Kansas Department of Health and Environment
Division of Health

Toxic Shock Syndrome [Other Than Streptococcal] (TSS)

Investigation Guideline

Contents

Attachments can be accessed through the Adobe Reader's navigation panel for attachments. Throughout this document attachment links are indicated by this symbol; when the link is activated in Adobe Reader it will open the attachments navigation panel. The link may not work when using PDF readers other than Standard Adobe Reader.

Revision History:

Date	Replaced	Comments
05/2018	**09/2011**	Notification section and Restriction section modified with requirements of revised regulations.
09/2011	**01/2010**	BEPHI replaced BSE throughout. Updated to CDC 2011 Case Definition. Updated web links. Addition of notification section. Removed references to KS-EDSS

Toxic Shock Syndrome (TSS)
Disease Management and Investigative Guidelines

CASE DEFINITION (CDC 2011)

Clinical Description for Public Health Surveillance:
An illness with the following clinical manifestations:

- Fever: temperature greater than or equal to 102.0°F (≥ 38.9°C)
- Rash: diffuse macular erythroderma
- Desquamation: 1-2 weeks after illness onset
- Hypotension: systolic blood pressure less than or equal to 90 mm Hg for adults or less than fifth percentile by age for children aged less than16 years
- Multisystem involvement (three or more of the following organ systems):
  - *Gastrointestinal*: vomiting or diarrhea at onset of illness
  - *Muscular*: severe myalgia or creatine phosphokinase level at least twice the upper limit of normal
  - *Mucous membrane*: vaginal, oropharyngeal, or conjunctival hyperemia
  - *Renal*: blood urea nitrogen or creatinine at least twice the upper limit of normal for laboratory or urinary sediment with pyuria (greater than or equal to 5 leukocytes per high-power field) in the absence of urinary tract infection
  - *Hepatic*: total bilirubin, alanine aminotransferase enzyme, or asparate aminotransferase enzyme levels at least twice the upper limit of normal
  - *Hematologic*: platelets less than 100,000/mm3
  - *Central nervous system*: disorientation or alterations in consciousness without focal neurologic signs when fever and hypotension are absent.

Laboratory Criteria for Case Classification:

Negative results on the following tests, if obtained:

- Negative blood or cerebrospinal fluid cultures (blood culture may be positive for *Staphylococcus aureus*)
- Negative serologies for Rocky Mountain spotted fever, leptospirosis, or measles

Note: Cultures positive for Group A Streptococcus should be investigated as Streptococcal Toxic Shock Syndrome. Refer to the Streptococcal Invasive Disease Investigation Guideline.

Case Classification:

- **Confirmed:** case which meets the laboratory criteria and in which all five of the clinical findings described above are present, including desquamation, unless the patient dies before desquamation occurs
- **Probable:** case which meets the laboratory criteria and in which four of the five clinical findings described above are present

LABORATORY ANALYSIS

- Specimens are not required to be sent to the Kansas Health and Environmental Laboratory (KHEL); but they are equipped to assist with the analysis of *S. aureus* isolates if requested as part of an epidemiological investigation.

EPIDEMIOLOGY

A majority of the early cases of TSS were associated with menstruation and most with vaginal tampon use. Today only 55% of the reported cases are associated with menses. Contraceptive diaphragm or vaginal contraceptive sponge use and infection following childbirth or abortion are additional risk factors. Men and women have also been associated to a growing number of cases where S. aureus was isolated from focal lesions of skin, bone, respiratory tract and surgical sites. For one-third of the cases, no source of infection has been found; such cases were often characterized a scant or undetectable rash.

DISEASE OVERVIEW

A. Agent:
Usually exotoxin producing strains of Staphylococcus aureus, a bacterium. Most cases associated with toxic shock syndrome toxin 1.

B. Clinical Description:
Acute illness characterized by the sudden onset of a high fever (> 102°F [38.9°C]), myalgia, weakness, vomiting, diarrhea, hypotension, diffuse macular erythroderma, and multi-organ system disorders. During the acute phase of TSS a “sunburn-like” rash is present; 1-2 weeks later, desquamation of the skin occurs, especially on the soles and palms.

