Public Health Agency of Canada
Agence de la santé publique du Canada

Transfusion Transmitted Injuries Surveillance System

User's Manual

Version 3.0

Canada

Transfusion Transmitted Injuries Surveillance System

User's Manual

Version 3.0

To be used as a guide for completion of the:

Canadian Transfusion Adverse Event Reporting Form

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Transfusion Transmitted Injuries Section
Blood Safety Surveillance and
Health Care Acquired Infections Division
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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, blood components, or blood products (plasma derivatives), 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). TTISS is a national surveillance and monitoring system for reporting of adverse reactions to blood, blood components, or blood products (plasma derivatives). It provides data that will be used for managing the risks related to the transfusion of these products in Canada.

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

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Definitions

Adverse Event: An undesirable and unintended occurrence during or after the administration of blood, blood components, or blood products (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 blood products (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 blood products (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 blood products (plasma derivatives); or

b) the safety of recipients.

Adverse Reaction: An undesirable and unintended response to the administration of blood, blood components, or blood products (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 components, or blood products (plasma derivatives).

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

Blood Product (Plasma Derivative): A product derived from human or animal plasma by a fractionation process. Note: Examples of blood products (plasma derivatives) are human serum albumin, solvent detergent products, immunoglobulin preparations, factor IX, or factor VIII concentrate products. Examples of related products are porcine factor VIII and coagulation factors produced using recombinant DNA.

Provincial/Territorial Blood Office: An office/department established 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 event that may result or has resulted in untoward consequences from blood, blood components, or blood products (plasma derivatives) 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.

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 the patient has had more than one adverse event in **separate** transfusion episodes*, then the separate adverse event details should be completed on separate forms.

If a patient has had more than one adverse event in the **same** transfusion episode*, then all the adverse event details can be reported on the same form.

* A transfusion episode is all blood, blood components or blood products (plasma derivatives) received within a 24 hour period or blood component/product received on different admissions even if discharged and readmitted on the same day.

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 blood office responsible for overseeing this program. See Guidelines for Hospitals to Report Adverse Events to Provincial/Territorial Blood Offices and Canadian Blood Services/HÉMA-QUÉBEC. Please refer to the appropriate Contact List within the Appendices.

What information is transferred to the federal level?

Some of this information of national significance will be electronically transferred to the Public Health Agency of 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 identifiers are transferred to the provincial/territorial or federal level. Additional information may have to be transferred to meet Health Canada regulatory requirements. For a copy of the data elements transferred to the Public Health Agency of Canada for surveillance purposes, contact your provincial/territorial blood office or the Public Health Agency of Canada. Please refer to the appropriate Contact List within the Appendices.

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., suspicion of acute bacterial infection related to a blood component), the Medical Director responsible for blood transfusion and, if appropriate, the local Canadian Blood Services/HÉMA-QUÉBEC blood supplier centre or manufacturer of the blood product (plasma derivative) 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 in the Guidelines to Report Adverse Events.

Guidelines for Hospitals to Report Adverse Events to Provincial/Territorial Blood 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, or blood products (plasma derivatives) must be reported. Provincial/territorial blood offices, blood supplier centres, 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., exclude, defer or special code donors);

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

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

All relevant information (data) from the Canadian Transfusion Adverse Event Reporting Form is to be provided to provincial/territorial blood offices for any adverse events/incidents as per each Provincial/Territorial agreement with their hospitals.

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.

Please refer to the appendix "Serious Adverse Events Requested By CBS" for a list of data elements that the Canadian Blood Services requires.

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

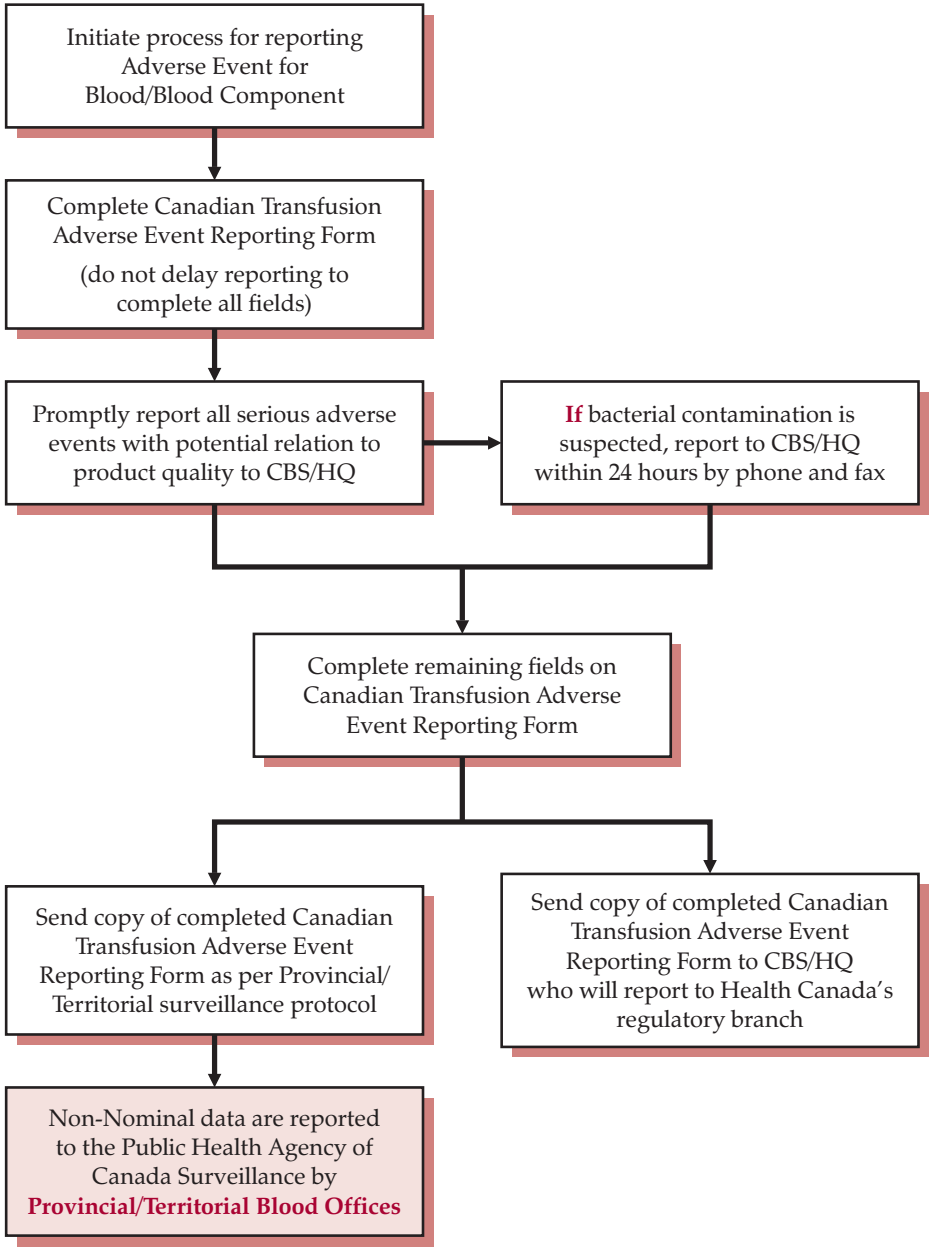
  Refer to the Circular of Information for the Use of Human Blood and Blood Components or contact your local Canadian Blood Services blood supplier centre. (www.bloodservices.ca) Please refer to the CBS Contact List within the Appendices.

