

Investigation of Transfusion Complications

Guideline:
RT.010(Rev1.0)

Guideline Effective Date:
DDMMYY

Revision Date:
01JAN05

1.0 Principle

To investigate suspected transfusion complications.

2.0 Scope and Related Policies

- 2.1. There shall be policies and procedures for documentation, reporting, evaluation and follow-up of all transfusion reactions. ^{9.1 (N1.1), 9.6 (17.1.1)}
A list of common signs and symptoms of suspected transfusion reaction shall be included in both the nursing and hospital transfusion service policy manuals. ^{9.1 (N2.1), 9.6 (17.2.1)}
- 2.2. In the event of a suspected transfusion complication, the personnel attending the recipient shall immediately notify the transfusion service ^{9.1 (N2.2), 9.6 (17.2.1)} and the physician ordering the transfusion. ^{9.2 (7.4.1)} Records of the complication shall be maintained in the recipient's medical record. ^{9.1 (N2.6), 9.6 (17.2.3)}
- 2.3. The recipient shall be observed during the transfusion and for an appropriate time thereafter for suspected adverse reactions. ^{9.1 (L3.12), 9.6 (11.4.14)} When direct medical monitoring will not be available after transfusion, instructions concerning possible adverse events shall be provided to the recipient or a responsible caregiver. ^{9.6 (11.4.14)}
- 2.4. All suspected hemolytic transfusion reactions shall be investigated immediately. The transfusion shall be stopped and intravenous access maintained with 0.9% saline. ^{9.1 (N3.1), 9.6 (17.3.1)} The remaining implicated blood component shall be returned to the transfusion service. ^{9.1 (N3.1; N4.1), 9.6 (17.3.1)}
 - 2.4.1. If there are symptoms or findings suggestive of an immediate transfusion reaction, the transfusion should be interrupted and evaluated. ^{9.1 (N3.1; N4.1), 9.6 (17.3.1)} The evaluation shall not delay proper clinical management of the recipient. ^{9.2 (7.4.3)}
- 2.5. The following serious adverse transfusion events, if they are considered to have definitely, possibly, or probably occurred, shall be immediately reported to the transfusion service and blood centre/supplier ^{9.1 (N2.2), 9.6 (17.2.1)}:
 - immediate hemolytic reactions
 - delayed hemolysis
 - transfusion-related acute lung injury
 - systemic allergic reactions, including anaphylactic shock
 - bacterial sepsis
 - other transfusion transmissible infections
 - deaths



Investigation of Transfusion Complications

Guideline:
RT.010(Rev1.0)

Guideline Effective Date:
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01JAN05

- transfusion-associated graft-versus-host disease
 - post-transfusion purpura
 - other serious reactions.
- 2.6. Circulatory overload or mild allergic reactions (e.g., urticarial) need not be evaluated as possible hemolytic transfusion reactions. ^{9.2 (7.4.3)}
- 2.7. When bacterial sepsis is suspected, the transfusion shall be stopped and an investigation begun immediately.
- The remainder of the involved unit(s) shall be returned to the transfusion service maintaining conditions that avoid further contamination.
 - Tests should be done as outlined in procedural step #6.6.
 - The transfusion service shall promptly notify the blood centre of the suspected bacterial sepsis (in order for the blood centre to immediately quarantine all implicated blood components still in inventory and initiate a traceback investigation). ^{9.1 (N4.1; N4.2; N4.3; N4.4; N4.5), 9.6 (17.4.1; 17.4.2; 17.4.3; 17.4.4)}
- 2.8. The hospital transfusion service shall maintain indefinitely the records of recipients who have had serious transfusion complications^{9.1 (App. A), 9.6 (19.6.3.2)} or evidence of alloimmunization. ^{9.1 (App. A), 9.6 (19.6.3.1)}
- 2.9. Interpretation of the evaluation shall be recorded in the recipient medical record, and if suggestive of a hemolytic reaction (HTR), bacterial contamination or other serious complication of transfusion, shall be reported immediately to the attending physician. ^{9.2 (7.4.3.3)}
- 2.10. All serious transfusion reactions shall be reported to the blood supplier within the required time frame for reporting to Health Canada where required. ^{9.1 (N2.4; N2.5), 9.6 (17.2.2; 17.2.5; 17.2.6)}
- 2.11. All cases of suspected transfusion transmitted disease shall be reported to the hospital transfusion service and to the blood supplier. ^{9.1 (N5.1), 9.6 (17.5.1)}
- 2.12. There shall be a system in place to identify all blood products implicated in cases of suspected transfusion-transmitted diseases. A record of these blood products and their serial numbers shall be sent to the blood supplier. ^{9.1 (N5.2; N5.3), 9.6 (17.5.1)}
- 2.13. Empty blood product containers should normally only be returned to the transfusion service when a serious immediate transfusion reaction occurs or is suspected (e.g., hemolytic transfusion reactions and bacteriogenic transfusion reactions). ^{9.1 (N4.1), 9.6 (17.3.1; 17.4.1)}



Investigation of Transfusion Complications

Guideline:
RT.010(Rev1.0)

Guideline Effective Date:
DDMMYY

Revision Date:
01JAN05

- 2.14. When an error has resulted in the incorrect identification of a recipient or specimen or a laboratory error is discovered, each step of the process shall be reviewed to find the source of error and corrective action initiated to prevent recurrence. 9.1 (A5.1), 9.6 (4.6.1.5)

3.0 Specimens

Pretransfusion specimen

Post-transfusion specimen (including at least one EDTA specimen)

Remainder of unit (or empty bag) with which the complication occurred, if available

Administration tubing, if available

4.0 Materials

Notification of Transfusion Complication form – RT.010F1

Notification of Delayed or Disease Transmission Transfusion Complication form – RT.010F2

Worksheet or request form used for compatibility testing

5.0 Quality Control/Management

- 5.1. If a hemolytic transfusion reaction is suspected, the transfusion shall be discontinued and the following shall be done immediately:
- The compatibility label on the blood container and all other records shall be examined to determine if there has been an error in identifying the recipient or the blood
 - A new, properly labelled blood specimen shall be obtained from the recipient and shall be sent promptly to the transfusion service. In addition, the blood container, whether or not it contains any blood, shall be sent along with, whenever possible, the attached transfusion set and attached intravenous solutions
 - The post-reaction serum or plasma shall be inspected for evidence of hemolysis. Pretransfusion specimens, if available, shall be used for comparison
 - A direct antiglobulin test (DAT) shall be done on the post-reaction specimen. If the result is positive, the most recent pretransfusion specimen, if available, shall be used for comparison.



Investigation of Transfusion Complications

Guideline:
RT.010(Rev1.0)

Guideline Effective Date:
DDMMYY

Revision Date:
01JAN05

- 5.2. Although all types of transfusion reactions cannot be investigated in the laboratory, a comprehensive list of signs and symptoms associated with types of transfusion reactions is valuable in assisting personnel in determining the cause of the transfusion associated conditions.^{9.3, 9.4, 9.5}

Reaction Type	Etiology	Signs and Symptoms
Acute (<24 hours)		
Hemolytic (HTR) - Immune	Red cell incompatibility	Chills, fever (increase of >1° C) Hemoglobinuria, renal failure, hypotension, DIC, oliguria, oozing from IV site, back pain, pain along infusion vein
Hemolytic (HTR) – non immune	Physical or chemical destruction of blood (freezing, heating, hemolytic drug or solution added to blood)	Hemoglobinuria
Sickle cell hemolytic transfusion reaction	Multiple theories; most common is bystander immune cytolysis or the development of autoantibodies	Same symptoms as a sickle cell pain crisis. Development of a more severe anemia after transfusion than was present before transfusion
Hypotensive episodes associated with ACE inhibition	Inhibited metabolism of bradykinin with infusion of bradykinin or activators of prekallikren	Flushing, abrupt onset of hypotension with or without mild respiratory symptoms, shortly after the beginning of the transfusion
Fever/chill, non hemolytic	Antibody to donor leukocytes; accumulated cytokines in bag	Rigors, rise in temperature (>1° C), headache, malaise, vomiting
Allergic	Antibody to donor plasma proteins	Pruritis, rash, urticaria, flushing
Anaphylactic	Antibody to donor plasma (most commonly anti-IgA)	Urticaria, erythema, anxiety, respiratory distress, hypotension, laryngeal/pharyngeal edema, bronchospasm
Circulatory overload	Volume overload	Dyspnea, orthopnea, productive cough with pink frothy sputum, tachycardia, hypertension, headache
Transfusion Related Acute Lung Injury (TRALI)	Anti HLA or anti-neutrophil antibody in donor plasma reacting with recipient antigens	Acute respiratory distress with or without hypotension within 1-2 hours of the transfusion of plasma containing blood components
Hypocalcemia	Massive transfusion of citrated blood and/or delayed metabolism of citrate	Paresthesia, tetany, arrhythmia
Bacterial contamination	Infusion of bacterially contaminated blood products	Fever (most commonly over 40 C), tachycardia, rigors, shock, DIC, nausea, vomiting, shortness of breath, lumbar pain, rise or drop in systolic pressure, circulatory collapse. Any of these symptoms within four hours of the blood transfusion event. No evidence of hemoglobinemia or hemoglobinuria
Hypothermia	Rapid infusion of cold blood	Cardiac arrhythmia
Air Embolism	Transfusion of air into vein	Sudden onset of severe hypotension, breathlessness, cyanosis and collapse
Hyperkalemia	Transfusion of large volumes of older blood with high supernatant potassium levels	Cardiac arrhythmia



Investigation of Transfusion Complications

Guideline:
RT.010(Rev1.0)

Guideline Effective Date:
DDMMYY

Revision Date:
01JAN05

Reaction Type	Etiology	Signs and Symptoms
Delayed (>24 hours)		
Alloimmunization	Immune response to foreign antigens on RBC, or WBC (HLA) and platelets	Usually none, but may result in platelet refractoriness, difficulty finding compatible blood for subsequent transfusion, delayed hemolytic transfusion reactions and hemolytic disease of the newborn
Hemolytic	Anamnestic immune response to RBC antigens	Weakness, unexplained fall in hemoglobin, elevated serum bilirubin
Graft versus host disease	Functioning lymphocytes transfused to immunosuppressed recipient; may occur in immunocompetent recipient receiving HLA-matched lymphocytes	Erythroderma, maculopapular rash, anorexia, nausea, vomiting, diarrhea, hepatitis, pancytopenia, fever
Post transfusion purpura	Platelet antibodies (usually against PI ^{AI})	Purpura, bleeding, fall in platelet count 8-10 days following transfusion
Immunomodulation	Incompletely understood interaction of donor WBC or plasma factors with recipient immune system	Tolerance induction, post surgical wound infection, possibly other transfusion effects
Iron overload	Multiple transfusions in transfusion dependent recipients	Cardiomyopathy, arrhythmia, hepatic and pancreatic failure

Other Transfusion Transmitted Diseases	
Blood routinely tested for ^{9.4}	Blood not routinely tested for
<ul style="list-style-type: none"> • Antibodies to Human Immunodeficiency Virus (HIV 1 & 2) • Antibodies to Human T-Cell Lymphotropic Virus (HTLV I & II) • Hepatitis B (HbsAg) • antibodies to Hepatitis C (HCV) • Syphilis • Nucleic Acid Testing (NAT) for HIV, HCV, and West Nile Virus 	<ul style="list-style-type: none"> • Hepatitis A (HAV) • Hepatitis D (HBV screening does reduce risk) • Hepatitis E • Hepatitis F • Hepatitis G • TT Virus (TTV) • Antibody to CMV • Epstein-Barr Virus (EBV) • Human Herpes Virus 6 (HHV-6) • Human Herpes Virus 7 (HHV-7) • Human Herpes Virus 8 (HHV-8) • Human Parvovirus B19 (HPV-19) • Creutzfeld-Jakob Disease (CJD), including vCJD • Lyme disease • Malaria • Chagas disease • Leishmaniasis • Babesiosis • Taxoplasmosis • Microfiliariasis

6.0 Procedure

- 6.1. When the transfusion service is notified that a recipient receiving a transfusion may be having a reaction, the technologist should perform the following steps.



Investigation of Transfusion Complications

Guideline:
RT.010(Rev1.0)

Guideline Effective Date:
DDMMYY

Revision Date:
01JAN05

- 6.1.1. Verify that the transfusion has been stopped.
 - 6.1.2. Ask what the symptoms are.
 - 6.1.3. For additional information refer to the Clinical Transfusion Resource Manual.
- 6.2. When post-transfusion specimens and bag with attached administration set and form RT.010F1 are received in the transfusion service, regardless of the type of blood product infused, perform the following steps immediately.
- 6.2.1. Check for clerical errors.
 - 6.2.1.1. Check the compatibility label attached to the blood product container for errors. Ensure that the blood types of the donor and recipient are compatible and that the correct tag is attached to the correct blood product container.
 - 6.2.1.2. Retrieve the pretransfusion specimen and request form or worksheet. Ensure that the information on both coincides exactly and that they match the compatibility label.
 - 6.2.1.3. If a clerical error is discovered:
 - Notify a pathologist or designate immediately
 - Initiate a search of appropriate records to determine whether misidentification or incorrect issue of other specimens or components has put other recipients at risk
 - Complete an incident report and submit it to a supervisor.
 - 6.2.2. Centrifuge the post-transfusion specimen and visually inspect the plasma or serum for hemolysis.
 - 6.2.2.1. Compare the serum or plasma of the post-transfusion specimen with the serum or plasma of the pretransfusion specimen.



Investigation of Transfusion Complications

Guideline:
RT.010(Rev1.0)

Guideline Effective Date:
DDMMYY

Revision Date:
01JAN05

- 6.2.2.2. If hemolysis is present in the post-transfusion specimen contact the phlebotomist to ensure that the venipuncture was not a difficult draw.
- If a difficult collection is suspected, have a second specimen drawn and repeat visual inspection of serum or plasma
 - If the specimen was drawn more than 5-7 hours after the suspected reaction time, see procedural note 8.2.
- 6.2.2.3. If a hemolytic reaction is suspected, the pathologist or designate may request testing of a post-transfusion urine specimen. See procedural note 8.3.
- 6.2.3. Perform a direct antiglobulin test (DAT) on the post-transfusion EDTA specimen. See RT.004 – Direct Antiglobulin Test.
- If the post-reaction specimen DAT is positive, perform a DAT on the pretransfusion specimen (unless this has already been done as part of pretransfusion testing). See procedural note 8.4.
- 6.3. If any of the observations or test results is positive or suspicious, or if the recipient's clinical condition suggests a HTR, additional testing may be requested by the pathologist. If the pathologist or recipient's physician requests additional laboratory evaluation of suspected hemolytic transfusion reaction, the following steps may be performed as part of the investigation.
- 6.3.1. ABO and Rh testing on the pre- and post-reaction specimens as well as on the donor unit(s) in question.
- If results are not as expected, suspect a specimen mix up or mislabelling incident; another recipient's specimen may also have been incorrectly labelled. An incident report shall be completed by the person discovering the error. The process should be reviewed to ensure that the root cause of errors is identified and, when applicable, procedures and processes revised to prevent recurrence.



Investigation of Transfusion Complications

Guideline:
RT.010(Rev1.0)

Guideline Effective Date:
DDMMYY

Revision Date:
01JAN05

6.3.2. Antibody screen on pre- and post-reaction specimens (and on the donor unit plasma if possible).

If a previously undetected antibody is discovered, antibody identification testing should be done. If the antibody is discovered in the post-transfusion specimen but not the pretransfusion specimen, suspect a passively acquired antibody from the blood product (especially if fractionated products such as IVIG have been transfused). Alternatively, an anamnestic response resulting in antibody production following a recent transfusion may have occurred. Any donor units transfused should be phenotyped for the corresponding antigen that the recipient has formed the antibody against.

6.3.3. Crossmatch the donor unit that the recipient reacted to with the post-reaction specimen by the indirect antiglobulin technique.

If an incompatibility is found, repeat the crossmatch tests with the pretransfusion specimen using an indirect antiglobulin technique.

6.3.4. Perform a blood culture on the **blood products only**:

- for all febrile transfusion reaction (an increase of temperature of > 1 °C above the pretransfusion baseline, without any other explanation), which occurs during or within one hour of a transfusion.

6.3.5. Perform a blood culture on the **blood unit and on the patient** if symptoms include at least one of the following:

- Tachycardia of > 120 /min or an increase in the heart rate of > 30 /min above baseline heart rate.
- Rigors (shaking chills)
- Hypotension (drop in systolic blood pressure of > 30 mm Hg below baseline blood pressure)
- Nausea, vomiting, diarrhea, dyspnea, oliguria or other symptoms of shock.



Investigation of Transfusion Complications

Guideline:
RT.010(Rev1.0)

Guideline Effective Date:
DDMMYY

Revision Date:
01JAN05

- 6.4. Examine the blood remaining in the unit and the administrative tubing for evidence of hemolysis, especially if a non-immune HTR is suspected. Perform steps in 6.4 if requested by a pathologist and if hemolysis is found in either the administration set or the unit. See procedural note 8.5.
- 6.5. If the symptoms suggest an anaphylactic reaction, send a pretransfusion specimen for quantitation of IgA levels and testing for anti-IgA. IgA deficient blood products should be provided until the results of the test for anti-IgA are available and have been evaluated.
- 6.6. Examine the returned unit for any abnormal appearance, including clots or any brownish, opaque, muddy, or purple discoloration. If symptoms suggest bacterial sepsis:
- A gram stain of the content of the bag should be done.
 - Cultures of the blood component should be prepared on appropriate media and incubated at both 25°C and 35°C
 - Segments should not be used to culture
 - Blood cultures should be retained from the recipient
 - Any strain isolated from the donor or recipient should be retained for further typing, if indicated.
- See procedural notes 8.5–8.7.
- 6.7. If symptoms and/or clinical presentation suggest TRALI, contact the blood supplier for further instructions.
- 6.8. When a physician contacts the transfusion service to report a suspected transfusion transmitted disease or any other type of transfusion complication as described in 5.2, fax a Notification of Delayed or Disease Transmission Transfusion Complication form - RT.010F2 to the physician's office. Instruct the physician to return the form to the hospital transfusion service as soon as possible.
- 6.8.1. Action to take when a Notification of Delayed or Disease Transmission Transfusion Complication form - RT.010F2 is received:
- If a delayed transfusion reaction is suspected, an antibody screen should be performed on a post- transfusion specimen. If an antibody is identified, complete section "D" of the notification form. Sign and date the form and refer to a pathologist for review. Complete a history file card on the recipient if the antibody is clinically significant.



Investigation of Transfusion Complications

Guideline:
RT.010(Rev1.0)

Guideline Effective Date:
DDMMYY

Revision Date:
01JAN05

- If a transmissible disease is suspected, a traceback should be initiated. Complete the blood supplier's form for traceback notification.
- 6.9. Ensure that the results of the transfusion reaction investigation are reviewed by a pathologist or designate.
- 6.10. File the results of the investigation and the pathologist review.

7.0 Reporting

- 7.1. Report all severe complications of transfusion to the blood supplier. The blood supplier will have a form that shall be completed for these types of reactions. Fatalities shall be reported within one working day and a written report submitted within 7 days. Further information may be obtained from the Circular of Information for the use of human blood and blood components.
- 7.2. Results of transfusion reactions should be reviewed by a pathologist or designate and the interpretation of the results should be retained on the recipient medical record.

8.0 Procedural Notes

- 8.1. If the post-transfusion specimen is not drawn until 5–7 hours after an episode of acute hemolysis, hemoglobin degradation products, especially bilirubin, may be in the bloodstream and cause yellow or brown discoloration. Rising bilirubin may begin as early as one hour post-reaction, peak at 5–7 hours and disappear within 24 hours if liver function is normal.
- 8.2. The post-transfusion urine may be examined for hematuria, hemoglobinuria and myoglobinuria. In acute hemolytic transfusion reactions, free hemoglobin released from damaged cells can cross the renal glomeruli and enter the urine, but hematuria and myoglobinuria would not be expected. Urine examination should be done on the supernatant fluid after centrifugation of a freshly collected specimen; misleading free hemoglobin may be present if previously intact red cells in a specimen undergo in-vitro hemolysis during transportation or storage.



Investigation of Transfusion Complications

Guideline:
RT.010(Rev1.0)

Guideline Effective Date:
DDMMYY

Revision Date:
01JAN05

- 8.3. If transfused incompatible cells have been coated with antibody but not immediately destroyed, the post-reaction specimen DAT is likely to be positive, often with a mixed field agglutination pattern. If the transfused cells have been rapidly destroyed, the post-transfusion DAT may be negative if there has been a delay in collection of the post-transfusion specimen. Non-immune hemolysis (e.g., overheating or freezing of the unit) causes hemoglobinuria but not a positive DAT.
- 8.4. If blood in the administration tubing is hemolyzed and the blood in the unit is not, a faulty infusion device may be the cause. If the blood in both the unit and the administration set is hemolyzed, suspect a physically hemolyzed unit or the addition of a solution to the container that destroyed the cells.
- 8.5. Because of their storage temperature, platelets are the blood component most commonly implicated in bacterial contamination. Some facilities make a segment of the pooled product to store in case of transfusion reaction. If this is not done, all platelet bags from the pool should be cultured.
- 8.6. Treatment for suspected bacterial contamination should be based on clinical considerations, since delay in therapy may result in severe morbidity or death.
- 8.7. Care should be taken when collecting samples for culture from both product and recipient to avoid external contamination of samples.

9.0 References

- 9.1. Canadian Society for Transfusion Medicine. Standards for hospital transfusion services, version 1. Ottawa: Canadian Society for Transfusion Medicine, 2004: A5.1, L3.12, N1.1, N2.1, N2.2, N2.4, N2.5, N2.6, N3.1, N4.1, N4.2, N4.3, N4.4, N4.5, N5.1, N5.2, N5.3, Appendix A.
- 9.2. Fridey JL, ed. Standards for blood banks and transfusion services, 22nd ed. Bethesda, MD: American Association of Blood Banks, 2003: 7.4.1, 7.4.3, 7.4.3.3.
- 9.3. British Columbia Provincial Blood Coordinating Office. Physician's Guide 2004: Blood and blood product utilization. Vancouver: BC Provincial Blood Coordinating Office, 2004.
- 9.4. Canadian Blood Services. Circular of information for the use of human blood and blood components. Ottawa: Canadian Blood



Investigation of Transfusion Complications

Guideline:
RT.010(Rev1.0)

Guideline Effective Date:
DDMMYY

Revision Date:
01JAN05

Services, November 2002.

- 9.5. Popovsky MA, ed. Transfusion Reactions, 2nd ed. Bethesda, MD: American Association of Blood Banks, 2001.
- 9.6. Canadian Standards Association. Blood and blood components (CAN/CSA Z902-04). Mississauga, Ontario: Canadian Standards Association, 2004: 4.6.1.5, 11.4.14, 17.1.1, 17.2.1, 17.2.2, 17.2.3, 17.2.5, 17.2.6, 17.3.1, 17.4.1, 17.4.2, 17.4.3, 17.4.4, 17.5.1, 19.6.3.1, 19.6.3.2.

Facility endorsement if guideline is used as a Standard Operating Procedure (SOP)

Approved By:

_____ (Senior Management)

_____ (Senior Management)

Facility effective date:

_____ DDMMYY
(Date of implementation)

Change Log

Change Description	Effective Date
Original	01 April 2000
Revision 1 Changed "patient" to "recipient", "must" to "shall" and updated to CAN/CSA Z902-04 in all cases where applicable 2.3: Added "When direct medical monitoring will not be available after transfusion, instructions concerning possible adverse events shall be provided to the recipient or a responsible caregiver." (CAN/CSA Z902 #11.4.14) 2.4: Added that intravenous access is to be maintained "with 0.9% saline" (CSTM N3.1) Added "The remaining implicated blood component shall be returned to the transfusion service." (CAN/CSA Z902 #17.3.1) 2.4.2–2.4.3: Reorganized to become 2.6–2.7 respectively 2.5: Changed "shall be promptly reported" to "shall be immediately reported". (CSTM N2.2) Added a list of serious adverse transfusion events that shall be promptly reported to the transfusion service and blood centre/supplier (CAN/CSA Z902 #17.2.1) 2.7 (was 2.4.3): Added investigative requirements when bacterial sepsis is suspected (CAN/CSA Z902 #17.4.1 – 17.4.4) 2.8 (was 2.5): Added "serious" to the types of transfusion complications for which transfusion services shall maintain records indefinitely. (CAN/CSA Z902 #19.6.3.2) Added "or evidence of alloimmunization" (CAN/CSA Z902 #19.6.3.1)	01 January 2005



Investigation of Transfusion Complications

Guideline:
RT.010(Rev1.0)

Guideline Effective Date:
DDMMYY

Revision Date:
01JAN05

2.10 (was 2.7): Changed “clinically significant” to “serious” (CAN/CSA Z902 # 17.2.2; 17.2.6)
2.13 (was 2.10): Changed “immediate transfusion reaction” to “serious immediate transfusion reaction” (CAN/CSA Z902 #17.3.1; 17.4.1) Added examples of serious reactions requiring the unit to be returned to the transfusion service (e.g., hemolytic transfusion reactions and bacteriogenic transfusion reactions)
5.0: Updated title
5.2: Updated table to include latest CBS tests for transmissible diseases
6.1.1: Replaced entire section to verify the transfusion has been stopped.
6.1.1.1: Changed “Flush saline through the lines” to “Maintain IV access (e.g., with 0.9% saline) in such a way as to prevent further infusion of the blood product.” (CSTM N3.1) Added “Refer to hospital policies and procedures related to the identification and management of transfusion reactions.”
Moved 6.1.1.2 and part of 6.1.1.3 (notify attending physician of the symptoms) here.
6.1.1.2 – 6.1.1.3: Deleted
6.2: Deleted section and subpoints
6.3.1.1: Updated to read “Check the compatibility label attached to the blood product container for errors.”
6.7: Added “Cultures of the blood component should be prepared on appropriate media and incubated at both 25°C and 35°C. Segments should not be used to culture. Blood cultures should be retained from the recipient. Any strain isolated from the donor or recipient should be retained for further typing, if indicated.” (CAN/CSA Z902 ##17.4.2–17.4.4)
Renumbered procedural notes and added new procedural note 8.7.
6.8: Deleted “to test the donor plasma for HLA antibodies”, added “for further instructions”
8.2: Deleted since it was duplicate of 8.1
8.6: Removed list of included treatments
8.7: Added note about being careful when collecting culture samples from both the blood product and recipient (CAN/CSA Z902 #17.4.2)
9.0: Deleted previous reference 9.3; added new reference 9.6.
Updated Competency Companion (RT.010C, RT.010D, RT.010E) and form (RT.010F1)

