

Definitions of Current SHOT Categories & What to Report

Revised March 2011

ADVERSE EVENTS

TERM	DEFINITION	WHAT TO REPORT
<p>IBCT - Wrong Blood Transfused (Incorrect Blood Component Transfused)</p>	<p>Where a patient was transfused with a blood/blood component:</p> <p>a) which was intended for another patient b) in which the primary error occurred in the laboratory during the selection, testing or issuing of blood or other procedural error which resulted in a patient being transfused with an incorrect unit. c) phlebotomy errors resulting in "Wrong Blood In Tube"</p> <p>NB – Cases involving failure to provide special requirements should be reported in the SRNM category.</p>	<p>This category currently includes:</p> <ul style="list-style-type: none"> • Patients receiving blood/blood component intended for a different patient. • Patients receiving blood/blood component of an incorrect group, including those due to "WBIT" and changes in grouping requirements following BMT/SCT or solid organ transplant. • Patients receiving the wrong blood/blood component in which the primary error occurred in the blood bank laboratory such as <ul style="list-style-type: none"> – wrong sample selected for testing – ABO/RhD grouping error – incorrect component selected – other testing and procedural errors.
<p>IBCT- SRNM (Special Requirements Not Met)</p>	<p>Where a patient was transfused with a blood/blood component that did not meet their specific requirements.</p>	<p>Transfusion of blood/blood component of inappropriate specification or that did not meet the patient's individual requirements.</p> <p>Examples currently include failure to provide;</p> <ul style="list-style-type: none"> • MB-FFP or apheresis platelets to patients born after 1996 • CMV negative components • Irradiated components • HLA matched or blood of incorrect phenotype • Components with a neonatal specification • Failure to use a blood warmer when required.
<p>I and U (Inappropriate, unnecessary and under/delayed transfusion)</p>	<p>a) Where the intended transfusion is carried out, and the blood/blood component itself is suitable for transfusion and compatible with the patient, but where the decision leading to the transfusion is flawed. b) Where a transfusion of blood/blood component was clinically indicated but was not undertaken or was significantly delayed c) When O negative units were transfused despite group specific or crossmatched units being available.</p>	<p>This category currently includes:</p> <ul style="list-style-type: none"> • Prescription of components that are not required or are inappropriate as a result of erroneous laboratory results, transcription errors or faulty clinical judgement. • Prescription for an inappropriate indication • Prescription at a dose or rate inappropriate for the patient's needs, excluding those cases which result in TACO (see TACO section) • Failure to transfuse when indicated, under-transfusion and significant delays in transfusion.

ADVERSE EVENTS

TERM	DEFINITION	WHAT TO REPORT
<p>HSE (Handling and Storage Errors)</p>	<p>Transfusion of the correct blood/blood component to the intended patient, where handling or storage errors may have rendered the component less safe for transfusion.</p>	<p>Cases of 'unsafe' blood component where there was handling or storage errors involved such as:</p> <ul style="list-style-type: none"> • Cold chain errors such as transfusion of a unit that has been out of CTS for too long or stored inappropriately, including equipment failure. • Transfusion of an expired unit • Excessive time to transfuse • Technical errors – i.e. using an inappropriate giving set. • Transfusion of a unit where the interval between sampling and transfusion exceeds BCSH guidelines or a risk-assessed local policy. • Transfusion of a component that has had a drug added. • Component transfused despite the component being damaged.
<p>Right Blood Right Patient (RBRP)</p>	<p>Incidents where a patient was transfused correctly despite one or more serious errors which in other circumstances might have led to an IBCT.</p>	<p>This category currently includes errors associated with labelling and patient ID such as:</p> <ul style="list-style-type: none"> • administration with incorrect or incomplete/missing details on the label • transposition of labels between units that are all intended for the same patient. • Absence of a patient ID band.
<p>Near Miss</p>	<p>A near miss is an error or deviation from standard procedures or policies that is discovered before the start of the transfusion and that could have led to a wrongful transfusion or a reaction in a recipient if transfusion was to have taken place.</p>	<p>For all incidents where transfusion did NOT take place, and the error was detected prior to commencing the transfusion.</p>