- HÉMA-QUÉBEC

  Refer to the Circular of Information for the Use of Labile Blood Products or contact your local HÉMA-QUÉBEC blood supplier centre. (www.hema-quebec.qc.ca) Please refer to the HÉMA-QUÉBEC Contact List within the Appendices.

Please see the flowchart titled "Guidelines for Hospitals to Report Adverse Events for Blood/Blood Components to Provincial/Territorial Blood Offices and Canadian Blood Services/Héma-Québec (CBS/HQ)".

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



Guidelines for Hospitals to Report Adverse Events to Manufacturers of Blood Products (Plasma Derivatives)

What Adverse Events are to be Reported to Manufacturers of Blood Products (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 blood products (plasma derivatives) to allow appropriate investigation, assessment and action.

Manufacturers of blood products (plasma derivatives) are required to report suspected serious adverse reactions to the Canadian Adverse Drug Reaction Monitoring Program (CADRMP), Marketed Health Products Directorate, within 15 days of receiving the report. See the Guidance for industry on reporting adverse reactions to marketed drugs to Health Canada at:

http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/guide/guide-ldir_indust_e.html

Manufacturers of blood products (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 titled "Guidelines for Hospitals to Report Adverse Events for Blood Products (Plasma Derivatives) to Manufacturers".

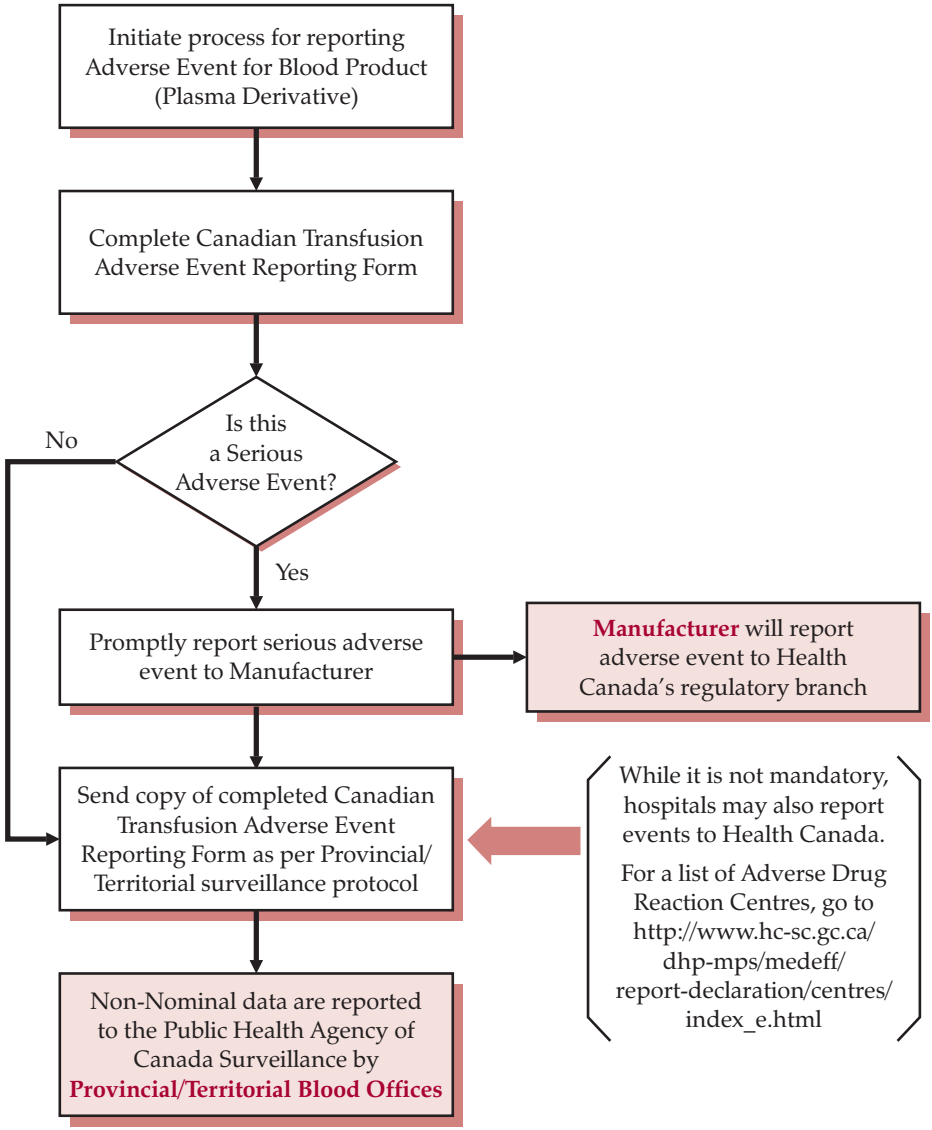
Note: A hospital may also choose to use the Canadian Transfusion Adverse Event Reporting Form to report these events directly to CADRMP through the Regional Adverse Drug Reaction Centre.

Contact information for the manufacturers of blood products (plasma derivatives) can be found on the Canadian Blood Services' website at the following address:

http://www.blood.ca/centreapps/internet/uw_v502_mainengine.nsf/page/E_PlasmaProducts

or in the yellow pages of the Compendium of Pharmaceuticals and Specialties.

