Government of **Western Australia**
Department of **Health**

Appendix 1: WA Haemovigilance Program Transfusion-Related Adverse Event Definitions

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WA Haemovigilance Program Transfusion-Related Adverse Event Definitions

The criteria for reporting of transfusion-related adverse events (TRAE) to the WA Haemovigilance Program are aligned with the Australian Haemovigilance Minimum Data Set (AHMDS 2024). Where possible, the criteria are derived from International Society of Blood Transfusion (ISBT) and Serious Hazards of Transfusion (SHOT) definitions and the National Health Data Dictionary (NHDD 2010).

TRAE type	Definition

Avoidable, delayed, under or over transfusion (ADU)	Avoidable transfusion: Where the intended transfusion is carried out, and the blood component itself is suitable for transfusion and compatible with the patient, but where the decision leading to the transfusion is flawed.
	
	Delayed transfusion: Where a transfusion of a blood component was clinically indicated but was not undertaken or non-availability of suitable blood components led to a significant delay.
	
	Under (or over) transfusion: A transfusion dose/rate inappropriate for the patient's needs, excluding those cases which result in TACO.
	
	Examples of avoidable, delayed, under or over transfusion (ADU) events include:
	• Prescription errors associated with:
	  ◦ Components that are not required or are inappropriate as a result of erroneous laboratory results, transcription errors or faulty clinical judgement
	  ◦ Components that are for an inappropriate indication
	  ◦ Inappropriate volume transfused
	  ◦ Infusion pump errors leading to under or over transfusion
	• Transfusion of asymptomatic patients with a haematinic deficiency
	• Avoidable use of emergency Rh D negative blood where group-specific or crossmatched blood was readily available for the patient or the laboratory could have supplied a more suitable component
	• Delays in provision of blood components in an emergency
	• Instances where a delay in transfusion adversely affected the patient's clinical outcome
	
	(SHOT definition modified)

TRAE type	Definition
Acute haemolytic transfusion reaction (other than ABO incompatibility) (AHTR)	An AHTR has its onset within 24 hours of a transfusion. Clinical or laboratory features of haemolysis are present. Common signs of AHTR are: • fever • chills/rigors • facial flushing • chest pain • abdominal pain • back/flank pain • nausea/vomiting • diarrhoea • hypertension • pallor • jaundice • oligoanuria • diffuse bleeding • dark urine Common laboratory features of AHTR are: • haemoglobinaemia • haemoglobinuria • decreased serum haptoglobin • unconjugated hyperbilirubinaemia • increased LDH and AST levels • decreased haemoglobin levels Not all clinical or laboratory features are present in cases of AHTR. (ISBT definition)
Allergic reaction (Allergic)	An allergic reaction may present only with mucocutaneous signs and symptoms during or within 4 hours of transfusion: • morbilliform rash with itching • urticaria • localised angioedema • oedema of lips, tongue and uvula • periorbital pruritus, erythema and oedema • conjunctival oedema (ISBT definition) An allergic reaction that involves respiratory and/or cardiovascular systems should be reported as an anaphylactic reaction.

TRAE type	Definition
Anaphylactic reaction (Anaphylactic)	An allergic reaction can also involve respiratory and/or cardiovascular systems and present like an anaphylactic reaction. There is anaphylactic reaction when, in addition to mucocutaneous symptoms, there is airway compromise or severe hypotension requiring vasopressor treatment (or associated symptoms like hypotonia, syncope). The respiratory signs and symptoms may be: • laryngeal (tightness in the throat, dysphagia, dysphonia, hoarseness, stridor) or • pulmonary (dyspnoea, cough, wheezing/bronchospasm, hypoxemia) Such a reaction usually occurs during or very shortly after transfusion. (ISBT definition) This type of reaction is usually associated with an outcome severity of severe morbidity, life threatening or death.
Delayed haemolytic transfusion reaction (DHTR)	A DHTR usually manifests between 24 hours and 28 days after a transfusion and clinical or laboratory features of haemolysis are present. Signs and symptoms are similar to AHTR but are usually less severe. DHTR may sometimes manifest as an inadequate rise of post-transfusion haemoglobin level or unexplained fall in haemoglobin after a transfusion. Blood group serology usually shows abnormal results. (ISBT definition)
Delayed serologic transfusion reaction (DSTR)	DSTR is defined by the demonstration of post transfusion clinically significant red blood cell antibodies against red blood cells which were previously undetected and when there are no clinical or laboratory features of haemolysis. This term is synonymous with alloimmunisation. (ISBT definition modified)

