Burton Hospitals NHS Foundation Trust





BLOOD TRANSFUSION REACTION POLICY				
Approved by:	Trust Executive Committee			
On:	6 March 2018			
Review Date:	January 2021			
Corporate / Directorate	Corporate			
Clinical / Non Clinical	Clinical			
Department Responsible for Review:	Hospital Transfusion Team			
Distribution:				
 Essential Reading for: 	All clinical staff			
Information for:	All staff with responsibility for any step of the blood transfusion process at Queens Hospital Burton.			
Policy Number:	284			

Version Number: 2

Kuscott-South. Signature:

Chief Executive

Date: 6 March 2018

Burton Hospitals NHS Foundation Trust POLICY INDEX SHEET

Title: Blood Transfusion Reaction Policy

Original Issue Date: December 2014

Date of Last Review : January 2018

Reason for amendment: Policy review and update

Responsibility: Hospital Transfusion Team

Hospital Transfusion Group

Stored: Trust Intranet

Linked Trust Policies: Guidance on Indication for

Transfusion of Blood Resuscitation Policy

Policy For The Management and Reporting of Adverse Incidents and

Near Misses
Consent Policy

Patient Identification Policy

Learning and Development Policy

Induction Policy Being Open Policy

E & D Impact assessed EIA 356

Consulted Hospital Transfusion Team

Hospital Transfusion Group Risk and Compliance Group

Clinical Directors

Divisional Medical Directors Divisional Nurse Directors

Matrons

Practice Development

Learning and Development

REVIEW AND AMENDMENT LOG

Version	Type of Change	Date	Description of Change
1	New Policy	December 2014	
2	Review of Policy	January 2018	Updated references and to reflect changes in the Trusts computer ordering system.

Blood Transfusion Reaction Policy

CONTENTS

Paragraph No.	Subject	Page No.
1	Keyword Search	1
2	Summary	1
3	Definition	1
4	Background	1
5	Purpose and Aim	1
6	Policy Statement	2
7	Scope	2
8	Key Contacts	2
9	Duties	2 - 3
10	Risk Management	3 - 4
11	Introduction	4
12	Recognition Of Transfusion Reaction	4 - 6
13	Causes of Serious Adverse Reactions and Events	7
14	Immediate Management of Suspected Transfusion Reaction	7 - 8
15	Laboratory Investigation of Transfusion Reactions	9
16	Classification of Severity of The Transfusion Reaction	9 - 12
17	Delayed Transfusion Reactions	12
18	Subsequent Management of The Patient	12
19	Reporting Blood Administration Errors	13
20	Definitions for Blood Safety and Quality Regulations	13 - 14
21	Training Needs Analysis and Competency	14
22	Monitoring and Evaluation	14
23	References	14 - 15

Appendix 1	Abbreviations	16
Appendix 2	ISBT/IHN classification of ATRs	17 - 18
Appendix 3	Minimum Standards For The Investigation Of Transfusion Related Adverse Reactions	19
Appendix 4	Investigation Of Moderate Or Severe Acute Transfusion Reactions	20
Appendix 5	Comparison Of TRALI And TACO	21
Appendix 6	Consequence score (severity levels)	22

Burton Hospitals NHS Foundation Trust

Blood Transfusion Reaction Policy

1. KEYWORD SEARCH

Blood transfusion, transfusion reaction, red blood cell, Blood Bank, cross match, observations.

2. SUMMARY

The Blood Transfusion Reaction Policy includes information required to identify patients experiencing a transfusion reaction, to investigate and treat appropriately and to report as required.

3. **DEFINITION**

An acute transfusion reaction is defined as any reaction that occurs within 24 hours post transfusion of any component. For the purpose of this Policy, packed red cells, platelets, fresh frozen plasma and cryoprecipitate are referred to collectively as blood components.

4. BACKGROUND

A blood transfusion is a potentially hazardous procedure, which should only be undertaken when the clinical benefits outweigh the potential risks to the patient. The most important of these being acute haemolytic reaction, circulatory overload and transfusion transmitted infections. Stringent procedures must be followed to ensure the correct blood product is given and any adverse reactions are dealt with promptly and efficiently.

The 2012 British Society for Haematology (BSH) Guideline on the Investigation and Management of Acute Transfusion Reactions (ATR) provides clear guidance on the recognition, investigation and management of acute adverse reactions to blood. This Policy is based on the BSH guidelines. The emphasis is on the immediate management of potentially life-threatening reactions but it also makes recommendations about appropriate investigation.

5. PURPOSE AND AIM

The purpose of the Blood Transfusion Reaction Policy is to ensure that patients under the care of the Trust receive safe blood transfusions.

The aim of the Policy is to provide staff with the knowledge / information required to identify patients experiencing a blood transfusion reaction, to investigate and treat appropriately and to report as required.

6. POLICY STATEMENT

The Trust will provide guidance to staff to ensure the safe administration of blood products.

7. SCOPE

This Policy applies to all Trust staff in all locations involved in administering transfusions of blood products. This includes, but is not exhaustive to Nurses, Midwives, Doctors, locum Doctors, Healthcare Support Workers and Operating Department Practitioners (ODP's). This Policy relates to the transfusion of blood to both adults and children. When transfusing blood to children, please also refer to the Paediatric Blood Transfusion Guideline.