C. Reservoirs:
Humans.

D. Mode(s) of Transmission:
S. aureus commonly colonizes skin and mucous membranes in humans. TSS is not transmitted person-to-person but requires a favorable situation to allow the organism to thrive resulting in disease.

E. Incubation Period:
The incubation period ranges from 1-10 days. Post-surgical TSS can be as short as 12 hours. Menses-related cases can occur anytime during menses.

F. Period of Communicability:
Person-to-person transmission does not occur.

G. Susceptibility and Resistance:
Susceptibility to both *S. aureus* is universal. Immunity develops only against specific strains or exotoxins.

H. Treatment:
Treatment includes aggressive fluid replacement therapy and strict management of the respiratory and cardiac systems. Antimicrobial therapy may also be initiated.

NOTIFICATION TO PUBLIC HEALTH AUTHORITIES

Suspected cases of toxic-shock syndrome, staphylococcal shall be reported within 24 hours, except if the reporting period ends on a weekend or state-approved holiday, the report shall be made by 5:00 p.m. on the next business day after the 24-hour period.

1. Health care providers and hospitals: report to local health jurisdiction
2. Laboratories: report to KDHE - BEPHI
3. Local health jurisdiction: report to KDHE - BEPHI

Kansas Department of Health and Environment (KDHE)
Bureau of Epidemiology and Public Health Response (BEPHI)
Phone: 1-877-427-7317 Fax: 1-877-427-7318

Further responsibilities of state and local health departments to the CDC:

As a nationally notifiable condition, toxic-shock syndrome, non-strep (TSS) cases require a STANDARD report to the Center of Disease Control and Prevention (CDC).

1. STANDARD reporting requires KDHE-BEPHI to file an electronic report for within the next reporting cycle.
   - KDHE-BEPHI will file electronic reports weekly with CDC.
2. **Local public health jurisdiction** will report information requested in the Kansas electronic surveillance system, as soon as possible, ensuring that the electronic form is completed within 7 days of receiving a notification of a report.

INVESTIGATOR RESPONSIBILITIES

1) Report all confirmed, probable and suspect cases to the KDHE.

2) Begin the public health investigation within 3 days of receiving a report; completing the investigation within 7 days.

3) The goal of the case investigation is to collect epidemiological data as required by current surveillance objectives.
- Contact the medical provider to collect additional information and confirm diagnosis using the current case definition.
- The Rapid Assessment Worksheet will help in the confirmation of the case and with the initial organization and the collection of essential data
- Collect all information requested in Step 1) of case investigation.
- Most data can be collected from the medical provider, and the patient may not need to be contacted.
- Routine contact investigation is not needed for cases of TSS. Current surveillance objectives depend on the local health department's assistance with confirmation of cases and completion of the supplemental form.

4) Record data, collected during the investigation, in the KS EpiTrax system under the data's associated [tab] in the case morbidity report (CMR).

5) As appropriate, use the disease fact sheet to notify individuals or groups.

STANDARD CASE INVESTIGATION AND CONTROL METHODS

Case Investigation

1) Contact the medical provider who reported or ordered testing of the case to obtain the following from the patient's medical records.
   - Identify evidence of TSS based on case definition. (Refer to Section 1 of the Rapid Assessment Worksheet for assistance.)
   - Collect case's demographic data and contacting information (birth date, county, sex, race/ethnicity, address) [Demographic]
   - Record hospitalizations: location and duration of stay [Clinical]
   - Record outcomes: survived or date of death [Clinical]
2) Only after the case is determined to be probable or confirmed, collect information on possible risks associated with illness:
   - Post-surgery associated infections.
   - Infected wounds or skin rashes or lesions.
   - For women, information related to contraceptive use, product use during concurrent menstruation or associated births or abortions
3) Investigate epi-links among cases (clusters, commonalities, etc).
   - For suspected outbreaks refer to Managing Special Situations.