TRAE type	Definition
Febrile non-haemolytic transfusion reaction (FNHTR)	Only the most serious cases of FNHTR defined below should be reported to the WA Haemovigilance Program. FNHTR presents with the following during or within 4 hours of transfusion without any other cause such as haemolytic transfusion reaction, bacterial contamination or underlying condition: • rise in temperature of 2ºC or more above baseline or • absolute temperature of 39ºC or over FNHTR may be accompanied by chills/rigors, headache and nausea. (SHOT and ISBT definitions modified) Definitions with a lower temperature rise may still be considered as FNHTR for the purposes of local hospital reporting.
Hypotensive transfusion reaction (Hypotensive)	This reaction is characterized by hypotension occurring during or within one hour of completing transfusion and defined as: Adults: drop in systolic blood pressure of ≥30 mm Hg and a systolic blood pressure ≤ 80 mm Hg (ISBT definition modified) Infants, children and adolescents (1 year to 18 years): > 25% drop in systolic blood pressure from baseline Neonates and small infants (<1 year): > 25% drop in baseline blood pressure value by whichever measurement is being recorded (e.g., mean blood pressure) (CDC definition modified)

TRAE type	Definition
Incorrect blood component transfused - ABO incompatibility (IBCT-ABOi)	Where a blood component was transfused which was unintentionally ABO incompatible. Include even if: • only a small quantity of blood was transfused and/or • there was no adverse reaction All cases are to be included, regardless of where the first error occurred e.g. Lifeblood, the blood transfusion laboratory or clinical areas. Examples include: • Wrong blood in tube (WBIT) phlebotomy errors where the error was not identified prior to transfusion • Changes in grouping requirements following haemopoietic stem cell transplant or solid organ transplant • Testing and procedural errors associated with ABO grouping • Component selection errors • Collection and administration errors • Incorrect component selected from stock (ISBT and SHOT definition modified) Do NOT report if a clinical decision has been taken to knowingly transfuse components not meeting specifications in view of clinical urgency. Note: Haemolytic blood transfusion reactions associated with ABO incompatibility resulting in serious harm or death may be considered as a 'sentinel event' and subject to additional reporting channels outside of the WA Haemovigilance Program. For additional information, refer to the Australian Sentinel Events List at: https://www.safetyandquality.gov.au/our-work/indicators-measurement-and-reporting/incident-management-and-sentinel-events

TRAE type	Definition
Incorrect blood component transfused - Specific requirements not met (IBCT-SRNM)	Where a patient was transfused with a blood component that did not meet their specific transfusion requirements. Examples include failure to transfuse where indicated: • Cytomegalovirus (CMV)-negative components • Irradiated components • Human leucocyte antigen (HLA)-matched platelets • Red blood cells of correct phenotype for patients with a clinical requirement for phenotype matching e.g. haemoglobinopathy • Antigen-negative red blood cells for patients with known clinically significant red blood cell antibodies • appropriate components due to invalid, incomplete or errors in laboratory testing (SHOT definition modified) Do NOT report if a clinical decision has been taken to knowingly transfuse components not meeting specification in view of clinical urgency.
Incorrect blood component transfused - Wrong component transfused (IBCT-WCT)	Where a patient was transfused with a blood component: • which was incompatible with the recipient (excluding ABO incompatibility) e.g. antigen/antibody incompatibility, including Rh(D). • which was intended for another patient but was compatible with the recipient. • other than prescribed, e.g., platelets instead of red blood cells. Examples include: • WBIT phlebotomy errors where the error was not identified prior to transfusion • Changes in grouping requirements following haemopoietic stem cell transplant or solid organ transplant • Testing and procedural errors associated with antigen/antibody (including Rh D grouping) • Component selection errors • Collection and administration errors • Incorrect component selected from stock • Failure to supply low titre negative group mismatched platelets or plasma components (SHOT definition modified) Do NOT report if a clinical decision has been taken to knowingly transfuse components not meeting specifications in view of clinical urgency.