Guidelines for Hospitals to Report Adverse Events for Blood Products (Plasma Derivatives) to Manufacturers



Instructions to Complete the Canadian Transfusion Adverse Event Reporting Form

For database users only:
Record closed
Select "Record closed" in the database if the record has been closed.

Category of Event

Select ONLY one of the following categories:

a) **Incident**

Select "Incident" with an (x) or (✓) if an accident or error occurred. Additional details are provided in Section 3a Incident Information.

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

Complete All Sections of the Form for incidents that occurred/were noted during or after the transfusion.

b) **Adverse Reaction**

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

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

Complete All Sections of the Form

c) **Product Transfused**

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

Select "No" with an (x) or (✓) if the blood, blood component or blood product (plasma derivative) was not administered to the recipient.

Please note that for Adverse Reactions, "Yes" should always be selected for "Product Transfused". In the database, if "Adverse Reaction" is selected, then "Product Transfused" will automatically be selected. For Incident, either "Yes" or "No" could be selected for "Product Transfused".

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) **Hospital Code**

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

c) **City**

Enter the city of the facility.

d) **Province**

Enter the province of the facility.

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) **Date of birth**

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

f) **Sex**

Enter the recipient's sex.

Select "Male" with an (x) or (✓) if the recipient is male.

Select "Female" with an (x) or (✓) if the recipient is female.

Select "Other" with an (x) or (✓) if the recipient is a transgender individual (or any other classification not described by the other headings).

Select "Unknown" with an (x) or (✓) if the recipient's sex information is not known.

Section 2 Clinical History

a) **Blood group**

Enter the recipient's ABO (A or B or O or AB) with an (x) or (✓) and enter the recipient's Rh type (Pos or Neg) with an (x) or (✓).

b) **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.

c) **Transfusions**

Select "Yes < 3 mo" with an (x) or (✓) if the recipient received a previous transfusion of a blood, blood component or blood product (plasma derivative) 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, blood component or blood product (plasma derivative) 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.

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 transplantation, chemotherapy, leukemia, hepatitis, hypogammaglobulinemia or other.

e) **Patient Diagnosis/Category**

Enter the patient diagnosis/category from the standardized list 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.

Standardized List for the patient diagnosis/category:

- Hematology/Bone Marrow Transplant
- Oncology
- Medical
- Surgical
- Obstetrics/Gyne/Perinatal
- Trauma
- Neonatal

f) **Other Clinical History**

Select "Other Clinical History" 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, blood components or blood products (plasma derivatives).

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

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

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

b) **Place adverse event occurred**

Enter the location where the adverse event occurred using the following categories:

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

ICU	Intensive Care Unit	**OR**	Operating Room
ER	Emergency	**REC**	Recovery Room
MSW	Medical/Surgical Ward	**CHR**	Chronic Care
OB	Obstetrics	**OP**	Outpatient Clinic

ICU All intensive care units including i.e. neonatal, special care nursery, neuro, medical, burn unit

ER Emergency and/or Trauma areas

MSW All inpatient care areas within a facility i.e. medical ward, surgical, hematology

OB Obstetrics including labour and delivery, case room and birth centre

OR Operating room including day surgery

REC Recovery Room including post anesthesia recovery

CHR Chronic Care refers to long term care facilities/units

OP Outpatient refers to ambulatory care areas, medical day units, essentially where outpatients would come to receive a transfusion during daylight working hours

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 manufacturer ABO error
- Product checked in with wrong group
- Error in product selection and labelling
- Expired product was dispensed
- Incorrect product was ordered for patient
- Product did not meet transfusion requirements
- Incorrect product issued
- Product temperature was unacceptable
- Product was not available.

Specify the details of the incident.

c) **Equipment Related Incident**

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

Examples:

- Filter
- Pump
- Pressure device
- Blood warmer
- Reinfusion device

Specify the details of the incident.

d) **Other Incident**

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

Examples:

- Defective reagents
- Discrepancy with computer history
- Equipment malfunction
- Incorrect IV fluid used to administer product
- Incorrect patient information on blood bank tag
- Incorrect product info entered
- Misinterpretation of results
- Patient info entered incorrectly into system
- Quality control not performed correctly
- Rejected sample

Specify the details of the incident.

Section 3b Premedication and Anesthesia

a) **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 antipyretics (i.e., acetaminophen), antihistamines (i.e., diphenhydramine hydrochloride), corticosteroids (i.e., hydrocortisone, prednisone, solucortef, etc.).

Select "Yes" with an (x) or (✓) if the recipient received medication(s) before the transfusion.

Specify the drug, dose, route administered.

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

b) **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

Section 3c Report of Possible Transfusion Related Blood Borne Infection

a) **Bacterial infection**

Select "Bacterial infection" with an (x) or (✓) if a bacterial infection is suspected.

b) **Viral infection**

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

c) **Other infection**

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

Section 4 Clinical Signs and Laboratory Results

Section 4a Clinical Signs and Symptoms

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

a) **No Clinical Sign/Symptom**

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

b) **Temperature**

"**Before**": Indicate the recipient's temperature in Celsius before the start of transfusion.

"**After**": Indicate the highest recipient temperature in Celsius obtained during the transfusion or within 4 hours of its completion.

c) **Pulse**

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

d) **Respiration**

Indicate the recipient's respiration rate per minute **before** and **after** the transfusion.

e) **Blood Pressure (BP)**

"**Before**": Indicate the recipient's systolic and diastolic BP in mm of Hg before the start of the transfusion.

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

f) **Chills/rigors**

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

g) **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 the transfusion or within 4 hours of its completion.

h) **Other skin rash**

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

i) **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 the transfusion or within 24 hours of its completion.

j) **Hypoxemia**

Select "Hypoxemia" with an (x) or (✓) if the recipient experienced

- $PaO_2/FiO_2 < 300$ mm Hg
  or
- Oxygen saturation < 90% on room air
  or
- Other clinical evidence of hypoxemia

Indicate the recipient's oxygen saturation on the line provided to the right of "O_2 sat:"

k) **Nausea/vomiting**

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

l) **Pain**

Select "Pain" with an (x) or (✓) if the recipient experienced pain during the transfusion or within 4 hours of its completion.

Specify the site of the pain in the space provided.

