Temperature Excursion Procedures

Tennessee Immunization Program – Quality Assurance

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What is a Temperature Excursion?

A temperature excursion (TE) occurs anytime the refrigerator unit is outside 2.0°C through 8.0°C (36° through 46°F) or the temperature in a freezer unit is above -15°C (5°F). VFC providers are required to report to TIP immediately, within 24 hours, if a temperature excursion meets one of the five below criteria:

1. Refrigerator temperature dipped below 2.0°C (36°F) for 15 consecutive minutes (or longer).
    a. Freezing temperatures below 0°C (32°F) quickly damages vaccine and quick intervention may be necessary to save vaccine if temperature begins to get too cold.
2. Refrigerator was above 8.0°C (46°F) for at least 60 consecutive minutes.
3. Freezer temperature above -15°C (5°F) for more than 60 consecutive minutes.
    a. Routine defrost cycles may go above -15°C (5°F) for less than 60 minutes. There is vaccine stability data to support these types of excursions.
4. TE is part of a pattern of frequent excursions, regardless of duration.
5. Provider is concerned about TE even though it doesn't meet above criteria.

Please Note: The Fridge Tag digital data loggers that were supplied by TIP have the alarm parameters set to trigger after 15 consecutive minutes below 2.0°C (36°F) and 60 consecutive minutes above 8.0°C (46°F) for the refrigerator and -15°C (5°F) for the freezer. If a provider is using another digital data logger, the alarm parameters could be different and only show the time out-of-range.

Document Temperature Excursion

A temperature excursion will be reported either by the provider office or the Regional Immunization Representative (RIR). The following steps should be completed when documenting a temperature excursion:

1. Complete the Temperature Excursion Worksheet.
2. Instruct person reporting TE to:
    a. Place a "Do Not Use Vaccine until Notified by TIP" sign on vaccine unit.
    b. Fax data logger report (temperature logs) to 615-401-6829.
    c. Send list of private vaccine (Merck products will need lot number and

expiration dates) that is currently in the unit with the data logger report.

d. Reconcile inventory and ensure all vaccine orders have been accepted in TennIIS.

3. While waiting on fax, log into TennIIS and complete the following:
    a. Verify provider has accepted all vaccine orders into their inventory. If not, have VFC Contact accept orders in TennIIS. This will provide an accurate inventory when checking vaccine stability data.
    b. Review Reconciliation Report
        - Has the provider reconciled inventory in the past 30 days? If no, remind provider of this program requirement.
        - Are there expired vaccines that need to be sent to McKesson? If yes, inform provider that vaccines need to be returned within 30 days of expiration.
        - If the provider needs assistance on reconciling inventory or returning vaccine, refer them to the Vaccine Ordering Administrator, sarah.moore2@tn.gov (615-253-6915), and to the guidance located on the TennIIS homepage under the TennIIS Training tab. Notify via email the Vaccine Ordering Administrator (Sarah Moore), VFC Vaccine Manager (Lisa Dunn) and the RIR to inform them that the provider is delinquent.
    c. Print Reconciliation Report
        - Check/Circle vaccines on the back of the Temperature Excursion Worksheet that are listed on the report.
        - If private vaccine is being evaluated, distinguish between VFC and private (recommend using the back of another Temperature Excursion Worksheet and label private).
    d. Print Provider Agreement – First page only
        - Verify the VFC Contacts are up-to-date. If not, notify the VFC Program Enrollment team and the RIR. Remind provider that the Provider Agreement needs to be updated when there is a change in staff.
4. Print and review data logger report (temperature logs) for the following:
    a. Review the upper and lower alarm parameters; this is helpful as a

reference for evaluating alarms.

b. Review the alarm(s) temperature, duration and time occurred.
c. Any below freezing temperatures (0ºC or 32ºF)? What date(s) did it occur?
d. Review Average temperatures; target temperature is 5ºC (40ºF).
e. Review the minimum and maximum (upper and lower) daily temperatures.
f. Are there any out-of-range temperatures that did not trigger an alarm? Important information to assist in evaluating if the unit might need to be serviced or replaced.
g. Are twice a day temperatures being recorded on data logger report?
h. Calculate the total amount of alarm time (adding the duration of each alarm). If provider had a previous TE, need to get the oldest date that is marked on the vaccine boxes in their storage unit. Will need to calculate the cumulative time out-of-range beginning with that date for vaccines involved in a previous TE.

