1.0 Principle

1.1 To provide guidelines for recognizing and managing an adverse reaction to the transfusion/infusion of a blood component or plasma protein product. The early recognition and clinical management of a transfusion adverse reaction is critical to ensure patient safety during and after a transfusion/infusion.

2.0 Definitions

2.1 Adverse event - an undesirable and unintended occurrence before, during, or after the administration of blood components or plasma protein products, whether or not considered to be related to the administration. 

2.2 Adverse reaction - a type of adverse event, where an undesirable and unintended response develops to the administration of blood components or plasma protein products that is considered to be definitely, probably, or possibly related to the administration of blood components or plasma protein products.

2.3 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.

2.4 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.

2.5 Sign - objective evidence of that can be observed or measured, discoverable on examination of a patient.

2.6 Symptom - subjective description by the patient of a feeling or sensation.

3.0 Acronyms

3.1 CBS - Canadian Blood Services

3.2 SK TAER form - Saskatchewan Transfusion Adverse Event Report Form
4.0 Scope and Related Policies

4.1 There shall be established policies, processes and procedures for documenting, reporting, evaluating and following-up on all adverse events involving blood components and plasma protein products. WCDAA TM.13.1.1; CSA 14.8, 18.1.1, 18.1.2

4.2 The criteria for the recognition of adverse reactions and the immediate clinical actions that need to be taken in the event of a suspected adverse reaction shall be outlined in the local transfusion policy and procedure manual. WCDAA TM.13.1.1; CSA 18.1.1

4.3 Health care personnel shall be trained and competent in the administration of blood components and plasma protein products, the recognition and management of adverse reactions, and facility and/or program specific protocols. WCDAA TM.1.2.3, TM 1.2.4; CSA 4.3.2.1, 4.3.2.2, 4.3.4, 4.3.6.2, 14.4.2

4.3.1 Refer to Guideline SK 13 Administration of Blood Components and Plasma Protein Products for health care personnel authorized to administer blood components and plasma protein products in Saskatchewan.

4.4 All clinically significant adverse reactions and any error or accidents that contribute to an adverse reaction or have the potential to do so, shall be evaluated with documented follow-up. WCDAA TM.13.1.1; CSA 18.1.2

4.5 Health care personnel shall immediately document and report any suspect adverse reaction to the physician/authorized health care practitioner responsible for ordering the transfusion and the transfusion service/laboratory. WCDAA TM.13.2.1; CSA 18.2.1

Serious adverse reactions include, but are not limited to:

a) immediate hemolytic reaction;
b) delayed hemolytic reaction;
c) transfusion-related acute lung injury (TRALI);
d) systemic allergic reactions, including anaphylactic shock;
e) bacterial contamination and associated sepsis;
f) other transfusion-transmissible infections (TTI);
g) transfusion associated graft versus host disease (TA-GVHD);
h) post-transfusion purpura;
i) other serious reactions; and
j) death. (Clause 18.2.5 shall apply)

4.6 A list of common signs and symptoms of serious adverse reactions that should be reported to the transfusion service/laboratory shall be included in the nursing and transfusion service/laboratory manuals. WCDAA TM.13.2.1; CSA 18.2.1
4.7 The typical signs and symptoms associated with the various types of adverse reactions related to transfusion include, but are not limited to:

Transfusion Transmitted Injury Surveillance System (TTISS) User Manual Version 3.0

<table>
<thead>
<tr>
<th>Severity of Adverse Reactions</th>
<th>Signs and Symptoms</th>
</tr>
</thead>
</table>
| Minor                         | • Skin rash or pruritus (itch) only and involving <¼ body with onset >15 minutes from the start of transfusion  
   • Temp rise ≥1°C from baseline but ≤38°C and no other symptoms with onset >15 minutes from the start of transfusion |
| Serious                       | • Onset <15 minutes from the start of transfusion  
   • Temp rise ≥1°C from baseline and ≥38°C  
   • Hypotension/tachycardia/shock  
   • Hypertension  
   • Dizziness  
   • Rigors/chills/sensation of cold  
   • Back/chest pain  
   • Headache  
   • Wheezing  
   • Facial/tongue swelling  
   • Dyspnea/hypoxemia/tachypnea  
   • Heat/pain or bleeding at IV site  
   • Nausea/vomiting  
   • Generalized flushing  
   • Hives/rash covering >¼ body or generalized itching  
   • Restlessness/anxiety  
   • Jaundice  
   • Red/brown urine  
   • Oliguria |

4.8 Patient vital signs are to be monitored before, during and after transfusion. 

4.9 The patient shall be observed during the transfusion and for an appropriate time thereafter for suspected adverse events. Instructions concerning possible adverse events shall be provided to the patient or to a responsible caregiver, when direct medical observation or monitoring of the patient will not be available after transfusion.

