Definitions of current SHOT reporting categories & what to report

SHOT
Serious Hazards of Transfusion

The SHOT definitions document is reviewed and updated annually. Further information on reporting to SHOT can be found at this link: https://www.shotuk.org/reporting/. For any additional queries please email SHOT@nhsbt.nhs.uk.

SHOT accepts reports on serious adverse reactions and events related to blood components, including any novel components such as 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:

Adverse events related to the administration of anti-D Ig and prothrombin complex concentrates (PCC) should be reported to SHOT. Adverse events related to lyophilised plasma (LyoPlas) and blood factor products should NOT be reported to SHOT.

SAE/SAR related to blood components used within a clinical trial remit should be reported to SHOT/MHRA as appropriate. Choose the clinical trials drop down menu on Dendrite when completing the questionnaire.

For additional resources to facilitate decisions regarding reporting please see the SHOT or NOT reporting guide and the Joint UK Haemovigilance user guide

SHOT does not accept reports on adverse reactions related to manufactured blood products except those related to solvent detergent fresh frozen plasma (Octaplas). Reactions to anti-D Ig, PCC, LyoPlas and blood factor products should be reported on the Yellow Card scheme (https://yellowcard.mhra.gov.uk/).

Summary of Changes 2025

Category:	Date of Change
ADU: • In the Delay section under "What to report", bullet point 1, added "**or where there was a delay in the component being issued or delayed administration due to poor venous access** into the sentence • In the Delay section under "What to report", bullet point 4 sentence changed to: **Situations where transfusion would have been clinically necessary but could not be given due the unavailability of blood components (including shortages of blood components, IT downtime, cyber-attacks) irrespective of the patients' outcome**	January 2025
HSE: • Added as an additional bullet point under "What to report": **Expired units – transfusion of blood components which expire: 1) Prior to administration or 2) After commencing and continue to be administered** • Clarification to include other blood components **"Excessive time to transfuse components (e.g. red cells > 5h from removal from cold storage to completion of transfusion)"**	January 2025
Cell Salvage: • Section changes to the wording and grammar • Under "What to report", 4th bullet point: addition of "**with potential impact on patient outcome, for example marked hypotension, rigors or pyrexia on reinfusion of salvaged blood"**. • Under "What to report", 5th bullet point, deleted: "**pathological reactions to reinfused blood"**	January 2025
IBCT- WCT • Moved the following narrative from under "What to report" to the section under Definition: "Incidents where a patient has a transfusion reaction as a result of an IBCT-WCT these must be reported under the relevant SAR category except for haemolytic reactions due to an ABO-incompatible transfusion, which stay in IBCT-WCT" • Clarified bullet point 3, testing and procedural errors associated with ABO/D grouping by adding "**including inappropriate issue of group specific components without a confirmed blood group.**	January 2025
IBCT-SRNM • Removed from the Definition section "or where error detected prior to commencing transfusion report as 'Near Miss'. This is covered in the Near Miss section • Under Definition section remove "*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".* • Changes to wording in the "What to report" section to provide clarification when reporting	January 2025
RBRP • Under "What to report" additional clarification under bullet point 1 to include samples. Wording changed to "**Administration with incorrect/incomplete details on the sample and/or component label**"	January 2025
ANTI-D Ig • Added to definition reference to potentially sensitising events	January 2025

Definitions document index:

All items are hyperlinked to relevant parts of the document- please click on the item you wish to explore further.

Examples included under 'What to Report' are for illustrative purposes and are not an exhaustive list. Please contact us by emailing shot@nhsbt.nhs.uk if you are still unsure which category to report under after using this document.

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 encourages 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 • Teamwork 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/acknowledging-continuing-excellence/

SERIOUS 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.*** Incidents where a patient has a transfusion reaction as a result of an IBCT-WCT must be reported under the relevant SAR category except for haemolytic reactions due to an ABO-incompatible transfusion, which stay in IBCT-WCT. .	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 • Patient transfused the incorrect component type Example of errors which may contribute to IBCT-WCT 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 (including inappropriate issue of group specific components without a confirmed blood group) • 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 (including those as a result of incorrect sex/gender allocation)

SERIOUS 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 the unit has not been collected to be transfused or if 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:* • Cytomegalovirus (CMV)-negative components • Irradiated components • Human leucocyte antigen (HLA)-matched platelets • Antigen-negative red cells for patients with known irregular red cell antibodies • K negative red cells when indicated (including those as a result of incorrect sex/gender allocation or other process error) • Red cells of correct phenotype in accordance with national guidelines e.g., haemoglobinopathy, regularly transfused patients Also: • Testing or release of components when the status of the sample does not comply with the guidelines (e.g. outside validity 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

