SHOT Serious Hazards of Transfusion

Definitions of current SHOT reporting categories & what to report

SHOT accepts reports on serious adverse reactions and events related to blood components, including any novel components such as convalescent plasma and whole blood. Where blood components are being used in clinical trials this must be recorded in the SHOT submission.

Serious adverse reaction (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
All transfusion transmitted infections (TTI) must be reported to MHRA.

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.

SAR and SAE must be submitted for all transfusion settings, including pre-hospital (ambulance/helicopter), home and community transfusion.

Note:
SHOT does not accept reports on adverse reactions or events related to manufactured blood products except those relating to anti-D Ig, prothrombin complex concentrates (PCC), solvent detergent fresh frozen plasma (Octaplas) and lyophilised plasma (LyoPlas). All serious adverse reactions and adverse events related to manufactured blood products should be reported on the Yellow Card scheme. (https://yellowcard.mhra.gov.uk/).

Examples included under 'What to Report' are for illustrative purposes and are not an exhaustive list.Please email shot@nhsbt.nhs.uk if you need any further information or clarification.

Summary of Changes 2022

Chapter	Date of Change
General page 1: Included requirement for reporting novel blood components in clinical trials	December 2021
General page 1: Included reporting for pre-hospital, home and community settings	December 2021
IBCT-WCT and SRNM: Incorrect specification of red cells provided as a result of errors in sex/gender allocation	December 2021
ADU - PCC reporting moved to ADU category	December 2021
ADU: Clarification around reporting delays due to lack of availability of stock – local or national	December 2021
HSE: Clarification of reporting category where there has been an error in the rate of transfusion	December 2021
Anti-D Ig: Clarification of reporting anti-D Ig use where D-positive blood components have been given to D-negative patient with child-bearing potential	December 2021

ACKNOWLEDGING CONTINUING EXCELLENCE		
TERM	**DEFINITION**	**WHAT TO REPORT**
ACE (Acknowledging Continuing Excellence)	Exceptional transfusion practice by a team or department, that was above and beyond routine practice and has widespread learning opportunities. Please do not name individuals within reports, the staff group (e.g., BMS, or Transfusion Practitioner) should be used where required. All reports should have been discussed and agreed at the Hospital Transfusion Team/Committee (HTT/HTC) level before submitting to SHOT. *NB – SHOT encourage local processes to be put in place to recognise excellent contributions by individuals and sharing best practices between teams. Please focus on team or departmental excellence and avoid individual compliments unless they have widespread learning opportunities.* ***Reporting in this category will not be included in participation data for SAE and SAR. All SAE/SAR must also be reported to SABRE and SHOT as normal.***	This category currently includes excellence within: • Transfusion Practice - Clinical • Transfusion Practice – Laboratory • Education & Research • Audit • Patient or public engagement • Team work and collaboration Examples include: • Innovative solutions to previous adverse events (all SAE/SAR must also be reported to SABRE and SHOT as normal) • Implementation of new procedures with positive patient outcomes • Multidisciplinary collaboration and communication • Patient involvement in agreeing individual transfusion treatment plans For illustrative examples of ACE reports please visit https://www.shotuk.org/reporting/ace-reporting/

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 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 ***NB** – Cases involving failure to provide patient-specific requirements such as extended phenotype, irradiated or CMV-seronegative components should be reported in the IBCT-SRNM category.* *Samples that are rejected by the laboratory at booking in, as a result of the quality management system checks, are not reportable to SHOT.*	This category currently includes: • Patients receiving a blood component intended for a different patient • Patient transfused a component of an incorrect group due to clinical and/or laboratory errors in the transfusion process Examples of errors include: • Wrong blood in tube (WBIT) associated with group & screen phlebotomy errors • Failure to provide appropriate blood group following allogeneic 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) • Failure to supply high titre negative group mismatched platelets or plasma components • D-positive component given inadvertently to D-negative patient as a result of incorrect sex/gender allocation

