Saskatchewan Transfusion Adverse Event Report Form

Sask Blood

Patient Demographics

Please print both sides and place patient identifiers on PAGES 1 & 2

Patient Legal Last Name: _____

Patient Legal First Name: _____

HSN/MRN: _____

Date of Birth (dd/mm/yyyy): _____

❑ Male ❑ Female ❑ Other

Reporting Facility Name: _____

Phone Number: _____ **Fax Number:** _____

Diagnosis: _____

Indication for Transfusion: _____

Category (choose one): ❑ Hematology/BMT ❑ Oncology ❑ Medical ❑ Surgical ❑ Obstetrics/Gyn/Perinatal ❑ Trauma ❑ Neonatal/Peds

1. Patient and Blood Component/Product Unique Identifier Verification (Clerical check)

Is the information **IDENTICAL** on all the following: ❑ Patient ID band ❑ Issue document/tag ❑ Blood component/product label? ❑ **YES** ❑ **NO**

IF NO, contact TM Lab **IMMEDIATELY**. **Another patient may be at risk.** Date /Time TM Lab notified: Person contacted:

2. Clinical History (Check all that apply)

❑ Pre-existing fever (T ≥ 38.0°C before transfusion)	❑ History or pre-transfusion evidence of hypervolemia	❑ Immune-compromised (specify):
❑ Transfused under GENERAL anesthesia ❑ Transfused under REGIONAL anesthesia	❑ Transfusion pre-medication (specify):	Patient currently prescribed: ❑ ACE inhibitor ❑ Diuretic ❑ Antibiotic(s) (specify):

History of transfusion:	❑ Yes (within 3 months)	❑ Yes (> 3 months)	❑ No	❑ Unknown
History of pregnancies/miscarriages:	❑ Yes (within 3 months)	❑ Yes (> 3 months)	❑ No	❑ Unknown

3. Patient Care Area, Date and Time of Transfusion Reaction

Choose one: ❑ ICU ❑ ER ❑ Medical Ward ❑ Surgical Ward ❑ OR/PACU ❑ OB/Gyn ❑ Outpatient ❑ Chronic Care ❑ Other:

Date (dd/mm/yyyy)	Time Transfusion **Started**	Time Reaction **Occurred**	Time Transfusion **Stopped**	Time Transfusion **Restarted** **Only upon medical direction**	Time Transfusion **Completed**

4. Vitals & Clinical Signs and Symptoms

Pre-transfusion	Temp: °C (route)	BP:	Pulse:	Resp:	SpO_2:	O_2 Source:
During reaction	Temp: °C (route)	BP:	Pulse:	Resp:	SpO_2:	O_2 Source:
Post-transfusion	Temp: °C (route)	BP:	Pulse:	Resp:	SpO_2:	O_2 Source:

Clinical Signs and Symptoms (Check all that apply; attach medication record, nursing notes, physician notes, and transfusion administration record, if available)

❑ Fever **(Oral T ≥38°C AND ≥1°C rise above baseline temp)**
❑ Chills (sensation of cold)
❑ Rigors (involuntary shaking)
❑ Urticaria (hives)
❑ Pruritus (itching)
❑ Skin rash other than urticarial
  ❑ < ⅔ body affected
  ❑ > ⅔ body affected
❑ Dyspnea (shortness of breath)
❑ Hypoxemia: SpO_2 _____% or PaO_2_____ mm Hg on
  ❑ Room air
  ❑ Supplementary O_2 _____L/min
❑ Wheezing
❑ Hypotension (SBP drop by ≥ 30mmHg)
  - 18 years and older → Drop in systolic BP > 30 mmHg AND systolic BP ≤ 80 mmHg
  - < 18 years → Greater than 25% drop in systolic BP or MAP from baseline
❑ Flushing
❑ Jaundice
❑ Facial or tongue swelling
❑ Nausea/vomiting
❑ Restlessness/anxiety
❑ Dizziness
❑ Headache
❑ Back/chest pain
❑ Heat/pain at IV site
❑ Joint/muscle pain
❑ Red or brown urine
❑ Oliguria
❑ Diffuse hemorrhage
❑ Shock or hemodynamic instability requiring cardiorespiratory support
❑ Other relevant clinical information:

5. Blood Component/Product(s) and Equipment Information (Attach sheet with additional information if needed)

Blood Component/Product Type	Product ABO/Rh	Unit Number or Lot Number	Expiry Date (dd/mm/yyyy)	Volume Transfused (mL)	Transfusion Rate (mL/hr)

Blood Filters or Medical Devices Used	❑ Standard blood filter	❑ Other blood filter	❑ IV pump	❑ Blood warmer	❑ Rapid infusion device
	❑ Hemodialysis machine	❑ Apheresis machine	❑ Cell saver	❑ Other:	

6. Measures Taken and Notifications

6a. Transfusion Reaction Treatment Measures Taken (Check all that apply)

❑ None	❑ Antipyretics	❑ Diuretics	❑ Code Blue Activated	❑ Other Measures Taken Specify:
❑ Transfusion Interrupted & Restarted	❑ Analgesics	❑ Vasopressors	❑ ICU Transfer	
❑ Transfusion Discontinued	❑ Antihistamines	❑ Antibiotics	❑ Chest X-ray	
	❑ Steroids	❑ Respiratory Support	❑ Patient Blood Culture Ordered	