Example: headache, dorso-lumbar, abdominal, thoracic

m) **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 "Section 4b. Abnormal Tests/ Laboratory Results" as well as the pre-transfusion results, if available.

n) **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

o) **Oliguria**

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

p) **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 the transfusion or within 4 hours of its completion.

q) **Shock**

Select "Shock" with an (x) or (✓) if, with severe 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.

r) **Other**

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

Specify the other signs and symptoms.

Example: diaphoresis, diarrhea, epistaxis, bronchospasm, itching, hyperkalemia, hypercalcemia, disseminated intravascular coagulation, other

Clinical Information for TRALI

s) **Chest X-ray Results**

Select "Bilateral Infiltrates" with an (x) or (✓) if recipient had bilateral pulmonary infiltrates or white lungs or signs of bilateral pulmonary edema.

Select "Other" with an (x) or (✓) if the recipients chest x-ray shows other relevant signs and **describe**.

t) **Evidence of Circulatory Overload**

Select "Yes" with an (x) or (✓) if there is evidence of circulatory overload. **Explain** in the space provided.

Select "No" with an (x) or (✓) if there is no evidence of circulatory overload. **Explain** in the space provided.

u) **Hospital Sample Collection to be sent to blood supplier centre**

Call your local blood supplier centre to obtain the most up-to-date shipping and sample requirements for patient samples; transfused unit(s) sample(s) when available; and crossmatch testing samples (time-sensitive samples).

Section 4b Abnormal Tests/Laboratory Results

a) **Name of Laboratory Tests**

This section reports on the results of laboratory tests related to the investigation of the adverse event. Enter the **Name of Laboratory Tests** and enter the **Date Specimen Taken** (ddmmmyyyy) then select the **Results** with an (x) or (✓) as positive, negative, elevated or decreased.

Example: indirect bilirubin, total bilirubin, plasma hemoglobin, creatinine, haptoglobin, LDH, Coombs' test (DAT), other

b) **Blood Culture Results**

If a blood culture was performed on the **recipient** post transfusion, indicate

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

If a blood culture was performed on the product [blood, blood component, or blood product (plasma derivative)], indicate

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

Additional information regarding bacterial infection can be found in Section 7, Relationship of Adverse Event to Transfusion of this manual.

Section 5 Suspect Blood, Blood Components, or Blood Products (Plasma Derivatives)

All blood, blood components, or blood products (plasma derivatives) that might be related to the adverse transfusion must be identified. The first blood, blood component, or blood product (plasma derivative) listed should be the one most likely associated with the reported adverse event. If it is not possible to identify which blood, blood component, or blood product (plasma derivative) was related to the transfusion, all products should be listed and a note made in the Comments in Section 5 to explain that no one product could be determined to be the likely cause of the reaction.

a) **Transfused blood, blood components, or blood products (plasma derivatives):**

Product code/name

Enter the numeric product code or the name of the blood component/ blood product (plasma derivative) related to the transfusion incident/ adverse reaction from the Blood Component Names and Codes or the Plasma Derived Product Names and Trade Names area in the Appendices.

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 in the Comments in Section 5. Please note: Multiple modifications may be entered e.g. CMV, Pooled.

Product Modification Codes

IRR	Irradiated
CMV	Negative for anti-CMV
D	Deglycerolized
DV	Divided
LV	Low volume
PR	Plasma reduced
W	Washed
P	Pooled
T	Thawed

b) **Group of unit**

Enter the "ABO" and "Rh" group indicated on the bag or the label on the bag.

c) **Blood Supplier Centre Code (formerly "Blood Centre Code")**

Enter the blood supplier centre code, formerly the blood centre code, indicated on the bag or container. Please refer to your local Canadian Blood Services or HÉMA-QUÉBEC codes.

d) **Unit no. or Lot no.**

Enter the unit # of the blood, blood component or lot number of the vial of blood product (plasma derivative) 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 "**Amount**" administered along with the "**Unit of measure**".

or

Enter the estimated "**Fraction**" (1/4, 1/2, 3/4, 4/4) that was administered.

g) **Transfusion Started**
Enter the date (ddmmmyyyy) and time (00:00 to 23:59) the transfusion was started.

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

h) **Comments**

This area should be used to:

- Document if no one product could be determined to be the likely cause of the reaction.
- Document if it was an autologous donation or directed/designated donation.
- Document any abnormal findings, e.g., discoloration, temperatures, presence of clots.
- Document the trade name if the blood product (plasma derivative) was identified, e.g., Gamunex.

Section 6 Measures Taken

Select all that apply:

a) **None**

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

b) **Transfusion Stopped**

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

c) **Transfusion Restarted**

Select "Transfusion Restarted" with an (x) or (✓) if the transfusion was restarted.

d) **Antipyretics**

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

e) **Analgesics**

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

f) **Antihistamines**

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

g) **Steroids**

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

h) **Diuretics**

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

N.B. This information is important particularly when TRALI is suspected.

i) **Vasopressors**

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

j) **Antibiotics**

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

k) **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.

l) **Mechanical Ventilation**

Select "Mechanical Ventilation" with an (x) or (✓) if the recipient was given mechanical ventilation before transfusion and the concentration had to be increased, or if mechanical ventilation administration became necessary for a recipient who had not previously required it. If mechanical ventilation occurred, indicate the **duration** in the space provided.

m) **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.

n) **Chest x-ray**

Select "Chest x-ray" with an (x) or (✓) if a chest x-ray was performed on the recipient.

o) **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.

p) **Product Culture**

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

q) **Other Measures Taken**

Select "Other Measures Taken" 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

Section 7 Results of Investigation & Conclusion

a) **No Transfusion Reaction**

Select "No Transfusion Reaction" with an (x) or (✓) if the investigation indicated the recipient did not experience a transfusion reaction.

b) **Febrile Non-Hemolytic Reaction**

Select "Febrile Non-Hemolytic Reaction" with an (x) or (✓) if the recipient experienced one or more of the following:

- fever (≥38°C and a change of ≥1°C from pretransfusion value),
- chills,
- sensation of cold or
- rigors

(these symptoms may be accompanied by headache and nausea) during the transfusion or within four hours of its completion without any other cause such as hemolytic transfusion reaction, bacterial contamination or underlying condition.

c) **Allergic Reaction**

Minor

Select "Minor" with an (x) or (✓) if the recipient experienced a skin reaction characterized by a transient urticarial or other skin rash with pruritus associated with the transfusion. This reaction may be associated with localized angioedema without respiratory distress.