4.10 In an anesthetized patient, classic signs of an adverse reaction may be masked by anesthesia and an adverse reaction should be considered if the following signs develop: drop in blood pressure, hemoglobinuria, fever, or diffuse uncontrollable bleeding.

4.11 Epinephrine should be readily available whenever transfusion is carried out.

4.12 The transfusion/infusion must be stopped if the patient exhibits signs and symptoms of an adverse reaction. The qualified transfusionist must follow established policies, processes and procedures for management of an adverse reaction.
4.13 Following the transfusion, the blood transfusion record (or a copy) shall be added to the patient’s health record.\footnote{WCDAA TM.11.3.6; CSA 11.4.17}

4.14 Transfusion adverse reaction investigations are conducted in the following cases:

4.14.1 Upon request from a physician/authorized health practitioner.

4.14.2 When the transfusion of a red cell product is required to be discontinued because of adverse reaction.

4.14.3 In the event of a patient receiving unit(s) for which they were not the intended recipient, whether or not a clinical reaction is observed.

4.14.4 In the event that the transfusion service/laboratory becomes aware that a serological incompatibility exists.

4.14.5 At the discretion of the Medical Director/Pathologist or Laboratory Manager/Supervisor.

4.15 Following the results of the adverse reaction investigation, the treating physician/authorized health practitioner will determine if any special instructions will be required prior to further blood components being transfused.

5.0 Materials

5.1 Post-transfusion sample (2 EDTA vials)

5.2 0.9% saline and IV infusion set

5.3 Implicated blood component(s) or plasma protein product and administration set

5.4 Component/product compatibility tag

5.5 Transfusion Services requisition with Transfusion Adverse Reaction Investigation order as per established protocols

5.6 Appendix # 7 Transfusion Reaction Chart

5.7 Appendix # 8 Bedside Transfusion Reaction Algorithm

5.8 Appendix # 9 Saskatchewan Transfusion Adverse Event Report Form

5.9 Related documents:

- Guideline SK 13 Administration of Blood Components and Plasma Protein Products

- Guideline SK 14 Patient Monitoring during the Transfusion/Infusion Procedure

- Guideline SK 17 Transfusion Associated Adverse Reaction Investigation and Reporting

6.0 Quality Management

6.1 The transfusion service/laboratory shall have a quality improvement system in place to monitor positive compliance with the policies, processes and procedures for the recognition and management of transfusion adverse reactions. This may be through random patient and chart audits and/or other such mechanisms in place in the quality improvement program.\footnote{CSA 4.6.1.1, 4.6.2.1}
6.2 The transfusion service/laboratory shall have an established process or system in place to verify patient adverse event information and future transfusion recommendations prior to administration of subsequent blood components or products.  
WCDAA TM.7.0.7, TM 13.2.3; CSA 10.4.8, 18.2.7

6.3 The Transfusion Committee shall evaluate reports of all transfusion associated adverse reactions and errors/accidents within the facility, as well as relevant federal and provincial reports on adverse transfusion events.  
WCDAA TM.1.1.2; CSA 4.4

6.4 A formal, documented training program that includes both initial and ongoing training of personnel in the necessary skills related to their responsibilities in the recognition and management of a transfusion adverse reaction 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

6.5 A formal competency assessment program shall be in place for all personnel involved in the recognition and management of a transfusion adverse reaction. 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 STOP the transfusion immediately if any sign or symptom of an adverse reaction is observed.

7.1.1 Do not discard the implicated blood component(s) or plasma protein product and administration set.

7.2 Maintain IV patency with compatible IV fluid but do NOT infuse the remaining blood component/product in the line.

7.2.1 Flushing large amounts of remaining blood product in the original line may exacerbate the patient’s symptoms. It is suggested that a new site, a new IV set, or a Y connector with limited extension volume be used to limit this risk.

