

INCIDENT (Complete sections 1,3, & 6 before & complete all sections during/after) }
 ADVERSE REACTION (Complete all sections) } PRODUCT TRANSFUSED YES NO

FACILITY IDENTIFICATION

NAME OF FACILITY	HOSPITAL CODE	CITY	PROVINCE
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1. RECIPIENT IDENTIFICATION

LAST NAME	FIRST NAME	Date of Birth: <table style="display: inline-table; border: none;"><tr><td style="width: 20px; border-bottom: 1px solid black;"></td><td style="width: 20px; border-bottom: 1px solid black;"></td><td style="width: 20px; border-bottom: 1px solid black;"></td><td style="width: 20px; border-bottom: 1px solid black;"></td><td style="width: 20px; border-bottom: 1px solid black;"></td><td style="width: 20px; border-bottom: 1px solid black;"></td></tr></table> Sex: <input type="checkbox"/> Male <input type="checkbox"/> Other <input type="checkbox"/> Female <input type="checkbox"/> Unknown						
HEALTH CARD NUMBER	HOSPITAL CARD NUMBER							

2. CLINICAL HISTORY

Blood Group: ABO: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> O <input type="checkbox"/> AB Rh: <input type="checkbox"/> Pos <input type="checkbox"/> Neg Pregnancies/Miscarriages <input type="checkbox"/> Yes <3 mo. <input type="checkbox"/> Yes >3 mo. <input type="checkbox"/> No <input type="checkbox"/> Unknown Transfusions <input type="checkbox"/> Yes <3 mo. <input type="checkbox"/> Yes >3 mo. <input type="checkbox"/> No <input type="checkbox"/> Unknown Immune-Compromised <input type="checkbox"/> Yes.....Describe: _____	Patient Diagnosis/Category: _____ <i>Please see reverse for categories.</i> <input type="checkbox"/> Other Clinical HistoryDescribe: _____
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3. DATE, TIME AND PLACE OF INCIDENT / ADVERSE REACTION

Date and time occurred:	Day	Month	Year	Time (hh:mm)	Place occurred: <input type="checkbox"/> ICU <input type="checkbox"/> ER <input type="checkbox"/> MSW <input type="checkbox"/> OB <input type="checkbox"/> OR <input type="checkbox"/> REC <input type="checkbox"/> CHR <input type="checkbox"/> OP <i>Please see reverse for definitions.</i>
Date and time reported:	Day	Month	Year	Time (hh:mm)	

3a. Incident Information

Patient Identification Incident.....Specify: _____
 Product Related Incident.....Specify: _____
 Equipment Related Incident.....Specify: _____
 Other Incident.....Specify: _____

3b. Premedication and Anesthesia

Premedication: Yes No

Specify drug/dose/route: _____

Transfused under anesthesia: General Local/regional None

3c. Report of Possible Transfusion Related Blood Borne Infection

Bacterial Infection Viral Infection Other Infection

4. CLINICAL SIGNS AND LABORATORY RESULTS

4a. Clinical Signs and Symptoms

<input type="checkbox"/> No Clinical Sign/Symptom <input type="checkbox"/> Temperature before: ____ after: ____ <input type="checkbox"/> Pulse before: ____ after: ____ <input type="checkbox"/> Respiration before: ____ after: ____ <input type="checkbox"/> Blood Pressure... before: ____ after: ____	<input type="checkbox"/> Chills/rigors <input type="checkbox"/> Urticaria <input type="checkbox"/> Other skin rash <input type="checkbox"/> Shortness of breath <input type="checkbox"/> Hypoxemia O ₂ sat: ____ <input type="checkbox"/> Nausea/vomiting	<input type="checkbox"/> Pain Specify: _____ <input type="checkbox"/> Jaundice <input type="checkbox"/> Hemoglobinuria <input type="checkbox"/> Oliguria <input type="checkbox"/> Diffuse Hemorrhage <input type="checkbox"/> Shock <input type="checkbox"/> Other Specify: _____
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Clinical Information for TRALI:

Chest X-ray Results: Bilateral Infiltrates Other Describe: _____
 Evidence of Circulatory Overload: Yes No } Explain: _____
 Hospital Sample Collection to be sent to blood supplier centre – *please see reverse for instructions*

4b. Abnormal Tests/Laboratory Results

Name of Laboratory Tests:	Date Specimen Taken (ddmmyyyy)	Results			
		Positive	Negative	Elevated	Decreased
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Blood Culture Results:	Date/Time Specimen Taken		# of Positive	# of Negative	If positive, specify organism(s) identified (genus/species)	Unit no. or Lot no.
	(ddmmyyyy)	(hh:mm)				
For culture performed on recipient post transfusion						
For culture performed on the product						

1. RECIPIENT IDENTIFICATION					
LAST NAME	FIRST NAME	Date of Birth:	Day	Month	Year
HEALTH CARD NUMBER	HOSPITAL CARD NUMBER				
		Sex:	<input type="checkbox"/> Male	<input type="checkbox"/> Other	<input type="checkbox"/> Female
			<input type="checkbox"/>	<input type="checkbox"/> Unknown	

7. RESULTS OF INVESTIGATION & CONCLUSION (CONTINUED)										
<input type="checkbox"/> TACO <i>*Please see reverse for definitions.</i>	<input type="checkbox"/> Hypotensive Reaction ↳ <input type="checkbox"/> ACE Inhibitors	<input type="checkbox"/> Aseptic Meningitis								
<input type="checkbox"/> TAD*	<input type="checkbox"/> PTP	<input type="checkbox"/> IVIg headache								
<input type="checkbox"/> TRALI* Time to Recovery (hrs) _____	<input type="checkbox"/> TA-GVHD	<input type="checkbox"/> Unknown								
<input type="checkbox"/> Possible TRALI* Time to Recovery (hrs) _____	<input type="checkbox"/> Hemochromatosis	<input type="checkbox"/> Other Results of Investigation ↳ Specify: _____								
<input type="checkbox"/> Risk Factors: _____										
Relationship of Adverse Event to Transfusion:	<i>Please see reverse for definitions.</i>	<input type="checkbox"/> Definite	<input type="checkbox"/> Probable	<input type="checkbox"/> Possible	<input type="checkbox"/> Doubtful	<input type="checkbox"/> Ruled Out	<input type="checkbox"/> Not Determined			
Severity of Adverse Event: <i>Please see reverse for definitions.</i>	<input type="checkbox"/> Grade 1 (Non-Severe)	<input type="checkbox"/> Grade 2 (Severe)	<input type="checkbox"/> Grade 3 (Life-threatening)	<input type="checkbox"/> Grade 4 (Death) ↳ Describe the circumstances of death: _____	Outcome of Adverse Event: <i>Please see reverse for definitions.</i>	<input type="checkbox"/> Death ↳ Relationship of transfusion to recipient's death:	<input type="checkbox"/> Major or Long-Term Sequelae	<input type="checkbox"/> Minor or No Sequelae	<input type="checkbox"/> Not Determined	<input type="checkbox"/> Definite <input type="checkbox"/> Doubtful <input type="checkbox"/> Probable <input type="checkbox"/> Ruled Out <input type="checkbox"/> Possible <input type="checkbox"/> Not Determined
Hospital Procedure Involved:	Describe: _____	Action: _____								
Equipment/Supplies Involved:	Describe: (include brand names/lot/model numbers) _____	Action: _____								
Medical Follow-up:	Treatment or Preventative Measures: _____									
Blood Supplier Centre/Manufacturer Notified:	<input type="checkbox"/> Yes Name of person contacted: _____	Date & Time:	Day	Month	Year	Time (hh:mm)				
Status of Investigation:	<input type="checkbox"/> In progress	<input type="checkbox"/> Concluded	<input type="checkbox"/> Cannot be conducted Reason: _____							