PHYSIOLOGICAL REACTIONS

TERM	DEFINITION	WHAT TO REPORT
<p>ATR (Acute Transfusion Reaction)</p>	<p>Reactions occurring at any time up to 24 hours following a transfusion of blood/blood component.</p> <p>NB - Cases of acute reactions due to;</p> <ul style="list-style-type: none"> • Incorrect blood/blood component being transfused (IBCT), • Haemolytic transfusion reactions (HTR), • Transfusion-related acute lung injury (TRALI), • Transfusion-associated circulatory overload (TACO), • Transfusion Associated Dyspnoea (TAD) • Suspected bacterial contamination of the component <p>should be reported under the appropriate heading.</p>	<p>This category currently includes:</p> <ul style="list-style-type: none"> • Febrile type reaction • Allergic type reaction • Reactions with both febrile and allergic features • Hypotensive reactions <p>Further features of these reactions are provided in the Table on page 9, which should also be used to grade and report the severity of the reaction</p>
<p>HTR Acute (Haemolytic Transfusion Reaction)</p>	<p>Acute HTRs are defined as fever and other symptoms/signs of haemolysis within 24 hours of transfusion; confirmed by one or more of the following:</p> <ul style="list-style-type: none"> • a fall of Hb • rise in LDH • positive DAT • positive crossmatch 	<p>Cases with relevant features (see definition) should be reported together with results of all laboratory investigations including antibody identification if available.</p>
<p>HTR Delayed (Haemolytic Transfusion Reaction)</p>	<p>Delayed HTRs are defined as fever and other symptoms/signs of haemolysis more than 24 hours after transfusion; confirmed by one or more of the following:</p> <ul style="list-style-type: none"> • a fall in Hb or failure of increment • rise in bilirubin • positive DAT • positive crossmatch not detectable pre-transfusion. <p>NB - Simple serological reactions (development of antibody without positive DAT or without development of haemolysis) should be reported in the Alloimmunisation category.</p>	<p>Cases with relevant features (see definition) should be reported together with results of all laboratory investigations including antibody identification if available.</p> <p>Cases will be included with no clinical or laboratory features of haemolysis provided that the DAT is positive.</p> <p>Please note that the severity of the reactions must be assessed and recorded as per the Severity Grades for Haemolytic Transfusion Reactions. See Table on Page 10</p>

PHYSIOLOGICAL REACTIONS

TERM	DEFINITION	WHAT TO REPORT
<p>PTP (Post Transfusion Purpura)</p>	<p>Thrombocytopenia arising 5 – 12 days following transfusion of red cells, associated with the presence in the patient of alloantibodies directed against the HPA (Human Platelet Antigen) systems.</p>	<p>Cases where the platelet count drops more than 50% following transfusion should be investigated, and reported if complete or partial serological evidence is available.</p>
<p>PUCT (Previously Uncategorised Complication of Transfusion)</p>	<p>Physiological reaction or adverse effect in temporal association with transfusion which cannot be attributed to already defined side effects and with no risk factor other than transfusion.</p>	<p>Any reaction or adverse effects that cannot otherwise be classified into existing categories. To include reactions or adverse effect that may be due to the introduction by the Blood Services of new component processing techniques e.g. prion filtration.</p>
<p>TA-GvHD (Transfusion Associated Graft-versus-Host Disease)</p>	<p>Characterised by fever, rash, liver dysfunction, diarrhoea, pancytopenia and bone marrow hypoplasia occurring less than 30 days after transfusion. The condition is due to engraftment and clonal expansion of viable donor lymphocytes in a susceptible host.</p>	<p>All cases where diagnosis is supported by skin / bone marrow biopsy appearance or confirmed by the identification of donor-derived cells, chromosomes or DNA in the blood and/or affected tissues. Cases with a very high index of clinical suspicion.</p>
<p>TACO (Transfusion Associated Circulatory Overload)</p>	<p>Cases of TACO are confirmed by any four of the following which occur within six hours of transfusion:</p> <ul style="list-style-type: none"> • Acute respiratory distress. • Tachycardia. • Increased blood pressure. • Acute or worsening pulmonary oedema. • Evidence of positive fluid balance. 	<p>See definition.</p>
<p>TAD (Transfusion Associated Dyspnoea)</p>	<p>TAD is characterised by respiratory distress within 24 hours of transfusion that does not meet the criteria of TRALI, TACO, or allergic reaction. Respiratory distress should not be explained by the patient's underlying condition.</p>	<p>See definition.</p>

<p>TRALI (Transfusion Related Acute Lung Injury)</p>	<p>Acute dyspnoea with hypoxia and bilateral pulmonary infiltrates during or within six hours of transfusion, not due to circulatory overload or other likely cause.</p>	<p>Suspected cases should be discussed with a Blood Service Consultant, and reported if there is a high index of suspicion, even if serological investigations are inconclusive.</p>
<p>TTI (Transfusion- Transmitted Infections)</p>	<p>Include as a TTI if, following investigation, the recipient had evidence of infection post-transfusion, and there was no evidence of infection prior to transfusion and no evidence of an alternative source of infection.</p> <p>Plus; Either at least one component received by the infected recipient was donated by a donor who had evidence of the same transmissible infection.</p> <p>Or at least one component received by the infected recipient was shown to contain the agent of infection.</p>	<p>Cases currently include:</p> <ul style="list-style-type: none"> • Bacterial transmission from blood components, where cultures from the patient's blood match cultures from the component bag and/or from the donor. • Transmissions of viruses, whether routinely tested for by the Blood Services or not. • Transmissions of other agents such as prions, protozoa and filaria.