8. KEY CONTACTS

81 The key personnel with regard to transfusion and their contact details are listed below, they constitute the Hospital Transfusion Team (HTT) which meets monthly.

Title	Extension	
Consultant Haematologist	4047	
Haematology Specialist Practice Registrar	4394 (Bleep, 423)	
Site Lead Blood Transfusion 4087		
Transfusion Practitioner	4126	

The Blood Bank is staffed from 09.00 – 17.30 Monday to Friday. Outside of these hours, and during bank holidays, contact the on-call Biomedical Scientist via internal bleep 367. When phoning from outside the Trust, bleep via switchboard.

9. DUTIES

Chief Executive

9.1 The Chief Executive has overall responsibility for ensuring that the Trust meets its statutory and non-statutory obligations in respect of maintaining appropriate standards contained in this policy. The Chief Executive devolves the responsibility for monitoring and compliance to the Hospital Transfusion Group.

Directors

Directors are responsible for ensuring that the requirements of the Policy are effectively managed within their Directorate and that their staff are aware of, and implement, the requirements.

Hospital Transfusion Group

9.3 The Hospital Transfusion Group (HTG) is responsible for ensuring that Trust staff uphold the principles and guidelines within this Policy and that appropriate polices and procedures are developed, maintained, and communicated throughout the organisation and that those policies and procedures are developed and implemented in co-ordination with other relevant organisations and stakeholders. The HTG reports to the Risk and Compliance Group.

Divisional Responsibilities

9.4 Any incident arising from transfusion of blood should be investigated at a local level and any actions taken to prevent reoccurrence and to minimise risk. Any lessons to be learnt should be shared at the relevant Divisional Business Unit Meeting. Any ongoing blood transfusion risks should be registered on the relevant Risk Register.

Head Nurse/Midwife, Matron and Senior Sister/Midwife Responsibilities

95 It is the Senior Sisters responsibility to ensure that staff are made aware of this Policy. These procedures should be included in the induction of all staff that may be involved in the care of the patient. Any acute transfusion reaction incidents reported must be investigated and reported to the Matron or Senior Manager via the Trusts adverse incident reporting system.

Medical Staff Responsibilities

All medical staff involved with the transfusion of blood must ensure they are familiar with this policy. Senior medical staff responsible for the supervision and training of doctors in training should ensure that junior medical staff are competent to undertake procedures within this Policy. Any acute transfusion reaction incidents reported must be investigated and reported to the Clinical Lead via the Trusts adverse incident reporting system.

All Staff

9.7 It is the responsibility of every healthcare professional given responsibility for administering and/or observing a patient during their transfusion to ensure they understand the procedures laid down in this Policy. All acute transfusion reaction must be reported via the Trusts Adverse Incident reporting system. The Senior Sister/Departmental Manager should be informed of the incident.

10. RISK MANAGEMENT

10.1 The Clinical staff will record on the Trusts adverse incident system all relevant blood transfusion related incidents reported through the risk reporting route. This data will be included in reports to the Heads of Departments and the Divisional Governance Lead. Any specific trends identified will be discussed at the relevant

Divisional Business Unit Meetings, HTT and/or HTG meetings. The HTG reports to the Trust Risk and Compliance Group.

11. INTRODUCTION

- 11.1 Acute transfusion reactions vary in severity from minor febrile reactions to life threatening allergic, haemolytic or hypotensive events. Allergic and febrile non-haemolytic transfusion reactions (FNHTR) are those most commonly reported, but the true incidence of ATR is uncertain as most haemovigilance systems only collect information on the more serious reactions, there are wide variations in institutional reporting rates. ATR rates of 0.5-3% of transfusions are commonly quoted. Data from SHOT annual reports, which tend to have fewer reports of mild FNHTR, suggest an incidence of more clinically serious ATR of around 14/100,000 products transfused, ranging from 11/100,000 for red cells to 29/100,000 for platelets. (BSH, 2012)
- 11.2 Patients with severe ATR often present with a complex overlapping of symptoms and signs, the differential diagnosis of which includes potentially life threatening allergy or anaphylaxis, acute haemolytic transfusion reactions, bacterial transfusion-transmitted infection, transfusion-associated acute lung injury (TRALI) and transfusion-associated circulatory overload (TACO). Where the predominant clinical feature is respiratory distress, Transfusion-Associated Dyspnoea (TAD) may be suspected (IHN, 2011). The initial clinical picture is also often obscured by factors related to the patients underlying medical condition, such as febrile septic episodes in neutropenic patients who also happen to be receiving a blood component transfusion. For this reason, this Policy will consider all causes of a possible reaction during the transfusion of blood. The main intention is to focus on initial recognition and general management of the clinical problem, guided in the main by symptoms and clinical signs and assessment of the severity of the problem. This allows for appropriate investigation, specific treatment and prevention, where possible, of future episodes.

