Guideline SK 18

Instructions to Complete the Saskatchewan Transfusion Adverse Event Report Form

1.0 Principle

1.1 To provide instructions for completing the fillable Saskatchewan Transfusion Adverse Event Report (SK TAER) Form.

2.0 Definitions

2.1 Adverse event – an undesirable and unintended occurrence before, during, or after the administration of blood components or blood products, whether or not considered to be related to the administration. CSA 3.1; Blood Regulations Section 1

2.1.1 Accident – an unexpected or unplanned event, not attributable to a deviation from standard operating procedures or applicable laws or regulations, that could adversely affect:

a) the safety, efficacy, or quality of blood components or blood products; or

b) the safety of donors, patients, or facility personnel.

2.1.2 Adverse reaction – a type of adverse event, where an undesirable and unintended response develops to the administration of blood components or blood products that is considered to be related to the administration of blood components or blood products.

2.1.3 Error – an unexpected or unplanned deviation from standard operating procedures or applicable laws and regulations, usually attributable to a human or system problem, that could adversely affect:

a) the safety, efficacy, or quality of blood components or blood products; or

b) the safety of donors, patients, or facility personnel.

2.1.4 Incident – an accident or error that could lead to an adverse outcome affecting:

a) the safety, efficacy, or quality of blood components or blood products; or

b) the safety of donors, patients, or facility personnel.

2.1.5 Serious adverse event – an adverse event or adverse reaction that meets one or more of the following criteria:

a) requires in-patient hospitalization or prolongation of existing hospitalization directly attributable to the event;

b) results in persistent or significant disability or incapacity;

c) necessitates medical or surgical intervention to preclude permanent damage or impairment of a body function;

d) is life threatening; or

e) results in death.

2.1.6 Unexpected adverse reaction – an adverse reaction that is not identified among the possible adverse reactions either in the CBS Circular of Information or in any other information provided to the patient.

2.2 Critical incident – an incident that arises as a result of the provision of a health service provided by the Saskatchewan Health Authority or a health services provider; means the incident is a serious adverse health event, including but not limited to, the actual or potential loss of life, limb or function related to the health service provided. SHA Approved Policy and Clinical Standards Definitions

3.0 Acronyms

3.1 MRP – Most Responsible Physician

3.2 SK TAER Form – Saskatchewan Transfusion Adverse Event Report Form

3.3 SK TTISS – Saskatchewan Transfusion Transmitted Injury Surveillance System

3.4 TML – Transfusion Medicine Laboratory

3.5 TMP – Transfusion Medicine Physician

4.0 Scope and Related Policies

4.1 The Transfusion Medicine Laboratory (TML) shall have operating procedures for documenting, reporting, investigating, and following-up of all adverse events involving blood components and blood products, including the necessary notifications of the distributor, manufacturer and regulatory authorities. WCDAA TM.13.1.1; CSA 14.8, 18.1.1, 18.1.2

4.2 Health care personnel shall promptly report all suspected adverse events to the physician/authorized health care practitioner responsible for ordering the transfusion and the TML. WCDAA TM.13.2.1; CSA 18.2.1

4.2.1 Prompt reporting is essential because all other crossmatched or implicated blood components must be immediately quarantined so that another patient is not put at risk.

4.2.2 Completion of all fields on the fillable Saskatchewan Transfusion Adverse Event Report (SK TAER) Form is critical to ensure timely investigation, evaluation, follow-up and reporting of all adverse events.

4.2.3 Report one transfusion adverse reaction per adverse event form. If a patient experiences two reactions, two separate forms must be completed.

4.3 The TML shall investigate all adverse events reported to the TML. WCDAA 13.2.2; CSA 18.2.2

4.4 The conclusions of the investigation of the adverse reaction (including recommendations for future transfusions) shall become part of the patient's medical chart. A copy of the investigator's report on the serious adverse event, including any communications or conclusion letters received from CBS, shall be kept on file by the TML. WCDAA TM.13.2.3; CSA 18.2.5

A system shall be in place for accessing and reviewing this information if the patient requires subsequent transfusion to ensure safety.

