

Government of Newfoundland and Labrador

Department of Health and Community Services Provincial Blood Coordinating Program

IDENTIFICATION AND MANAGEMENT OF ADVERSE TRANSFUSION REACTIONS

NLBCP-036

Office of Administrative	Issuing Authority
Responsibility	
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Overview

An adverse transfusion reaction is defined as an undesirable and unintended response to the administration of blood components and/or blood products that is considered to be definitely, probably, or possibly related to the administration of blood components and/or blood products. Transfusion of a blood component and/or product is not without risks and should involve a risk versus benefit discussion with the patient and/or substitute decision maker to ensure informed consent is obtained (see <u>Consent for or Refusal of Administration of Blood Components and/or Blood Products</u>).

Once an adverse transfusion reaction occurs, the transfusion should be stopped, the reaction reported to the Transfusion Medicine Laboratory (TML) for investigation (see <u>Investigation of Adverse</u> <u>Transfusion Reactions</u>), and the physician/nurse practitioner notified for a clinical assessment of the recipient. Depending on the type and severity of reaction, treatment may be required and a decision made on whether or not to resume the transfusion, proceeding with caution.

The Transfusion Safety Officer (TSO) for the specific site further investigates the reaction and determines the type and severity of reaction (collaborating with the Provincial Blood Coordinating Program including the Medical Advisor, Canadian Blood Services (CBS), and Health Canada as needed - see <u>Reporting of Adverse Events</u>). The TSO then enters the information into the Transfusion Transmitted Injury Surveillance System (TTISS), a program of the Public Health Agency of Canada. The data inputted into TTISS is used to compile an Annual Report on Adverse Transfusion Reactions in Newfoundland and Labrador. This report assists the Provincial Blood Coordinating Program and the Regional Health Authorities (RHAs) in identifying areas to improve early identification and appropriate management of adverse transfusion reactions and assists in identifying required educational needs for transfusion practice in general.

Policy

- 1. All RHAs shall have policies, processes and procedures in place for documentation, reporting, evaluation, investigation and follow-up of all adverse transfusion reactions.
- All RHAs shall have policies in place for monitoring of recipients during transfusion of blood components or administration of blood products to detect signs and symptoms that indicate onset of an adverse transfusion reaction (see <u>Transfusion of Blood Components and</u> <u>Administration of Blood Products</u>).
- 3. All RHAs shall include a list of common signs and symptoms of transfusion-related adverse reactions in nursing practice policy manuals and TML policy manuals.
- 4. Transfusionists shall provide education to recipients regarding signs and symptoms that may indicate onset of an adverse transfusion reaction.
- 5. Transfusionists shall **immediately** report, to the health care provider and the TML, the following suspected adverse transfusion reactions:

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- 5.1. hemolytic transfusion reactions, both immediate/acute and delayed,
- 5.2. transfusion-related acute lung injury (TRALI),
- 5.3. systemic allergic reactions including anaphylactic shock,
- 5.4. bacterial sepsis,
- 5.5. other transfusion-transmissible infections,
- 5.6. transfusion-associated graft versus host disease (TA-GVHD),
- 5.7. post-transfusion purpura,
- 5.8. other serious reactions, and
- 5.9. death.
- 6. All clinically significant adverse transfusion events shall be evaluated with documented follow-up.
 - 6.1. Investigation shall be conducted by the TML to determine probable cause.
 - 6.2. Investigation shall include appropriate laboratory tests.
 - 6.3. Reports shall be submitted to appropriate authorities (CBS, Health Canada, product manufacturer) in accordance with applicable requirements.
- 7. All errors or accidents that contribute, may contribute, or have the potential to contribute to a transfusion-related adverse reaction shall be investigated with documented follow-up. This information will be inputted/captured in the Clinical Safety Reporting System (CSRS).