12. RECOGNITION OF TRANSFUSION REACTION

- Although anaphylactic and haemolytic reactions can present after only a small volume of blood has been transfused (Heddle et al, 2009), reactions can present much later, on occasion several hours after completion of the transfusion (Taylor et al, 2009). Therefore, observation and monitoring is required throughout the transfusion and patients should be asked to report symptoms, which develop during the next 24 hours (BSH, 2009). Unconscious patients, or those unable to report symptoms, require direct monitoring.
- All patients are to be transfused in clinical areas where they can be directly observed by staff that are trained to administer blood products. Services must be available to administer first line treatment in the event of a transfusion reaction including anaphylaxis (BSH, 2009).
- A dedicated Transfusion care pathway chart (observation chart) must be used for documenting observations as per the Transfusion Policy (BSH, 2009). As per the

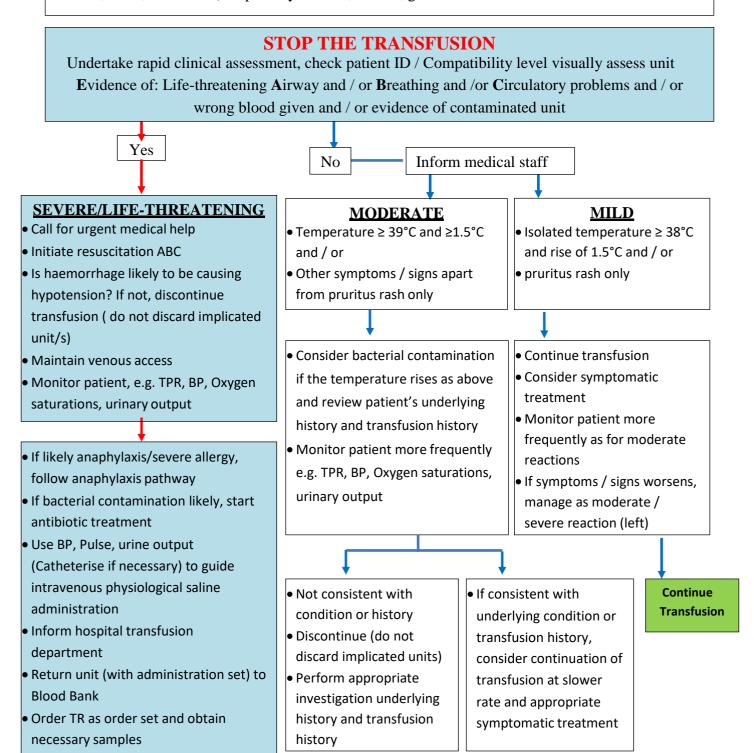
Blood Transfusion Policy, the patient must also continue to be monitored with the observation chart appropriate for the patient's treatment and care. This is usually the monitoring chart in use prior to commencement of the transfusion.

- 124 Initial treatment of ATR is not dependent on classification, but should be directed by symptoms and signs. Treatment of severe reactions should not be delayed until results of investigations are available.
- In the first 15 minutes, look for: feeling of apprehension or "something is wrong". It must be remembered if someone is unable to communicate their feelings of apprehension they might become agitated and/or irritable. Other reactions to note include;
 - Fever
 - Dyspnoea
 - Rigor
 - Clammy
 - Flushing
 - Itching
 - Rash
 - Agitation
 - Hypotension
 - Tachycardia
 - Dark Urine
 - Haemoglobinuria
 - Oozing from wounds
 - Lumbar region pain
 - Nausea
 - Abdominal Pain
 - Confusion.

SUMMARY 1 MANAGEMENT OF TRANSFUSION REACTION

PATIENT EXHIBITING POSSIBLE FEATURES OF AN ACUTE TRANSFUSION REACTION WHICH MAY INCLUDE:

Fever, chills, rigors, tachycardia, hyper- or hypotension, collapse, flushing, urticaria, pain (bone, muscle, chest, abdominal) respiratory distress, nausea, general malaise



(Adapted from the Handbook of Transfusion Medicine, BSQR, 2014)

13. CAUSES OF SERIOUS ADVERSE REACTIONS AND EVENTS

13.1 Non-infectious

- Incorrect blood component transfused
- Acute and Delayed transfusion reaction
- Transfusion associated graft-vs.-host disease (TA-GvHD)
- Transfusion related acute lung injury (TRALI)
- Post transfusion purpura (PTP)
- Transfusion associated circulatory overload (TACO).

132 Infectious

- Transfusion transmitted Infections
- Bacterial contamination.

14. IMMEDIATE MANAGEMENT OF SUSPECTED TRANSFUSION REACTION

- 14.1 If the presumed ATR is severe or life-threatening, the blood transfusion must be stopped and a doctor called immediately. Caution is required in bleeding patients where hypotension may be associated with haemorrhage and continuing the transfusion may be life-saving; the reviewing doctor will be required to decide if this is appropriate. Summary 1 (page 6) depicts a diagrammatic reference to management of patients during a suspected transfusion reaction.
- 142 If the patient develops new symptoms or signs during the transfusion, the transfusion should be stopped temporarily until the doctor has reviewed the patient.
 - 1. The senior Nurse/Midwife/ODP in the department must be informed immediately.
 - 2. Inform the patient's doctor and request a medical review.
 - 3. Identification details should be checked between the patient, their identity band and the luggage tag on the unit of blood. (Surname, Forename, Patient identifier and Date of Birth).
 - 4. Perform a visual inspection of the unit of blood.
 - 5. Assess the patient with a standard observation set.
 - 6. For patients with mild reactions, such as pyrexia (temperature of ≥ 38°C and/or rise of up to 1.5°C from the baseline observations) and /or pruritis or rash but without other features, the doctor may request that the transfusion is continued with appropriate treatment and direct observation.