Evaluate Vaccine Stability

The vaccine stability data needs to be evaluated to determine if the vaccine is still useable and can continue to be administered. To evaluate vaccine:

1. Review the Vaccine Manufacturer Info for Temp Excursions spreadsheet prior to contacting the vaccine manufacturers. Each vaccine needs to be evaluated by the following parameters:
    a. Coldest and/or warmest temperature according to data logger report (temperature log).
    b. Total cumulative time out-of-range; this includes any previous alarms.
    c. If stability data is not available on the spreadsheet, call the vaccine manufactures.
2. Document the vaccine usability information on the back of the Temperature Excursion Worksheet.

Please Note: If unable to complete a TE evaluation by the end of the business day, save all working documents in the “Working TEs” folder located at: H:\CEDS\Imm\04 - FILE ROOM\401 - eRecord storage by Employees\Working TEs

Provider Follow-up Plan

1. Document the manufacturer's and TIP's recommendations on the Temperature Excursion Worksheet. The following recommendations should be considered:
    a. All vaccines are good to use through the expiration date – based on stability data
    b. Mark vaccine boxes with TE information each time – date and duration (hours and minutes) of TE
    c. List any vaccines that have been spoiled and need to be returned to McKesson.
        - Provider will need to submit to TIP the number of doses lost for each vaccine. Calculate the amount of each vaccine lost then add the amounts for the total cost of vaccine lost; use the most recent CDC vaccine price list.
        - Do not discard any unopened vaccine, it should be place in a bag marked "Do Not Use" and returned to McKesson. Any open multi-dose vials should be discarded in a bio-hazard sharps container.
        - Vaccine needs to be reconciled in TennIIS within 30 days.
            - **Open** vials of vaccine should be marked as spoiled under "category" and the "reason" will be temperature was too cold or warm. The opened vials need to be removed under the "option" column on the return page prior to printing your packing slip.
            - **Unopen** vials of vaccine should be marked as spoiled under "category" and the "reason" will be temperature was too cold or warm
            - Once inventory is reconciled in TennIIS, provider can create a return shipping label to McKesson. Provider should only return unopened vaccine to McKesson.
    d. Defrost freezer vaccine storage unit – if there is currently ice build-up in unit. It is also recommended to defrost unit twice a year (unless the unit is an automatic defrost unit).
    e. Vacuum coils/vents on vaccine storage unit – anytime there isn't an

obvious reason for TE.

f. Adjust thermostat – if the average temperature is not meeting the target refrigerator temperature of 5ºC (40ºF).
    - Provider should review data logger report after 24 hours to determine current average temperature, then if needed adjust thermostat again; this allows time for unit to acclimate.
    - After 48 hours send TIP a data logger report (temperature log) for review.

g. Service or replace vaccine storage unit within six weeks (TIP approval is **required prior to vaccine being moved back in unit**, need to send TIP five days of good temperatures along with invoice) – whenever the minimum/maximum temperatures are continually out-of-range and/or multiple temperature excursions.
    - Provider's vaccine ordering privileges should be placed on hold until unit has been approved to store vaccine. Notify provider that they have six weeks to service or replace unit.
    - Provider needs to send a copy of the invoice to verify the unit was serviced or replaced. If unit was replaced and invoice is not available the provider can email a picture of the new unit. An invoice or picture must be received before unit is approved to store vaccine.
    - When reviewing five days of temperatures look for the following:
        - Average temperatures – refrigerator temperature should be close to 5ºC (40ºF)
        - Minimum and maximum temperature should be in-range – regardless if alarm was triggered

h. Clear data logger alarm (press read 3 times to mark and 4 times to clear alarm for Fridge Tag) – If using a Fridge Tag have provider check current temperature and see if there is an "X" on display. If using another type of digital data logger check to see if alarm is still showing on display and follow manufacturer instructions to clear alarm.

i. Execute Emergency Vaccine Storage Plan when temperature is not currently in range or power outage expected to last over 4 hours. **Please Note:** TIP approval is **required** prior to moving vaccine back

into unit, need to send TIP five days of in-range temperatures; unless moved due to a power outage. If vaccine was moved due to a power outage, provider can send a copy of data logger report to TIP for approval to move vaccine back into unit once the temperatures are back in-range.