Guidelines

- 1. Adverse transfusion reactions can occur with transfusion of any type of blood component or administration of any (plasma-derived) blood product.
- 2. Acute transfusion reactions occur *during or within 24 hours* following transfusion of blood components or administration of plasma-derived blood products.
- 3. Delayed transfusion reactions typically occur 2 to up to 50 days following transfusion of blood components or administration of blood products.
- 4. Common signs and symptoms of adverse transfusion reactions include the following:
 - 4.1. fever greater than 38°C and greater than 1°C above baseline temperature;
 - 4.2. chills with or without rigors;
 - 4.3. nausea/vomiting;
 - 4.4. shortness of breath/dyspnea, wheezing;
 - 4.5. HYPOtension (SBP drop of greater than or equal to 30 mmHg);
 - 4.6. HYPERtension (SBP rise of greater than or equal to 30 mmHg);
 - 4.7. tachycardia (pulse increase of greater than 40 beats per minute from baseline);
 - 4.8. skin manifestations-pruritus, rash, urticaria, flushing, jaundice, localized edema;
 - 4.9. pain back, chest, headache, joint/muscle, intravenous (IV) site pain,
 - 4.10. edema;
 - 4.11. hemoglobinuria, oliguria, anuria;



- 4.12. abnormal bleeding;
- 4.13. hypoxemia;
- 4.14. neurological manifestations dizziness, restlessness/anxiety, confusion; and
- 4.15. shock.

Procedure

If an adverse transfusion reaction is suspected:

- 1. Stop the transfusion or administration immediately.
- 2. Disconnect administration set to ensure that the recipient does not receive any additional component or product that is potentially causing the reaction.
- 3. Infuse 0.9% sodium chloride (or compatible intravenous solution) through new administration set connected directly to the intravenous insertion site.
- 4. Check vital signs and assess the transfusion recipient.
- 5. Perform a clerical check of the recipient's identification and the blood component or product.
- 6. Request a physician/nurse practitioner assessment. Based on this assessment, the type of reaction, and the severity of symptoms, the prescriber will decide to interrupt the transfusion/administration, treat the symptoms, and proceed with caution once symptoms have subsided or whether to discontinue the transfusion/administration
- 7. Notify the TML.
- 8. Document the details of the reaction in the recipient health record including assessment details (signs/symptoms, vital signs), interventions, and follow-up assessments.
- 9. Complete the blood component or blood product issue card, including volume infused, reaction type, and time transfusion/administration stopped.
- Implement physician orders for therapeutic interventions and serological testing. Refer to adverse transfusion reaction algorithms (Appendices A to F) to identify recommended course of treatment based on symptoms.
- 11. Obtain instructions from TML regarding the need to return any un-transfused implicated blood component(s), container(s) and tubing to the TML. Follow facility policy regarding return of blood products. If this is required, please ensure sterility is maintained to ensure any growth cultured is not due to contamination at the bedside.
- **12.** Implement facility protocol for transfusion reaction investigation.
- 13. Complete the facility transfusion reaction reporting form and enter report into Clinical Safety Reporting System (CSRS), if applicable.
- 14. Document all information surrounding transfusion, adverse reaction, interventions, and reevaluation of the recipient.



Quality Control

- 1. For each blood component or blood product issued, a record system shall be in place which documents:
 - 1.1. recipient's family and given names,
 - 1.2. recipient's unique identification number,
 - 1.3. recipient's ABO group,
 - 1.4. recipient's Rh group (red cells, platelets, and granulocytes),
 - 1.5. type of blood component and/or blood product,
 - 1.6. blood component:
 - 1.6.1. identification number,
 - 1.6.2. ABO group,
 - 1.6.3. Rh group (red cells, platelets, and granulocytes),
 - 1.6.4. verification of compatibility (red cells and granulocytes),
 - 1.7. blood product:
 - 1.7.1. lot number,
 - 1.7.2. volume and/or potency,
 - 1.7.3. manufacturer,
 - 1.7.4. dosage/vials used,
 - 1.8. visual inspection,
 - 1.9. expiry date,
 - 1.10. date and time of issue,
 - 1.11. identity of the individual issuing the blood component or blood product,
 - 1.12. identity of the individual transporting the blood product to the recipient's location,
 - 1.13. identity of the individual who administered the transfusion,
 - 1.14. start and end date and time of transfusion, and
 - 1.15. total volume infused.
- All documentation surrounding transfusion of blood components or administration of blood products must be retained as per the <u>Records Retention for Transfusion Medicine Documents</u> <u>policy</u>.