- 7. Patients with mild isolated febrile reactions may require symptomatic treatment with oral paracetamol (500-1000mg in adults).
- 8. Patients with mild allergic reactions should be treated with an antihistamine and slowing the rate of the transfusion.
- 9. Anaphylaxis should be treated with intramuscular Epinephrine (Adrenaline) according to the <u>Trust Resuscitation Policy</u>. Patients with Thrombocytopenia or who have deranged coagulation should also receive intramuscular epinephrine if they have an anaphylactic reaction.
- 10. If the patient transfused for a haemorrhage develops hypotension, careful clinical risk assessment is required. If hypotension is suspected to be caused by haemorrhage (external or internal), continuation of the transfusion might be life saving. In contrast, if the blood component is considered the most likely cause of hypotension, the transfusion must be stopped or switched to an alternative component and appropriate management and investigation commenced. The doctor is required to make this clinical judgement.
- 11. Save any urine the patient passes. Blood Bank will require a post transfusion urine sample.
- The patients pulse rate, blood pressure, temperature and respiratory rate (BSH, 2009) and oxygen saturations (NICE 2007) should be monitored. Assessment for abnormal clinical features such as fever, rashes or angioedema should be undertaken frequently. The frequency of monitoring may need to be increased as requested by the doctor or senior clinician. A patient who has experienced a transfusion reaction should be observed directly until the clinical picture has improved.
- If the doctor suspects an acute transfusion reaction has occurred, inform Blood Bank immediately. Care is to be provided as directed by the doctor. The doctor will be required to order the following tests; FBC, COAGSC, UELFT, BILC, G&S, Blood Culture, Urine sample (identified on HISS order entry sets as TR).
- 14.5 If the doctor requests the transfusion to be stopped; use a new giving set and keep the line open with 0.9% Sodium Chloride. The BMS in Blood Bank will request the return of the implicated unit and giving set and advise regarding further blood samples from the patient.
- 14.6 Provide on-going reassurance to the patient. Complete an Adverse Incident form under the category "Blood/Plasma Products: product administration to patient". Document fully in the patient notes. When handing over the patient to following clinicians, ensure they are aware of the event.

15. LABORATORY INVESTIGATION OF TRANSFUSION REACTIONS

- 15.1 Standard laboratory investigations provide a baseline in case of subsequent clinical deterioration and may give an early indication of whether haemolysis or platelet transfusion refractoriness has occurred. This is largely determined by the pattern of symptoms and clinical signs and the severity of the reaction.
- All reactions considered to be a result of the transfusion, except minor allergic or febrile reactions, and without a history of comparable, non-serious reactions, must be investigated with a standard battery of tests; FBC, COAGSC, UELFT, BILC, G&S, Blood Culture, post transfusion urine sample (identified on HISS order entry under order sets category TR).
- Additional investigations will be required based on the complexity of symptoms (Appendix 2). The urgency of investigations and clinical details must be communicated to the laboratory so that, where necessary, results can be obtained rapidly and contribute to decisions regarding the risk of continued transfusion and the management of the acute event. Samples must be collected and labelled in line with local and national guidelines (Refer to the Trust Blood Transfusion Policy).
- 15.4 If febrile symptoms of moderate severity are sustained, bacterial contamination or a haemolytic reaction should be considered. The unit of blood and the infusion set must be returned as soon as possible to the Blood Bank laboratory for further investigation.

16. CLASSIFICATION OF SEVERITY OF THE TRANSFUSION REACTION

Transfusion reactions are categorised as mild, moderate or acute. In all cases, the transfusion must be stopped immediately and the doctor informed. After a clinical assessment, the transfusion may be continued depending upon the findings of the clinical assessment, but this decision must be made by the reviewing doctor. Refer to Appendix 3 for a table representation of the categories.

Mild Transfusion Reactions

- If the reaction is *mild*, medical staff should be informed, but the transfusion may be restarted under medical supervision.
- Mild reactions are defined as having no or limited change in vital signs; for example an isolated fever > 38 °C and rise of 1.5°C from baseline and/or puritus or rash but without other features. In these cases it is reasonable to restart the transfusion with direct observation.
- A doctor should make a medical assessment of the risks of medication against the severity of the reaction in each case. Caution would be required in the use of

non-steroidal anti-inflammatory drugs (NSAIDs) in patients with thrombocytopenia or reduced platelet function. There are no reported trials of *treatment* of skin symptoms but clinical experience suggests that patients with skin reactions such as itch or rash with no other features may continue to receive the transfusion. Reducing the rate of transfusion and the use of a systemic antihistamine may be helpful. There is no evidence of benefit to the use of steroids (SHOT, 2017).

Moderate Transfusion Reactions

In the case of reactions considered *moderate*, for example a rise in temperature of up to 1.5°C from baseline with chills, rigors or other change in observations; nurses/midwives/ODP's must request urgent medical review. The doctor may request continuation of the transfusion if there is an obvious alternative explanation for the symptoms/signs or the patient has a history of similar, previously investigated, non-serious transfusion reactions. In most cases it is prudent to discontinue or switch to an alternative unit. Appendix 4 identifies the laboratory investigations required for moderate transfusion reaction.

Moderate allergic symptoms

Symptoms may include angioedema and dyspnoea, but not sufficiently severe to be life-threatening. Antihistamines, such as chlorphenamine orally or intravenous (IV), may be effective and in addition oxygen therapy and a short-acting inhaled beta-2 agonist such as salbutamol may be useful for respiratory symptoms (McClelland, 2007, in BTS/SIGN guideline, 2011).