SERIOUS 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. Every unit transfused should be an individual decision, so this might include transfusion of multiple units where not all were appropriate/ necessary. **Do NOT report** instances where to avoid significant transfusion delays, Group O components are transfused until a more appropriate group can be remotely allocated from a remote release refrigerator system. **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) and usually resulting in a haemoglobin or platelet level significantly outside the intended target range. Infusion pump errors leading to under or over transfusion with clinical consequences (if no clinical consequences please report as HSE).	**Avoidable** • Components that are not required or are inappropriate because of erroneous laboratory results, transcription errors, miscommunication, or faulty clinical judgement • Components that are for an inappropriate indication • Transfusion of asymptomatic patient with haematinic deficiency • Avoidable use of emergency group O blood (O D-negative or positive) where group-specific or crossmatched blood was **readily** available or the laboratory could have supplied a more suitable component without delay **Under (or over) transfusion:** • Inappropriate volume transfused for patient's weight • Blood component support in major haemorrhage failing to meet or overshooting targets • Incidents where the contingency component of reduced dose apheresis platelets (specification here) were issued and administered to a bleeding patient (used in situations of severe platelet shortages) **Delays** • Situations where transfusion would have been clinically appropriate but could not be given due to lack of availability of a suitable component, delay in the component being issued or delayed administration due to poor venous access • Delays in provision of blood components in an emergency, including delays in clinical recognition of major haemorrhage or need for blood components • Delays where specialist testing is required (e.g., monoclonal antibody therapy, complex antibodies) • Situations where transfusion would have been clinically necessary but was delayed due the unavailability of blood components (including shortages of blood components, IT downtime, cyber-attacks) irrespective of the patients' outcome • 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

SERIOUS 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 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 components (e.g. red cells > 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 which deviates from the current recommended practice in national guidelines (BSH Guidelines (2018)) • Component transfused despite the component being visibly damaged, or having been tampered with • Expired units – transfusion of blood components which expire: 1) Prior to administration or 2) After commencing and continue to be administered

SERIOUS 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 sample and/or 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

SERIOUS 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.* ***NB –*** Cases where NM- wrong blood in tube (WBIT) are identified please ensure that the correct category is selected as a different set of questions need completing.	**For near miss incidents <u>not related</u> to WBIT:** • The incident is only reportable if the blood component has been collected from a blood refrigerator and taken to the clinical area. If laboratory quality management system (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-WBIT:** **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, before or after the sample is tested, 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 • Cases where cord blood samples are mislabelled, or a discrepant group is detected when tested **Do NOT report** • Incidents where samples have been rejected by the laboratory QMS before testing, i.e., zero tolerance labelling

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 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 2ºC temp rise over baseline, or an absolute temp of 39ºC) • 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 where the clinicians feel that the issue was caused by the patients underlying condition or sepsis.***

SERIOUS ADVERSE REACTIONS		
TERM	**DEFINITION**	**WHAT TO REPORT**
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 in non-bleeding patients • Rise in LDH (Lactate dehydrogenase) • Rise in bilirubin • Positive DAT (Direct Antiglobulin Test) • 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 to increment in non-bleeding patients • 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. ***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.

SERIOUS ADVERSE REACTIONS		
TERM	**DEFINITION**	**WHAT TO REPORT**
HTR Hyperhaemolysis (Acute and Delayed)	**Hyperhaemolysis** is characterised by more severe haemolysis than DHTR with haemolysis affecting the transfused red cells and the patient's own red cells, causing a haemoglobin drop to below post-transfusion levels. Further features may include: • Decline in post transfusion HbA level • Reticulocytopenia • Raised bilirubin and lactate dehydrogenase With or without: • The presence of a new alloantibody • Positive DAT Hyperhaemolysis can be divided into acute (<7 days post-transfusion) and delayed hyperhaemolysis (>7 days post-transfusion).	Cases with relevant features should be reported together with results of all laboratory investigations including antibody identification if available. Wherever possible, reporters are requested to provide the details of the treatment provided to the patient.
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.

SERIOUS ADVERSE REACTIONS		
TERM	**DEFINITION**	**WHAT TO REPORT**
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 **Any cases involving PCC should be reported under the Avoidable, delayed or under/overtransfusion (ADU) category** **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.

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**
Reporting 'non-TACO' pulmonary complications of transfusion TAD (Transfusion-Associated Dyspnoea) and TRALI (Transfusion-Related Acute Lung Injury)	**TAD** Respiratory distress within 24 hours of transfusion that does not meet the criteria of TRALI (see box below), TACO or allergic reaction. Respiratory distress in such cases should not be explained by the patient's underlying condition.	Cases where there is a respiratory deterioration within 24 hours of transfusion is not adequately explained by the patient's underlying condition and which do not meet the ISBT TACO criteria are considered for these categories. Cases submitted are reviewed by the SHOT pulmonary working expert group members and are assigned to appropriate categories. All non-TACO pulmonary complications will be analysed and included in a single composite chapter in the Annual SHOT Report. Fluid overload is still suspected as a contributory factor in many cases which do not meet TACO criteria. It is recommended that a structured TACO investigation is performed for all suspected pulmonary reactions. Leukocyte antibodies do not play a role in the International Revised Consensus definition of TRALI but remain an established cause of TRALI. It remains important to consider investigating cases of acute lung injury occurring in association with transfusion to identify donors who could cause a future reaction. Monitoring cases associated with antibodies also remains a haemovigilance concern. Cases where there is acute lung injury occurring within 6 hours of transfusion should be discussed with a Blood Service consultant, to decide whether to investigate donors for antibodies.
	TRALI Acute dyspnoea with hypoxia and clear evidence of pulmonary oedema on imaging • Occurring during or within 6 hours of transfusion • the patient's respiratory state in the last 12 hours is considered as stable or improving. • AND circulatory overload (i.e., objective or supporting evidence of left atrial hypertension) is not thought to be the major contributor to the reaction	