Key Words

Adverse, reaction, transfusion

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Supplemental Materials

Appendix A: Fever (and/or chills/rigors) Algorithm

Appendix B: Allergic Reactions Algorithm

Appendix C: Respiratory Symptom Algorithm

Appendix D: Hypotension Algorithm

Appendix E: Job Aide for Adverse Transfusion Reaction Investigation

Appendix F & G: Adverse Transfusion Reaction Tables

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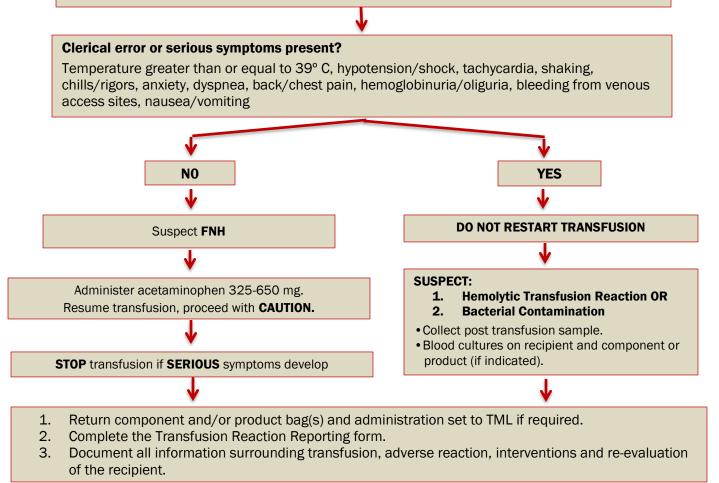
Appendix A

Fever (and/or chills/rigors) Algorithm

Temperature increase of greater than 1° C from baseline AND temperature above 38° C during or up to 4 hours post infusion

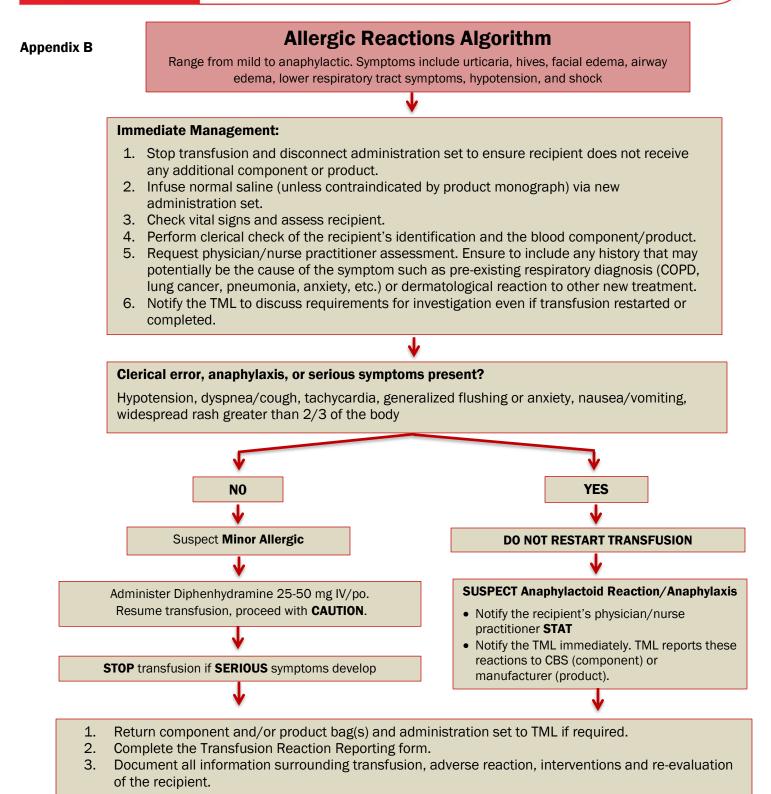
Immediate Management:

- 1. Stop transfusion and disconnect administration set to ensure recipient does not receive any additional component or product.
- 2. Infuse normal saline (unless contraindicated by product monograph) via new administration set.
- 3. Check vital signs and assess recipient.
- 4. Perform clerical check of the recipient's identification and the blood component/product.
- 5. Request physician/nurse practitioner assessment. Ensure to include any history that may potentially be the cause of the symptom (history of fevers within previous 24-48 hours, underlying infection/diagnosis such as UTI, pneumonia, cellulitis, etc.).
- 6. Notify the TML to discuss requirements for investigation even if transfusion restarted or completed.