5.0 Materials

5.1 Patient's health and transfusion record

5.2 Appendix # 7 SK TTISS Acute Transfusion Reaction Chart

5.3 Appendix # 8 SK TTISS Bedside Transfusion Reaction Algorithm

5.4 Appendix # 9 Saskatchewan Transfusion Adverse Event Report Form

5.5 Related documents:

- Appendix # 10 Adverse Reaction Workup Categories and Testing Protocols – Job Aid for the Transfusion Medicine Laboratory (TML)
- Appendix # 12A Saskatchewan Guide for Reporting Adverse Transfusion Events
- Appendix # 12B Reporting Adverse Events to Appropriate Authorities – Job Aid for TML
- Guideline SK 17 Transfusion Associated Adverse Reaction Investigation and Reporting
- Guideline SK 19 Transfusion Associated EA Investigation and Reporting

6.0 Quality Management

6.1 The TML shall have a quality improvement system in place to monitor positive compliance with the policies and procedures for adverse event reporting. This may be through random patient and chart audits and/or other such mechanisms in place in the quality improvement program. CSA 4.6.1.1, 4.6.3.1

6.2 The TML shall have an established process or system in place to verify results of an adverse event investigation and future transfusion recommendations if the patient requires subsequent transfusion. WCDAA TM.7.0.7, 13.2.3; CSA 10.4, 18.2.5.

6.3 A formal, documented training program that includes both initial and ongoing training of health care personnel in the necessary skills related to their responsibilities in completing the SK TAER form shall be in place. A system shall be in place to assess the effectiveness of their training programs and the frequency of this assessment shall be defined. WCDAA TM.1.2.3; CSA 4.3.2.1, 4.3.2.2, 4.3.4, 4.3.6.2, 14.4.2

6.4 A formal competency assessment program shall be in place for health care personnel involved in completing the SK TAER form. Competency shall be assessed and documented following training and at regular and routine intervals thereafter. The effectiveness of the competency assessment program shall be evaluated periodically as needed and this evaluation shall be documented. WCDAA TM.1.2.4; CSA 4.3.3.1, 4.3.3.2, 4.3.4, 4.3.6.2, 14.4.2

7.0 Procedure

7.1 Definitions:

7.1.1 Time – 24 hour clock (00:00 to 23:59).

7.1.2 Date – should use DD-MMM-YYYY format to ensure that no errors are made due to transposition of day/month/year.

7.2 The SK TAER form contains 2 pages.

7.2.1 Page 1 is used by nurse/transfusionist to report the details of the:

- Patient and transfusion
- Signs and symptoms of the transfusion adverse event
- Clinical management of transfusion adverse event

7.2.2 Page 2 is used by the TML and the Transfusion Medicine Physician (TMP) (or designate) to:

- Provide results of TML based investigations for the adverse event
- Correlate the signs, symptom and investigation results for the adverse event
- Make a conclusion on the type of event that occurred
- Provide recommendations for future transfusion requirements (e.g. future pre-medication or special requirements, if applicable)

INSTRUCTIONS FOR COMPLETION:

7.3 PAGE 1 – TO BE COMPLETED BY THE NURSE/TRANSFUSIONIST:

Important: The SK TAER Form has been converted to a fillable pdf to save data entry time and improve legibility of information. The fillable pdf form can be downloaded from saskblood.ca.

7.3.1 Refer to Table 1 for a Completeness Checklist.

7.3.2 *Patient Demographics*

- Last and first name
- Health Services Number (HSN) or Medical Record Number (MRN)
- Date of birth
- Sex
- The information from the facility addressograph may be used to complete this section. Any information not on addressograph should be provided.
- Ensure patient demographics are included on page 1 and 2 of the form.

7.3.3 *Reporting Facility Name, Phone and Fax Number*

- Name, phone and fax number of the facility reporting the adverse event to the TML.

7.3.4 *Diagnosis, Indication for Transfusion and Category*

- This information could be obtained from the hospital admission/discharge system, physician progress notes or verbally from the Most Responsible Physician (MRP).

7.3.5 *Section 1 – Patient and Blood Component/ Product Unique Identifier Verification (Clerical Check)*

- Record if the patient and blood component/product identifier checks are the same. Select YES or NO.
- If NO (any discrepancy is found) contact the TML IMMEDIATELY and record the date/time of contact and individual spoken with. Another patient may be at risk!

7.3.6 *Section 2 – Clinical History*

- Indicate all known aspects of the clinical history, according to check boxes and text boxes within this section.