Moderate febrile symptoms

16.7 Bacterial contamination or a haemolytic reaction are very unlikely if the reaction is transient and the patient recovers with only symptomatic intervention. If the reaction is sustained however these possibilities should be considered.

Acute Transfusion Reactions

- Acute transfusion reactions can present with a range of signs and symptoms of varying severity. These include:
 - Rise in temperature from the baseline of 1.5°C or more
 - Fever and related inflammatory symptoms or signs such as chills, rigors, myalgia, nausea or vomiting
 - Cutaneous symptoms and signs including urticaria (hives), other skin rashes and pruritus Angioedema (localised oedema of the subcutaneous or submucosal tissues), which may be preceded by tingling
 - Respiratory symptoms and signs including dyspnoea, stridor, wheeze and hypoxia
 - Hypotension
 - Pain
 - Severe anxiety or feeling of impending doom
 - Bleeding diathesis with acute onset.

- Rapidly developing features of airway, breathing or circulation problems, usually associated with skin and mucosal change would suggest anaphylaxis (UKRC, 2008). Treatment of anaphylaxis will be according to the Trust Resuscitation Policy.
- 16.10 Whilst awaiting medical support manage the patient as appropriate for an acutely ill patient (NICE, 2007). In all cases disconnect the component and giving set from the patient and retain for further investigation, maintaining venous access with intravenous normal saline. If the patient is severely dyspnoeic, ensure the airway is patent and give high flow oxygen through a mask with a reservoir. If wheeze is present without upper airways obstruction, consider nebulising a shortacting inhaled beta-2 agonist such as salbutamol (British Thoracic Society/SIGN guideline on the management of asthma, 2011). Position hypotensive patients flat with leg elevation, or in the recovery position if unconscious or nauseated and at risk of vomiting. Further management is dependent on expert medical assessment and appropriate specialist support, such as the resuscitation team or Critical Care Outreach Team, who should be alerted. Prompt treatment may be life-saving, and it may not be appropriate to wait for the results of investigation. Appendix 4 identifies the laboratory investigations required for severe transfusion reaction. A rational outline of management is provided below.

Shock/severe hypotension associated with wheeze or stridor

- This is strongly suggestive of anaphylaxis with airways obstruction, especially if 16.11 examination reveals angioedema and/or urticaria. This requires immediate intervention to ensure the airway is patent and the administration of adrenaline (epinephrine) according to the UK Resuscitation guidelines (Refer to the Trust Resuscitation Policy). Intramuscular (IM) adrenaline is rapidly effective and prevents delay in attempting to get venous access in a patient with peripheral venous shutdown. It should not be prohibited in patients with thrombocytopenia or coagulopathy. Intravenous adrenaline should only be given by expert practitioners such as intensive care specialists or anaesthetists. For adults, and children over 12 years, administer IM adrenaline: 0.5 ml of 1:1,000 adrenaline (500mcg) into the anterolateral aspect of the middle third of the thigh. For children between 6 and 12 years give 0.3 ml of 1:1,000 IM adrenaline (300mcg). For children less than 6 years give 0.15 ml of 1:1,000 IM adrenaline (150mcg). Adrenaline is repeated, if necessary, at 5-minute intervals according to blood pressure, pulse and respiratory function under the direction of appropriately trained clinicians.
- Shock/severe hypotension without clinical signs of anaphylaxis or fluid overload

 16.12 Consider ABO incompatibility or bacterial contamination. Both require supportive care with fluid resuscitation, expert evaluation for inotropic, renal and/or respiratory support, and blood component therapy for disseminated intravascular coagulation with bleeding. Isolated hypotension can occur in anaphylaxis and severe hypotension can occur with Transfusion Related Acute Lung Injury (TRALI). In the latter the clinical picture is usually dominated by dyspnoea. If the identity check shows ABO incompatibility due to transfusion of a unit intended for another patient, contact the Blood Bank immediately to prevent a further wrong blood incident.

- 16.13 If bacterial contamination is suspected, take blood cultures from the patient (peripheral vein and through central line, if present) and start broad spectrum IV antibiotics. Refer to the Trust <u>Sepsis Proforma</u>. Immediately notify the Blood Bank staff and haematologist to arrange culture of the implicated unit/units and contact with the blood service so that any other components from the implicated donation can be recalled and quarantined.
- 16.14 Consider TRALI or Transfusion Associated Circulatory Overload (TACO), although dyspnoea can be a feature of allergic reactions and occasionally occurs as an unexplained complication of transfusion and may be designated Transfusion Associated Dyspnoea (Davies, 2008; IHN 2011). Ensure the airway is patent and high-flow oxygen therapy started while urgent expert medical assessment is obtained. Initial investigation should include chest X-ray and oxygen saturation.
- 16.15 Detailed investigation and treatment of TRALI (non-cardiogenic pulmonary oedema) and TACO (left ventricular failure due to fluid overload) is beyond the scope of this Policy. However, the distinction is clinically important as the primary treatment of TRALI is ventilatory support and mortality/morbidity may be increased by loop diuretic therapy in patients who already have depleted intravascular volume (Kopko and Holland, 1999). Appendix 5 summarises the major diagnostic features of, and differences between, these conditions.