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ADVERSE EVENTS		
TERM	**DEFINITION**	**WHAT TO REPORT**
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.* *N.B. Occurrences where pathogen inactivated plasma components or apheresis platelets are not supplied for those born after 1996 or with TTP are no longer SHOT reportable. SaBTO (the advisory committee on the Safety of Blood, Tissues and Organs), review on this matter can be found here.*	Transfusion of a blood component of inappropriate specification or that did not meet the patient's individual requirements Examples currently include *failure to transfuse:* • Cytomegalovirus (CMV)-negative components • Irradiated components • Human leucocyte antigen (HLA)-matched platelets • Antigen-negative red cells for patients with known irregular red cell antibodies • Incorrect specification of component transfused to patient as a result of incorrect sex/gender allocation (e.g., K negative not provided) • Red cells of correct phenotype in accordance with national guidelines e.g., haemoglobinopathy, patients with childbearing potential Also: • 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 (including internal quality control) • Failure to use blood warmer when clinically indicated • Inappropriate use of electronic issue

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ADVERSE EVENTS		
TERM	**DEFINITION**	**WHAT TO REPORT**

ADU
 	
(Avoidable transfusion, Delayed transfusion or Under- or Over-transfusion, including PCC)
	Failure to transfuse when indicated, under or over-transfusion, avoidable transfusion and significant delays in transfusion, whether caused by the laboratory or the clinical area. This includes all errors relating to the order, issue or administration of prothrombin complex concentrate (PCC).
	
	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.
	
	DELAYED: Where a transfusion of a blood component was clinically indicated but was not undertaken or non-availability of blood components led to a significant delay (e.g., that caused patient harm, resulted in admission to ward or return on another occasion for transfusion).
	
	UNDER (OR OVER) TRANSFUSION: A dose inappropriate for the patient's needs, excluding those cases which result in TACO (see TACO section).
		This category includes:
		• 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
		• Transfusion of asymptomatic patient with haematinic deficiency
		• Inappropriate volume transfused
		• Infusion pump errors leading to under or over transfusion with clinical consequences (if no clinical consequences please report as HSE)
		• Avoidable use of emergency group O blood (O D-negative or positive) 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 group O when time would allow a more appropriate group to be remotely allocated from a remote release refrigerator system
		Delays
		• Situations where transfusion would have been clinically appropriate but could not be given due to lack of availability of a suitable component (e.g., rare component, recognised blood shortage)
		• Delays in provision of blood components in an emergency, including delays in clinical recognition of major haemorrhage or need for blood components (e.g., transfusion in sickle cell patients)
		• Delays where specialist testing is required (e.g., monoclonal antibody therapy, complex antibodies)
		• Cases where a delay in transfusion affected the patient's health/wellbeing, for example:
		  ○ An out-patient who must return to hospital the next day as components were not available at the allotted time
		  ○ Delayed treatment

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ADVERSE EVENTS		
TERM	**DEFINITION**	**WHAT TO REPORT**
HSE (Handling 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, 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 to be transfused to 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, except where the component has **not** been collected from a remote storage device.*	Cases of potentially '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 • Improperly prepared component/product e.g., cryoprecipitate issued before fully thawed • 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 leading to incorrect transfusion rate or time (if this led to patient harm then is reportable under ADU, if resulted in TACO then report as TACO) • 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

ADVERSE EVENTS		
TERM	**DEFINITION**	**WHAT TO REPORT**
RBRP (Right Blood Right Patient)	Incidents where a patient was transfused correctly despite one or more serious identification (ID) or prescription errors which in other circumstances might have led to an IBCT. ***NB** – Cases involving reactions should be reported under the appropriate SAR category.*	This category includes errors associated with labelling and patient ID such as: • Administration with incorrect/incomplete details on the component 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 • Pre-administration check not being performed correctly • Access cards being used inappropriately

ADVERSE EVENTS		
TERM	**DEFINITION**	**WHAT TO REPORT**
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 to be transfused to the patient (including blood in temperature-controlled transport boxes and satellite refrigerators). These events are reportable to the MHRA but not SHOT.* *Blood for potential transfusion and available in the clinical area* ***IS REPORTABLE,*** *except where components have* ***not*** *been collected from storage devices in clinical areas.*	**For near miss incidents not related to wrong blood in tube (WBIT):** • The incident is only reportable if the blood component has been collected from a blood fridge and taken to the clinical area. If laboratory QMS processes have picked up the error or a component has not been ordered or collected, then it is not SHOT-reportable **For near miss WBITs:** Do report • Cases where the sample was tested, and group or antibody testing found to be discrepant with historic results • Samples or tests rejected following a communication from the clinical area to inform the laboratory of an actual or potential error (e.g., patient misidentified) • Cases where a WBIT was discovered by other fortuitous circumstances e.g., two samples apparently from the same patient arriving close together and discovered to be erroneous Do NOT report • Incidents where samples have been rejected by the laboratory QMS before testing, i.e., zero tolerance labelling