7.3.7 *Section 3 – Patient Care Area, Date and Time of Transfusion Reaction*

- Select the patient care area where the transfusion adverse event occurred.
- Include the following details:
    - Date of the transfusion reaction
    - Time the transfusion was started
    - Time the transfusion adverse event occurred
        - For acute reactions, use the date and time the symptoms were first observed.
        - For delayed reactions, use the date of test identifying new antibodies or date patient noticed symptoms.
    - Time the transfusion was stopped
    - Time the transfusion was restarted, if applicable
    - Time the transfusion was completed

7.3.8 *Section 4 – Vitals & Clinical Signs and Symptoms*

- *Vitals:*
    - Record all of the vital signs taken at:
        - Pre-transfusion
        - At the time of the adverse event
        - Post-transfusion
    - *Temperature* – in degrees Celsius
        - Include the route of temperature measurement – oral (PO), rectal (R), tympanic membrane (TM)
        - Highest temperature is needed for definition of fever

- *Pulse* – in beats per minute
- *Blood Pressure* – systolic and diastolic blood pressure in mmHg
- *Respiratory Rate* – breaths per minute
- *Oxygen Saturation*
- *Oxygen Source:*
  - Room air, or
  - Oxygen supplementation modality (e.g. nasal prongs @ 5L/min; non-rebreather mask with flush oxygen)

- *Clinical Signs and Symptoms* – select all clinical signs and symptoms that apply. (At least one clinical sign must be present.)
- *Other relevant clinical information* – additional information/history that may be relevant to the transfusion, which may include any previous reaction to drugs, allergies or clinical reactions to transfusion.

7.3.9 *Section 5 – Blood Component/Product(s) and Equipment Information*

- Record the blood component or blood product that is part of the transfusion episode. Identify the blood component/product by type and unit or lot number.
- Record volume transfused if known. Enter estimate if volume is not known.
- Record blood filters or medical devices used. Select all that apply.

7.3.10 *Section 6 – Measures Taken and Notifications*

- 6a. *Transfusion Reaction Treatment Measures Taken*
  - Check all applicable treatment measures taken.
  - Use “Other” to enter additional information. Specify other medication or measures used for the transfusion reaction.
- 6b. *Notifications*

  Print notification and reporter information legibly (required for traceability of information):
  - Printed name of notified MRP, notification date and time.
  - Printed name of notified TMP on-call, notification date and time, if there was notification of an acute transfusion.
  - Printed name of notified lab personnel, notification date and time.
  - Signature and printed name of reporter, designation, name of reporting facility, notification date and time.

7.3.11 Ensure **ALL** sections on page 1 are fully completed and patient demographics are provided on pages 1 and 2.

7.3.12 Print the form and sign page 1.

7.3.13 Submit pages 1 and 2 to the TML.

7.4 PAGE 2 – TO BE COMPLETED BY THE TML:

7.4.1 *Testing Lab Name(s)*

- Name(s) of the TML conducting the laboratory investigations.

7.4.2 *Patient Demographics*

- Refer to section 7.3.2.

7.4.3 *Section 7 – Laboratory Investigation and Notifications*

- 7a. *History of Previous Transfusion Reactions*
- 7b. *Investigation Required*
  - Type of laboratory investigation performed – e.g. no serological investigation needed, Level 1 investigation, Level 2 investigation.
- 7c. *Lab Results*
  - LIS order number for each pre- and post-transfusion workup.
  - Attach all reports with the results of completed investigations, where applicable.
- 7d. *Notifications/ Reports*
  - Depending on the severity, type and root cause of the adverse event the following personnel and organizations may require notification
    - TMP on-call;
    - local safety/risk management program;
    - CBS/other blood product manufacturer;
    - Health Canada (either Canada Vigilance Program for adverse reactions and/or Regulatory Operations & Enforcement Branch for errors and accidents) as required.
  - Refer to:
    - Guideline SK 17 Transfusion Associated Adverse Reaction Investigation and Reporting
    - Guideline SK 19 Transfusion Associated EA Investigation and Reporting

7.4.4 Ensure all nursing sections are fully completed on PAGE 1 and the TML section on the upper third of PAGE 2 before submitting this form to the TMP (or designate) for review.