SERIOUS ADVERSE REACTIONS		
TERM	**DEFINITION**	**WHAT TO REPORT**
TTI (Transfusion-Transmitted Infections)	Include as a TTI if, following investigation, the recipient had evidence of infection post-transfusion, there was no evidence of infection prior to transfusion and no evidence of an alternative source of infection. AND **Either** at least one component received by the infected recipient was donated by a donor who had evidence of the same infection. **Or** at least one component received by the infected recipient was shown to contain the agent of infection. **(Reporters should continue to explore all other possible risk exposures in parallel with the Blood Service investigations, to determine the patient's most likely source of infection. This includes checking that the recipient was not infected prior to transfusion by demonstrating that the blood sample obtained before receiving the implicated transfusion did not contain markers 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 this should be discussed at the hospital level with the haemovigilance team and the Consultant Haematologist in charge of transfusion and then discussed with the attending medical consultant of the WBS to guide and coordinate investigation • 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

OTHER REPORTING CATEGORIES		
TERM	**DEFINITION**	**WHAT TO REPORT**
ANTI-D Ig	Events relating to the requesting and/or administration of anti-D immunoglobulin (Ig) following potentially sensitising event (PSE) and RAADP (routine antenatal anti-D prophylaxis) during pregnancy and after delivery. ***Please note*** that this category also 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 i.e. error is detected **prior** to administering anti-D Ig, should be reported under the Near Miss category. ***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*	This category currently includes anti-D Ig and RAADP during pregnancy and after delivery that has been: • Omitted or administered late **(>72hrs following PSE)** • Administered to a D-positive individual • Administered to a woman with immune individual • Administered erroneously to a mother of a D-negative infant • Given to the wrong individual (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) screening for RHD, including false negative and false positive results, failure to confirm results, misinterpretation of results • Inadequate follow up of fetal cell clearance post sensitising event or post delivery Errors relating to administration of anti-D Ig to D-negative patients with childbearing potential, including paediatric, following transfusion of D-positive blood components.

OTHER REPORTING CATEGORIES		
TERM	**DEFINITION**	**WHAT TO REPORT**
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 the index pregnancy. *If there was an error in administering anti-D Ig which may have caused the immunisation (late or omitted), then a separate report must also be submitted for the anti-D Ig administration error in the usual way (see above).* **HOW TO REPORT** These cases should be reported as SAE via SABRE by selecting 'Other/Anti-D immunisation' for 'Event involving'. Please provide an estimated date of delivery on the 2nd page of the SHOT questionnaire. Details of the outcome of the current pregnancy are required to complete the report, so SHOT will start sending reminders once this date has passed	This category includes: • All reports for women who have produced an immune anti-D that is detectable for the first time in the current pregnancy, whether detected at booking, 28 weeks, delivery or at any other time within the pregnancy The purpose of this study is to gain a better understanding of the causes of continuing anti-D immunisations. So, all cases should be reported regardless of whether there was an error, patient non-compliance, or no identifiable reason for the immunisation. Examples include cases where: • The sensitising event that caused the anti-D formation is unknown • The anti-D was developed during the current pregnancy even though the correct management of the pregnancy was followed • Pregnant women that did not received any antenatal care due to non-compliance and anti-D was found at delivery • Where the patient developed an immune anti-D and samples were not referred for quantification • Anti-D is detected at any point during pregnancy and no reason for alloimmunisation is identified Do report to both Immune anti-D and Anti-D Ig administration category cases • Where the omission or late administration of anti-D Ig was the cause of anti-D formation at any point during pregnancy • Where inappropriate management of pregnancy e.g., late or no RAADP appointment, resulted in anti-D formation

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 has potential impact on patient care • Adverse events due to machine or disposable failure where the event has potential impact on patient care • Adverse events related to the availability of trained staff which impact the patient • Adverse clinical events during the cell salvage process with potential impact on patient outcome, for example marked hypotension, rigors, or pyrexia on reinfusion of salvaged blood

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- 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

* *Acute kidney injury (AKI), as per the 2012 kidney disease: Improving Global Outcomes Clinical Practice Guideline for AKI is defined as any of the following (Not Graded):*

- *Increase in Serum Creatinine (SCr) by ≥ 0.3 mg/dl (≥ 26.5 µmol/l) within 48 hours; or*
- *Increase in SCr to ≥ 1.5 times baseline, which is known or presumed to have occurred within the prior 7 days; or*
- *Urine volume <0.5 ml/kg/h for 6 hours*

IMPUTABILITY

Imputability in the context of clinical transfusion means the likelihood that a serious adverse reaction in a patient can be attributed to the transfusion.

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

Current IHN/SHOT/BSH classification of acute transfusion reactions/Febrile, Allergic, Hypotensive reactions (FAHR)				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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