8. COMMENTS									
Reporting Physician or Designate:	Last Name	First Name	Signature:						
Telephone Number: () () ()	Ext	Date & Time:	Day	Month	Year	Time (hh:mm)			

9. COMMENTS – COMPLETED BY CANADIAN BLOOD SERVICES (CBS)									
CBS Medical Director:	Last Name	First Name	Signature:						
Telephone Number: () () ()	Ext	Date & Time:	Day	Month	Year	Time (hh:mm)			

2. CLINICAL HISTORY

Standardized List for the patient diagnosis/category:

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

3. DATE, TIME AND PLACE OF INCIDENT / ADVERSE REACTION

Place of Incident/Adverse Reaction

- | | |
|---|---|
| ICU Intensive Care Unit
All intensive care units including i.e. neonatal, special care nursery, neuro, medical, burn unit | OR Operating Room
Operating room including day surgery |
| ER Emergency
Emergency and/or Trauma areas | REC Recovery Room
Recovery Room including post anesthesia recovery |
| MSW Medical/Surgical Ward
All inpatient care areas within a facility i.e. medical ward, surgical, hematology | CHR Chronic Care
Chronic Care refers to long term care facilities/units |
| OB Obstetrics
Obstetrics including labour and delivery, case room and birth centre | OP Outpatient Clinic
Outpatient refers to ambulatory care areas, medical day units, essentially where outpatients would come to receive a transfusion during daylight working hours |

4. CLINICAL SIGNS AND LABORATORY RESULTS

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
 - crossmatch testing samples (time-sensitive samples)

5. SUSPECT BLOOD, BLOOD COMPONENTS, OR BLOOD PRODUCTS (PLASMA DERIVATIVES)

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 |

Blood Supplier Centre Codes

Please refer to your local Canadian Blood Services or HÉMA-QUÉBEC codes.



7. RESULTS OF INVESTIGATION & CONCLUSION

Definition of Transfusion Associated Dyspnea (TAD)

TAD 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.

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
 - ▷ $\text{PaO}_2 / \text{FiO}_2 < 300$ 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

Definition of Possible Transfusion Related Acute Lung Injury

- In patients with no evidence of ALI prior to transfusion, possible TRALI is diagnosed if:
 - **New ALI is present:**
 - Acute onset
 - Hypoxemia
 - ▷ $\text{PaO}_2 / \text{FiO}_2 < 300$ 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:
Predisposing factors for ALI include:
 - 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

7. RESULTS OF INVESTIGATION & CONCLUSION (CONTINUED)

Relationship of Adverse Event to Transfusion

Definite

Select "Definite" 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.

Probable

Select "Probable" 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.

Possible

Select "Possible" 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.

Doubtful

Select "Doubtful" 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 the blood, blood component, or blood product (plasma derivative) culture is positive or the recipient's blood culture is positive but contamination of the sample or laboratory specimen is suspected.

Ruled out

Select "Ruled Out" 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.

Not Determined

Select "Not Determined" 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

Grade 1 (Non-Severe)

Select "Grade 1 (Non-Severe)" 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.

Grade 2 (Severe)

Select "Grade 2 (Severe)" 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.

Grade 3 (Life-threatening)

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

Grade 4 (Death)

Select "Grade 4 (Death)" if the recipient's death was suspected to be the consequence of a transfusion reaction.

Not determined

Select "Not determined" if the consequences of the transfusion reaction are not certain.

Outcome of Adverse Event

Death

Select "Death" 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" 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" 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" 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" 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" 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" if it cannot be determined if the recipient's death was related to the transfusion.

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).

Minor or No Sequelae

Select "Minor or No Sequelae" if the recipient had no sequelae or permanent disability from the reaction or developed antibodies to low or medium frequency antigens (<95%) or other minor reactions.

Not Determined

Select "Not Determined" if the outcome of the adverse event is not certain.