

Definitions of current SHOT reporting categories & what to report

Revised April 2017

ADVERSE EVENTS

TERM	DEFINITION	WHAT TO REPORT
<p>IBCT – WCT</p> <p>(Incorrect Blood Component Transfused – Wrong Component Transfused)</p>	<p>Where a patient was transfused with a blood component:</p> <ol style="list-style-type: none"> a) of an incorrect blood ABO/D group. b) which was incompatible with the recipient. c) which was intended for another patient but was fortuitously compatible with the recipient. d) other than that prescribed, e.g. platelets instead of red cells. <p>NB – Cases involving failure to provide patient-specific requirements such as extended phenotype, irradiated or CMV-seronegative & HEV-screened components should be reported in the SRNM category.</p> <p><i>Samples that are rejected by the laboratory at booking in are not reportable to SHOT</i></p>	<p>This category currently includes:</p> <ul style="list-style-type: none"> • Patients receiving a blood component intended for a different patient OR a component of an incorrect group due to clinical and/or laboratory errors in the transfusion process. <p>Examples include:</p> <ul style="list-style-type: none"> ➤ ‘Wrong blood in tube’ associated with group & screen phlebotomy errors ➤ Changes in grouping requirements following haemopoietic stem cell transplant or solid organ transplant. ➤ Testing and procedural errors associated with ABO/D grouping ➤ Component selection errors ➤ Collection & administration errors ➤ Incorrect component selected from stock. (Includes adult units to neonates)
<p>IBCT – SRNM</p> <p>(Incorrect Blood Component Transfused – Specific Requirements Not Met)</p>	<p>Where a patient was transfused with a blood component that did not meet their specific transfusion requirements.</p> <p>Do NOT report if a clinical decision has been taken to knowingly transfuse components not meeting specification in view of clinical urgency.</p>	<p>Transfusion of a blood component of inappropriate specification or that did not meet the patient’s individual requirements.</p> <p>Examples currently include <i>failure to transfuse</i>:</p> <ul style="list-style-type: none"> • Pathogen-inactivated plasma components to patients born on or after 1st January 1996. • Cytomegalovirus (CMV)-negative components where indicated • Irradiated components where indicated • Human leucocyte antigen (HLA)-matched platelets where indicated • Red cells of correct phenotype including inappropriate use of electronic issue and patients with a specific clinical condition e.g. haemoglobinopathy • Antigen-negative red cells for patients with known irregular red cell antibodies • HEV-screened components where indicated <p>Also:</p> <ul style="list-style-type: none"> • Testing or release of components when the status of the sample does not comply with the guidelines. • Release of components prior to completion of laboratory testing • Failure to use blood warmer when required

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<p>ADU</p> <p>(Avoidable transfusion, Delayed transfusion or Under- or Over-transfusion)</p>	<p>AVOIDABLE: 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.</p> <p>DELAYED: Where a transfusion of a blood component was clinically indicated but was not undertaken or was significantly delayed.</p> <p>UNDER (OR OVER) TRANSFUSION: A dose/rate inappropriate for the patient's needs, excluding those cases which result in TACO (see TACO section)</p>	<p>Failure to transfuse when indicated, under-transfusion, avoidable transfusion and significant delays in transfusion, whether caused by the laboratory or the clinical area.</p> <p>This category currently includes:</p> <p>Prescription errors associated with:</p> <ul style="list-style-type: none"> • 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 • Infusion pump errors leading to under or over transfusion <p>Also:</p> <ul style="list-style-type: none"> • Transfusion of asymptomatic patients with a haematinic deficiency • Avoidable use of emergency O 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, including use of O D-negative when time would allow a more appropriate group to be remotely allocated from a remote release refrigerator system. <p>Delays</p> <ul style="list-style-type: none"> • Delays in provision of blood components in an emergency • Cases where a delay in transfusion affected the patient's health/well being, for example: <ul style="list-style-type: none"> ○ An out-patient who has to return to hospital the next day as components were not available at the allotted time ○ Delayed surgery ○ Delayed red cell exchange