- Provider's vaccine ordering privileges should be placed on hold until approved to move vaccine back into main unit.

2. If TE is not reported immediately **and there is vaccine loss** the following actions will be taken:
    a. Provider will be placed on six month probation.
    b. Provider will need to submit four weeks (first month of probation) of weekly temperature logs to their RIR. Monthly temperature logs will need to be submitted to the RIR for the remaining five months. **Please Note:** The RIR can decide, based on their observations, to request more frequent submission or extend the time period for reviewing temperature logs. Any change in follow-up activities should always be discussed with the VFC Quality Assurance Coordinator or the Program Manager.
    c. RIR will conduct an on-site education visit for the provider, VFC Primary and Back-up Contact.
    d. If using a combination R/F unit, provider must purchase a stand-alone refrigerator (within six weeks); vaccine orders will be placed on hold until purchased. TIP will need to a copy of invoice and/or picture of unit and five consecutive days of within range temperature readings prior to being able to approve the new unit to store vaccine.
    e. If not using a DDL, provider must purchase a DDL.
    f. Provider will receive at least one Unannounced Storage and Handling visit by the RIR. If there is a need for additional visits, the RIR should communicate with the VFC Quality Assurance Coordinator or Program Manager. **Please note:** An Unannounced Storage and Handling Visit (USH) will not be able to be entered into PEAR if provider already has an open VFC Compliance Visit. The RIR will need to enter visit as a VFC Contact in PEAR; unless TE was discovered during a Compliance or

USH site-visit. In that situation the visits will be part of the site-visit follow-up activities.

g. At the end of the six month probation provider will resume routine monitoring if in compliance. If not in compliance the provider will be suspended from the VFC Program. At that time:
    - The Program Manager (Catherine Haralson) will be notified of suspension.
    - The Regional Immunization Representative will pick up any VFC vaccine.
    - The VFC Operations Manager (Missy Brown) needs to be notified to inactivate provider.
    - The VFC Vaccine Manager (Lisa Dunn) needs to be notified to suspend vaccine ordering privileges.
    - The VFC Quality Assurance Coordinator (Deborah Key) needs to be notified to inactivate provider in PEAR.
    - TIP will notify TennCare of the suspension.

h. At the end of the six month suspension the provider will need to go through the enrollment process to participate in the VFC Program. This includes:
    - Receiving an enrollment visit from the RIR. All previous non-compliant issues will need to be resolved at this time.
    - If approved, provider will maintain the same VFC PIN.
    - Provider will need to receive an Unannounced Storage and Handling Visit within 60 days of reenrollment.
    - Provider will need to receive a VFC Compliance Visit within 6 months of reenrollment.

3. If TE is not reported immediately and there is **no** vaccine loss the following actions will be taken:
    a. Provider will be placed on six month probation.
    b. Provider will need to submit four weeks (first month of probation) of weekly temperature logs to their RIR. Monthly temperature logs will need to be submitted to RIR for the remaining five months. **Please Note:** The RIR can decide, based on their observations, to request more frequent submission or extend the time period for reviewing temperature logs. Any change in follow-up activities should always be

discussed with the VFC Quality Assurance Coordinator or the Program Manager.

c. RIR will conduct an on-site education visit for the provider, VFC Primary and Back-up Contact.
d. If not using a DDL, provider must purchase and use a DDL.
e. If using a combination R/F unit, provider must purchase a stand-alone refrigerator (within six weeks); vaccine orders will be placed on hold until purchased. TIP will need to a copy of invoice and/or picture of unit and five consecutive days of within range temperature readings prior to being able to approve the new unit to store vaccine.
f. At the end of the six month probation provider will resume routine monitoring if in compliance. If not in compliance the provider will be suspended from the VFC Program. At that time:
    - The Program Manager (Catherine Haralson) will be notified of suspension.
    - The Regional Immunization Representative will pick up any VFC vaccine.
    - The VFC Operations Manager needs to be notified to inactivate provider and send out termination checklist.
    - The VFC Vaccine Manager needs to be notified to suspend vaccine ordering privileges.
    - The VFC Quality Assurance Coordinator needs to be notified to inactivate provider in PEAR.
    - TIP will notify TennCare of the suspension.
g. At the end of the six month suspension the provider will need to go through the enrollment process to participate in the VFC Program. This includes:
    - Receiving an enrollment visit from the Regional Immunization Representative. All previous non-compliant issues will need to be resolved at this time.
    - If approved, provider will maintain the same VFC PIN.
    - Provider will need to receive an Unannounced Storage and Handling Visit within 60 days of reenrollment.
    - Provider will need to receive a VFC Compliance Visit within 6 months of reenrollment.