Contact Investigation

Contact investigation is of no practical value for routine situations.

Isolation, Work and Daycare Restrictions

K.A.R 28-1-6 for Staphylococcal disease:
Control of Cases

- Each person with a case shall be excluded from working as a food employee until the purulent lesions are healed or unless each wound is covered with an impermeable cover and a single-use glove is worn over the impermeable cover.

.

Case Management

If identified, report on any changes in patient status (i.e., date of death). [Clinical]

Contact Management

None required.

Education

- To prevent TSS, the following messages may be delivered to at risk groups:
  - Keep all skin wounds clean to prevent infection. This includes:
  - Cuts, punctures or scrapes
  - Burns
  - Sores from shingles or other skin rashes
  - Insect and animal bites
  - Surgical incisions
- Signs and symptoms of infected wounds or surgical incisions that require medical attention can include fever and redness, swelling, heat, or pain at the site. Drainage of cloudy fluid or sudden opening of the wound can also suggest infection.
- Females: follow the directions on package inserts when using tampons, contraceptive diaphragms, and contraceptive sponges.
  - Wash your hands with soap and water before inserting or removing a tampon, diaphragm, or contraceptive sponge.
  - Change your tampon at least every 8 hours or use tampons for only part of the day and use tampons with the lowest absorbency that you need. (The risk of toxic shock syndrome is higher with super-absorbent tampons.)
  - Do not leave your diaphragm or contraceptive sponge in for more than 12 hours.
- Women who are menstruating and develop a high fever with vomiting and diarrhea must discontinue any vaginal tampon use immediately and contact their health care provider

MANAGING SPECIAL SITUATIONS

A. Outbreak Investigation:

1. Consider further investigation of any invasive cases clustered in time and place among groups that share common space (i.e. daycare, institutions)
2. Notify KDHE immediately, 1-877-427-7317.
3. Case finding and additional case investigation will be an important part of any investigation.

DATA MANAGEMENT AND REPORTING TO THE KDHE

A. Accept the case assigned to the LHD and record the date the LHD investigation was started on the [Administrative] tab.

B. Organize and collect data.
- The Rapid *Assessment Worksheet* Section 1 is provided to assist the investigator but does not have to be submitted to CDC or KDHE.
- Investigators can collect and enter all required information directly into EpiTrax [Clinical], [Demographics], [Epidemiological], and [Notes] tabs without using the paper forms.
- During outbreak investigations, refer to guidance from a KDHE epidemiologist for appropriate collection tools.

C. Report data collected during the course of the investigation via EpiTrax**.**
- Verify that all data requested in Step 1) has been recorded on an appropriate EpiTrax [tab], or that actions are completed for a case lost to follow-up as outlined below.
- Some data that cannot be reported on an EpiTrax [tab] may need to be recorded in [Notes] or scanned and attached to the record.
- Paper report forms do not need to be sent to KDHE after the information is recorded in EpiTrax. The forms should be handled as directed by local administrative practices.

D. If a case is lost to follow-up, after the appropriate attempts:
- Indicate 'lost to follow-up' on the [Administration] tab with the number of attempts to contact the case recorded.
- Record at least the information that was collected from the medical records.
- Record a reason for 'lost to follow-up' in [Notes].

E. Once the investigation is completed, the LHD investigator will click the "Complete" button. This will trigger an alert to the LHD Administrator so they can review the case before sending to the state.
- The LHD Administrator will then "Approve" or "Reject" the CMR.
- Once a case is "Approved" by the LHD Administrator, BEPHI staff will review the case to ensure completion before closing the case.

Review the EpiTrax User Guide, Case Routing for further guidance.

ADDITIONAL INFORMATION / REFERENCES

A. Treatment / Differential Diagnosis: American Academy of Pediatrics. Red Book: Report of the Committee on Infectious Disease, 29th Edition. Illinois, Academy of Pediatrics, 2014.