TRAE type	Definition
Other types of adverse events (Other)	Other types of adverse events not defined in this reporting guideline. Information on a range of other types of transfusion-related adverse events is available from the ISBT website at: http://www.isbtweb.org/working-parties/haemovigilance/ (ISBT definition modified)
Post-transfusion purpura (PTP)	PTP is characterized by thrombocytopenia arising 5-12 days following transfusion of cellular blood components with findings of antibodies in the patient directed against the Human Platelet Antigen (HPA) system. (ISBT definition)
Transfusion-associated circulatory overload (TACO)	TACO is characterised by the presence of 3 or more of criteria A-E below, including at least one required criterion, during or up to 12 hours after transfusion. Required criteria: A. Acute or worsening respiratory compromise and/or B. Evidence of acute or worsening pulmonary oedema Additional criteria: C. Evidence of cardiovascular system changes e.g., development of tachycardia, hypertension, jugular venous distension, enlarged cardiac silhouette and/or peripheral oedema D. Evidence of fluid overload e.g., a positive fluid balance; clinical improvement following diuresis E. Supportive result of a relevant biomarker, e.g., an increase of B-type natriuretic peptide levels (SHOT definition modified)
Transfusion-associated dyspnoea (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 be the most prominent clinical feature and should not be explained by the patient's underlying condition or any other known cause. (ISBT definition)

TRAE type	Definition
Transfusion associated graft-versus-host disease (TA-GVHD)	TA-GVHD is characterised by the following clinical features 1-6 weeks post transfusion, with no other apparent cause: • fever • rash • liver dysfunction • diarrhoea • pancytopenia TA-GVHD is confirmed by GVHD-typical biopsy and genetic analysis to show chimerism of donor and recipient lymphocytes. (ISBT definition modified)

TRAE type	Definition

Transfusion-related acute lung injury (TRALI)	In patients with no evidence of acute lung injury (ALI) prior to transfusion, TRALI is diagnosed if a new ALI is present (all five criteria should be met) during or within 6 hours of completion of transfusion:
	• Acute onset
	• Hypoxemia:
	  • Pa02 / Fi02 < 300 mm Hg or
	  • Oxygen saturation is < 90% on room air or
	  • Other clinical evidence
	• Bilateral infiltrates on frontal chest radiograph
	• No evidence of left atrial hypertension (i.e. circulatory overload)
	• No temporal relationship to an alternative risk factor for ALI, during or within 6 hours of completion of transfusion (see below).
	
	Alternate risk factors that may cause ALI (independent of TRALI) 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
	
	TRALI events presenting with a temporal relationship to an alternative risk factor for ALI as described above should be assigned an imputability rating of possible.
	
	(ISBT definition modified)
	
	TRALI events should also be reported to Lifeblood for investigation and if required, quarantine of implicated blood and blood products.

TRAE type	Definition
Transfusion transmitted bacterial infection (TTI-B)	The recipient had evidence of infection following transfusion of blood components and there was no evidence of infection prior to transfusion and no evidence of an alternative source of infection. (ISBT definition) Transfusion transmitted bacterial infection should be clinically suspected if: • fever ≥39°C or a change of ≥2°C from pre transfusion value and • rigors and/or • tachycardia In the event of a suspected TTI-B the following can be used as guidance in assigning imputability: Possible transfusion transmitted bacterial infection: • detection of bacteria by approved techniques in the transfused blood component but not in the recipient's blood (excluding initial pre-release blood component bacterial screening in the absence of evidence of infection or a reaction) or • detection of bacteria in the recipient's blood following transfusion but not in the transfused blood component and no other reasons are ascertainable for the positive blood culture Definite transfusion transmitted bacterial infection: • detection of the same bacterial strain in the recipient's blood and in the transfused blood product by approved techniques (NHDD 2010) TTI-B events should also be reported to Lifeblood for investigation and if required, quarantine of implicated blood and blood products.
Transfusion transmitted parasitic infection (TTI-P)	The recipient had evidence of infection following transfusion of blood components and there was no evidence of infection prior to transfusion and no evidence of an alternative source of infection. (ISBT definition) TTI-P can be demonstrated by detection of the same parasite in the recipient and the donors' blood or demonstration of parasite specific antibodies in the donor blood. (NHDD 2010) TTI-P events should also be reported to Lifeblood for investigation and if required, quarantine of implicated blood and blood products.

TRAE type	Definition
Transfusion transmitted viral infection (TTI-V)	Following investigation, the recipient has evidence of infection post transfusion and no clinical or laboratory evidence of infection prior to transfusion and either, at least one component received by the infected recipient was donated by a donor who had evidence of the same infection, or, at least one component received by the infected recipient was shown to have been contaminated with the virus. Reports should at least consider HIV, Hepatitis B, Hepatitis C and CMV. (NHDD 2010) TTI-V events should also be reported to Lifeblood for investigation and if required, quarantine of implicated blood and blood products.

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