<p>HSE</p> <p>(Handling and Storage Errors)</p>	<p>Transfusion of the correct blood component to the intended patient, where handling or storage errors may have rendered the component less safe for transfusion.</p> <p>Do NOT report events where there is failure to complete collection paperwork or misuse of access cards, but the blood component was transfused safely to the correct patient.</p> <p>Do NOT report events where the blood is available for issue, but has not been collected for the patient (including blood in temperature-controlled boxes and satellite refrigerators).</p> <p><i>Blood available and incorrectly handled/stored in the clinical area but not transfused IS REPORTABLE as a near miss HSE.</i></p>	<p>Cases of potentially 'unsafe' blood component where there were 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 controlled temperature storage (CTS) for times exceeding national guidance or stored inappropriately, including equipment failure. • Transfusion of a time-expired unit. • Transfusion of a unit of red cells that should have been cleared from the issue refrigerator and re-crossmatched. • Excessive time to transfuse (> 5h from removal from cold storage to completion of transfusion) • Technical administration errors – e.g. using an inappropriate giving set or setting an infusion pump incorrectly, despite the prescription being correct. • Transfusion of a component that has had a drug added, or co-administration of a blood component and drug through the same venous access. • Component transfused despite the component being visibly damaged, or having been tampered with.
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ADVERSE EVENTS

TERM	DEFINITION	WHAT TO REPORT
<p>RBRP (Right Blood Right Patient)</p>	<p>Incidents where a patient was transfused correctly despite one or more serious identification or prescription errors which in other circumstances might have led to an IBCT.</p> <p>NB – Cases involving reactions should be reported under the appropriate SAR category.</p>	<p>This category includes errors associated with labelling and patient ID such as:</p> <ul style="list-style-type: none"> • Administration with incorrect/incomplete details on the label. • Transposition of labels between units intended for the same patient. • Absence of patient ID band or equivalent risk-assessed alternative identification system. • Transfusion of a blood component that was intended for the patient, but was not formally prescribed/authorised.
<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 wrong transfusion or a reaction in a recipient if transfusion had taken place.</p> <p>Do NOT report failures of the laboratory quality system which are not linked to a transfusion request for a specific named patient.</p> <p>Do NOT report events where the blood is available for issue, but has not been collected for the patient (including blood in temperature controlled transport boxes and satellite refrigerators). Blood for potential transfusion and available in the clinical area IS REPORTABLE.</p>	<p>For all incidents where transfusion did NOT take place, and the error was detected prior to commencing the transfusion.</p>

Serious adverse events (SAE):

MHRA Definition: Any untoward occurrence associated with the collection, testing, processing, storage and distribution of blood or blood components that might lead to **death or life threatening, disabling or incapacitating** conditions for patients or which results in, or prolongs, hospitalisation or morbidity

PATHOLOGICAL REACTIONS

All pathological reactions should also be reported to MHRA if they are 'Serious' – see definition bottom of page 7

TERM	DEFINITION	WHAT TO REPORT
<p>ATR</p> <p>(Acute Transfusion Reaction – allergic/febrile, etc)</p>	<p>Allergic/febrile transfusion reactions occurring at any time up to 24 hours following a transfusion of a blood component.</p> <p>NB – Acute reactions due to the following causes should be reported under the appropriate heading:</p> <ul style="list-style-type: none"> • Incorrect blood component being transfused (IBCT). • Haemolytic transfusion reaction (HTR). • Transfusion-related acute lung injury (TRALI). • Transfusion-associated circulatory overload (TACO). • Transfusion-associated dyspnoea (TAD) • Suspected bacterial contamination of the component (TTI). 	<p>This category includes:</p> <ul style="list-style-type: none"> • Febrile type reaction (simple febrile reactions associated with chills and/or rigors or involving a 2°C temp rise over baseline, or an absolute temp of 39 °C) • Allergic type reaction. • Reactions with both febrile and allergic features. • Hypotensive reactions. <p>Please note that further features of these reactions are provided in the table on page 12, which should also be used to grade and report the severity of the reaction. Please note that those graded as 'Mild' are NOT SHOT reportable.</p>
<p>HTR Acute</p> <p>(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 • rise in bilirubin • positive DAT • positive crossmatch <p>NB – Cases of haemolytic reactions due to the following should be reported under the appropriate heading:</p> <ul style="list-style-type: none"> - ABO-incompatible RED CELLS are reported under Incorrect Blood Component Transfused (IBCT-WCT) - ABO-incompatible PLATELETS are reported under Haemolytic Transfusion Reaction (HTR) 	<p>Cases with relevant features (see definition) should be reported together with results of all laboratory investigations including antibody identification if available. Please include Blood Service reference laboratory investigation numbers where possible</p>
<p>HTR Delayed</p> <p>(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. • Incompatible crossmatch not detectable pre-transfusion. <p>NB – Simple serological reactions (development of antibody with or without a positive DAT but without clinical or laboratory evidence of haemolysis) are no longer reportable</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>This category includes cases of suspected hyperhaemolysis. Please note the SHOT expert will use the information given in the report to categorise the severity Grades for Haemolytic Transfusion Reactions as defined in the Table on page 12., so please refer to this table and include sufficient information.</p>