Severe/Anaphylactic/Anaphylactoid

Select "Severe/Anaphylactic/Anaphylactoid" with an (x) or (✓) if the recipient, in addition to mucocutaneous signs/symptoms experiences airway compromise or severe hypotension requiring vasopressor treatment. The respiratory signs/symptoms may be laryngeal (tightness in the throat, dysphagia, dysphoria, hoarseness, strider) or pulmonary (dyspnea, cough, wheezing/bronchospasm, hypoxemia).

Anaphylactic Shock

Select "Anaphylactic Shock" with an (x) or (✓) if the recipient experiences, in addition to the above mentioned, profound hypotension with loss of consciousness, circulatory collapse or death.

d) **Incompatible Transfusion**

Select "Unintentional" with an (x) or (✓) if the recipient was unintentionally given an incompatible transfusion.

Select "Intentional" with an (x) or (✓) if the recipient was intentionally given an incompatible transfusion.

Select "ABO System" with an (x) or (✓) if the incompatibility of this transfusion was in the ABO system.

Specify the antibody or antibodies identified.

Examples: anti-A, anti-B

If ABO is selected, complete section 3a (Incident Information) to identify the errors, if any, that existed at the origin of the ABO incompatible transfusion.

Select "Other System" with an (x) or (✓) if the incompatibility of the transfusion was exclusive of the ABO system.

Specify the antibody or antibodies identified.

Examples: anti-C, anti-E, anti-c, anti-e, anti-K1, anti-K2, anti-JK^a, anti-JK^b, anti-S, anti-s, anti-Fy^a, anti-Fy^b, anti-M, anti-Le^a, anti-Le^b, HLA.

e) **Hemolytic Reaction**

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

Acute

Select "Acute" with an (x) or (✓) if the recipient experienced a hemolytic reaction within 24 hours of the receipt of the transfusion.

Delayed

Select "Delayed" with an (x) or (✓) if the recipient experienced a hemolytic reaction more than 24 hours and up to 1 month following the transfusion.

Indicate the **cause** of acute and delayed hemolysis such as the antibodies involved in hemolysis of immune origin, ABO incompatibility, equipment or processes involved in mechanical hemolysis.

f) **Delayed Serological Transfusion Reaction (new alloantibodies)**

Select "Delayed Serological Transfusion Reaction (new alloantibodies)" with an (x) or (✓) f the recipient developed new alloantibodies in the 28 days following a transfusion with or without positive Direct Antiglobulin Test (DAT) but no clinical or laboratory signs of hemolysis.

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.

g) **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 type of infection. Refer to Section 4 to obtain this information.

h) **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 type of infection.

Examples: hepatitis B (HBV), hepatitis C (HCV), human immuno-deficiency 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** with an (x) or (✓).

i) **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 type of infection.

Examples: malaria (P. Falciparum, P. Vivax), babesiosis, Lyme disease, syphilis, toxoplasmosis, Creutzfeldt-Jakob Disease, other.

j) **Donor**

Select "Infected" with an (x) or (✓) if the donor is infected.

Select "Uninfected" with an (x) or (✓) if the donor is uninfected.

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

Specify the type of infection.

k) **TACO**

Select "TACO" with an (x) or (✓) if the recipient experienced Transfusion Associated Circulatory Overload (TACO) characterized by dyspnea, cyanosis, orthopnea, hypertension, or congestive heart failure during or within 6 hours of completion of a transfusion.

l) **TAD**

Select "TAD" with an (x) or (✓) if the recipient experienced Transfusion Associated Dyspnea (TAD) which is characterized by respiratory distress within 24 hours of transfusion that does not meet the criteria of TRALI, TACO, or allergic reaction. Respiratory distress should not be explained by the patient's underlying condition.

m) **TRALI**

Select "TRALI" with an (x) or (✓) if the recipient's condition meets the following definition of Transfusion Related Acute Lung Injury (TRALI):

- In patients with no evidence of Acute Lung Injury (ALI) prior to transfusion, TRALI is diagnosed if:
  - New ALI is present:
    - Acute onset
    - Hypoxemia
      - $PaO_2 / FiO_2 \leq 300$ or
      - Oxygen saturation is $< 90\%$ on room air or
      - Other clinical evidence
    - Bilateral lung infiltrates on frontal chest x-ray
    - No evidence of circulatory overload
  - It occurs during, or within 6 hours of completion of transfusion
  - There are no other risk factors for ALI

Indicate the **time to recovery** in hours in the space provided.

n) **Possible TRALI**

Select "Possible TRALI" with an (x) or (✓) if the recipient's condition meets the following definition :

- In patients with no evidence of ALI prior to transfusion, possible TRALI is diagnosed if:
  - New ALI is present
    - Acute onset
    - Hypoxemia
      - $PaO_2 / FiO_2 \leq 300$ or
      - Oxygen saturation is < 90% on room air or
      - Other clinical evidence
    - Bilateral lung infiltrates on frontal chest x-ray
    - No evidence of circulatory overload
  - It occurs during, or within 6 hours of completion of transfusion
  - There are one or more risk factors for ALI:
    - Direct Lung Injury
      - Aspiration
      - Pneumonia
      - Toxic inhalation
      - Lung contusion
      - Near drowning
    - Indirect Lung Injury
      - Severe sepsis
      - Shock
      - Multiple trauma
      - Burn injury
      - Acute pancreatitis
      - Cardiopulmonary bypass
      - Drug overdose

Indicate the **time to recovery** in hours in the space provided.

Indicate the **risk factors for ALI** involved in the space provided.

o) **Hypotensive Reaction**

Select "Hypotensive Reaction" with an (x) or (✓) if the recipient experienced a drop in systolic blood pressure by ≥ 30 mm Hg and a systolic blood pressure below 80 mm Hg or "shock" during the transfusion or within 4 hours of its completion without any other explanation for hypotension such as bacterial infection, bleeding, or severe allergic reaction.

Select "**ACE Inhibitors**" with an (x) or (✓) if the recipient was on ACE inhibitors.

p) **PTP**

Select "PTP" with an (x) or (✓) if the recipient develops Post Transfusion Purpura (PTP) characterized by a sudden severe thrombocytopenia (platelet count <10,000/L) 5-12 days after a cellular blood component transfusion. This condition is most often associated with the presence of antibodies directed against the Human Platelet Antigen (HPA) system in the patient's serum.

q) **TA-GVHD**

Select "TA-GVHD" with an (x) or (✓) if the recipient develops Transfusion Associated Graft Versus Host Disease (TA-GVHD) characterized by 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 occurring 1 to 6 weeks following transfusion. The reaction is very severe and results in death in over 90% of cases.