7.5 PAGE 2 – TO BE COMPLETED BY THE TRANSFUSION MEDICINE PHYSICIAN (TMP):

7.5.1 *Section 8 – Review of Investigation & Conclusion*

In this section the TMP reports his/her final conclusion using the standardized list of report options provided on the form, including:

- No transfusion reaction – problem was not related to the product or the transfusion process, likely due to patient condition or other factors
- Transfusion reaction – options for selection ranging from mild to serious
- Unknown - cannot classify reaction, but is new and unexpected AND of clinical significance
- Other – reaction occurred, but unable to classify as any type, including “unknown”
- Incident – error/accident occurred that is related to this reaction

7.5.2 *Section 9 – Relationship, Severity and Outcome of Adverse Reaction*

This section is completed in accordance with information required for TTISS reporting, including:

- Relationship of the transfusion adverse event to the blood component or blood product
- Severity (grade) of reaction
- Outcome of reaction
- Status of investigation

7.5.3 *Section 10 – Comments and Recommendations*

- Free text space to write conclusion/advice for clinician and recommendations for future transfusions, if indicated.

7.5.4 *Section 11 – Conclusion Sign Off*

- The reporting TMP (or designate) signs off the form in this location.
- For cases reported to Health Canada, the local TM Medical Director/Pathologist must also sign off the form in this location.
- The printed name of the TMP (or designate) and local TM Medical Director/Pathologist (where applicable) and date of completion must also be documented for legibility and traceability of information.
- To assist SK TTISS staff, the TMP (or designate) indicates if the case is reportable to the Blood Safety Contribution Program (national TTISS).

7.6 PAGE 2 – TO BE COMPLETED BY SK TTISS:

7.6.1 SK TTISS Number – provincial TTISS case number.

7.6.2 CNPHI Number – national TTISS case number.

8.0 Reporting

8.1 Health care personnel must immediately report all suspected transfusion adverse events to the MRP and the TML. Complete page 1 of Appendix # 9 Saskatchewan Transfusion Adverse Event Report Form and submit to TML for investigation of adverse event.

8.2 Health care personnel must report all transfusion associated E/A's and critical incidents through their local safety/risk management program. Complete an occurrence/incident safety report and submit according to local process.

8.2.1 If the transfusion related E/A led to adverse event, a SK TAER form must be completed and submitted to the TML.

8.2.2 Any potential transfusion associated critical incident must be **immediately** reported. SK Ministry of Health must be notified within 3 business days.

8.3 TML staff must report adverse events to blood components and blood products to the Northern or Southern SK TTISS designate as follows:

8.3.1 Immediately if there is a serious and/or unexpected adverse event.

8.3.2 On completion of the laboratory investigation for any minor adverse event not related to bacterial contamination.

8.3.3 Fax the completed SK TAER form and laboratory investigation results to your appropriate SK TTISS designate; either Saskatoon (306) 655-2222 or Regina (306) 766-4382.

8.4 TML shall immediately report any fatality or serious/unexpected adverse event to the appropriate authorities in accordance with applicable regulatory requirements. Federal and provincial regulations can apply. WCDAA 13.2.3; CSA 18.1.2.2, 18.2.2, 18.2.3.2, 18.2.3.3,18.2.4

8.4.1 Appropriate authorities may include:

a) Local safety/risk management program

b) Provincial Transfusion Transmitted Injuries Surveillance System (TTISS)

c) CBS

d) Other blood product manufacturer

e) Canada Vigilance Program

f) Health Canada's Biological Product Compliance Program (BPCP) of the Regulatory Operations and Enforcement Branch (ROEB)

8.4.2 Refer to:

a) Appendix 12A Saskatchewan Guide for Reporting Adverse Events

b) Appendix 12 B Reporting Adverse Reactions to Appropriate Authorities – Job Aid for TML

9.0 Documentation

9.1 The TMP (or designate) will classify the adverse event type, relationship to transfusion, outcome and conclusion, as well as any future transfusion recommendations.

9.2 The final adverse event report, including interpretation of the investigation results and recommendations for future transfusions, shall be placed in the patient's permanent health record. WCDAA TM.13.2.3; CSA 18.2.7

9.3 A copy of the investigator's report on the serious or unexpected adverse event shall be kept on file by the TML. WCDAA TM.13.2.3; CSA 18.2.7

9.4 Investigations and reports of the following adverse events shall be retained for 10 years: WCDAA TM.2.1.5; CSA 20.6.3.3, Blood Regulations Table to Section 122

a) errors and accidents that could lead to serious adverse reactions; or

b) serious or unexpected adverse reactions.