6b. Notifications

❑ **Most Responsible Physician Name:**	Date/Time:	❑ **TM Physician Name:**	Date/Time:	❑ **TM Lab Person:**	Date/Time:

Reported By:	Signature:	Name (print):	Designation:
	Facility:		Date/Time:

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❑ Male ❑ Female ❑ Other

TO BE COMPLETED BY THE TRANSFUSION MEDICINE LABORATORY

Testing Lab Name(s):

7. Laboratory Investigation and Notifications

7a. History of Previous Transfusion Reactions

❑ None ❑ Unknown ❑ Yes (within 3 months) ❑ Yes (> 3 months)

Type of previous reaction:

7b. Investigation Required ❑ Lab Clerical Check, Visual Plasma Check; **NO** serological investigation needed ❑ DSTR ❑ Level 1 ❑ Level 2

7c. Lab Results (attach all reports with the results of completed investigations, where applicable)

	Lab Order #:	Lab Order #:		Lab Order #:	Lab Order #:
Level 1 Investigation	**Pre-transfusion Result**	**Post-transfusion Result**	**Level 2 Investigation**	**Pre-transfusion Result**	**Post-transfusion Result**
Lab Clerical Check	❑ pass ❑ fail	❑ pass ❑ fail	DAT	❑ negative ❑ positive	
Visual Plasma Check	❑ negative ❑ positive	❑ negative ❑ positive	ABO/Rh	❑ patient ❑ RBC unit	
DAT		❑ negative ❑ positive	Ab Screen	❑ negative ❑ positive	❑ negative ❑ positive
Patient ABO/Rh			IAT Crossmatch		
❑ **Investigation for Bacterial Contamination/Sepsis** (attach all blood culture reports)		❑ Patient	Lab Order #:	Date taken:	❑ positive ❑ negative
		❑ Product	Lab Order #:	Date taken:	❑ positive ❑ negative

7d. Notifications / Reports (check and provide details for all that apply)

Local Safety/Risk Management Program ❑ No ❑ Yes → Contact Person: _____ Date Reported: _____

CBS or Product Manufacturer ❑ No ❑ Yes → Contact Person: _____ Date Reported: _____

Health Canada ❑ ARs ❑ E/As ❑ No ❑ Yes → Contact Person: _____ Date Reported: _____

Fax SK Adverse Event Report Form to Saskatoon 306-655-2222 or Regina 306-766-4382

TO BE COMPLETED BY TRANSFUSION MEDICINE PHYSICIAN OR DESIGNATE

8. Review of Investigation & Conclusion (based on 2007 PHAC definitions and 2020 CBS TRALI Data Form)

❑ No transfusion reaction ❑ FNHR ❑ Minor allergic ❑ Severe allergic/anaphylactic/anaphylactoid ❑ Anaphylactic shock

❑ Incompatible transfusion ❑ Intentional ❑ Unintentional ❑ ABO System Anti-_____ ❑ Other System Anti-_____

❑ Acute hemolytic reaction ❑ Delayed hemolytic reaction Cause: _____

❑ Delayed serological transfusion reaction (DSTR) Specify new alloantibody(ies) within 28 days of transfusion: Anti-_____

❑ Blood-borne infection: ❑ Bacterial ❑ Viral ❑ Other (specify): _____

❑ Recipient Specify organism: _____

❑ Donor/product infected ❑ Yes ❑ No If yes, specify organism: _____

❑ TACO → ❑ Diuretics effective ❑ TAD ❑ PTP ❑ TA-GVHD ❑ Hypotensive reaction

❑ Definitive TRALI* ❑ Possible TRALI** → Risk factors: _____

Number of CBS TRALI criteria met: ❑ CBS TRALI form sent Date: _____

❑ Hypoxemia → ❑ SpO2 < 90% on Room Air **or** ❑ PaO2/FiO2 ≤ 300 mmHg ❑ ALI onset within 6 hours of cessation of transfusion

❑ New Chest X-Ray findings of bilateral infiltrate ❑ No evidence of circulatory overload (Diuretics ineffective)

*Definitive TRALI: No evidence of lung injury pre-transfusion *Possible TRALI: Evidence of other causes of lung injury

❑ Aseptic meningitis (IVIG related) ❑ IVIG headache ❑ IVIG associated hemolysis ❑ Unknown ❑ Other (specify):

Implication Cause of Transfusion Reaction (if applicable):

❑ Incident (Error/Accident) ❑ Patient identification ❑ Product related ❑ Equipment related ❑ Other (specify):

9. Relationship, Severity and Outcome of Adverse Reaction

a. Relationship of reaction to transfusion	❑ Definite	❑ Probable	❑ Possible	❑ Doubtful	❑ Ruled out	❑ Not determined
b. Severity (Grade)	❑ 1 (non-severe)	❑ 2 (severe)	❑ 3 (life-threatening)		❑ 4 (death)	❑ Not determined
c. Outcome	❑ Minor or no sequelae		❑ Major or long-term sequelae		❑ Death	❑ Not determined
d. Status of investigation	❑ In progress	❑ Concluded	❑ Cannot be concluded → Reason (specify):			

10. Comments and Recommendations

11. Conclusion Sign Off

TM Physician	Signature:	Name (print):	Date:
For cases reported to Health Canada: **Local TM Medical Director/Pathologist**	Signature:	Name (print):	Date:

SK TTISS Number: _____ **CNPHI Number:** _____