17. DELAYED TRANSFUSION REACTIONS

- 17.1 Delayed transfusion reactions can be defined as;
 - Fever and any other symptoms/signs of haemolysis more than 24 hours after transfusion
 - An unexpected fall in Haemoglobin post transfusion
 - Failure to obtain an expected rise in Haemoglobin level.

18. SUBSEQUENT MANAGEMENT OF THE PATIENT

Patients who have experienced anaphylactic reactions associated with transfusion must be discussed with a Haematology Consultant. For patients with recurrent febrile reactions, a trial of premedication with oral paracetamol given an hour before the reaction is anticipated. Patient reactions that consist predominantly of chills and rigors, non-steroidal anti-inflammatory drugs may be considered but an assessment of the risks of medication and the severity of the reaction should be made in each case. Patients who continue to react may require a trial of washed blood products, but this should be discussed with a Haematologist. For recurrent mild allergic reactions, there is no evidence to support routine prophylaxis with antihistamine or steroids. Alternative causes such as allergy to drugs or latex gloves should be excluded.

19. REPORTING BLOOD ADMINISTRATION ERRORS

- 19.1 In the unfortunate event of a blood transfusion error, each practitioner must make an immediate, open and honest disclosure to the Senior Sister/department manager or midwife to ensure, that in the interest of patient safety, appropriate action is taken and errors are reviewed.
- The incident must also be reported to the blood transfusion laboratory by telephone.
- The Senior nurse/midwife/ODP/doctor must report the incident to a senior member of the clinical team dealing with the patient, who will determine how the situation should be dealt with clinically and the Trusts Being Open Policy. The senior nurse/midwife where appropriate should inform the consultant/senior medical staff prior to the error being discussed with the patient and carers. A Trust incident report must be completed via the Datix system. All errors and incidents require thorough and careful investigation, which takes full account of the circumstances, staff involved and context of the event.
- 19.4 The Senior Nurse/Midwife/department manager has overall responsibility for ensuring that, where identified, action is taken to provide education and training for individuals to correct any deficits in knowledge or competence. It is recognised that individuals and the Trust as a whole can learn from mistakes and events of this kind. To do this, errors must be monitored in order to detect trends and identify training/policy issues. A sensitive management approach and a comprehensive assessment of all the circumstances are required before professional and managerial decisions are taken.
- The Site Lead Blood Transfusion or Transfusion Practitioner will report errors to external bodies as required by Serious Hazards of Transfusion (SHOT) and Serious Adverse Blood Reactions and Events (SABRE). Refer to the SHOT Definitions of Current SHOT Categories and What to Report.
- The administration of incompatible blood products is classified as a Never Event and must be reported immediately to the Clinical Risk Manager. The Blood Bank Manager or Transfusion Practitioner must also report this to SHOT and SABRE.
- 19.7 Moderate or acute transfusion reactions must be reported as adverse incidents on Datix. It is not necessary to report a mild transfusion reaction on Datix. Appendix 6 provides advice on how to grade adverse incidents when reporting on Safeguard

20. DEFINITIONS FOR BLOOD SAFETY AND QUALITY REGULATIONS

20.1 "Near Miss" is any error which if undetected could have resulted in a wrong blood group or issue of an incorrect/inappropriate component, but is recognised before the blood/blood component is administered.

- 202 'Serious adverse event' is any untoward occurrence associated with the collection, testing, processing, storage and distribution of blood and blood products that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity.
- 203 'Serious adverse reaction' an unintended response in donor or in patient associated with the collection or transfusion of blood or blood products that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity.

21. TRAINING NEEDS ANALYSIS AND COMPETENCY

21.1 It is essential that staff involved in the transfusion process are sufficiently educated in transfusion matters and assessed as competent to perform critical tasks. The Medicines & Healthcare Regulatory Authority (MHRA) dictate that all staff involved in administering blood undertake dedicated, mandatory blood transfusion training on a regular basis. The National Patient Safety Agency (NPSA) defines a need for competency assessments to be undertaken every three years. Training requirements are defined in the Blood Transfusion Policy.

22. MONITORING AND EVALUATION

- 221 A quarterly report is produced by the Transfusion Practitioner and presented to the HTG and HTT. This report defines blood transfusion training compliance and adverse incidents reported relating to blood transfusion, including transfusion reactions. The minutes of the HTG meeting are reported to the Risk and Compliance Group.
- The Trust participates in relevant national audits relating to transfusion as agreed by the HTT/HTG. Audit findings are reported to the HTT/HTG.
- 223 Audit findings and analysis of adverse incident reports are used to inform teaching programmes and ward / department based education.