Temperature Excursion Summary

As soon as all required information has been gathered and reviewed a summary needs to be completed and sent to the provider. The provider is required to attach the summary to the data logger report (temperature log) and retain for three years.

1. The Temperature Excursion Summary needs to include:
    a. Date TE was reported
    b. VFC PIN
    c. Name of Clinic
    d. VFC Contact
    e. Date and Time of TE
    f. Description of Events
    g. TIP Recommended Actions
    h. Manufacturer Recommendations
    i. Wasted Vaccines and their cost
    j. If placed on probation, requirements expected of provider
2. Call the VFC Contact that reported TE to review the recommendations and to answer any questions. If vaccine was lost, inform VFC Contact that you need the following information within 48 hours:
    a. The number of doses lost by vaccine brand.
    b. If vaccine loss was due to below freezing temperatures, need a list of patients who received any vaccines between the date of the below freezing temperature through the date the TE was reported. Due to confidentiality provider should fax the list if they are unable to send via secure email.
        - List should include: name of child, DOB, vaccine brand received, date vaccines was administered.
3. Email the Temperature Excursion Summary to the following people:
    a. Primary and Back-up VFC Contact
    b. Regional Immunization Representative
    c. Public Health Nurse Consultant 2 (Susan Copeland)
    d. VFC Quality Assurance Coordinator (Deborah Key)

e. Program Manager (Catherine Haralson)
f. AFIX Coordinator (Lisa Williams)
g. CDC Public Health Advisor (Cristi Chambers)
h. If vaccine loss occurred, copy the VFC Vaccine Manager and Vaccine Ordering Administrator
i. If TE involved a health department, copy the Medical Officer for the region

4. If needed, email the VFC Vaccine Manager and Vaccine Ordering Administrator to request vaccine ordering privileges to be held.
5. If provider is being placed on probation, the RIR will need to know the following:
    a. If a new storage unit or digital data logger needs to be purchased (within six weeks) prior to vaccine ordering privileges being reinstated.
    b. How many weeks the provider is required to send them weekly data logger reports (temperature logs).
    c. Expected due dates for unannounced site visits.
    d. Instruct to notify the VFC Quality Assurance Coordinator if the provider remains non-compliant.

Revaccination Procedures

The recommendation to revaccinate is determined by the Director (Dr. Kelly Moore), based upon consultation with manufacturers and, in some cases, CDC; all decisions are based on the specific circumstances of the TE. Revaccination is most likely to be recommended for freeze-sensitive vaccines exposed to temperatures below 0ºC (32ºF).

1. If there has been vaccine loss for a below freezing temperature and vaccines had been administered, gather the below information:
    a. Summary of temperature excursion
    b. Data logger reports
    c. Manufacturers recommendations on vaccines
    d. List of patients who received any vaccines between the date of the below freezing temperature through the date the TE was reported.
        - List should include: name of child, DOB, vaccine brand received, date vaccines was administered.
        - Provider does not need to send patient list if TE is greater than

three months. The provider will receive guidance from TIP for self-screening of their patients that received vaccinations during the incident.

e. Request shipping logs from VTrckS from the VFC Vaccine Manager.

