SERIOUS HAZARDS OF TRANSFUSION SHOT

Definitions of current SHOT reporting categories & what to report

Revised January 2016

ADVERSE EVENTS		
TERM	**DEFINITION**	**WHAT TO REPORT**
IBCT – WCT (Incorrect Blood Component Transfused – Wrong Component Transfused)	Where a patient was transfused with a blood component: a) of an incorrect blood group. b) which was incompatible with the recipient. c) which was intended for another patient but was fortuitously compatible with the recipient. d) which was other than that prescribed, eg platelets instead of red cells. ***NB*** *– Cases involving failure to provide patient-specific requirements such as extended phenotype, irradiated or CMV-seronegative components should be reported in the SRNM category.*	This category currently includes: - Patients receiving a blood component intended for a different patient, due to request, testing, selection, collection or administration errors. • Patients receiving a blood component of an incorrect group, including those due to 'wrong blood in tube' phlebotomy errors and changes in grouping requirements following haemopoietic stem cell transplant or solid organ transplant. • Patients receiving a blood component of a type other than that prescribed or intended (eg platelets instead of red cells). • Patients receiving a blood component of the wrong group in which the primary error occurred in the blood transfusion laboratory such as: - wrong sample selected for testing. - ABO/RhD grouping error. - incorrect component selected from stock.Includes adult units to neonates - other testing and procedural errors contributing to the selection and issue of the incorrect blood group or blood component e.g. failure to adhere to group selection aspects related to' 2nd check' sample guidelines

IBCT – SRNM (Incorrect Blood Component Transfused – Specific Requirements Not Met)	Where a patient was transfused with a blood component that did not meet their specific transfusion requirements. ***Do NOT report*** *if a clinical decision has been taken to knowingly transfuse components not meeting specification in view of clinical urgency.*	Transfusion of a blood component of inappropriate specification or that did not meet the patient's individual requirements. Examples currently include *failure to transfuse:* • Pathogen-inactivated plasma components to patients born on or after 1st January 1996. • Cytomegalovirus (CMV)-negative components where indicated in accordance with SaBTO guidance) • Irradiated components where indicated. • Human leucocyte antigen (HLA)-matched platelets where indicated. • Antigen-negative red cells for patient with known antibodies. • Red cells of extended phenotype required for a patient with a specific clinical condition eg haemoglobinopathy. • HEV negative components where indicated (in accordance with SaBTO guidance) Also: • Failure to use blood warmer when required. • Inappropriate use of Electronic Issue. • 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

ADVERSE EVENTS		
TERM	**DEFINITION**	**WHAT TO REPORT**
ADU (Avoidable transfusion, Delayed transfusion or Undertransfusion	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.	Failure to transfuse when indicated, under-transfusion and significant delays in transfusion, whether caused by the laboratory or the clinical area. This category currently includes: • 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). • Infusion pump errors leading to under or over transfusion • Transfusion of asymptomatic patients with a haematinic deficiency. • Avoidable use of emergency O RhD 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 RhD negative when time would allow a more appropriate group to be remotely allocated from a remote release refrigerator system.
HSE (Handing and Storage Errors)	Transfusion of the correct blood component to the intended patient, where handling or storage errors may have rendered the component less safe for transfusion. ***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. ***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). *Blood available and incorrectly handled/stored in the clinical area but not transfused **IS REPORTABLE** as a near miss HSE.*	Cases of 'unsafe' blood component where there were handling or storage errors involved such as: • 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 errors – ie using an inappropriate giving set or setting an infusion pump incorrectly. • 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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RBRP (Right Blood Right Patient)	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.	This category includes errors associated with labelling and patient ID such as: • 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/wristband or equivalent risk-assessed alternative identification system. • Transfusion of a blood component that was intended for the patient, but was not formally prescribed/authorised.
Near Miss	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. ***Do NOT report*** *failures of the laboratory quality system which are not linked to a transfusion request for a specific named patient.* ***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***.	For all incidents where transfusion did NOT take place, and the error was detected prior to commencing the transfusion.