B. Epidemiology, Investigation and Control: Heymann. D., ed., Control of Communicable Diseases Manual, Washington, DC, American Public Health Association, 2010.

C. Case Definitions: wwwn.cdc.gov/nndss/

D. Kansas Regulations/Statutes Related to Infectious Disease: www.kdheks.gov/epi/regulations.htm

E. Additional Information (CDC): www.cdc.gov/vaccines/pubs/surv-manual/index.html

ATTACHMENTS

To view attachments in the electronic version:

1. Go to <View>; <Navigation Pane>; <Attachments> – OR – Click on the "Paper Clip"  icon at the left.
2. Double click on the document to open.

TSS Rapid Assessment Form

(Please refer to the Disease Investigation Guideline for additional guidance.)

Section 1

Clinical Case Definition Criteria for TSS (Confirmed= yes to all 5; probable= yes to 4 of the 5 criteria)

❑ Yes ❑ No **Fever present (102.0°F [> 38.9°C])** Highest temperature measured: _____

❑ Yes ❑ No **Hypotension present** (Systolic ≤ 90 mmHg in adults or <5th percentile in children < 16 years; orthostatic drop in diastolic pressure ≥15 mmHg from lying to sitting; orthostatic syncope or orthostatic dizziness present)

Systolic Blood pressure (lowest measurement): _____

Diastolic blood pressure (lowest measurement): _____

Orthostatic syncope present: ❑ Yes ❑ No ❑ Unknown

Orthostatic dizziness present: ❑ Yes ❑ No ❑ Unknown

❑ Yes ❑ No **Diffuse macular erythroderma rash present**

If yes: ❑ Generalized ❑ Focal Describe:

❑ Yes ❑ No **Desquamation: 1-2 weeks after illness onset** (may not occur if patient dies)

If yes, describe:

❑ Yes ❑ No **3 or more of the following multi-organ manifestations present:**

❑ **Gastrointestinal Symptoms** (As shown by one of the following below)

- ❑ Vomiting at onset of illness
- ❑ Diarrhea at onset of illness

❑ **Muscular involvement** (As shown by one of the following below)

- ❑ Severe myalgia
- ❑ Creatine phosphokinase (CPK) level ≥2x normal upper limit, CPK level: _____ IU/L

❑ **Mucous membrane involvement** (As shown by one of the following below)

- ❑ Conjunctival hyperemia
- ❑ Oropharyngeal hyperemia
- ❑ Vaginal hyperemia

❑ **Renal impairment** (As shown by one of the following below)

- ❑ Blood urea nitrogen (BUN) level ≥2x the normal upper limit, BUN level: _____ mg/dl
- ❑ Creatinine level ≥2x the normal upper limit, Creatinine level: _____ mg/dl
- ❑ No urinary tract infection, but urine sediment with pyuria (≥5 WBC/HPF): _____ WBC/HPF

❑ **Hepatic involvement** (As shown by one of the following below)

- ❑ Alanine aminotransferase (ALT) ≥2x the normal upper limit, ALT level: _____ IU/L
- ❑ Aspartate aminotransferase (AST) ≥2x the normal upper limit, AST level: _____ IU/L
- ❑ Total Bilirubin ≥2x the normal upper limit, Total Bilirubin level: _____ mg/dl

❑ **Hematological complications (coagulopathy)** (≤100,000/mm^3 platelets)

Platelet level (lowest): _____ mm^3

❑ **Central nervous system involvement** (As shown by one of the following below)

- ❑ Disorientation
- ❑ Consciousness alterations w/o focal neurologic signs when fever and hypotension are absent

Laboratory Testing Criteria = titer and culture results should be negative *

Serology, rise in titer to: ❑ Rocky Mountain Spotted Fever ❑ Leptospirosis ❑ Measles

❑ No rise in titer detected ❑ Titer results not obtained

CSF cultures: ❑ Negative ❑ Not done ❑ Positive, indicate organism(s): _____

Throat cultures: ❑ Normal Flora ❑ Not done ❑ Abnormal, indicate organism(s): _____

Urine cultures: ❑ Negative ❑ Not done ❑ Positive, indicate organism(s): _____

Blood cultures: ❑ Negative ❑ Not done ❑ Positive, indicate organism(s): _____

** For TSS cases, blood cultures can be **positive for S. aureus**.*

If cultures are positive for Strep Group A (S. pyogenes) investigate as an STSS case.