2. As soon as possible schedule a meeting with the Director to review the incident and patient list. As soon as guidance is provided, complete the following documents:
    a. Revaccination letter to provider
    b. Revaccination Guidance Table
    c. Patient list for revaccination
3. As soon as documents are complete send the Program Manager and Director the revaccination package for review and approval. The package should include:
    a. Revaccination letter to provider – should include:
        - Events Resulting in Revaccination Recommendation
        - Revaccination Recommendations
        - Steps to Follow in the Revaccination Process
        - Conditions for your Continued Participation in the VFC Program
    b. Revaccination Guidance Table
    c. Patient list for revaccination
    d. Parent Revaccination Letter Template
    e. Data Logger Reports involved in incident
    f. Shipping Logs from VTrcks
4. As soon as you receive approval from the Director email (with read receipt) the revaccination package to the provider and Primary and Back-up VFC Contacts. If the providers email is not available, need to call provider to ensure receipt of the package and to answer any questions.
5. Scan and save the revaccination documents in the provider's eRecord on the "h" ShareDrive (should also be saved in REDCap).
6. Follow-up of Private Practice Revaccination Efforts, the RIR, or a designee, is expected to do the following to ensure that parents of affected children are informed:

a. Assist in educating practice physicians and staff as needed, coordinating with TIP.
b. Assist in explaining the use of revaccination resource documents, if needed.
c. Where applicable, assure that practices are submitting correct weekly temperature logs during a 4-8 week probationary period to ensure that vaccines are consistently stored and monitored correctly going forward.
d. Notify TIP if provider does not notify families of revaccination recommendations. [TIP will work with region to address these unusual situations]
e. Obtain copy of corrective action plan from practice (send copy to TIP for file).
f. If the practice sends letters to affected families, rather than phone calls, obtain a copy of letter sent by practice to affected families for review for accuracy by the Director (if the practice does not use the template). A copy of the final letter and date sent should be kept on file at the region, with a copy to TIP for its files.
g. Assist practice as needed with information to help them succeed in their efforts.
h. Share information with TIP and the RHO.

Not Routinely Recommended:

i. Helping the practice implement revaccination plans
j. Monitoring the actual number of children revaccinated
k. Revoking school or day care immunization certificates

7. Follow-up of Health Department Clinic Revaccination Efforts, if revaccination of more than one person is recommended in a health department clinic, close collaboration among Regional Directors, RHOs and TIP is necessary. Steps may include the following:

    a. Ensure correction of any vaccine storage irregularities
    b. Use PTBMIS to identify affected individuals.
    c. Follow TIP guidance on timing of doses to be repeated for each affected individual.
    d. If follow up is of a significant number of persons and phone calls are not done, send certified or registered letter approved by Office of General Counsel to any parents or affected individuals. Send a copy to TIP.
    e. If persons cannot be reached by phone or certified/registered letter,

make second attempts to notify individuals whose certified letters are not received (search for better addresses through other databases, such as Accurint).

f. Provide all repeat vaccinations without charging vaccine or administration fees.
g. Schedule alternate clinic times (evenings, weekends) to reduce inconvenience.
h. If media attention is anticipated, collaborate with the TDH Communications Office to handle media as needed.
i. If the event involves large numbers of patients, notify other area immunization providers who may be consulted by these patients requesting revaccination.

Maintaining Temperature Excursion Documents

Once the temperature excursion is completed the records need to be maintained in the following locations.

1. Person completing Temperature Excursion needs to enter data into REDCap within 48 hours.
2. All TE documents will be saved in REDCap. If revaccination is recommended a copy of documents should be saved in both REDCap and the provider's eRecord.
    - Data Logger Report (temperature logs)
    - Temperature Excursion Worksheet
    - Temperature Excursion Summary
    - Provider Vaccine Inventory List
    - Provider Agreement (First Page)
    - Revaccination Documents (if applicable)

Provider Corrective Action Follow-up

1. The VFC Quality Assurance Coordinator will be responsible to follow-up with the RIR to ensuring all probation activities have been completed and provider has remained compliant.
2. The VFC Quality Assurance Coordinator will be responsible for maintaining the Provider Compliance Issue Tracker spreadsheet located: H:\CEDS\Imm\04 - FILE ROOM\401 - eRecord storage by Employees\Provider Compliance Issues Tracker

3. The Public Health Nurse Consultant (PHNC) 2 will be responsible to follow-up with a provider that is required to purchase a new storage unit and/or DDL due to a temperature excursion; includes approving unit. If provider has not completed corrective action within six weeks the PHNC will notify the VFC Quality Assurance Coordinator.
    - VFC Quality Assurance Coordinator will contact the provider to determine their intent for remaining in the VFC Program. If provider does not have an acceptable plan for complying with program requirements the Regional Immunization Representative will pick up vaccine.