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Appendix C

Respiratory Symptom Algorithm

(Dyspnea, shortness of breath, wheezing, hypoxia with O_2 saturation less than 90%)

Immediate Management:

- 1. Stop transfusion and disconnect administration set to ensure recipient does not receive any additional component or product.
- 2. Infuse normal saline (unless contraindicated by product monograph) via new administration set.
- 3. Check vital signs and assess recipient.
- 4. Perform clerical check of the recipient's identification and the blood component/product.
- 5. Request physician/nurse practitioner assessment. Ensure to include any history that may potentially be the cause of the symptom such as pre-existing respiratory diagnosis (COPD, lung cancer, pneumonia, anxiety, etc.).
- 6. Notify the TML to discuss requirements for investigation even if transfusion restarted or completed.

DO NOT RESTART TRANSFUSION (If suspect TRALI notify Transfusion Medicine Laboratory ASAP)

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Possible Reaction	Signs and Symptoms	Time of Onset	Management				
Anaphylactic or Severe Allergic	Angioedema–localized non-pitting deep edema; upper airway obstruction–laryngeal edema, hoarseness, stridor, 'lump in the throat;' lower airway obstruction– bronchospasm, wheeze, chest tightness, dyspnea, cyanosis; profound hypotension.	1-45 minutes after start of infusion; majority occur within 5 minutes.	Epinephrine 0.3 - 0.5mg S/C or IV (up to 3 doses); fluid bolus; vasopressors if intractable hypotension.				
Transfusion Associated Circulatory Overload (TACO)	Dyspnea, orthopnea, cyanosis, hypoxemia, tachycardia, hypertension, pedal edema, elevated JVP, pulmonary edema or pleural effusions with evidence of cardiomegaly on chest x-ray.	Within 1-2, up to 6 hours following start of transfusion.	Oxygen, diuretics, elevate head of bed, chest x-ray.				
Transfusion Related Acute Lung Injury (TRALI)	Acute respiratory distress, dyspnea, cyanosis, severe hypoxemia, severe bilateral pulmonary edema or bilateral infiltrates on chest x-ray with no evidence of cardiomegaly, hypotension unresponsive to fluid bolus.	Within 1-2 hours during transfusion or within 6 hours post-transfusion.	Oxygen, chest x-ray, intubation and ventilation, vasopressors. Collect CBS samples as requested.				
Transfusion Associated Dyspnea (TAD)	Respiratory distress that does not meet criteria of TACO, TRALI, or allergic reaction and cannot be explained by the recipient's underlying condition.	Within 24 hours of transfusion.	Oxygen, chest x-ray to rule out other possibilities (TACO, TRALI).				

- 1. Return component and/or product bag(s) and administration set to TML if required.
- 2. Complete the Transfusion Reaction Reporting form.
- 3. Document all information surrounding transfusion, adverse reaction, interventions and re-evaluation of the recipient.

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Appendix D

Hypotension Algorithm

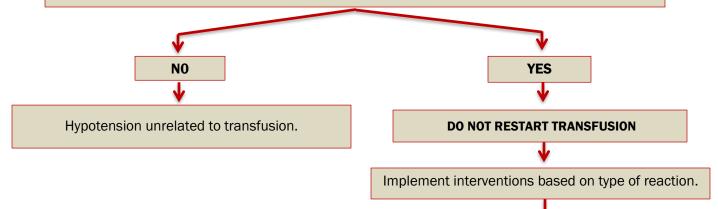
(Greater than 30 mmHg drop in systolic or diastolic blood pressure)