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SERIOUS ADVERSE REACTIONS		
TERM	**DEFINITION**	**WHAT TO REPORT**
FAHR (Febrile, allergic and hypotensive reactions formerly known as Acute Transfusion Reactions – ATR)	Allergic/febrile transfusion 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-WCT or IBCT-SRNM)* • *Haemolytic transfusion reaction (HTR Acute or HTR Delayed)* • *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 other inflammatory symptoms, 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 Note that the reactions reported in patients with selective IgA deficiency – both allergic and acute non-allergic reactions will be included here. ***Please note** that further features of these reactions and how to classify them in SABRE are provided in the classification of acute transfusion reactions table, 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.*** ***Do not report cases of apparent transfusion reactions that are consistent with, and explained by, the patients underlying condition.***

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SERIOUS ADVERSE REACTIONS		
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***: • Failure to increment or Hb drop to lower than pre-transfusion levels • Rise in LDH • Rise in bilirubin • Positive DAT • Incompatible crossmatch not detectable pre-transfusion **NB** – Cases of haemolytic reactions due to the following should be reported under the appropriate heading: - ABO-incompatible **RED CELLS** are reported under Incorrect Blood Component Transfused (IBCT-WCT) - ABO-incompatible **PLATELETS** are reported under haemolytic transfusion reaction (HTR)	Cases with relevant features should be reported together with results of all laboratory investigations including antibody identification if available. Please include Blood Service reference laboratory investigation number where possible. Specific HTR acute or delayed related to failures in the processing of samples from patients prior to or undergoing treatment with monoclonal antibody therapy.
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***: • Fall in Hb or failure of increment • Rise in bilirubin • 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 should be reported together with results of all laboratory investigations including antibody identification if available. 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, so please refer to this table and include adequate information.

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SERIOUS ADVERSE 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 to support PTP.
UCT* (*Uncommon and new Complications of Transfusion not fitting into any of the other categories)	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 and do not fit under any of the other reportable categories, including cases of transfusion-associated hyperkalaemia.	This category includes • Cases of transfusion-associated necrotising enterocolitis (NEC) i.e., NEC occurring within 48h of red cell transfusion in pre-term infants • Cases of transfusion-associated hyperkalaemia, where it is noted that a patient has an unexpectedly high potassium level following transfusion. An example is hyperkalaemia following rapid transfusion of red cells **NB** – Please contact the SHOT office to discuss any UCT cases to get clarification prior to reporting on 0161 423 4208 or email shot@nhsbtpmhs.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.

SERIOUS ADVERSE REACTIONS		
TERM	**DEFINITION**	**WHAT TO REPORT**
TACO (Transfusion-Associated Circulatory Overload)	*** Required criteria (A and/or B)** **A**. Acute or worsening respiratory compromise and/or **B**. Evidence of acute or worsening pulmonary oedema based on: • clinical physical examination, and/or • radiographic chest imaging and/or other non-invasive assessment of cardiac function **Additional criteria** **C.** Evidence for cardiovascular system changes not explained by the patient's underlying medical condition, including development of tachycardia, hypertension, jugular venous distension, enlarged cardiac silhouette and/or peripheral oedema **D.** Evidence of fluid overload including any of the following: 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 (BNP) or N-terminal-pro brain natriuretic peptide) NT-pro BNP to greater than 1.5 times the pre-transfusion value	Patients classified with TACO (surveillance diagnosis) should exhibit the following during or up to 12 hours after transfusion* • At least one required criterion (i.e., A and/or B) • With a total of at least 3 or more criteria (A to E) *SHOT continues to accept cases where patient's symptoms have started up to 24 hours after transfusion.

SERIOUS ADVERSE REACTIONS		
TERM	**DEFINITION**	**WHAT TO REPORT**
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.
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 • in the presence of human leucocyte antigen (HLA) 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 to SHOT if there is a high index of suspicion, even if serological investigations are inconclusive.

