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): _____

Gender: ❑ Male ❑ Female ❑ Unknown

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 TMS/Lab **IMMEDIATELY**. **Another patient may be at risk.** Date /Time TMS/Lab notified: Person contacted:

2. Clinical History (Check all that apply)

❑ Pre-existing fever (T ≥ 38.0ºC 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:	❑ No	❑ Unknown	❑ Yes (within 3 months) ❑ Yes (> 3 months)
History of pregnancies/miscarriages:	❑ No	❑ Unknown	❑ Yes (within 3 months) ❑ Yes (> 3 months)

3. Location, Date and Time of Transfusion Reaction

Choose one: ❑ ICU ❑ ER ❑ Medical Ward ❑ Surgical Ward ❑ OR/Post Anesthesia Care ❑ OB/Gyn ❑ Outpatient ❑ Chronic Care ❑ Lab (Serologic)

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)**
❑ Urticaria (hives)
❑ Pruritus (itching)
❑ Skin rash other than urticarial
→ ❑ < ¼ body affected ❑ > ¼ body affected
❑ Dyspnea (shortness of breath)
❑ Headache
❑ Chills (sensation of cold)
❑ Rigors (involuntary shaking)
❑ Flushing
❑ Restlessness/anxiety
❑ Nausea/vomiting
❑ Joint/muscle pain
❑ Back pain
❑ Chest pain
❑ Heat/pain at IV site
❑ Dizziness
❑ Jaundice
❑ Red or brown urine
❑ Oliguria
❑ Diffuse hemorrhage
❑ Facial or tongue swelling
❑ Wheezing
❑ Hypoxemia: SpO_2 _____% or PaO_2_____ mm Hg on
❑ Room air
❑ Supplementary O_2 _____L/min
❑ Hypertension
❑ Hypotension (SBP drop by ≥ 30mmHg)
❑ Tachycardia (HR rise by > 40bpm)
❑ Shock

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/min)

Filters or Equipment Used: ❑ Standard blood filter ❑ Other blood filter ❑ IV pump ❑ Blood warmer ❑ Rapid infusion device ❑ Re-infusion device ❑ Cell saver Details:

6. Measures Taken and Notifications

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

❑ None	❑ Analgesics	❑ Vasopressors	❑ ICU	❑ Other Measures Taken
❑ Transfusion Stopped	❑ Antihistamines	❑ Antibiotics	❑ Chest X-ray	Specify:
❑ Transfusion Restarted	❑ Steroids	❑ Supplementary O_2	❑ Patient Blood Culture Ordered	
❑ Antipyretics	❑ Diuretics	❑ Mechanical Ventilation	❑ Product Sent to Lab	

6b. Notifications

❑ **Physician Name:** Date/Time: ❑ **TMS/Lab Name:** Date/Time:

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

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TO BE COMPLETED BY THE TRANSFUSION SERVICE/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)

Facility Risk Management	❑ No	❑ Yes →	Contact Person: _____	Date Reported: _____
CBS or Product Manufacturer	❑ No	❑ Yes →	Contact Person: _____	Date Reported: _____
Health Canada	❑ 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 SK TRANSFUSION MEDICINE CONSULTANT OR DESIGNATE

8. Review of Investigation & Conclusion (based on 2007 PHAC definitions)

❑ No transfusion reaction ❑ FNH ❑ 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-_____

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

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

❑ Recipient Specify organism: _____

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

❑ TRALI ❑ Possible TRALI → Risk factors: _____

❑ CBS TRALI criteria met (1+2+3+4): ❑ CBS TRALI form sent Date: _____

1 ❑ Hypoxemia → ❑ SpO_2 < 90% on Room Air **or** ❑ PaO_2 < 60 mm Hg on Room Air **or** ❑ PaO_2/FIO_2 < 300 2 ❑ Transfusion within 6 hours of TRALI

3 ❑ New Chest X-Ray findings of bilateral infiltrates 4 ❑ No evidence of circulatory overload → ❑ Diuretics ineffective Ventilation Duration: _____

❑ 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

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

Reportable to PHAC: ❑ **Yes** ❑ **No** **SK TTISS Number:** _____ **CNPHI Number:** _____