Immediate Management:

- 1. Stop transfusion and disconnect administration set to ensure recipient does not receive any additional component or product.
- 2. Infuse normal saline (unless contraindicated by product monograph) via new administration set.
- 3. Check vital signs and assess recipient.
- 4. Perform clerical check of the recipient's identification and the blood component/product.
- 5. Request physician/nurse practitioner assessment. Ensure to include any history or medications that may potentially be the cause of hypotension (orthostatic hypotension, dehydration, ace inhibitors, diuretics, beta-blockers, calcium channel blockers, antidepressants, anti-Parkinson agents, drugs used to treat erectile dysfunction, etc.).
- 6. Notify the TML to discuss requirements for investigation even if transfusion restarted or completed.

Consider the following reactions:

- 1. Acute hemolytic transfusion reaction
- 2. Bacterial sepsis
- 3. Severe febrile non-hemolytic transfusion reaction
- 4. Bradykinin mediated hypotension
- 5. Transfusion related acute lung injury (TRALI)
- 6. Anaphylaxis



- 1. Return component and/or product bag(s) and administration set to TML if required.
- 2. Complete the Transfusion Reaction Reporting form.
- 3. Document all information surrounding transfusion, adverse reaction, interventions and re-evaluation of the recipient.

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Appendix E Job Aide for Adverse Transfusion Reaction Investigation

Febrile Non-Hemolytic

Question	Yes	No	Comments
Temperature change >1° from baseline and ≥38°C			
Preexisiting fever within last 24-48hrs?			
Any abnormal CBC results (elevated WBC, neutropenia)?			
Any preexisting infectious processes (pneumonia, UTI, wound			
infection) or microbiological reports?			
Was recipient on any antibiotic and/or antifungal treatment?			
Did symptoms which occurred during transfusion occur			
previously/prior to transfusion?			
Did symptoms occur during or within 4 hours of completion of			
transfusion?			
Any abnormalities noted on serological investigation (if			
indicated)? Any hemolysis present?			
Were cultures completed on recipient and/or product? Report			
any positive findings.			
Was transfusion stopped?			
What treatment was given?			
Was transfusion restarted and completed? If not, what was the			
total volume transfused?			

Minor Allergic

Question	Yes	No	Comments
Any documentation of preexisting rash or itchiness?			
How severe was the reaction? Any respiratory involvement?			
Was transfusion stopped?			
What treatment was given?			
Was transfusion restarted and completed? If not, what was the			
total volume transfused?			

Severe Allergic/Anaphylactic

Question	Yes	No	Comments
Respiratory symptoms present?			
What treatment was given?			
Total volume transfused?			
Reaction reported to CBS? NLPBCP? Manufacturer (if product)?			



Hypotension

Question	Yes	No	Comments
Was change in systolic or diastolic >30 mmHg from baseline?			
What treatment was given?			
Total volume transfused?			
Did blood pressure return to baseline once transfusion			
stopped?			
Did blood pressure drop shortly after transfusion initiated? Is			
patient on ACE inhibitors? Did blood pressure rebound once			
transfusion stopped (no other intervention required)?			
Does medication regime include any other drugs which may			
cause hypotension (beta blockers, calcium channel blockers,			
diuretics, antidepressants, anti-Parkinson agents, drugs used			
to treat erectile dysfunction, etc.)?			
Any other symptoms which in combination with hypotension			
may indicate another type of reaction? Fever? Respiratory			
symptoms-specify? Bleeding and/or hemolysis?			

Hypertension

Question	Yes	No	Comments
Was change in systolic or diastolic >30 mmHg from baseline?			
What treatment was given?			
Total volume transfused?			
Did blood pressure return to baseline once transfusion			
stopped?			
Was there any history of preexisting hypertension? See nursing			
admission, admission history and physical, ER triage note, etc.			
Recipient presently on any antihypertensive(s)? List meds if			
unsure of classification.			
Any other symptoms which in combination with hypertension			
may indicate another type of reaction? Elevated JVP? SOB?			