To prevent GVHD, in Canada, blood components are routinely irradiated 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 components.

r) **Hemochromatosis**

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

s) **Aseptic Meningitis**

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

t) **IVIg Headache**

Select "IVIg Headache" with an (x) or (✓) if the recipient develops a headache during or shortly after Intravenous Immunoglobulin (IVIg) administration.

u) **Unknown**

Select "Unknown" with an (x) or (✓) if the recipient experienced a reaction that cannot be classified and that represents something new and unexpected and is of clinical significance (i.e. red eye syndrome).

v) **Other**

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

Specify the diagnosis.

Examples: severe electrolyte imbalance, atypical pain syndrome, etc.

Note: Atypical pain syndrome 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, blood component, or blood product (plasma derivative) 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, blood component, or blood product (plasma derivative).
- Contamination of the blood sample or laboratory contamination 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, blood component, or blood product (plasma derivative) and did not seem to be explainable by any other cause.

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

- Positive blood, blood component, or blood product (plasma derivative) culture.
- Contamination of the blood sample or laboratory contamination is not suspected.
- The recipient presents signs and symptoms of sepsis (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.

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, blood component, or blood product (plasma derivative) but could also 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 or laboratory contamination is not suspected.
- The recipient presents signs and symptoms of sepsis (nothing else explains it).
- A blood, blood component, or blood product (plasma derivative) culture was not done.
  - No specimen was available.
  - A blood culture was not ordered.

iv) **Doubtful**

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

Bacterial contamination is considered "Doubtful" if:

- The blood, blood component, or blood product (plasma derivative) culture is positive for one pathogen and the recipient's blood culture is positive for a different pathogen, or contaminations of the samples or laboratory specimen are 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, blood component, or blood product (plasma derivative)

or

if it occurred within a consistent time period, and it 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, blood component, or blood product (plasma derivative) 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 reaction.

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**

Select "Death" with an (x) or (✓) if the recipient died.

Relationship of Transfusion to Recipient's Death

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, blood component, or blood product (plasma derivative) 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, blood component, or blood product (plasma derivative) 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, blood component, or blood product (plasma derivative) 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 in relation to the transfusion but the 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, blood component, or blood product (plasma derivative) 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" with an (x) or (✓) 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 had no sequelae or permanent disability from the reaction or developed antibodies to low or medium frequency antigens (<95%).

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.

Blood Supplier Centre/Manufacturer Notified

The blood supplier centre/manufacturer of the blood, blood component, or blood product (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 blood supplier centre.

NOTE: See Reporting Guidelines To Provincial/Territorial Blood Offices and Canadian Blood Services/HÉMA-QUÉBEC or Reporting Guidelines to Manufacturers of Blood Products (Plasma Derivatives)

Select "Yes" with an (x) or (✓) if Canadian Blood Services or HÉMA-QUÉBEC was contacted for issues related to blood, blood components or the manufacturer of the blood product (plasma derivative) was contacted for issues related to it following an adverse transfusion event.

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

OR

Select "No" with an (x) or (✓) if the blood supplier centre/ 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.

Section 9 Comments – Completed by Canadian Blood Services (CBS)

a) **CBS Comments**

Enter comments on the case in the space provided.

b) **Last name**

Enter the last name of the CBS Medical Director.

c) **First name**

Enter the first name of the CBS Medical Director.

d) **Signature**

The CBS Medical Director 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 CBS Medical Director.

f) **Date**

Enter the date (ddmmmyyyy) on which the CBS Medical Director completed the form.

g) **Time**

Enter the time (00:00 to 23:59) at which the CBS Medical Director completed the form.

Appendices

Blood Component Names and Codes

Code	Name
Red Blood Cells (RBCs)	
00180	CP2D WHOLE BLOOD
01480	CPD2 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
04760	SAGM RBC LR
05760	SAGM RBC LR, Irradiated
34761	SAGM RBC LR, Divided-1
34762	SAGM RBC LR, Divided-2
Platelets (PLT)	
12700	CP2D PLATELETS, LRF
Buffy Coat Platelets (Buffy Coat PLT)	
12091	CPD Platelets Pooled LR
12691	CPD Platelets Pooled LR, Irradiated
Platelets – Apheresed (PLT-APH)	
12071	PLATELETS APHERESIS, LRF
Plasma	
18230	FRESH FROZEN PLASMA (CP2D), LRF
191701	FRESH FROZEN PLASMA DIVIDED (CP2D), LRF
18872	PLASMA (CP2D), LRF (AUTOLOGOUS ONLY)
18770	FRESH FROZEN PLASMA (CPDA-1), LRF

Code	Name
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
18161	CPD Frozen Plasma
18465	CPD Cryosupernatant Plasma
18210	ACD Fresh Frozen Plasma Apheresis
Cryoprecipitate (CRYO)	
19070	CRYOPRECIPITATED AHF (CP2D), LRF
10160	CPD Cryoprecipitate

Plasma Derived Product Names and Codes

Code	Name
IVIG	
IVIG	INTRAVENOUS IMMUNE GLOBULIN
RhIG	
RhIG	Rh IMMUNE GLOBULIN
Albumin	
A5	ALBUMIN 5 %
A25	ALBUMIN 25 %
Other Immune Globulin (Other Ig)	
HIBIG	HEPATITIS B IMMUNE GLOBULINE
ISG	IMMUNE SERUM GLOBULIN
RaBIG	RABIES IMMUNE GLOBULIN
TIG	TETANUS IMMUNE GLOBULINE
VZIG	VARICELLA ZOSTER IMMUNE GLOBULIN
Anti CMV	Anti CMV
Coagulation Factor (Coag Fac)	
FVIIa	FACTOR VIIa CONCENTRATE
FVIII	FACTOR VIII CONCENTRATE
FIX	FACTOR IX CONCENTRATE
F XI	FACTOR XI CONCENTRATE
FXIII	FACTOR XIII CONCENTRATE
Other Plasma Derivatives (Other PD)	
A1 P1	ALPHA I PROTEINASE INHIBITOR
AICC	ANTI INHIBITOR COAGULATION COMPLEX
AT3	ANTITHROBIN III
C1EI	ESTERASE INHIBITOR
FIB	FIBRINOGEN
FS	FIBRIN SEALANT
PRTC	PROTEIN C
SD	SD PLASMA

Serious Adverse Events Requested by CBS

As outlined in the current "Circular of Information", Canadian Blood Services (CBS) requires notification of all "serious adverse events" that are possibly related to transfusion of blood and blood components manufactured by CBS.