OTHER REPORTING CATEGORIES

TERM	DEFINITION	WHAT TO REPORT
Anti-D	<p>Events relating to the administration of anti-D immunoglobulin.</p> <p>Please note that this category now includes events relating to the administration of anti-D following transfusion of RhD-mismatched platelets.</p> <p>NB – Cases of near misses relating to Anti-D should be reported under the Near Miss category rather than as anti-D errors</p>	<p>This category currently includes:</p> <ul style="list-style-type: none"> • Omission or late administration of anti-D immunoglobulin. • Anti-D given to a RhD positive patient or a patient with immune anti-D. • Anti-D given to mother of a RhD negative infant. • Anti-D given to wrong patient. • Incorrect dose of anti-D given. • Handling and Storage errors associated with Anti-D Ig
Cell Salvage	<p>Events and reactions in relation to the use of intraoperative and postoperative cell salvage.</p>	<p>This category currently includes:</p> <ul style="list-style-type: none"> • Adverse events due to operator error • Adverse events due to machine failure • Adverse clinical events • Reactions to reinfused blood
Alloimmunisation	<p>Alloimmunisation occurs when, after a transfusion, there is demonstration of clinically significant antibodies against red blood cells which were previously absent (as far as is known) and when there are no clinical or laboratory signs of haemolysis. This term is categorised as a Delayed Serological Transfusion Reaction by the ISBT</p> <p>NB - Development of an antibody with positive DAT or development of haemolysis should be reported in the Haemolytic Transfusion Reaction category.</p>	<p>See definition.</p>
Haemosiderosis	<p>Iron overload as indicated by laboratory investigation or biopsy due to chronic transfusion and which can result in organ injury (Heart, Lung, Liver and or Endocrine glands)</p>	<p>Any cases of chronically transfused patients that require iron chelation therapy.</p>

Imputability		
N/A	Not assessable	When there is insufficient data for imputability assessment
0	Excluded or Unlikely	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to causes other than the blood or blood components or where the evidence is clearly in favour of alternative causes.
1	Possible	When the evidence is indeterminate for attributing the adverse reaction either to the blood or blood component or to alternative causes
2	Likely / probable	When the evidence is clearly in favour of attributing the adverse reaction to the blood or blood component.
3	Certain	When there is conclusive evidence beyond reasonable

Severity Grades for Acute Transfusion Reactions			
Category	1 = Mild	2 = Moderate	3 = Severe
Febrile type reaction	A rise in temperature up to 2°C with no other symptoms/signs	A rise in temperature of 2°C or more, and/or rigors, chills, other inflammatory symptoms/signs such as myalgia or nausea which precipitate stopping the transfusion.	A rise in temperature of 2°C or more and/or rigors, chills or other inflammatory symptoms/signs such as myalgia or nausea and/or hypotension which necessitate stopping the transfusion, medical review and/or hospital admission or prolongation of stay.
Allergic type reaction	Transient flushing, urticaria or rash	Wheeze or angioedema with or without flushing/urticaria/rash but without respiratory compromise or hypotension.	Bronchospasm, stridor, angioedema or circulatory problems which require urgent medical intervention and/or, directly result in or prolong hospital stay, or anaphylaxis (severe, life-threatening, generalised or systemic hypersensitivity reaction with rapidly developing airway and/or breathing and/or circulation problems, usually associated with skin and mucosal changes).
Reaction with both allergic and febrile features	Features of mild febrile and mild allergic reactions	Features of both allergic and febrile reactions, at least one of which is in the moderate category.	Features of both allergic and febrile reactions, at least one of which is in the severe category.
Hypotension		Isolated fall in systolic or diastolic pressure of 30mm or more in the absence of inflammatory, allergic or anaphylactic symptoms; no/minor intervention required.	Hypotension leading to shock (e.g. acidaemia, impairment of vital organ function) without allergic or inflammatory symptoms; urgent medical intervention required.

Severity Grades for Haemolytic Transfusion Reactions			
1 = DAT without haemolysis	2 = Mild	3 = Moderate	4 = Severe
Positive DAT only	<i>2 of the following:</i> <ul style="list-style-type: none"> • Falling haemoglobin • Positive DAT • Spherocytes 	<ul style="list-style-type: none"> • Falling haemoglobin • Rise in bilirubin • ± positive DAT • ± spherocytes 	<ul style="list-style-type: none"> • Falling haemoglobin • Rise in bilirubin • Renal impairment • ± positive DAT • ± spherocytes