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TERM	DEFINITION	WHAT TO REPORT
PTP (Post-Transfusion Purpura)	Thrombocytopenia arising 5 – 12 days following transfusion of cellular blood components (red cells or platelets), associated with the presence in the patient of alloantibodies directed against the HPA (Human Platelet Antigen) systems.	Cases where the platelet count drops more than 50% following transfusion should be investigated, and reported if complete or partial serological evidence is available.
UCT (Uncategorised Complication of Transfusion)	Pathological 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.	This category includes <ul style="list-style-type: none"> • Cases of transfusion-associated necrotising enterocolitis (NEC) i.e. NEC occurring within 48h of red cell transfusion in pre-term infants <p>NB – Please contact the SHOT office to discuss any UCT cases to get clarification prior to reporting on 0161 423 4208 or email shot@nhsbt.nhs.uk.</p>
TA-GvHD (Transfusion-Associated Graft versus Host Disease)	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.	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.
TACO (Transfusion-Associated Circulatory Overload) ** Please note the ISBT definition of TACO is under review. When the revised definitions have been approved the SHOT definition of TACO will also be modified. **	Cases of TACO characterised by <i>any four of the following which occur within six hours of transfusion</i> <ul style="list-style-type: none"> • Acute respiratory distress. • Tachycardia. • Increased blood pressure. • Acute or worsening pulmonary oedema. • Evidence of positive fluid balance. 	Cases should as far as possible include information about the confirmatory features for TACO (see definition). The following cases should also be reported: <ul style="list-style-type: none"> • Cases where TACO is suspected even if the available information suggests that fewer than 4 of the 5 defining criteria for TACO are met. • Cases with features of TACO which occur between 6 and 24 hours should also be reported.
TAD (Transfusion-Associated Dyspnoea)	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 in such cases should not be explained by the patient's underlying condition.	Cases with relevant features (see definition) should be reported together with, wherever possible, information on oxygen saturation/arterial blood gases and chest X-ray appearances.

PATHOLOGICAL REACTIONS

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TERM	DEFINITION	WHAT TO REPORT
TRALI (Transfusion-Related Acute Lung Injury)	Acute dyspnoea with hypoxia and bilateral pulmonary infiltrates during or within six hours of transfusion, not due to circulatory overload or other likely causes, or in the presence of human leucocyte antigen (HLA) Or human neutrophil (HNA) antigen antibodies cognate with the recipient	Suspected cases should be discussed with a Blood Service Consultant (who can arrange appropriate investigations), and reported if there is a high index of suspicion, even if serological investigations are inconclusive.
TTI (Transfusion-Transmitted Infections)	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. (Reporters should explore all possible risk exposures in parallel with the Blood Service investigations, in order to determine the patient's most likely source of infection. This includes checking records prior to the implicated transfusion(s) to check that the recipient was not infected prior to transfusion). Plus: Either at least one component received by the infected recipient was donated by a donor who had evidence of the same transmissible infection. Or at least one component received by the infected recipient was shown to contain the agent of infection.	Cases currently include: <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.

Serious adverse reactions (SAR):

MHRA Definition: an unintended response in a patient that is associated with the transfusion of blood or blood components that is **fatal, life-threatening, disabling or incapacitating** or which results in or prolongs hospitalisation or morbidity

OTHER REPORTING CATEGORIES

TERM	DEFINITION	WHAT TO REPORT
ANTI-D	<p>Events relating to the requesting and administration of anti-D immunoglobulin (Ig) to women of childbearing potential.</p> <p>Please note that this category now includes events relating to the administration of anti-D Ig following transfusion of D-mismatched platelets</p> <p>NB – Cases of near misses relating to anti-D Ig should be reported under the Near Miss category rather than as anti-D Ig errors.</p> <p>NOT SHOT REPORTABLE</p> <ul style="list-style-type: none"> • Cases of pathological reaction (e.g. allergy) to anti-D Ig are not reportable to SHOT, but are reportable via the MHRA ‘Yellow Card’ system for medicines. • Cases of omission or late administration where the primary reason is patient non-compliance are not reportable to SHOT. • Due to inevitable variation in local practice, SHOT has defined late administration of RAADP as after 34 weeks of gestation. <p>IMMUNE ANTI-D Cases of D-negative women who become sensitised and are found to have developed immune anti-D, which is detected during pregnancy, either at booking or later should now be reported on the SHOT database rather than the previous Word based questionnaire. Any Anti-D immunisations should be reported as all SAEs i.e. via SABRE by selecting ‘Other/Anti-D immunisation’ for ‘Event involving’.</p>	<p>This category currently includes anti-D Ig that has been:</p> <ul style="list-style-type: none"> • Omitted or administered late • administered to a D-positive woman. • administered to a woman with immune anti-D • administered erroneously to a mother of a D-negative infant • given to the wrong woman (failure of bedside ID check) • Incorrect dose of anti-D Ig given according to local or national policy, due to erroneous selection of wrong dose or misinterpretation of Kleihauer results. • Handling and storage errors associated with anti-D Ig, including issue of expired anti-D Ig, inappropriately stored anti-D Ig, where batch numbers on the vials do not match with issue paperwork, or inappropriate route of administration.