23. REFERENCES

British Society for Haematology (2009) Guidelines on the administration of blood components. Accessed On-line 20/11/17

http://www.b-s-h.org.uk/guidelines/guidelines/administration-of-blood-components/
British Society for Haematology (2012) Guideline on the Investigation and Management of Acute Transfusion Reactions. Accessed on-line 20/11/17 h.org.uk/guidelines/guidelines/investigation-and-management-of-acute-transfusion-reactions/

British Thoracic Society/Scottish Intercollegiate Guideline Network guidelines on the management of asthma (2011) Accessed On-line 20/11/17 http://www.sign.ac.uk/guidelines/fulltext/101/

Blood Safety and Quality Regulations (2014), Statutory Instrument 2005/50, Handbook of Transfusion Medicine, 5th Edition. Accessed on-line 20/11/17 http://www.transfusionguidelines.org.uk/transfusion-handbook

Davies T (2008) SHOT Toolkit, SHOT, Manchester. Accessed on-line 20/11/17 http://www.shotuk.org/wp-content/uploads/2010/03/SHOT-Toolkit-Version-3-August-2008.pdf

International Haemovigilance Network/ International Society for Blood transfusion (2011) Proposed standard definitions for surveillance of non-infectious adverse transfusion reactions. Accessed on-line 20/11/17
http://www.isbtweb.org/fileadmin/user_upload/WP_on_Haemovigilance/ISBT_definitions_final_2011_4_.pdf

Heddle, N. (2009) Investigation of acute transfusion reactions *in: Practical Transfusion Medicine 3rd edition*, eds Murphy, M. & Pamphilon, D. Wiley-Blackwell ISBN 978-1-4051-8196-9.

Kopko, P. & Holland, P. (1999) Transfusion-related lung injury. *Br J Haematol*, **105**, 322-329

NPSA Model Matrix. Accessed on-line 20/11/17

National Institute for Health and Clinical Excellence (2007) Acutely ill patients in hospital. Accessed on-line 20/11/17 http://www.nice.org.uk/guidance/CG50

National Patient Safety Agency (2011) Risk Matrix for Risk Managers. Accessed online 20/11/17 NPSA - Risk matrix for risk managers.

Serious Hazards of Transfusion (2011) <u>SHOT Definitions of Current SHOT Categories and What to Report.</u> Accessed on-line 20/11/17 at http://www.shotuk.org/wp-content/uploads/2010/03/SHOT-definitions-Nov012-final.pdf

Serious Hazards of Transfusion (2017) Annual SHOT Report 2016. Accessed on-line 17/11/17 at https://www.shotuk.org/wp-content/uploads/SHOT-Report-2016 web 7th-July.pdf

Taylor, C.(Ed.) Cohen, H., Mold, D., Jones, H, *et al*, on behalf of the Serious Hazards of transfusion (SHOT) Steering Group (2009) The 2008 Annual SHOT Report ISBN 978-0-9558648-1-0

ABBREVIATIONS

Acute Transfusion Reaction
British Society for Haematology
Biomedical Scientist
Febrile non-haemolytic transfusion reactions
Hospital information Support System
Hospital Transfusion Group
Hospital Transfusion Team
International Haemovigilance Network
Intramuscular
International Society Blood Transfusion
intravenous
Medicine and Health products Regulatory Authority
National Heath Service Blood & Transplant
National Institute for Clinical Excellence
National Patient Safety Agency
Non-steroidal anti-inflammatory drugs
Operating Department Person
Serious Adverse Blood Reactions and Events
Serous Hazards of Transfusion
Transfusion Associated Circulatory Overload
Transfusion-associated dyspnoea
Transfusion Related Acute Lung Injury

MINIMUM STANDARDS FOR THE INVESTIGATION OF TRANSFUSION RELATED ADVERSE REACTIONS

Investigations to be carried out as listed below:

Acute Haemolytic Transfusion Reaction

Return the blood unit & giving set to the Blood Bank. On advice from Blood Bank, return any unused blood to the Blood Bank.

Test Reason for sending;

- Full Blood Count To check for falling Haemoglobin level
- Repeat Blood Group, Antibody Screen and Direct Antiglobulin Test
- Confirm the patient's blood group and transfusion staff will re cross-match all blood against pre and post reaction samples
- Liver Function tests and Urea & Electrolytes (U&E's)
- Check for evidence of red cell destruction, rise in bilirubin, LDH
- Assess renal function and creatinine
- Coagulation Screen (ask for DIC screen)
- Look for evidence of DIC (provide a post-transfusion urine sample to Blood Bank)
- Urinalysis Check for Haemoglobinuria
- Blood Cultures to check for bacterial contamination

DELAYED TRANSFUSION REACTIONS

May find a positive DAT/spherocytes and positive crossmatch not detectable pretransfusion – consider sending samples to the reference laboratory at the National Blood Service.

Investigations to be carried out as listed below

Test Reason for sending

- Full Blood Count To check for falling Haemoglobin level
- Repeat Blood Group, Antibody
- Screen and Direct Antiglobulin Test
- Confirm the patient's blood group and transfusion staff will re crossmatch all blood against pre and post reaction samples
- Liver Function tests and Urea & Electrolytes (U&E's)
- Check for evidence of red cell destruction, rise in bilirubin, LDH
- Assess renal function and creatinine

SUSPECTED TRANSFUSION TRANSMITTED BACTERIAL INFECTION

Investigations to be carried out as listed below;

- Blood Cultures from Patient
- Blood Cultures from the implicated pack
- Return blood unit with attached giving set to the Blood Bank.

ANAPHYLACTIC /SEVERE ALLERGIC REACTION

Investigations to be carried out as listed below. Test When;

- Chest X-ray If dyspnoeic
- Blood Gases If clinically hypoxic
- IgA level and Anti IgA
- Mast Cell Tryptase Take sample within first 2 hours of the reaction and then at 24 hours. Can be used in differentiating anaphylactic from allergic reaction.