The following adverse events related to blood and blood components should be promptly reported to CBS and any event that is related to a death or to suspected bacterial contamination of a product should be reported to Canadian Blood Services immediately (i.e. within 24 hours):

i. All deaths

ii. All serious reactions (immediate threat and/or major deterioration):
   - Major allergic/anaphylactic reaction
   - Acute hemolytic reaction
   - Significant Hyperkalemia
   - Delayed *hemolytic* reactions

iii. All of the following reactions regardless of their severity:
   - TRALI
   - Graft-versus-Host Disease
   - Post-transfusion purpura

iv. All cases of suspected bacterial contamination and/or any positive culture of a product. Canadian Blood Services should be contacted for any suspicious case of bacterial contamination, so that products related to the same donation be rapidly put in quarantine or recalled.

v. All post-transfusion infections (i.e. hepatitis A, parvovirus B19, malaria, Chagas, WNv, etc.)

vi. All reactions for which the product quality is doubtful

vii. All unusual reactions (ex: red eye syndrome, severe hypotensive reactions)

viii. Any other reaction with the potential for permanent disablement or loss of life

Adverse events such as febrile nonhemolytic transfusion reactions, allergic reactions and delayed *serologic* reactions would not normally require reporting but should not be excluded if the attending physician feels that the severity of the reaction warrants investigation by the Blood Supplier Centre.

Contact Lists

1. Public Health Agency of Canada (PHAC), Transfusion Transmitted Injuries (TTI) Section
2. Marketed Health Products Directorate
3. Contact List for Provincial/Territorial Blood Offices
4. Local Contact List for Canadian Blood Services
5. HÉMA-QUÉBEC Contact List

Public Health Agency of Canada (PHAC)
Transfusion Transmitted Injuries (TTI) Section

http://www.phac-aspc.gc.ca/hcai-iamss/tti-it

Email address: TTI_Section_IT@phac-aspc.gc.ca

Marketed Health Products Directorate

http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/mhpd-dpsc/index_e.html

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

Your experience with any problems associated with plasma derivatives is important to the Canadian Adverse Drug Reaction Monitoring Program (CADRMP). Adverse reaction information is used by Health Canada to help ensure the benefits of a health product continue to outweigh the risks, to update the labelling and product information for a health product, and to work with market authorization holders and other stakeholders to inform Canadians about adverse reactions.

While serious adverse events to plasma derivatives and those which may question the safety of these products should always be reported to the market authorization holder (manufacturer), who is in a position to take immediate action (whether by putting a product in quarantine, pulling a lot number from circulation, etc), CADRMP is interested in receiving copies of all these adverse reactions. Our reporting form can be found at the following address:

http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/form/index_e.html

However, for your convenience, we are pleased to inform you that we will gladly accept reports made on the Canadian Transfusion Adverse Event Reporting Form.

Health professionals may submit reports toll free to Health Canada at:

Tel: 866 234-2345
Fax: 866 678-6789

Your call will be directed to the appropriate Adverse Reaction Regional Centre. The Canadian Adverse Drug Reaction Monitoring Program at the Marketed Health Products Directorate MHPD is responsible for the collection and assessment of adverse reactions that have been submitted by health care professionals or consumers either directly or through market authorization holders. In Canada, Health Canada has had a system to gather information on adverse reaction reports since 1965. Information on all reported adverse reactions is maintained in a computerized database. This database is a major tool in the ongoing assessment of marketed therapeutic health products.

The Marketed Health Products Directorate (MHPD) of Health Canada is responsible for coordination of consistency of post-market surveillance and assessment of signals and safety trends concerning all marketed health products. The MHPD works in close collaboration with other Directorates in the Health Products and Food Branch and with other involved Branches.

The MHPD conducts the following range of activities:

- monitors and collects adverse reaction and medication incident data,
- reviews and analyses marketed health product safety data,
- conducts risk/benefit assessments,
- communicates product related risks to health care professionals and the public,
- coordinates regulatory advertising activities,
- develops post-approval policy, and
- conducts active surveillance and drug effectiveness projects.

Please be advised that the contact person for this initiative on post-market surveillance of plasma derivatives is Dr. Carole Légaré, Manager, Clinical section for Biologicals and Biotechnology Products, Marketed Biologicals Biotechnology and Natural Health Products Bureau, telephone (613) 946-6506, fax(613) 954-2354, e-mail address Carole_Legare@hc-sc.gc.ca.

We look forward to continuing to participate in this important work.

Christopher Turner, MD FRCPC
Director General
Marketed Health Products Directorate

Contact List for Provincial/Territorial Blood Offices

Northwest Territories

Robin Greig
Manager, Diagnostic & Therapeutic Services
Stanton Territorial Health Authority
550 Byrne Road
Yellowknife, NWT X1A 2N1
(867) 669-4165
Fax: (867) 669-4141

British Columbia & Yukon

Patti Thorne
Administrative Director
Provincial Blood Coordinating Office
St. Paul's Hospital – Hornby Site
1081 Burrard Street
Vancouver, BC V6Z 1Y6
Ph. 604-682-2344 Ext 63149
Fax. 604-806-8824

Alberta

Madeleine Swaters
A/Information Manager Health Surveillance
Population Health Division
Alberta Health and Wellness
10025 Jasper Avenue, 24th Floor
Edmonton, AB T6J 2N3
(780) 415-2833
Fax: (780) 422-3671

Saskatchewan

Judy Hoff
TTISS Project
LIS Specialist/Tech II
Transfusions Department, Regina General Hospital
1440-14th Avenue, Regina, SK S4P 0W5
Office phone: (306) 766-4474
Office fax: (306) 766-4004

Manitoba

Susan Turnbull
Provincial Blood Programs Coordinating Office (PBPCO)
Manitoba Health
3rd floor, 300 Carlton Street
Winnipeg, MB R3B 3M9
(204) 788-6355
Fax: (204) 944-0669

Ontario

1. PRIMARY CONTACT:

Nancy Heddle, MSc, FCSMLS(D)
McMaster Transfusion Research Program
McMaster University
1200 Main Street W, HSC-3N43
Hamilton, ON L8N 3Z5
Phone: 905.525.9140 ext. 22126
Fax: 905.524.2983
Email: heddlen@mcmaster.ca
Website: www.fhs.mcmaster.ca/mtrp