10.0 Table 1: Completeness Check for Page 1 of the Saskatchewan Transfusion Adverse Event Report Form

Section		Check for
	General	• All hand-written entries are clear, legible and there is no doubt about the numerals used.
	Patient Demographics	• Stamp is clear. • Facility is identified. • Diagnosis/ Indication for Transfusion/ Category (underlying disease/condition) are completed.
1.	Patient and Blood Component /Product Identifier Verification	• Usually the YES box is checked off. • If the NO box is checked off, check that contact with lab has been recorded in this section, and in section 6.
2.	Clinical History	• A check in the box is a "yes". • History of transfusion /pregnancies should be entered. • Previous transfusion history may be found in TMS patient record.
3.	Patient Care Area, Date & Time of Transfusion Reaction	• Patient care area should be checked off. • Entries are required for all cells. • Restart cell should only have a time entered if only minor symptoms were experienced by the patient. Refer to Appendix 8 SK TTISS Bedside Transfusion Reaction Algorithm.
4.	Vitals & Clinical Signs and Symptoms	• Entries are required for vital signs section. • At least one sign or symptom should be checked off from the options, or a note has been placed in the "Other relevant clinical information" section.
5.	Blood Component/Product(s) and Equipment Information	• Entries are required for all cells. • Attach additional sheet, if provided, to the SK TAER Form. • Documentation of filters and medical devices used during the transfusion or infusion.
6	6a. Transfusion Reaction Treatment Measures Taken	• Check if blood samples have been ordered or taken, as required. • Other options may or may not be checked.
	6b. Notifications	• MRP has been notified, date & time provided. Name is clear. • TMP contact name is recorded & date & time is

		provided if there was notification of an acute transfusion to the TMP on-call. • TM Lab person has been notified, date & time provided. Name is clear.
	6b. Reported by	• Name of the reporter is clear, printed, and signed. • Name of reporting facility if different from where the adverse reaction occurred. • Date & time are recorded.

11.0 References

11.1 BC Provincial Blood Coordinating Office. Responding to the Report of a Suspected Acute Transfusion Reaction. Unique Identifier: TR 0001. Ver: 2.0. 2012-08-16.

11.2 Canadian Society of Transfusion Medicine. Standards for Hospital Transfusion Services. Version 5. December 2021.

11.3 Canadian Standards Association. Blood and blood components. CAN/CSA-Z902:20. March 2020.

11.4 Saskatchewan Critical Incident Regulations, 2016. http://www.qp.gov.sk.ca/documents/english/Regulations/Regulations/r8-2r10.pdf.

11.5 Saskatchewan Critical Incident Reporting Guideline, 2004. http://www.saskatchewan.ca/government/government-structure/ministries/health/critical-incidents.

11.6 Public Health Agency of Canada. (2007). Transfusion Transmitted Injuries Surveillance System (TTISS). User's Manual Version 3.0. Ottawa, ON: Public Health Agency of Canada.

11.7 Saskatchewan Health Authority. Critical Incident Reporting Policy Directive. Document Number: SHA-02-003. Effective Date: December 4, 2017.

11.8 The Provincial Health Authority Act, Saskatchewan.

11.9 Western Canada Diagnostic Accreditation Alliance (WCDAA) Standards for Diagnostic Laboratory Accreditation: Transfusion Medicine, Version: February 2020-v8.

12.0 Revision History

Date Created: March 23, 2017	
Date Revised: August 26, 2020; May 5, 2022; October 3, 2022	
Section Number	**Summary of Revision**
Global	• Edited guideline to reflect conversion of SK TAER Form, Version May 5, 2022 to a fillable pdf
2.0	• Added new section for Definitions
3.0	• Added new acronyms for MRP, TML and TMP
4.4	• Removed list of applicable TM standards and provincial/national regulations. Updated list for appropriate authorities.
5.5	• Removed Appendix # 3 Standards and Regulations from

	list of related documents • Added NEW Appendix # 12A Saskatchewan Guide for Reporting Adverse Transfusion Events
7.3.7	• Changed “location” to “patient care area” for clarification
8.3	• Updated Saskatoon’s fax number
11.0	• Updated references