Cell Salvage	Events and reactions in relation to the use of intraoperative and postoperative cell salvage.	<p>This category currently includes:</p> <ul style="list-style-type: none"> • Adverse events due to operator error, where the event impacts on the care of the patient. • Adverse events due to machine failure where the event impacts on the care of the patient. • Adverse events related to the availability of trained staff which impact on the patient. • Adverse clinical events during the cell salvage process. • Pathological reactions to <i>reinfused</i> blood.
OTHER REPORTING CATEGORIES		
TERM	DEFINITION	WHAT TO REPORT
Prothrombin Complex Concentrate	SHOT is now interested in adverse incidents relating to Prothrombin Complex Concentrate (PCC) use	<p>Delays and inappropriate use of Prothrombin Complex Concentrate. Reported in UCT. Please contact the SHOT office on 0161 423 4208 or email shot@nhsbt.nhs.uk to discuss any cases for clarification prior to reporting.</p> <p>NB – Adverse reactions (e.g. allergic reactions) should be reported to MHRA via the ‘Yellow Card’ scheme.</p>

MAJOR MORBIDITY

Intensive care or high dependency admission and/or ventilation, renal dialysis and/or renal impairment:

- Major haemorrhage from transfusion-induced coagulopathy.
- Evidence of acute intravascular haemolysis e.g. haemoglobinaemia
- Life-threatening acute reaction requiring immediate medical intervention
- Persistent viral infection
- Acute symptomatic confirmed infection
- Sensitisation to D or K in a woman of childbearing potential.
- Reaction resulting in a low or high haemoglobin (Hb) level of a degree sufficient to cause risk to life unless there is immediate medical intervention

Potential for major morbidity:

- Potential risk of D or K sensitisation in a woman of childbearing potential.

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 where there may be alternative causes.
2	Likely / Probable	When the evidence is clearly in favour of attributing the adverse reactions to the blood or blood component
3	Certain	When there is conclusive evidence beyond reasonable doubt.

CURRENT IHN/SHOT/BCSH CLASSIFICATION OF ACUTE TRANSFUSION REACTIONS

	1 = Mild	2 = Moderate	3 = Severe
Febrile type reaction	A temperature $\geq 38^{\circ}\text{C}$ and a rise between 1°C and 2°C from pre-transfusion values, but no other symptoms/signs.	A rise in temperature of 2°C or more, or fever 39°C or over 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 fever 39°C or over, or other inflammatory symptoms/signs such as myalgia or nausea which precipitate stopping the transfusion, prompt medical review AND/OR directly results in, or prolongs hospital 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.
Hypotensive reaction		Isolated fall in systolic blood pressure of 30 mm or more occurring during or within one hour of completing transfusion and a systolic blood pressure 80 mm or less in the absence of allergic or anaphylactic systems. No/minor intervention required.	Hypotension, as previously defined, leading to shock (e.g. acidaemia, impairment of vital organ function) without allergic or inflammatory symptoms. Urgent medical intervention required.

Key - mild reactions are not SHOT reportable (NSR)

SEVERITY GRADES FOR HAEMOLYTIC TRANSFUSION REACTIONS

1 = DAT without haemolysis	2 = Mild	3 = Moderate	4 = Severe
Not SHOT reportable	<p><i>2 of the following:</i></p> <ul style="list-style-type: none"> Falling haemoglobin Positive DAT Spherocytes 	<ul style="list-style-type: none"> Falling haemoglobin Rise in bilirubin \pm positive DAT \pm spherocytes 	<ul style="list-style-type: none"> Falling haemoglobin Rise in bilirubin Renal impairment \pm positive DAT \pm spherocytes