). |
| <input type="checkbox"/> | Record temperatures on a Temperature Recording Form (C-105) prior to transport. Temperature of storage unit at the time the vaccines are removed: _____ Time vaccines were removed from the storage unit: _____ AM / PM Temperature of the transport unit at the time vaccines were placed inside: _____ |
| <input type="checkbox"/> | Record temperatures on a Temperature Recording Form (C-105) upon arrival at the emergency storage location. Temperature of transport container at the time the vaccines are removed: _____ Time vaccines were removed from transport container: _____ AM / PM Temperature of the storage unit at the time vaccines were placed inside: _____ |