2. SECONDARY CONTACT:

Blood Programs Coordinating Office
Acute Services Division,
Ministry of Health and Long-Term Care
5700 Yonge Street, 4th Floor
Toronto, ON M2M 4K5
Phone: 416-326-6478
Fax: 416-326-6481

Québec
Céline Poulin, MSc.
Conseillère en hémovigilance
Direction de la prévention clinique et de la biovigilance
Direction générale de la Santé publique
Ministère de la Santé et des Services sociaux
1075, Chemin Sainte-Foy, 12e étage
Québec, QC G1S 2M1 Canada
Office phone: (418) 266-6729
Office fax: (418) 266-7510

New Brunswick
Dr. Holy Akwar,
Communicable Disease Epidemiologist
Office of the Chief Medical Officer of Health
NB Department of Health
P. O. Box 5100, Carleton Place
Fredericton, NB E3B 5G8
(506) 453-2323
Fax: (506) 453-8702

Nova Scotia
Carol MacEachern
Program Manager
Nova Scotia Provincial Blood Coordinating Program
Room 7-130, 7th Floor Centennial Building,
1278 Tower Road,
Halifax, NS B3H 2Y9
Office phone: (902) 473-2121
Office fax: (902) 473-2249

Prince Edward Island
Dr. Eaid Kahwash
Hematopathologist – Division Head
PEI Transfusion Service
Dept of Lab Medicine
Queen Elizabeth Hospital
Charlottetown, PE C1A 8T5
Phone: (902) 894-2328
Fax: (902) 894-2415

Newfoundland and Labrador
Marilyn Collins
Provincial Blood Coordinating Office
Department of Health and Community Services
PO Box 8700, St. John's, NL A1B 4J6
Office phone: (709) 729-5246
Office fax: (709) 729-4009

Local Contact List for Canadian Blood Services

http://www.bloodservices.ca/

British Columbia & Yukon
4750 Oak Street
Vancouver, BC V6H 2N9
Tel. 604-879-7551
Fax. 604-875-8004
Blood Products Dist.: Tel. 604-876-7219
or 604-879-1433
Dr. Gershon Growe, Med. Cons.
Tel. 604-707-3449
Fax. 604-875-8004

Edmonton
8249 – 114th Street
Edmonton, AB T6G 2R8
Tel. 780-431-0202
Fax. 780-431-0461
Blood Products Dist.: Tel. 780-431-0777
Dr. Judith Hannon, Med. Dir.
Tel. 780-431-8714
Fax. 780-431-8770

Calgary
737 – 13th Avenue SouthWest
Calgary, AB T2R 1J1
Tel. 403-410-2650
Fax. 403-410-2794
Blood Products Dist.: Tel. 403-589-3399
Dr. Dale Towns, Med. Dir.
Tel. 403-410-2676
Fax. 403-410-2799

Saskatchewan (Saskatoon & Regina)
2571 Broad Street
Regina, SK S4P 3B4
Tel. 306-347-1666
Fax. 306-347-1603
Blood Products Dist.: Tel. 306-536-8444
Dr. Ted Alport, Med. Dir.
Tel. 306-347-1652
Fax. 306-347-1604

Winnipeg
777 William Avenue
Winnipeg, MB R3E 3R4
Tel. 204-789-1000
Fax. 204-775-9215
Blood Products Dist.: Tel. 204-789-1034
or Pager 204-932-1750
Dr. Debra Lane, Med. Dir.
Tel. 204-789-1079
Fax. 204-783-6780

Sudbury
235 Cedar Street
Sudbury, ON P3B 1M8
Tel. 705-674-2636
Fax. 705-674-7165
Blood Products Dist.: Tel. 705-674-4123
Dr. Peter Lesley, Med Dir.
Tel. 613-560-7209
Fax. 613-560-7226

London
850 Commissioners Road East
London, ON N6C 2V5
Tel. 519-690-3999
Fax. 519-690-3960
Blood Products Dist.: Tel. 519-681-6783
Dr. Morris Blajchman, Med. Dir.
Tel. 905-525-9140 Ext. 26276
Fax. 905-527-4866

Central Ontario
67 College Street
Toronto, ON M5G 2M1
Tel. 416-974-9900
Fax. 416-974-9851
Blood Products Dist.: Tel. 416-379-0559
Dr. Benjamin Saxon
Tel. 416-313-4560
Fax. 416-974-9757

Hamilton
299 Main Street East
Hamilton, ON L8N 1H8
Tel. 905-645-6555
Fax. 905-540-5803
Blood Products Dist.: Tel. 905-645-6558
Dr. Morris Blajchman, Med. Dir.
Tel. 905-525-9140 Ext. 26276
Fax. 905-527-4866

Ottawa
40 Concourse Gate
Ottawa, ON K2E 8A6
Tel. 613-560-7440
Fax. 613-560-7226
Blood Products Dist.: Tel. 613-560-7212
Dr. Peter Lesley, Med. Dir.
Tel. 613-560-7209
Fax. 613-560-7226

New Brunswick
405 University Avenue
Saint John, NB E2L 4G7
Tel. 506-648-5012
Fax. 506-648-5077
Blood Products Dist.: Tel. 506-648-5055
Dr. Karl Misik, Med Dir.
Tel. 709-758-8086
Fax. 709-758-2441

Halifax
1940 Gottingen Street
Halifax, NS B3J 3B7
Tel. 902-474-8200
Fax. 902-474-8206
Blood Products Dist.: Tel. 902-474-8300
Dr. Irene Sadek, Med. Cons.
Tel. 902-474-8286 or 8211
Fax. 902-474-8206

Newfoundland & Labrador
7 Wicklow Street
St. John's, NL A1B 3Z9
Tel. 709-758-5300
Fax. 709-758-5324
Blood Products Dist.: Tel. 709-682-4267
Dr. Karl Misik, Med. Dir.
Tel. 709-758-8086
Fax. 709-758-2441

HÉMA-QUÉBEC Contact List

http://www.hema-quebec.qc.ca

Service clientèle-hôpitaux
Héma-Québec
4045 chemin Côte-Vertu
Ville Saint-Laurent, Qc
H4R 2W7
Tel.: 514-832-5000 #6909
Fax: 514-904-2522