Acute Hemolytic Reaction

Question	Comments
What signs and symptoms were reported?	
Total volume transfused?	
What interventions were required?	
Findings of serological testing?	
Outcome of acute hemolytic reaction?	
Reaction reported to NLPBCP? CBS?	
Manufacturer (if product)?	

Delayed Hemolytic Reaction vs Delayed Serologic Transfusion

Question	Yes	No	Comments
Any symptoms present?			
Findings of serological workup? Hemolysis present?			



Transfusion Associated Circulatory Overload

Question	Yes	No	Comments
Total volume transfused? Rate of infusion (#mLs over			
#minutes)?			
Respiratory symptoms reported? Please specify in comments.			
Chest xray ordered? If so, indicate results in comments.			
Any history of congestive heart failure (CHF) noted?			
JVP elevation reported? If not was it noted that it was normal?			
Presence of any edema or swelling noted?			
Was fluid balance being monitored/recorded? If so, what was			
the balance (intake vs output, positive vs negative)?			
Was any change in systolic or diastolic >30 mmHg from			
baseline noted?			
Was there any history of preexisting hypertension? See nursing			
admission, admission history and physical, ER triage note, etc.			
Recipient presently on any antihypertensive(s)? List meds if			
unsure of classification.			
What treatment was given?			
Response to treatment? Please specify in comments.			

Transfusion Related Acute Lung Injury

Question	Yes	No	Comments
Respiratory symptoms reported? Please specify in comments.			
Oxygen saturation? Was oxygen therapy, intubation required?			
Chest xray ordered? If so, indicate results in comments.			
Hypotension present? If so, were IV fluids ordered and were they effective? Vasopressors given?			

Bacterial Contamination

Question	Yes	No	Comments
Highest temperature recorded during or within 4 hours of			
completion?			
Hypotension reported?			
Culture reports?			
Treatment with antibiotics?			
Reaction reported to NLPBCP? CBS? Manufacturer (if product)?			

Appendix F

Adverse Transfusion Reactions

For all signs and symptoms: <u>STOP TRANSFUSION IMMEDIATELY</u>! Maintain IV access with 0.9% sodium chloride.