7.3 Assess the patient’s vital signs and symptoms and stabilize the patient.

7.3.1 Obtain and document vital signs every 15 minutes until symptoms resolve.

7.3.2 Do not leave the patient unattended.

7.4 Notify the physician/authorized health practitioner immediately and obtain management directives.

7.4.1 The physician/authorized health practitioner will determine if the transfusion/infusion should continue based on the patient’s symptoms.

7.4.2 Treat the patient’s symptoms as prescribed by the physician/authorized health practitioner.
7.4.3 Request an order for a transfusion adverse reaction investigation. See Appendix # 8 Bedside Transfusion Reaction Algorithm for recommended investigations.

7.5 Perform a clerical check. Reconfirm unique identifiers on both patient and blood component/product as per established protocols.

7.5.1 Verify the information is identical on the (1) patient's hospital/transfusion identification band, (2) issue document/tag, and (3) blood component/product label.

7.5.2 Call the transfusion service/laboratory immediately if an error has occurred. A second patient may be at risk.

7.6 Notify the transfusion service/laboratory of the transfusion adverse reaction (even if the transfusion was restarted or completed).

7.7 For a transfusion adverse reaction with MINOR signs and symptoms:

7.7.1 Do not cancel any remaining crossmatched units.

7.7.2 Continue the transfusion cautiously as per physician/authorized health practitioner order.

7.7.3 The patient should be directly observed for the first 15 minutes after resuming the transfusion.

7.7.4 Stop the transfusion if the patient develops any serious signs and symptoms of an adverse reaction.

7.8 For a transfusion adverse reaction with SERIOUS symptom(s):

7.8.1 QUARANTINE all tagged blood component/products for the patient. Quarantine component/product for a second patient, if applicable.

7.8.2 Immediately notify the physician/authorized health practitioner and transfusion service/laboratory when:

7.8.2.1 A patient identity check error is found in relation to a transfused patient, or

7.8.2.2 A transfused patient shows any of the following:

- New onset of red/brown urine
- Sudden onset of hypoxemia
- Sudden onset of hypotension
- Any suspicion of bacterial sepsis or contamination

7.8.3 Obtain orders for further investigations as recommended by physician/authorized health practitioner. See Appendix # 7 Transfusion Reaction Chart.

7.8.4 Provide supportive care as directed by the physician/authorized health practitioner.

7.9 Document symptoms of the transfusion adverse reaction, vital signs, treatment measures taken and other required information in the patient's health record and on the Saskatchewan Transfusion Adverse Event Report (SK TAER) Form.
7.10 Report one transfusion adverse reaction per adverse event form. If a patient experiences two reactions, two separate forms must be completed.

7.11 Send the completed Saskatchewan Transfusion Adverse Event Report (SK TAER) Form, sealed blood component/product, administration set/fluid and component/product tag (if applicable) to the transfusion service/laboratory.

7.12 The transfusion service/laboratory should immediately contact their local TM Medical Director/Pathologist or SK Transfusion Medicine Consultant (or designate) if they receive a report of a adverse reaction with the following:

7.12.1 Patient or component/product identity check error
7.12.2 Suspected bacterial contamination of the component/product
7.12.3 Sudden onset of hypoxemia
7.12.4 Sudden onset of hypotension
7.12.5 New onset of red/brown urine (if hemoglobinuria is reported in patient’s post-transfusion urine sample)

8.0 Reporting

8.1 All suspected transfusion adverse reactions must be reported to the physician/authorized health practitioner and transfusion service/laboratory. TM.13.2.1; CSA 18.2.1

8.2 The transfusion service/laboratory shall report adverse reactions to the appropriate authorities as required by national and provincial regulations. WCDAA TM.13.2.3; CSA 18.2.2, 18.2.3, 18.2.5, 18.2.7

8.2.1 See Guideline SK 17 – Transfusion Associated Adverse Reaction Investigation and Reporting.

9.0 References


9.3 Callum, JL; Lin, Y; Pinkerton, PH; Karkouti, K; Pendergrast, JM; Robitaille, N.; Tinnmouth, AT; and Webert, KE. (2011) Bloody Easy 3: Blood Transfusions, Blood Alternatives and Transfusion Reactions (3rd edition). Toronto, ON: Ontario Regional Blood Coordinating Network.


Regina Qu’Appelle Health Region Nursing Procedures Manual (February 2010).


Saskatoon Health Region Policies and Procedures (June 2009).


Western Canada Diagnostic Accreditation Alliance (WCDAA) Standards for Diagnostic Laboratory Accreditation: Transfusion Medicine, Version: February 2016-v4.