If titers indicate RMSF or Measles, investigate using respective Disease Investigation Guidelines.

TSS Rapid Assessment Form

Section 2

Additional epidemiological data to collect for CONFIRMED and/or PROBABLE cases:

Date of Onset of Symptoms: ☐☐/☐☐/☐☐ *Review medical charts for first 4 days after day of onset.*

Additional symptoms (the first 4 days of illness) not recorded in Section 1:

Abdominal Pain	❑ Yes ❑ No ❑ Unk	Sore Throat	❑ Yes ❑ No ❑ Unk
Vaginal discharge	❑ Yes ❑ No ❑ Unk	Injected tongue	❑ Yes ❑ No ❑ Unk
Vaginal ulceration	❑ Yes ❑ No ❑ Unk	Cardiac Arrhythmia	❑ Yes ❑ No ❑ Unk
Seizures	❑ Yes ❑ No ❑ Unk	If yes, describe arrhythmia:	

If hospitalized, date of admission: ☐☐/☐☐/☐☐ Date of hospital discharge: ☐☐/☐☐/☐☐

Did the patient survive the infection? ❑ Yes ❑ No If NO, date of death: ☐☐/☐☐/☐☐

Did the patient have surgery 7 days before illness onset? ❑ Yes ❑ No If YES, date of surgery: ☐☐/☐☐/☐☐

Surgery provider:

Additional Laboratory Data (Most abnormal values in the first 4 days of illness)

Obtain copies of the following or record values on the TSS Supplemental Form.

- ❑ WBC counts and differentials.
- ❑ Liver enzyme test results (AST, ALT, Alkaline phosphatase, Amylase, Bilirubin)
- ❑ Urinalysis results (WBC, RBC, Protein)
- ❑ Chemistry panels including following values: Calcium, phosphorus, albumin, CPK, BUN, Creatinine
- ❑ CPK total and isoenzyme panels (CPK-myocardial band)
- EKG results: ❑ Unk ❑ Not done ❑ Normal ❑ Abnormal, describe:
- Chest X-ray results: ❑ Unk ❑ Not done ❑ Normal ❑ Abnormal, describe:
- Nose Culture: ❑ Unk ❑ Not done ❑ Done, describe organisms:
- Vaginal Culture: ❑ Unk ❑ Not done ❑ Done, describe organisms:

Examination of bacterial culture results:

1. If *S. aureus* isolated from Vaginal cultures, was it resistant to penicillin and ampicillin only: ❑ Yes ❑ No ❑ Unk
2. Was patient on antibiotics when ***any*** culture specimens were collected (including Section 1): ❑ Yes ❑ No ❑ Unk
   Note any specimens that may have been affected by antibiotic use:

For female patients only:

At time of illness, was the patient: ❑ Menstruating ❑ Postpartum ❑ Neither ❑ Unknown

If postpartum, outcome of delivery or abortion: ❑ Live birth ❑ Abortion /stillbirth ❑ Induced abortion ❑ C-section ❑ Vaginal birth ❑ Unknown

Date of delivery or abortion: ☐☐/☐☐/☐☐ Location:

If menstruating, date of onset of coincident menstrual period: ☐☐/☐☐/☐☐

During period when patient became ill, record products used (mark all that apply):

❑ Tampon ❑ Napkin ❑ Minipad ❑ Sea-sponge ❑ Other:

Record product brand(s) and style (absorbency) of each brand used:

If more than one brand, which brand was most frequently used:

How was the information on brand and absorbency obtained (who if any viewed the product packaging)?

Has the patient had similar illness during past menstrual periods: ❑ Unk ❑ No ❑ Yes, how many times: