Health Canada Santé Canada

User's Manual

Canadian Transfusion Adverse Event Reporting Form

Canada

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maintain and improve their health.

Health Canada

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Preface

In the 1997 Report of the Commission of Inquiry on the Blood System in Canada, Justice Krever emphasized the importance of surveillance and tracking of blood products, referring to the concept of vein-to-vein management of blood.

In response to this report the federal government launched a series of initiatives and provided additional funds to improve the safety of Canada's blood system. One such initiative is the Transfusion Transmitted Injuries Surveillance System (TTISS), which started as a pilot project in four provinces to carry out surveillance of both infectious and non-infectious transfusion related injuries (i.e. adverse events). The four provinces participating in the pilot project were Prince Edward Island, Nova Scotia, Quebec and British Columbia. TTISS is a surveillance and monitoring system for reporting of adverse reactions to blood, blood components, and plasma derivatives. It provides data that will be used for managing the risks related to the transfusion of these products in Canada. Implementation of TTISS has continued to expand since the pilot project and is now a national program that will include all provinces and territories.

The Canadian Transfusion Adverse Event Reporting Form and User's Manual have been developed by a Core Working Group consisting of representatives from the provinces/territories, manufacturers of blood components and Health Canada personnel. This manual is to be used as a resource for completing the Canadian Transfusion Adverse Event Reporting Form or database.

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Definitions

Adverse Event: An undesirable and unintended occurrence during or after the administration of blood, blood component, or plasma derivatives whether or not considered to be related to the administration of these products.
Note: The following are considered to be adverse events:

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

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

b) the safety of recipients.

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, blood components, or plasma derivatives; or

b) the safety of recipients.

Error: An unexpected, 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, blood components, or plasma derivatives; or

b) the safety of recipients.

Adverse Reaction: An undesirable and unintended response to the administration of blood, blood component, or plasma derivatives that is considered to be definitely, probably or possibly related to these products.

Serious Adverse Event: An adverse event that

- requires in-patient hospitalization or prolongation of hospitalization directly attributable to the event,
- results in persistent or significant disability or incapacity,

- necessitates medical or surgical intervention to preclude permanent damage to or impairment of a body function,
- is life-threatening, or
- results in death.

Unexpected Adverse Event: An adverse event that is not identified in nature, severity, or frequency among the currently known adverse effects associated with the administration of blood, blood component, or plasma derivatives.

Blood Component: A therapeutic component of blood intended for transfusion (e.g., red cells, granulocytes, platelets, plasma) that can be prepared using the equipment and techniques available in a blood centre (e.g., by centrifugation, filtration, or freezing).

Plasma Derivative: A product derived from plasma by a fractionation or manufacturing process. Note: Examples of plasma derivatives are human serum albumin, immunoglobulin preparations, factor IX, or factor VIII concentrate derived from plasma by a fractionation process, solvent detergent product and recombinant factor VIII.

Provincial/Territorial Surveillance Office: An office/department set up in each province or territory to manage the collection of data regarding adverse events related to transfusion.

Information About the Canadian Transfusion Adverse Event Reporting Form

What triggers completion of the Canadian Transfusion Adverse Event Reporting Form?

Any episode that may result or has resulted in untoward consequences from blood, blood component, or plasma derivative administration should trigger the completion of this form. This could consist of an event that places a patient at risk of poor outcome or an actual acute or chronic effect from the transfusion itself.

An adverse event could result from an incident (error or accident) or reaction. This form may be used within hospitals for the reporting of all adverse events. Only incidents described in Section 3A (page 16) should be addressed and reported to the provincial/territorial surveillance office as described on page 5.

Each institution is responsible for ensuring that a process is in place to notify the individual who will be completing the form.

Who can complete this form?

- Any health care professional can report a transfusion related adverse event.
- Sections 1 through 6 of the form can be completed by the nurse, laboratory technologist, or the individual in your institution with the responsibility for reporting, documenting, and investigating blood transfusion reactions.
- Section 7 should be completed by the individual responsible for interpreting blood transfusion reaction investigations (e.g., pathologist, blood bank medical director).

Under what circumstances must I complete two (2) forms on the same patient?

If a patient has had more than one type of adverse event during the transfusion process, separate forms must be completed. If an individual experiences only one adverse event but receives multiple products, only a single form requires completion.

What should I do after completion of this form?

When you have provided all the necessary information, this form should be forwarded to the appropriate location in your institution or province/territory by fax or mail, or electronically. If you are unaware of the process consult with the Manager/Director of Transfusion Services at your institution.

What information is transferred to the provincial/territorial level?

Certain information on the form, as agreed to within each province/territory, is entered into a centralized provincial/territorial database and is reviewed by the provincial/territorial surveillance office responsible for overseeing this program. See Guidelines for Hospitals to Report Adverse Events to Provincial/Territorial Surveillance Offices and Canadian Blood Services/HÉMA-QUÉBEC on page 5.

What information is transferred to the federal level?

Some of this information of national significance will be electronically transferred to Health Canada. The information provided is non-nominal data that has been negotiated with the provinces/territories. Patient anonymity is maintained in this process, as no specific patient information is transferred to the provincial/territorial or federal level. Additional information may be transferred to meet Health Canada regulatory requirements. For a copy of the data elements transferred to Health Canada for surveillance purposes, contact your provincial/territorial surveillance office or Health Canada.

What do I do if a matter requires urgent attention?

It is important to remember that timeliness of reporting adverse events may be life saving. In the event of a matter that requires immediate attention (e.g., acute bacterial infection related to a blood product), the Medical Director responsible for blood transfusion and, if appropriate, the local Canadian Blood Services/HÉMA-QUÉBEC blood centre or manufacturer of the plasma derived product should be informed immediately by telephone so that urgent measures may be taken. This form should then be completed to document the event and sent to the appropriate location, as described on pages 5 or 8.

Guidelines for Hospitals to Report Adverse Events to Provincial/Territorial Surveillance Offices and Canadian Blood Services/HÉMA-QUÉBEC

Timely reporting of serious, unexpected adverse reactions facilitates effective risk management and regulatory decision-making. All suspected serious adverse reactions to blood, blood components, and plasma derivatives must be reported. Provincial/territorial surveillance offices, blood suppliers, and manufacturers should be informed promptly of adverse events that may affect product safety and disposition in order that they can carry out the following:

i) quarantine during investigation, recall or destroy implicated associated products (e.g., in case of suspected bacterial contamination);.

ii) update donor safety profile (e.g., coding in case of transfusion related acute lung injury [TRALI]);

iii) fulfil their regulatory requirements to report serious adverse reactions/events to Health Canada.

What Adverse Events are to be Reported to Provincial/Territorial Surveillance Offices?

All relevant information (data) from the Canadian Transfusion Adverse Event Reporting Form is to be provided to provincial/territorial surveillance offices for any adverse events, including incidents as defined in Section 3A, page 16.

What Adverse Events Are To Be Reported to Canadian Blood Services/HÉMA-QUÉBEC?

All relevant information (data) from the Canadian Transfusion Adverse Event Reporting Form should be provided to Canadian Blood Services or HÉMA-QUÉBEC in accordance with their guidelines.

Canadian Blood Services and HÉMA-QUÉBEC are required to report transfusion-associated deaths to the Biologics and Genetic Therapies Directorate of Health Canada within 24 hours, and all other serious adverse events within 15 days of receiving a report.

Specific direction on reporting adverse events follows:

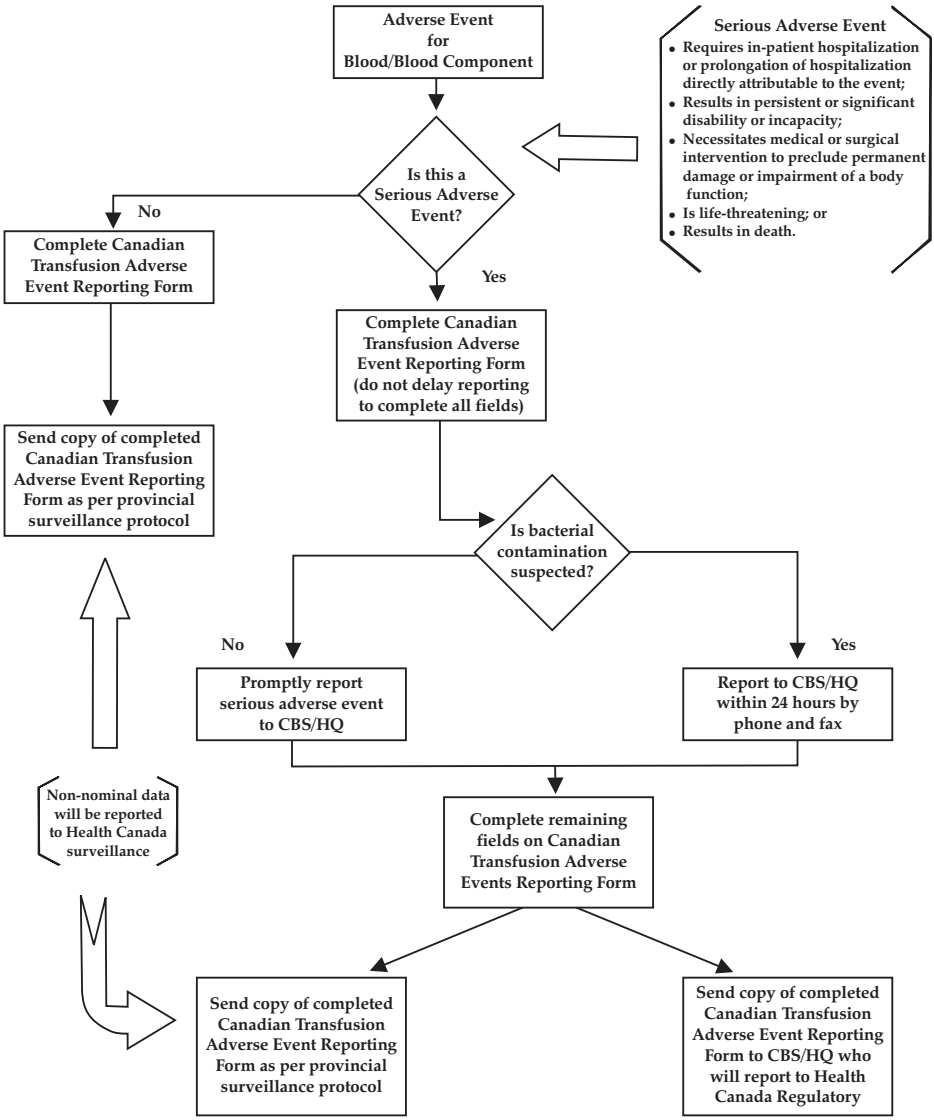
- Canadian Blood Services

  Refer to the Circular of Information for the Use of Human Blood and Blood Components or contact your local Canadian Blood Services blood centre.

- HÉMA-QUÉBEC

  Refer to the Circular of Information for the Use of Human Blood and Blood Components (also available at http://www.hema-quebec.qc.ca/pdf/circulaireA.PDF or http://www.hema-quebec.qc.ca/F/francais.htm) or contact your local HÉMA-QUÉBEC blood centre.

Guidelines for Hospitals to Report Adverse Events for Blood/Blood Components to Provincial/Territorial Surveillance Offices and Canadian Blood Services/HÉMA-QUÉBEC (CBS/HQ)



Guidelines for Hospitals to Report Adverse Events to Manufacturers of Plasma Derivatives

What Adverse Events are to be Reported to Manufacturers of Plasma Derivatives?

All relevant information (data) from the Canadian Transfusion Adverse Event Reporting Form concerning suspected serious adverse events is to be provided to manufacturers of plasma derivatives to allow appropriate investigation, assessment and action.

Manufacturers of plasma derivatives are required to report suspected product-associated deaths to the Canadian Adverse Drug Reaction Monitoring Program (CADRMP), Marketed Health Products Directorate, within 24 hours and all other serious and unexpected adverse events within 15 days of receiving the report.

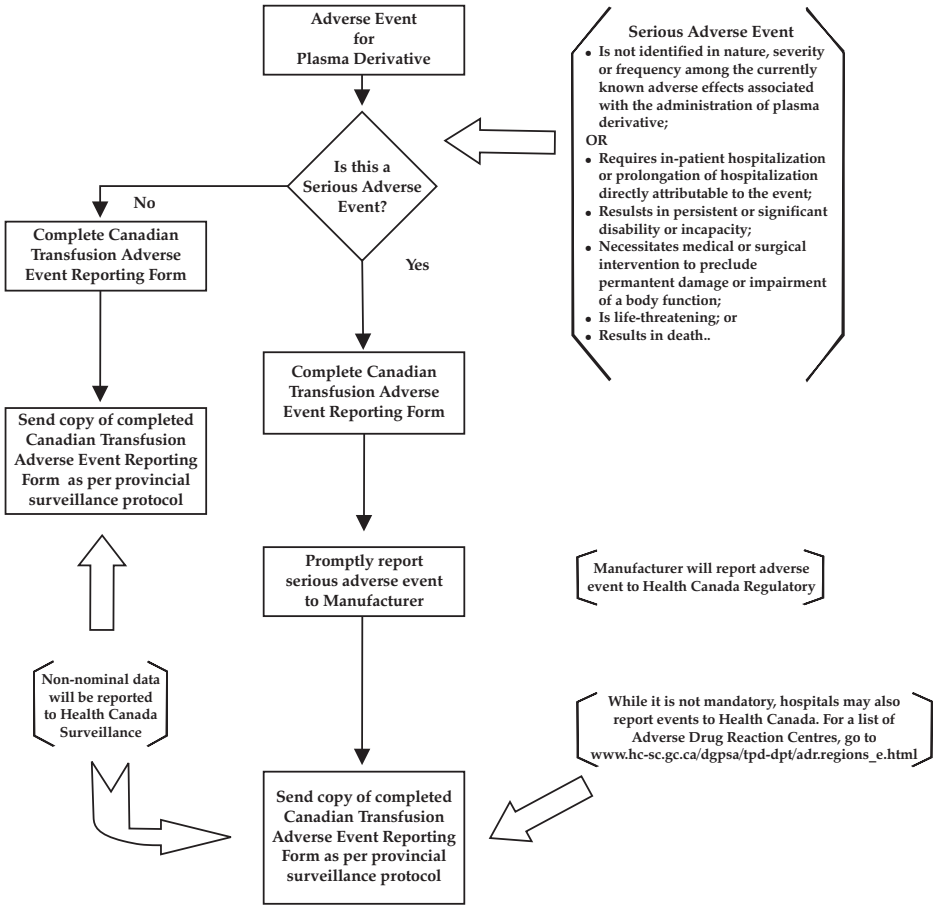
Manufacturers of plasma derivatives should receive reports of all unexpected or serious adverse events that

- require in-patient hospitalization or prolongation of hospitalization directly attributable to the event or adverse reaction,
- result in persistent or significant disability or incapacity,
- necessitate medical or surgical intervention to preclude permanent damage or impairment of a body function,
- are life-threatening, or
- result in death.

Please see the flowchart on page 9, Guidelines for Reporting to Manufacturers of Plasma Derivatives.

Note: A hospital may also choose to report these events directly to CADRMP through the Regional Adverse Drug Reaction Centre using the Canadian Transfusion Adverse Event Reporting Form.

Guidelines for Hospitals to Report Adverse Events for Plasma Derivatives to Manufacturers



Instructions to Complete the Canadian Transfusion Adverse Event Reporting Form

a) **Created by**

Enter the name (last name and first initial) of the individual who created the record in the Transfusion Transmitted Injuries Surveillance System (database).

b) **Date**

Enter the date (ddmmmyyyy) on which the record was created in the Transfusion Transmitted Injuries Surveillance System (database).

c) **Last modified by**

Enter the name (last name and first initial) of the individual who last modified the record in the Transfusion Transmitted Injuries Surveillance System (database).

d) **Date**

Enter the date (ddmmmyyyy) on which the record was modified in the Transfusion Transmitted Injuries Surveillance System (database).

e) **Record closed**

Place an (x) or (✓) in the box if the record has been closed in the Transfusion Transmitted Injuries Surveillance System (database).

f) **Case ID**

A case ID is assigned for each adverse event when entered into the Transfusion Transmitted Injuries Surveillance System (database). This identification number is used solely for the purposes of tracking within the database.

Category of Event

Select ONLY one of the following categories:

a) **Incident**

Select "Incident" with an (x) or (✓) if an accident or error occurred that could lead to the issuing or transfusion of ABO incompatible red cells or plasma. Additional details are provided in Section 3A, page 16.

Complete Sections 1, 3 and 6 of the Form for incidents that occurred before the transfusion.

Complete All Sections of the Form for incidents that occurred during or after administration.

b) **Adverse Reaction**

Select "Adverse Reaction" with an (x) or (✓) if the recipient experienced a reaction suspected to be related to the product.

Or

Select "Adverse Reaction" with an (x) or (✓) if an incident caused an adverse reaction.

Examples: Urticaria
Fever, chills, pain
Hypotension/hypertension
Bacterial or viral infection

Complete All Sections of the Form

Facility Identification

a) **Name of facility**

Enter the official name of the facility that reported the incident or adverse reaction (e.g., hospital, medical clinic, public health department).

b) **Telephone number**

Enter the telephone number of the facility, including the area code and extension, if applicable.

c) **Address of facility**

Enter the full address of the facility, including

- street number, name and street type
- PO Box, if applicable
- city
- province
- postal code

d) **Hospital Code**

Enter the hospital identification number assigned by the provincial/territorial department or Ministry of Health.

Section 1 Recipient Identification

a) **Last name**

Enter the recipient's last name.

b) **First name**

Enter the recipient's first name.

c) **Health card number**

Enter the recipient's health card number.

d) **Hospital card number**

Enter the recipient's provincial/territorial hospital card number (as applicable).

e) **Address of recipient**

Enter the full address of the recipient, including

- street number, name and street type
- apartment number or PO Box, if applicable
- city
- province
- postal code

f) **Home telephone**

Enter the recipient's home telephone number, including the area code.

g) **Work telephone**

Enter the recipient's work telephone number, including the area code and extension, if applicable.

h) **Date of birth**

Enter the recipient's date of birth (ddmmmyyyy).

i) **Sex**

Enter the recipient's sex (male, female, other, not given or unknown).

j) **Postal code**

Re-enter the first 3 characters of the recipient's postal code.

Section 2 Clinical History

a) **Pregnancies/Miscarriages**

Select "Yes < 3 mo" with an (x) or (✓) if the recipient is pregnant or has been pregnant within the past 3 months.

And/or

Select "Yes > 3 mo" with an (x) or (✓) if the recipient was pregnant over 3 months ago.

Or

Select "No" with an (x) or (✓) if the recipient has never been pregnant.

Or

Select "Unknown" with an (x) or (✓) if this information is unknown.

b) **Transfusions**

Select "Yes < 3 mo" with an (x) or (✓) if the recipient received a previous transfusion of a blood product within the past 3 months.

And/or

Select "Yes > 3 mo" with an (x) or (✓) if the recipient received a previous transfusion of a blood product more than 3 months ago.

Or

Select "No" with an (x) or (✓) if the recipient had not previously received a transfusion

Or

Select "Unknown" with an (x) or (✓) if this information is unknown.

c) **Principal Diagnosis**

Enter the diagnosis that is most likely related to the need for transfusion. This may be a clinical decision by the Blood Safety Officer and/or the Blood Bank Director, or the diagnosis could be obtained from the hospital admission/discharge system.

Use the ICD 10 code if available. If not available, use the general diagnosis field for data entry.

d) **Immune-compromised**

Select "Yes" with an (x) or (✓) if the recipient is immunodeficient, is taking medication that can cause immunosuppression, or has an immunosuppressive disease. Describe the reason for the recipient being immune-compromised.

Examples include chemotherapy, leukemia, transplantation or other.

Select "No" with an (x) or (✓) if the recipient is not thought to be immune-compromised.

Select "Unknown" with an (x) or (✓) if this information is unknown.

e) **Blood group**

Enter the recipient's ABO (A or B or O or AB) and Rh type (pos or neg).

f) **Other**

Select "Other" with an (x) or (✓) when providing additional information/history that may be relevant to the transfusion. Describe any previous reactions to drugs, or allergies or clinical reactions to blood products.

Section 3 Date, Time and Place of Incident/Adverse Reaction

a) **Date and time adverse event occurred**

Enter the date the adverse event occurred (ddmmmyyyy).

Enter the time the adverse event occurred (00:00 to 23:59)

b) **Place**

Enter the location where the adverse event occurred.
Examples: emergency room, outpatient, operating room, ward, etc.

In the event of both an incident and adverse reaction occurring enter the location where the adverse reaction occurred.

c) **Date and time reported**

Enter the date and time the adverse event was reported (ddmmmyyyy and 00:00 to 23:59).

Section 3a Incident Information

a) **Patient Identification Incident**

Select "Patient Identification Incident" with an (x) or (✓) if an incident occurred involving the identification of the patient during the collection of the sample for type/cross, processing in the blood bank, or during administration.

Examples:

- Order on wrong patient
- Sample labelled with incorrect patient name
- Wrong patient collected
- Paperwork and sample ID do not match
- Sample testing error
- Order for pickup on wrong patient
- Wrong blood to patient (+/- transfusion)

Specify the details of the incident.

b) **Product Related Incident**

Select "Product Related Incident" with an (x) or (✓) if an incident occurred related to the product.

Examples:

- blood supplier ABO error
- blood checked in with wrong group
- error in product selection and labelling

Specify the details of the incident.

c) **Other incident**

Select "Other Incident" with an (x) or (✓) if there was any other type of incident related to the transfusion process. Specify the details of the incident.

d) **Product Transfused**

Select "Product Transfused" with an (x) or (✓) if the blood component or plasma derivative was administered to the recipient.

Section 3b Use of Equipment and Premedication

a) **Filter**

Select "Used" with an (x) or (✓) if a filter was used for the administration of the transfusion but was not attached to the blood bag.

Select "Equip. Problem" with an (x) or (✓) if the filter used was in any way defective. Record the type and model number in Section 8 Comments.

b) **Pump**

Select "Used" with an (x) or (✓) when an infusion pump was used for the administration of the transfusion.

Select "Equip. Problem" with an (x) or (✓) if the pump used did not operate according to the operator's or manufacturer's standards. Record the type and model number in Section 8 Comments.

c) **Pressure Device**

Select "Used" with an (x) or (✓) if a manual or automatic device that administers blood at an accelerated rate was used for the administration of the transfusion.

Select "Equip. Problem" with an (x) or (✓) if the pressure device used did not operate according to the operator's or manufacturer's standards. Record the type and model number in Section 8 Comments.

d) **Blood warmer**

Select "Used" if a blood warmer was used to increase the temperature of the blood product.

Select "Equip. Problem" with an (x) or (✓) if the temperature exceeded what was intended, or if the warmer affected the flow of the transfusion, or if it did not operate according to the manufacturer's standards. Record the type and model number in Section 8 Comments.

e) **Reinfusion device**

Select "Used" with an (x) or (✓) if the recipient was administered blood recovered during a surgical procedure.

Select "Equip. Problem" with an (x) or (✓) if the reinfusion device did not operate according to the manufacturer's standards. Record the type and model number in Section 8 Comments.

f) **Other**

Select "Other" with an (x) or (✓) if any other type of equipment was used during the transfusion process and describe what equipment was used.

g) **Premedication**

Medication is often administered to individuals who have a history of febrile or allergic reactions in order to minimize their clinical symptoms. Commonly used medications include acetaminophen, diphenhydramine hydrochloride, and prednisone.

Select "No" with an (x) or (✓) if the recipient did not receive any medications before the transfusion.

Select "Yes" with an (x) or (✓) if the recipient received medication(s) before the transfusion. Specify the drug, dose, route administered.

Section 3c Report of Possible Transfusion Related Blood Borne Infection

a) **Viral**

Select "Viral" with an (x) or (✓) if a viral infection is suspected. Specify the type of viral infection.

Examples: hepatitis B (HBV), hepatitis C (HCV), human immunodeficiency virus (HIV), human T-cell lymphotropic virus type I (HTLV-I) and type II (HTLV-II), cytomegalovirus (CMV), and Epstein-Barr virus, other.

b) **Bacterial**

Select "Bacterial" with an (x) or (✓) if a bacterial infection is suspected. Specify the genus and species of the organism identified.

Examples: *Yersinia, Pseudomonas, Staphylococcus aureus, Staphylococcus epidermidis*, Lyme disease, syphilis, other

Provide result of gram stain, if available.

c) **Other**

Select "Other" with an (x) or (✓) if another type of infection is suspected. Specify the type of other infection.

Examples: malaria, babesiosis, toxoplasmosis, Creutzfeldt-Jakob Disease, other.

Section 4 Clinical Signs And Laboratory Results

NOTE: These definitions are guidelines and should not preclude the use of clinical judgement.

a) **None**

Select "None" with an (x) or (✓) if the recipient did not demonstrate any clinical signs of an adverse reaction.

b) **Pulse**

Indicate the recipient's pulse before and after the transfusion.

c) **Fever**

Select "Fever" with an (x) or (✓) if the recipient experienced a rise of ≥ 1°C in temperature over the pre-transfusion temperature during or within 4 hours of the completion of the transfusion. Record the "T. before" and "T. after" temperatures.

T. Before: Indicate the recipient's temperature in Celsius before the initiation of the transfusion.

T. After: Indicate the highest recipient temperature in Celsius obtained after the initiation of the transfusion or within 4 hours of its completion.

d) **Hypotension**

Select "Hypotension" with an (x) or (✓) if the recipient experienced a drop in systolic blood pressure by ≥ 30 mm Hg or "shock" during or within 4 hours of the completion of the transfusion.

Complete "BP Before" by entering the recipient's systolic and diastolic BP before the transfusion.

Complete "BP After" by entering the lowest systolic and diastolic BP (hypotension) or highest systolic and diastolic BP (hypertension) experienced by the recipient during transfusion or within 4 hours of its completion.

e) **Hypertension**

Select "Hypertension" with an (x) or (✓) if the recipient experienced a rise in systolic blood pressure by ≥ 30 mm Hg during or within 4 hours of the completion of the transfusion.

Complete "BP Before" by entering the recipient's systolic and diastolic BP before the transfusion.

Complete "BP After" by entering the lowest systolic and diastolic BP (hypotension) or highest systolic and diastolic BP (hypertension) experienced by the recipient during transfusion or within 4 hours of its completion.

f) **Oliguria**

Select "Oliguria" with an (x) or (✓) if the recipient experienced the new onset of decreased urinary output within 72 hours of the identification of the transfusion reaction (< 500 cc output per 24 hours).

g) **Diffuse Hemorrhage**

Select "Diffuse Hemorrhage" with an (x) or (✓) if the recipient experienced diffuse, uncontrollable bleeding at

- puncture sites or
- catheter sites (including hematuria) or
- surgical wounds or
- diffuse mucocutaneous bleeding during or within 4 hours of the completion of the transfusion.

h) **Urticaria**

Select "Urticaria" with an (x) or (✓) if the recipient experienced raised red spots with or without pruritis, or if the recipient experienced generalized pruritis even without redness during or within 4 hours of the completion of the transfusion.

i) **Nausea/Vomiting**

Select "Nausea/vomiting" with an (x) or (✓) if the recipient experienced nausea or vomiting during or within 4 hours of the completion of the transfusion.

j) **Jaundice**

Select "Jaundice" with an (x) or (✓) if the recipient experienced new onset or worsening of scleral icterus. Enter the total and indirect bilirubin results, if available, in "Abnormal Laboratory Results" as well as the pre-transfusion results, if available.

k) **Tachycardia**

Select "Tachycardia" with an (x) or (✓) if the recipient experienced an increase in heart rate to ≥ 120/min or if there was an increase of ≥ 40 beats per minute compared with the pre-transfusion pulse, during or within 4 hours of the completion of the transfusion.

l) **Chills/Rigors**

Select "Chills/rigors" with an (x) or (✓) if the recipient experienced chills and/or rigors during or within 4 hours of the completion of the transfusion.

m) **Shortness of breath**

Select "Shortness of breath" with an (x) or (✓) if the recipient experienced the new onset or significant worsening of shortness of breath or a significant increase in respiratory rate (with or without hypoxemia) during or within 24 hours of the completion of the transfusion.

n) **Shock**

Select "Shock" with an (x) or (✓) if, with the above hypotension, the recipient experienced a drop in cardiac output, including tachycardia, tachypnea, cutaneous vasoconstriction, pallor, sweating, oliguria, agitation and/or loss of consciousness that required fluid resuscitation, with or without inotropic support, and an unexpectedly higher level of care.

o) **Death**

Select "Death" with an (x) or (✓) if the recipient's death was suspected to be a consequence of the transfusion.

p) **Other skin rash**

Select "Other skin rash" with an (x) or (✓) if the recipient experienced a non-urticarial skin rash.

q) **Pain**

Select "Pain" with an (x) or (✓) if the recipient experienced pain during or within 4 hours of the completion of the transfusion. Specify the site of the pain in the space provided.

Example: headache, dorso-lumbar, abdominal, thoracic, other

r) **Hemoglobinuria**

Select "Hemoglobinuria" with an (x) or (✓) if the recipient's urine became dark or reddish and if a urinalysis showed hemoglobin with or without red blood cells

s) **Other**

Select "Other" with an (x) or (✓) if the recipient experienced any other relevant signs and symptoms during or within 4 hours of the completion of the transfusion. Specify the other signs and symptoms.

Example: diaphoresis, diarrhea, epistaxis, bronchospasm, O_2 saturation decrease, trembling, itching, hyperkalemia, hypercalcemia, disseminated intravascular coagulation, other

t) **Abnormal Laboratory Results**

This section is to identify the results of laboratory tests related to the investigation of the adverse event. Enter the name of the abnormal laboratory tests and the results. Also enter the date (ddmmmyyyy) the specimen was taken.

Example: indirect bilirubin, total bilirubin, plasma hemoglobin, creatinine, haptoglobin, LDH, positive direct Coombs, alloimmunization, other

u) **Transfused under anesthesia**

Select "General" with an (x) or (✓) if the recipient was receiving a general anaesthetic at the time of the reaction.

Select "Local/regional" with an (x) or (✓) if the recipient was receiving a local/regional anaesthesia at the time of the reaction. This category includes epidurals.

Select "None" with an (x) or (✓) if the recipient was not receiving anaesthesia at the time of the reaction.

Guidelines to identify a transfusion reaction in the anaesthetized patient

The operating room is a unique environment; therefore classic signs and symptoms of a transfusion reaction may not be identifiable.

When patients are anaesthetized, symptoms may be masked by the room temperature, muscular inactivity, and an inability to communicate signs and symptoms.

In the anaesthetized patient, a transfusion reaction should be suspected if any one of the following occurs during or within 4 hours of receiving a transfusion:

- Urticarial skin rash
- Unexplained increase in airway pressures
- Unexpected shock
- Unexpected death
- Hemoglobinuria
- A drop in hemoglobin in the absence of bleeding
- Unusual hemoglobin results with evidence of hemolysis
- Clinical evidence of disseminated intravascular coagulation

v) **Bacterial Infection**

If a blood culture was performed on the recipient, indicate

- date (ddmmmyyyy) and time (00:00 to 23:59) the sample(s) was obtained;
- results of the recipient's culture:
  - enter the number of "negative" results of the recipient's culture or
  - enter the number of "positive" results if the testing identified an organism(s), and specify the organism(s) identified (genus/species), if known.

If a blood culture was performed on the blood product, indicate

- date (ddmmmyyyy) and time (00:00 to 23:59) the blood product was received by the Microbiology Laboratory;
- results of the product culture:
  - enter the number of "negative" results of the blood product culture or
  - enter the number of "positive" results if the testing identified an organism(s) and specify the organism(s) identified (genus/species), if known.

Document the lot number of the blood bag and the unit number of the positive product(s) cultures in the space provided.

Additional information regarding bacterial infection can be found on pages 33-35 of this manual.

Note: Identification of a positive blood culture resulting from transfusion is usually a medical emergency. The medical director for blood transfusion of your hospital and your local Canadian Blood Services/HÉMA-QUÉBEC Centre should be immediately notified as soon as such a result is suspected.

Section 5 Suspect Products

All blood products that might be related to the adverse transfusion must be identified. The first blood product listed should be the product suspected of being associated with the reported adverse event. (Attach additional forms as required. A sample form to list additional products has been attached in Appendix 3.) If a second incident/adverse reaction occurs, a separate "Canadian Transfusion Adverse Event Reporting Form" must be completed.

a) **Transfused blood product:**

Product code/name

Enter the numeric product code or the name of the blood component/plasma derivative from Appendix 1 related to the transfusion incident/adverse reaction.

Product modification

If product modification occurred enter the specific code from the list below and indicate where the modification occurred (hospital or supplier). If it was an autologous donation or directed/designated donation please specify.

Product Modification Codes

IRR	Irradiated
LR	Leukoreduced
CMV	Negative for anti-CMV
D	Deglycerolized
DV	Divided
LV	Low volume
SR	Supernatant reduced
W	Washed
P	Pooled

b) **Group of unit**

Enter the ABO and Rh group indicated on the bag or the label on the bag. (Do not use the group on the transfusion transmittal slip.) Select "N/A" for products for which ABO or Rh groups do not apply.

c) **Blood centre code**

Enter the blood centre number indicated on the bag or container.

d) **Unit no. or lot no.**

Enter the unit or lot number indicated on the bag or container.

e) **Expiry Date (ddmmmyyyy)**

Enter the date of expiration indicated on the bag or container (ddmmmyyyy). If the product has been modified, enter the expiry date of the modified product.

f) **Amount administered**

Enter the volume of product administered in millilitres OR enter the estimated fraction (¼, ½, ¾, $^4/_4$) that was administered.

g) **Transfusion**

Started
Enter the date (ddmmmyyyy) and hour (00:00 to 23:59) the transfusion was started.

Finished
Enter the date (ddmmmyyyy) and hour (00:00 to 23:59) the transfusion was completed or discontinued.

h) **Comments**

Document any abnormal findings, e.g., discoloration, temperatures, presence of clots.

Section 6 Measures Taken

Select all that apply:

a) **None**

Select "None" with an (x) or (✓) if the reaction required no particular measures.

b) **Antihistamines**

Select "Antihistamines" with an (x) or (✓) if these were administered for the transfusion reaction (e.g., Benadryl).

c) **Antibiotics**

Select "Antibiotics" with an (x) or (✓) if these were administered for the transfusion reaction.

d) **Transfusion Stopped**

Select "Transfusion Stopped" with an (x) or (✓) if the transfusion was discontinued.

e) **Steroids**

Select "Steroids" with an (x) or (✓) if these were administered for the transfusion reaction (e.g., Solumedrol, Solucortef).

f) **Antipyretics**

Select "Antipyretics" with an (x) or (✓) if these were administered for the transfusion reaction (e.g., acetaminophen).

g) **Supplementary O_2**

Select "Supplementary O_2" with an (x) or (✓) if the recipient was given oxygen before transfusion and the concentration had to be increased, or if oxygen administration became necessary for a recipient who had not previously required it.

h) **Vasopressors**

Select "Vasopressors" with an (x) or (✓) if these were administered for the transfusion reaction (e.g., epinephrine, dopamine, norepinephrine).

i) **Analgesics**

Select "Analgesics" with an (x) or (✓) if these were administered for the transfusion reaction.

j) **ICU Required**

Select "ICU Required" with an (x) or (✓) if a transfusion reaction led to a substantial increase in the level of care or a transfer to an intensive care unit.

k) **Diuretics**

Select "Diuretics" with an (x) or (✓) if these were administered for the transfusion reaction (e.g., Lasix).

l) **Product Culture**

Select "Product Culture" with an (x) or (✓) if blood containers/bags were sent for culture.

m) **Blood Culture**

Select "Blood Culture" with an (x) or (✓) if a blood culture was ordered for the recipient and samples were taken and sent to the laboratory.

n) **Other**

Select "Other" with an (x) or (✓) if other types of medications or measures were used for the transfusion reaction. Specify the medications or measures.

Example: anxiolytics, bronchodilators, desferoxamine, other

o) **Name**

Print the name of the individual involved in the measures taken, including first and last name. Indicate whether the individual is a physician, transfusion safety officer, technologist, or other (please specify).

p) **Signature**

The individual involved in the measures taken must sign the form.

q) **Telephone number**

Enter the telephone number of the individual involved in the measures, including the area code and extension (if applicable).

r) **Date**

Enter the date the measures were taken (ddmmmyyyy).

Section 7 Results of Investigation & Conclusion

a) **Allergic Reactions**

Minor

Select "Minor" with an (x) or (✓) if the recipient experienced a skin reaction characterized by transient urticarial or other skin rash associated with the transfusion. This reaction is not usually associated with a fever or other symptoms.

Severe/Anaphylactic/Anaphylactoid

Select "Severe/Anaphylactic/Anaphylactoid" with an (x) or (✓) if the recipient experienced signs or symptoms of bronchospasm and airway edema associated with the transfusion. This may progress to cause hypotension, shock, respiratory or circulatory failure and death. Specify the signs and symptoms.

b) **Febrile Non-Hemolytic Reaction**

Select "Febrile Non-Hemolytic Reaction" with an (x) or (✓) if the recipient experienced a temperature increase of > 1°C associated with the transfusion and for no other apparent explanation in the absence of hemolysis. This reaction may be associated with chills and rigors.

c) **Incompatibility**

Pre-existing incompatibility

Select "ABO" with an (x) or (✓) if there was a pre-existing incompatibility in the ABO system. Specify the antibody or antibodies identified.

Examples: anti-A, anti-B, anti-A,B

Select "Other" with an (x) or (✓) if there was a pre-existing incompatibility exclusive of the ABO system. Specify the antibody or antibodies identified.

Examples: anti-C, anti-E, anti-c, anti-e, anti-G, anti-C^w
anti-K1, anti-K2, anti-JK^a, anti-JK^b, anti-S, anti-s
anti-Vel, anti-Fy^a, anti-Fy^b, anti-Wr^a, anti-Wr^b, anti-M,
anti-N, anti-P, anti-Le^a, anti-Le^b, anti-I, HLA.

New Alloantibodies

Select "New Alloantibodies" with an (x) or (✓) if the recipient developed antibodies associated with the transfusion. Specify the antibody associated with the reaction in the space provided.

Examples: anti-C, anti-E, anti-c, anti-e, anti-G, anti-C^w
anti-K1, anti-K2, anti-JK^a, anti-JK^b, anti-S, anti-s
anti-Vel, anti-Fy^a, anti-Fy^b, anti-Wr^a, anti-Wr^b, anti-M,
anti-N, anti-P, anti-Le^a, anti-Le^b, anti-I, HLA.

d) **Hemolytic Reaction**

Hemolytic reactions cause the destruction of red blood cells, as evidenced by a drop in hemoglobin, and increases in indirect bilirubin and LDH. Accompanying clinical signs and symptoms may occur such as fever, pain, and dyspnea.

Acute

Select "Acute" with an (x) or (✓) if the recipient experienced chills, fever, hemoglobinuria, renal failure, hypotension, diffuse hemorrhage, oliguria, oozing from IV site, back pain, or pain along the infusion vein within 24 hours of the receipt of the transfusion.

Delayed

Select "Delayed" with an (x) or (✓) if the recipient developed weakness, an unexplained fall in post-transfusion hemoglobin or elevated serum bilirubin greater than 24 hours and up to 3 months following the transfusion.

e) **Viral Infection**

Select "Viral Infection" with an (x) or (✓) if the recipient developed a viral infection associated with a transfusion, which has been verified by confirmatory tests. Specify the virus involved.

Examples: hepatitis B (HBV), hepatitis C (HCV), human immunodeficiency virus (HIV), human T-cell lymphotropic virus type I (HTLV-I) and type II (HTLV-II), cytomegalovirus (CMV), and Epstein-Barr virus, West Nile virus (WNV), other.

Indicate whether the donor is infected or uninfected, or whether this information is unknown.

f) **Bacterial Infection**

Select "Bacterial Infection" with an (x) or (✓) if the recipient developed a bacterial infection following a transfusion in association with the positive identification of a pathogen not previously identified in the recipient. Specify the genus and species. Refer to Section 4 to obtain this information.

Indicate whether the donor is infected or uninfected, or whether this information is unknown.

g) **Other Infection**

Select "Other Infection" with an (x) or (✓) if the recipient developed another infection associated with a transfusion, which has been verified by confirmatory tests. Specify the organism(s) involved.

Examples: malaria, babesiosis, Lyme disease, syphilis, toxoplasmosis, Creutzfeldt-Jakob Disease, other.

Indicate whether the donor is infected or uninfected, or whether this information is unknown.

h) **Transfusion Associated Graft Versus Host Disease (TA-GVHD)**

Select "TA-GVHD" with an (x) or (✓) if the recipient experienced fever, skin rash (which often starts on the palms, the soles of the feet and the ear lobes), elevated liver enzymes (ALT and AST, alkaline phosphatase) and bilirubin, pancytopenia and diarrhea in association with a transfusion. The reaction is very severe and results in death in over 90% of cases.

In Canada, blood products are routinely irradiated to prevent GVHD for directed donor transfusions, bone marrow transplant recipients, newborns who have received in utero transfusions and/or low birthweight newborns. Transfusion associated GVHD is rare and most commonly occurs in immunocompromised recipients who do not receive irradiated blood products.

i) **Transfusion Related Acute Lung Injury (TRALI)**

Select " TRALI" with an (x) or (✓) if the recipient experienced acute respiratory insufficiency and/or if x-ray findings are consistent with pulmonary edema but in the absence of cardiac failure within 24 hours of the receipt of a transfusion. The reaction may also include chills, fever, cyanosis, and hypotension.

j) **Hemochromatosis**

Select "Hemochromatosis" with an (x) or (✓) if the recipient developed clinical or pathological evidence of hemochromatosis as a result of transfusions.

k) **Circulatory Overload**

Select "Circulatory Overload" with an (x) or (✓) if the recipient experienced dyspnea, cyanosis, orthopnea, severe headache, hypertension, or congestive heart failure during or soon after the receipt of a transfusion.

l) **Post Transfusion Purpura**

Select "Post Transfusion Purpura" with an (x) or (✓) if the recipient develops a sudden severe thrombocytopenia (platelet count <10,000/L) 5-10 days after a red cell transfusion. This condition is most often associated with the presence of anti-HPA-1a (anti-PLA1) in the patient's serum

m) **Hypotensive Reaction**

Select "Hypotensive Reaction" with an (x) or (✓) if the recipient experienced a drop in systolic blood pressure by ≥ 30 mm Hg or "shock" during or within four hours of the completion of the transfusion, if not explained by any other type of reaction.

n) **Aseptic Meningitis**

Select "Aseptic Meningitis" with an (x) or (✓) if the recipient experienced fever, headache, meningismus and a change in mental status after receiving IVIG. Recipient may also have nausea, vomiting, pharyngitis and diarrhea.

o) **Unknown**

Select "Unknown" with an (x) or (✓) if the recipient experienced a reaction that cannot be diagnosed.

p) **Other**

Select "Other" with an (x) or (✓) if the recipient experienced any other type of transfusion reaction. Specify the diagnosis.

Examples: severe electrolyte imbalance, headache post IVIG, atypical pain, etc.

Note: Atypical pain is defined as pain not usually associated with receiving a blood transfusion.

Relationship of Adverse Event to Transfusion

Select **one** of the following:

i) **Definite**

Select "Definite" with an (x) or (✓) if a clinical and/or laboratory event occurred within a time period consistent with the administration of the blood product and was proven by investigation to have been caused by transfusion.

Bacterial contamination is considered "Definite" if it meets ALL of the following criteria:

- The same bacteria are found in the recipient and the blood product.
- Contamination of the blood sample and the laboratory is not suspected.

ii) **Probable**

Select "Probable" with an (x) or (✓) if a clinical and/or laboratory event occurred within a time period consistent with the administration of the blood product and did not seem to be explainable by any other cause.

Bacterial contamination is considered "Probable" if it meets the following criteria:

- Positive blood product culture.
- Contamination of the blood sample and the laboratory is not suspected.
- The recipient is symptomatic (nothing else explains it).

- The recipient's blood culture was not done.
  - No specimen was available.
  - A blood culture was not ordered.
- The recipient's blood culture is negative.
  - The recipient is already taking antibiotics.
  - There were problems with the recipient's blood culture.

iii) **Possible**

Select "Possible" with an (x) or (✓) if the clinical and/or laboratory event occurred within a time period consistent with the administration of the blood product but could be explained by a concurrent disease or by the administration of a drug or other agent.

Bacterial contamination is considered "Possible" if it meets the following criteria:

- The recipient's blood culture is positive.
- Contamination of the blood sample and the laboratory is not suspected.
- The recipient is symptomatic (nothing else explains it).
- A blood product culture was not done.
  - No specimen was available.
  - A blood culture was not ordered.
- The blood product culture is negative.
  - There were problems with the culture of the blood product.

iv) **Doubtful**

Select "Doubtful" with an (x) or (✓) if the clinical or laboratory event occurred within a reasonable time period but the clear preponderance of data supports an alternative explanation.

Bacterial contamination is considered "Doubtful" if:

- The blood product culture is positive for one pathogen and the recipient's blood culture is positive for a different pathogen , or the blood product culture is positive or the recipient's blood culture is positive but contamination of the sample or laboratory specimen is suspected.

v) **Ruled out**

Select "Ruled Out" with an (x) or (✓) if the clinical and/or laboratory event occurred within a time period inconsistent with the administration of the blood product or, if it occurred within a consistent time period, but was proven to have no relationship to the transfusion.

vi) **Not Determined**

Select "Not Determined" with an (x) or (✓) if it remains to be determined whether the event was related to the administration of the blood product and further information is forthcoming.

Severity of Adverse Event

Select **one** of the following:

i) **Grade 1 (Non-Severe)**

Select "Grade 1 (Non-Severe)" with an (x) or (✓) if the recipient may require medical intervention (e.g. symptomatic treatment) but lack of such would not result in permanent damage or impairment of a body function.

ii) **Grade 2 (Severe)**

Select "Grade 2 (Severe)" with an (x) or (✓) if

- the recipient requires in-patient hospitalization or prolongation of hospitalization directly attributable to the event;
- the adverse event results in persistent or significant disability or incapacity; or
- the adverse event necessitates medical or surgical intervention to preclude permanent damage or impairment of a body function.

Examples: aseptic meningitis (severe headache with neck stiffness but recipient's life not threatened), hemolytic reaction (fever, low back pain, laboratory signs of hemolysis but patient stable and life not threatened), and major allergic (generalized urticaria, dyspnea but no important bronchospasm).

iii) **Grade 3 (Life-threatening)**

Select "Grade 3 (Life-threatening)" with an (x) or (✓) if the recipient required major intervention following the transfusion (vasopressors, intubation, transfer to intensive care).

iv) **Grade 4 (Death)**

Select "Grade 4 (Death)" with an (x) or (✓) if the recipient's death was suspected to be the consequence of a transfusion. Describe the circumstances of death.

v) **Not determined**

Select "Not determined" with an (x) or (✓) if the consequences of the transfusion reaction are not certain.

Outcome of Adverse Event

Select **one** of the following:

i) **Death**

Relationship of Transfusion to Recipient's Death

If the recipient died, document the relationship of the transfusion to the recipient's death by selecting **one** of the following:

Definite

Select "Definite" with an (x) or (✓) if the recipient's death occurred within a time period consistent with the administration of the blood product and was proven by investigation to have been caused by transfusion.

Probable

Select "Probable" with an (x) or (✓) if the recipient's death occurred within a time frame consistent with the administration of the blood product and did not seem to be explainable by any other cause.

Possible

Select "Possible" with an (x) or (✓) if the death occurred within a time period consistent with the administration of the blood product but could be explained by a concurrent disease or by the administration of a drug or other agent.

Doubtful

Select "Doubtful" with an (x) or (✓) if the death occurred within a reasonable time period but the clear preponderance of data supports an alternative explanation.

Ruled Out

Select "Ruled Out" with an (x) or (✓) if the death occurred within a time period inconsistent with the administration of the blood product or, if it occurred within a consistent time period, but was proven to have no relationship to the transfusion.

Not Determined

Select "Not Determined" with an (x) or (✓) if it cannot be determined if the recipient's death was related to the transfusion.

ii) **Major or Long-Term Sequelae**

Select "major or long term sequelae" if the recipient developed either an infection with a persistent infectious agent (HIV, Hepatitis C, Hepatitis B), or a transfusion reaction with major or long-term sequelae or the anticipation of difficulties with future transfusions (e.g. development of antibodies to antigens present in more than 95% of donations).

iii) **Minor or No Sequelae**

Select "Minor or No Sequelae" with an (x) or (✓) if the recipient developed antibodies to low or medium frequency antigens (<95%) or other minor reactions.

iv) **Not Determined**

Select "Not Determined" with an (x) or (✓) if the outcome of the adverse event is not certain.

Hospital Procedure Involved

This section is to be completed if a hospital procedure was implicated in the incident/adverse reaction.

a) Describe

Describe the procedure related to the error/incident in the first column.

b) Action

List the name of the individuals or organizations notified of the situation (administration, attending physician, transfusion medicine committee, etc.), the date of contact, and the corrective measures/remedial actions taken, if any.

Equipment/Supplies

This section is to be completed if equipment or supplies were implicated in the incident/adverse reaction.

a) Describe

Describe the equipment or supplies implicated in the incident/adverse reaction. Include brand names, lot and model numbers.

b) Action

List the individuals or organizations notified of the situation (administration, attending physician, transfusion medicine committee, biomedical engineering etc.), the date of contact, and the actions taken.

Medical Follow-up

This section is completed when medical follow-up is applicable, for example, when long term sequelae are present.

a) Treatment or Preventative Measures

Describe any treatment or preventive measures taken following the reaction.

b) Action

List the individuals or organizations notified and date of contact. The reaction could require notification of other physicians to prevent the same situation from occurring again.

Supplier/Manufacturer Notified

The supplier/manufacturer of the blood, blood component or plasma derivative should be notified as soon as possible of the following:

- all transfusion reactions suspected of resulting in death as a consequence of the transfusion;
- all transfusion reactions suspected of resulting in serious morbidity, defined as a life-threatening reaction or a reaction resulting in long-term sequelae;
- all infections (bacterial, viral, parasitic, suspected bacterial contamination);
- all incidents that could possibly be traced back to the product or supplier.

NOTE: See page 5, Reporting Guidelines To Provincial/Territorial Surveillance Offices and Canadian Blood Services/HÉMA-QUÉBEC or page 8, Reporting Guidelines to Manufacturers of Plasma Derivatives

Select "Yes" if Canadian Blood Services or HÉMA-QUÉBEC was contacted for issues related to blood components or the manufacturer of the plasma derived product was contacted for issues related to it.

Document the name of the person contacted, as well as the date and time on which they were contacted.

OR

Select "No" if the supplier/manufacturer was not contacted.

Status of Investigation

The investigation is defined as an inquiry into the causes of the incident or adverse reaction within the hospital.

Select **one** of the following:

i) **In progress**

Select "In Progress" with an (x) or (✓) if an investigation is in progress.

ii) **Concluded**

Select "Concluded" with an (x) or (✓) if an investigation has been concluded.

iii) **Cannot be conducted**

Select "Cannot be Conducted" with an (x) or (✓) if an investigation was not conducted. Document the reason an investigation was not conducted.

Section 8 Comments

a) **Comments**

Record any relevant remarks concerning the incident or the adverse reaction. Attach another sheet of paper as required.

b) **Last name**

Enter the last name of the reporting physician or designate.

c) **First name**

Enter the first name of the reporting physician or designate.

d) **Signature**

The reporting physician or designate should sign the form in this location.

e) **Telephone number**

Enter the work telephone number (including the area code and extension, if applicable) of the reporting physician or designate.

f) **Date**

Enter the date (ddmmmyyyy) on which the reporting physician or designate completed the form.

g) **Time**

Enter the time (00:00 to 23:59) at which the reporting physician or designate completed the form.

Appendix 1:
Blood Product Names and Codes

Code	Official Name
Whole Blood/Red Blood Cell Components	
00180	CP2D Whole Blood
01480	CP2D Whole Blood, LRF*
01461	CP2D Whole Blood – Low Volume, LRF
04380	CP2D Red Blood Cells, LRF
04361	CP2D Red Blood Cells - Low Volume, LRF
04730	AS-3 Red Blood Cells, LRF
043771	AS-3 Red Blood Cells Divided, LRF
00160	CPDA-1 Whole Blood
01471	CPDA-1 Whole Blood Adjusted Anticoagulant
01467	CPDA-1 Whole Blood, LRF
043671	CPDA-1 Red Blood Cells Divided, LRF
04360	CPDA-1 Red Blood Cells, LRF
04371	CPDA-1 Red Blood Cells- Low Volume, LRF (Autologus Only)
04870	Red Blood Cells Washed, LRF
06400	Red Blood Cells Deglycerolized
06470	Red Blood Cells Deglycerolized, LRF
06270	Red Blood Cells Frozen, LRF
24000	Red Blood Cells (Non Injectable)
Platelet Components	
12700	CP2D Platelets, LRF
12071	Platelets Apheresis, LRF

Code	Official Name
Frozen Components	
18230	Fresh Frozen Plasma (CP2D), LRF
191701	Fresh Frozen Plasma Divided (CP2D), LRF
18872	Plasma (CP2D), LRF (Autologous Only)
19070	Cryoprecipitated AHF (CP2D), LRF
18770	Fresh Frozen Plasma (CPDA-1), LRF
191771	Fresh Frozen Plasma Divided (CPDA-1), LRF
18972	Plasma (CPDA-1), LRF (Autologous Only)
19800	Recovered Plasma Within 15 Hours of Phlebotomy
19600	Recovered Plasma
18872/077 (Combination Label)	(Cryosupernatant) Plasma (CP2D), LRF
18211	Fresh Frozen Plasma Apheresis
19611	Source Plasma
20000	Serum

* Leukocytes reduced by filtration

Appendix 2:
Plasma Derived Product Names and Codes

Code	Official Name
A1 P1	ALPHA I Proteinase Inhibitor
AICC	Anti Inhibitor Coagulation Complex
AT3	Antithrombin III
C1EI	Esterase Inhibitor
FIB	Fibrinogen
FS	Fibrin Sealant
PRTC	Protein C
FVIIa	Factor VIIa Concentrate
FVIII	Factor VIII Concentrate
FIX	Factor IX Concentrate
F XI	Factor XI Concentrate
FXIII	Factor XIII Concentrate
A5	Albumin 5%
A25	Albumin 25%
HIBIG	Hepatitis B Immune Globulin
ISG	Immune Serum Globulin
IVIG	Intravenous Immune Globulin
RaBIG	Rabies Immune Globulin
RhIG	Rh Immune Globulin
TIG	Tetanus Immune Globulin
VZIG	Varicella Zoster Immune Globulin
SD	SD Plasma

Appendix 3:
Additional Products for Section 5

Suspect Products
Canadian Transfusion Adverse Event Reporting Form

Use the form on the following page when you need to report additional products used. Attach to the completed Canadian Transfusion Adverse Event Reporting Form.

Suspect Products

Transfused blood product									Amount administered						
Product code/name	Product modification		Group of unit			Blood centre code	Unit no. or Lot no.	Expiry Date (ddmmmyyyy)	Volume	Fraction				Transfusion Started Date/Hour (ddmmmyyyy/ hh:mm)	Transfusion Finished Date/Hour (ddmmmyyyy/ hh:mm)
	Hospital	Supplier	ABO	Rh	N/A				ml	1/4	1/2	3/4	4/4		