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
☐ Transfusion Interrupted & Restarted
☐ Transfusion Discontinued
☐ Antipyretics
☐ Analgesics
☐ Antihistamines
☐ Steroids
☐ Diuretics
☐ Vasopressors
☐ Antibiotics
☐ Respiratory Support
☐ Code Blue Activated
☐ ICU Transfer
☐ Chest X-ray
☐ Patient Blood Culture Ordered
☐ Other Measures Taken Specify:

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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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:** _____