ISBT/IHN classification of ATRs

	1 = Mild	2 = Moderate	3 = Severe
Febrile type Reaction	A temperature 38 oC and a rise between 1and 2oC from pretransfusion values, but no other symptoms/signs	A rise in temperature of 2 _o C or more, or fever 39 _o 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 _o C or more, and/or rigors, chills, or fever 39 _o 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 symptoms. 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.

Febrile and allergic reactions may present within 4 hours, whilst hypotensive reactions are considered as presenting within one hour.

Investigation of moderate or severe acute transfusion reactions (adapted from BSH Guideline on the Investigation and Management of Acute Transfusion Reactions, 2012)

Symptoms	Investigations		
Fever (>2°C rise or >39°C)	Standard investigations ^a		
and/or chills, rigors, myalgia, nausea or vomiting and/or loin pain (note – Burton	Samples for repeat compatibility testing, direct antiglobulin test (DAT), lactate dehydrogenase (LDH) and haptoglobins		
Hospitals Trust refers to	Blood cultures from patient		
(>1.5°C)	Coagulation screen		
	Do not discard implicated unit		
	If febrile reaction sustained, return blood component to laboratory, repeat serological investigations (compatibility testing, antibody screen and DAT), measure haptoglobins and culture blood component. Contact a Blood Service consultant to discuss the need for recall of components from same donation.		
Mucosal swelling	Standard investigations ^a		
(angioedema)	Measure IgA level – if <0.07 g/L (in absence of generalised hypogammaglobulinaemia) perform confirmatory test with sensitive method and check for IgA antibodies		
Dyspnoea, wheeze or features of anaphylaxis	Standard investigations ^a Check O ₂ saturation or blood gases Chest X-ray (mandatory if symptoms severe) If severe or moderate allergic reaction suspected, measure IgA level (as above) If severe allergic/anaphylactic reaction, consider measurement of serial mast cell tryptase (immediate, 3 and 24 hours)		
Hypotension (isolated fall in	Standard investigations ^a plus investigations as for fever		
systolic blood pressure of >30 mm Hg resulting in a	If allergic reaction suspected measure IgA level		
level <80 mm Hg)	If severe allergic/anaphylactic reaction suspected, consider measurement of serial mast cell tryptase		
^a Standard investigations: full blood count, renal and liver function tests, assessment of urine for Hb			

Comparison of TRALI and TACO (adapted from BSH Guideline on the Investigation and Management of Acute Transfusion Reactions, 2012, by kind permission of British Society for Haematology)

	TRALI	TACO	
Patient characteristics	? More common in haematology and surgical patients	Most common in age >70 but can occur at any age	
Implicated blood components	Usually plasma or platelets	Any	
Onset	Up to 6 hours from transfusion (usually within 2 hours)	Within 6 hours of transfusion	
Oxygen saturation	Reduced	Reduced	
Blood pressure	Often low	Often high	
Jugular venous pressure	Normal or low	Elevated	
Temperature	Often raised	Normal	
Chest X-ray	Bilateral peri-hilar and nodular shadowing or 'white out', heart size normal	Enlarged heart and characteristics of pulmonary oedema	
Echocardiogram	Echocardiogram Normal		
Pulmonary artery wedge pressure	Normal	Elevated	
Blood count	Fall in neutrophils and monocytes followed by neutrophil leucocytosis	No specific changes	
Fluid challenge	Improves	Worsens	
Response to diuretics	Worsens	Improves	

A table incorporating both the ISBT/IHN and SHOT classifications, and gradations of severity, can be found in Appendix 3. Both these appendices can be found on the BSH website.

Consequence score (severity levels) utilised when entering Adverse incidents Adapted from the NPSA Model Matrix (NPSA 2011)

	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
	Negligible	Minor	Moderate	Major	Catastrophic
Impact on the safety of patients, staff or public (physical/psycholo gical harm)	Minimal injury requiring no/minimal intervention or treatment. No time off work	Minor injury or illness, requiring minor intervention Requiring time off work for >3 days Increase in length of hospital stay by 1-3 days	Moderate injury requiring professional intervention Requiring time off work for 4-14 days Increase in length of hospital stay by 4-15 days SABRE/SHOT reportable incident An event which impacts on a small number of patients	Major injury leading to long-term incapacity/disability Requiring time off work for >14 days Increase in length of hospital stay by >15 days Mismanagement of patient care with long-term effects	Incident leading to death Multiple permanent injuries or irreversible health effects An event which impacts on a large number of patients
Quality, complaints, audit	Peripheral element of treatment or service suboptimal Informal complaint	Formal complaint Overall treatment or service suboptimal Single failure to meet internal standards Reduced performance rating if unresolved	Treatment or service has significantly reduced effectiveness Formal complaint (stage 2) Repeated failure to meet internal standards Major patient safety implications if findings are not acted on	Non-compliance with national standards with significant risk to patients if unresolved	Gross failure to meet national standards Totally unacceptable level of quality of treatment or service
Statutory duty/inspections	No or minimal impact or breech of guidance or statutory duty.	Breech of statutory legislation Reduced performance rating if unresolved	Single breech in statutory duty	Multiple breeches in statutory duty	Multiple breeches in statutory duty
EXAMPLE	Poor documentation of administration on the Transfusion Issue Card	Non-return of the Transfusion Issue Card to Blood Bank (Trust unable to provide traceability)	Acute transfusion reaction requiring more than symptom control – i.e. admission to ITU	Significant delay in obtaining blood products	Incompatible blood product transfused resulting in death