Serious adverse events (SAE):

BSQR Definition: Any untoward occurance 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

TERM	DEFINITION	WHAT TO REPORT
ATR (Acute Transfusion Reaction – allergic/febrile, etc)	Reactions occurring at any time up to 24 hours following a transfusion of a blood component. ***NB** – Acute reactions due to the following causes should be reported under the appropriate heading:* • *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).*	This category includes: • Febrile type reaction (simple febrile reactions associated with chills and/or rigors or involving a 2^{o}C temp rise over baseline, or an absolute temp of 39 ^{o}C) • Allergic type reaction. • Reactions with both febrile and allergic features. • Hypotensive reactions. ***Please note** that 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. Please note that those graded as 'Mild' are **NOT SHOT reportable**, see page 11.*
HTR *Acute* (Haemolytic Transfusion Reaction)	**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**:* • a fall of Hb. • rise in LDH. • positive DAT. • positive crossmatch. **NB** – Cases of haemolytic reactions due to the following should be reported under the appropriate heading: - ABO-incompatible **RED CELLS** Incorrect Blood Component Transfused (IBCT) ABO-incompatible **PLATELETS** are reported under Haemolytic Transfusion Reaction (HTR)	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
HTR *Delayed* (Haemolytic Transfusion Reaction)	**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**:* • a fall in Hb or failure of increment. • rise in billirubin. • Incompatible crossmatch not detectable pre-transfusion. **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	Cases with relevant features (see definition) should be reported together with results of all laboratory investigations including antibody identification if available. This category includes cases of suspected hyperhaemolysis ***Please note** that the severity of the reactions must be assessed and recorded according to the Severity Grades for Haemolytic Transfusion Reactions as defined in the Table on page 11.*

PATHOLOGICAL REACTIONS		
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.	Examples include:- • Cases of transfusion-associated necrotising enterocolitis (NEC) i.e. NEC occurring within 48h of red cell transfusion • Errors in the issue or administration of prothrombin complex concentrate (PCC) **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 .
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 *any four of the following which occur within six hours of transfusion* • 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: • 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		
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.	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: • 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):

BSQR 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	Events relating to the requesting and administration of anti-D immunoglobulin to women of childbearing potential. ***Please note*** that this category now includes events relating to the administration of anti-D Ig following transfusion of RhD-mismatched platelets. ***NB*** *– Cases of near misses relating to anti-D should be reported under the Near Miss category rather than as anti-D errors.* ***NB*** *– Cases of pathological reaction (eg allergy) to anti-D Ig are not reportable to SHOT, but are reportable via the MHRA 'Yellow Card' system for medicines.* ***NB*** *– Due to inevitable variation in local practice, SHOT have defined late administration of RAADP as after 34 weeks of gestation.* ***NB*** *– Cases of omission or late administration where the primary reason is patient non-compliance are not reportable to SHOT.* ***NB*** *– Cases of RhD 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 be reported here:* *http://www.shotuk.org/reporting/anti-d-immunisation-reporting/*	This category currently includes: • Omission or late administration of anti-D immunoglobulin (Ig). • anti-D Ig administered to an RhD positive woman. • anti-D Ig administered to a woman with immune anti-D. • anti-D Ig administered erroneously to a mother of an RhD negative infant. • anti-D Ig 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, inappropriately stored anti-D, 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.	This category currently includes: • 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 ***reinfused*** blood.

OTHER REPORTING CATEGORIES		
TERM	**DEFINITION**	**WHAT TO REPORT**
Alloimmunisation	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. ***NB** – Development of an antibody with clinical or laboratory signs of haemolysis should be reported in the Haemolytic Transfusion Reaction category.*	Not SHOT reportable (from January 2016)
Haemosiderosis	Iron overload as indicated by laboratory investigation or biopsy due to chronic transfusion and which can result in organ injury (heart, liver and/or endocrine glands).	Cases of chronically transfused patients (other than haemoglobinopathy patients) who become iron overloaded due to inadequate iron chelation therapy.
Prothombin Complex Concentrate	SHOT is now interested in adverse incidents relating to Prothombin Complex Concentrate (PCC) use ***NB** – Adverse reactions (eg allergic reactions) should be reported to MHRA via the 'Yellow Card' scheme. Clinical reactions to pharmaceutical products are not reportable to SHOT.*	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.

MAJOR MORBIDITY

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

- Major haemorrhage from transfusion-induced coagulopathy.
- Evidence of acute intravascular haemolysis eg haemoglobinaemia or haemoglobinuria.
- 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 ≥ 38°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 (eg 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	*2 of the following:* • Falling haemoglobin • Positive DAT • Spherocytes	• Falling haemoglobin • Rise in billirubin • ± positive DAT • ± spherocytes	• Falling haemoglobin • Rise in billirubin • Renal impairment • ± positive DAT • ± spherocytes