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SERIOUS ADVERSE REACTIONS		
TERM	**DEFINITION**	**WHAT TO REPORT**
TTI (Transfusion-Transmitted Infections)	**(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).** 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. 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 filarial Please note that the joint NHSBT/UK Health Security Agency (UKHSA) staff support SHOT by acting as the national infections' coordinator. The unit works across both NHSBT and UKHSA the epidemiology database containing information on possible, probable, and confirmed transmissions hosted at UKHSA. The unit collates data from all the four UK Blood Services. Additional information for reporting TTI to the blood services: • If a TTI is suspected in England, then the webpage below provides guidance how to report an adverse event https://hospital.blood.co.uk/diagnostic-services/reporting-adverse-events/ • If a TTI is suspected in Wales, then the webpage below has a request form for the investigation of suspected contamination of blood components and/or a clinician at WBS can be contacted https://wbs-intranet.cymru.nhs.uk/bht/wp-content/bht-uploads/sites/4/2019/11/QAL-Templates-196-Request-form-for-the-Investigation-of-Suspected-Contamination-of-Blood-Components-1.pdf • If a TTI is suspected in Northern Ireland, then this should be discussed at the hospital level by the haemovigilance team and the Consultant Haematologist in charge of transfusion and then discussed with the medical consultant in NIBTS to guide and coordinate investigation • If a TTI is suspected in Scotland, then this should be reported to the on-call patient services consultant, via the local transfusion laboratory / blood bank. The on-call consultant should then notify the donor services consultant via the Donor Services (DS) medical team who will liaise with the national reference laboratory.

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OTHER REPORTING CATEGORIES		
TERM	**DEFINITION**	**WHAT TO REPORT**
ANTI-D	Events relating to the requesting and/or administration of anti-D immunoglobulin (Ig) and RAADP during pregnancy and after delivery. ***Please note*** that this category now includes events relating to the administration of anti-D Ig following inadvertent transfusion of D-mismatched red cells or platelets, as per national guidance. ***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.* ***NOT SHOT REPORTABLE*** • *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* ***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 in pregnancy, should be reported as SAE via SABRE by selecting 'Other/Anti-D immunisation' for 'Event involving'.*	This category currently includes anti-D Ig and RAADP during pregnancy and after delivery that has been: • 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 pre-administration ID check) • Incorrect dose of anti-D Ig given according to national policy, due to erroneous selection of wrong dose or misinterpretation of Kleihauer/quantification results • Failure to perform Kleihauer following potentially sensitising event/delivery • 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 • Errors associated with cell free fetal DNA (cffDNA) testing, including false negative and false positive results, failure to confirm results • Inadequate follow up of fetal cell clearance post sensitising event or post delivery Failures in requesting or administration of anti-D Ig to D-negative females with childbearing potential, including paediatric, following transfusion of D-positive blood components.

OTHER REPORTING CATEGORIES		
TERM	**DEFINITION**	**WHAT TO REPORT**
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 or disposable 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, such as hypotensive events • Pathological reactions to ***reinfused*** blood

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MAJOR MORBIDITY

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

- Transfusion induced coagulopathy in association with treatment for major haemorrhage (due to the dilution of haemostatic factors following unbalanced resuscitation or overuse of crystalloid/colloid
- Evidence of acute intravascular haemolysis e.g., haemoglobinaemia, gross 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 enough to cause risk to life unless there is immediate medical intervention

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 attributing the adverse reactions to the blood or blood component

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CURRENT IHN/SHOT/B(C)SH CLASSIFICATION OF ACUTE TRANSFUSION REACTIONS				SABRE Classification
	1=Mild **(not SHOT reportable)**	**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	Other/Febrile FAHR
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)	Anaphylaxis /Hypersensitivity /Allergic /FAHR
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.	Other /Mixed febrile /Allergic FAHR*
Hypotensive reaction		Isolated fall in systolic blood pressure of 30 mm Hg 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	Other /Hypotensive FAHR

*** This category may include mild symptoms/signs of one reaction type providing the other category is either moderate or severe**

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 bilirubin • ± positive DAT • ± spherocytes	• Falling haemoglobin • Rise in bilirubin • Renal impairment • ± positive DAT • ± spherocytes

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