Type of	Suspected Transfusion Reaction	Timing of Symptoms	Actions & <u>Suggested</u> Treatment /
Reaction	Signs & Symptoms		Investigations
ACUTE (< 24 hours)		·	·
Minor Allergic Reaction	Intensely pruritic localized/or widespread urticaria less than 2/3 of the body; generalized erythema or flushing	During transfusion up to 2-3 hours from start	Consult with Physician–diphenhydramine hydrochloride 25-50 mg PO/IM or IV; proceed with CAUTION
Anaphylactic	Angioedema-localized non-pitting deep edema; upper airway obstruction-laryngeal edema, hoarseness, stridor, 'lump in the throat;' lower airway obstruction-bronchospasm, wheeze, chest tightness, dyspnea, cyanosis; profound hypotension	1-45 minutes after start of infusion; majority within 5 minutes	Epinephrine 0.3 - 0.5mg S/C or IV (up to 3 doses); fluid bolus; vasopressors if intractable hypotension; DO NOT RESTART TRANSFUSION
Hypotension	Abrupt onset of clinically significant hypotension-facial flushing with or without mild respiratory symptoms	Within 5 minutes after start of infusion	Supportive therapy; DO NOT RESTART TRANSFUSION
Febrile Non-Hemolytic	Cold sensation, rigors, nausea, vomiting with/without temperature greater than 1°C above baseline.	Usually within 30 minutes after start of infusion; up to one (1) hour after completed	Consult with Physician–Acetaminophen 325-500 mg PO; proceed with CAUTION
Acute Hemolytic (AHTR)	Temperature ≥39 °C, hypotension, tachycardia, rigors/chills, anxiety, dyspnea, anemia, hyperbilirubinemia, anxiety, hemoglobinuria/oliguria, bleeding at IV site, nausea/vomiting, DIC, pain-back/chest/head/flank/abdomen/groin/IV site	Usually within first 15 minutes; up to 24 hours following transfusion.	Serologic testing: group and screen, cross-match, DAT, LDH, BUN, creatinine, TB; IV Fluids DO NOT RESTART TRANSFUSION
Transfusion Associated Circulatory Overload (TACO)	Dyspnea, orthopnea, cyanosis, hypoxemia, tachycardia, hypertension, pulmonary/pedal edema, elevated JVP	Within 1-2, up to 6 hours following start of transfusion	Oxygen, diuretics; elevate head of bed. DO NOT RESTART TRANSFUSION
Transfusion Related Acute Lung Injury (TRALI)	Acute respiratory distress, dyspnea, cyanosis, severe hypoxemia, severe bilateral pulmonary edema, bilateral infiltrates on x-ray, hypotension unresponsive to fluid bolus	Within 1-2 hours during transfusion or within 6 hours post-transfusion	Oxygen, intubation and ventilation, vasopressors DO NOT RESTART TRANSFUSION
Bacterial Contamination	Fever, chills, hypotension, shock, nausea/vomiting, tachycardia, hypotension	During or within 4 hours of transfusion	Treatment of shock, DIC, renal failure, product and recipient cultures, antibiotics-broad spectrum initially; anti-pseudomonas if red cells implicated
DELAYED (>24 hours)	•	•	
Delayed Hemolytic	Weakness, unexplained fall in post-transfusion hemoglobin, elevated serum bilirubin	Within 3-7 days post-transfusion and up to 21 days post-transfusion	Provide antigen negative blood products for subsequent transfusions
Transfusion Associated Graft Versus Host Disease	Fever, erythematous cutaneous pruritic rash which progresses to generalized erythroderma, watery/bloody	Within 2-50 days of transfusion (usually 1-2 weeks)	Largely ineffective-Immunosuppressive therapy, cyclosporine/OKT3, cyclophosphamide/antithymocyte,
	diarrhea, pancytopenia, liver dysfunction, anorexia, nausea/vomiting		T cell monoclonal antibodies, HPC transplants, irradiated components. Mortality is greater than 90%
Post Transfusion Purpura	Purpura, bleeding, platelet count less than 10x 10 ⁹ /L	1-24 days post transfusion	IVIG

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Adverse Transfusion Reaction (Based on signs and symptoms cluster)

For all signs and symptoms: **STOP TRANSFUSION IMMEDIATELY**! Maintain IV access with 0.9% sodium chloride.

Symptom Reported	Suspected Transfusion Reaction Signs & Symptoms	Timing of Symptoms	Possible Etiology
Fever ≥ 38 °C and > 1 °C and/or Chills/rigors	Temperature >38 °C, < 39°C and 1 °C above baseline.	Towards the end of transfusion or within 1 hour after transfusion.	Febrile non-hemolytic
	Temperature >38.5 °C; chills, rigors, nausea, vomiting, headache, hypotension, pain.	Early in transfusion, or shortly after transfusion.	Bacterial contamination.
	Temperature >39; chills, rigors, nausea, vomiting, headache, hypotension, tachycardia, pain, bleeding, hemoglobinuria.	Early in transfusion (50-100mL required), up to 24 hours following.	Hemolytic reaction.
Urticaria and/or Itching and/or Rash	<2/3 of body; no other symptoms.	Within 2-3 hours of start of transfusion.	Minor Allergic
	> $2/3$ of body, +/- dyspnea, SOB, hypotension, decreased SPO ₂ .	1-45 minutes after start of transfusion.	Severe Allergic/ Anaphylactic/Anaphylactoid
	And profound hypotension, loss of consciousness.	Early in transfusion.	Anaphylactic Shock
Dyspnea and/or Decreased oxygen saturation	With hypertension, tachycardia, cyanosis, pulmonary edema.	During or within 6 hours of transfusion.	TACO
	With hypotension, fever/chills,+/- nausea/vomiting, DIC, hemoglobinuria, renal failure, +/- pain.	Early in transfusion, up to 24 hours following.	Acute Hemolytic, Bacterial Contamination
	Bilateral infiltrates on chest x-ray, +/-hypotension, +/- fever/chills, cyanosis.	During or within 6 hours of transfusion.	TRALI

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