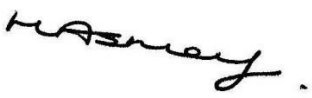
University Hospitals of Derby and Burton NHS Foundation Trust

POLICY DOCUMENT

Burton Hospitals

BLOOD TRANSFUSION CONSENT POLICY

Approved by:	**Clinical Management Committee**
On:	**14 August 2015**
Review Date:	~~**July 2018**~~ **Extended until Feb 2019**
Corporate / Directorate	**Corporate**
Clinical / Non Clinical	**Clinical**
Department Responsible for Review:	**Hospital Transfusion Team**
Distribution:	
• Essential Reading for:	**All clinical staff involved in prescribing or administering blood components.**
• Information for:	**Learning and Development Unit Governance**
Policy Number:	**300**
Version Number:	**1**
Signature:	 **Chief Executive**
Date :	**14 August 2015**

Burton Hospitals NHS Foundation Trust

POLICY INDEX SHEET

Title:	**Blood Transfusion – Consent**
Original Issue Date:	**New Policy**
Date of Last Review :	**New Policy**
Reason for amendment:	
Responsibility:	**Hospital Transfusion Team** **Hospital Transfusion Group**
Stored:	**Trust Intranet: Clinical Policies**
Linked Trust Policies:	– **Blood Transfusion Policy** – **Consent Policy** – **Policy For The Management and Reporting of Adverse Incidents and Near Misses** – **Patient Identification Policy** – **Learning and Development Policy** – **Induction Policy**
E & D Impact assessed	**EIA 363**
Consulted	**Hospital Transfusion Team** **Hospital Transfusion Group** **Risk and Compliance Group** **Legal Department** **Safeguard Matron** **Learning and Development** **Midwifery Department** **Governance Department** **Medical Directors** **Clinical Directors**

REVIEW AND AMENDMENT LOG

Version	Type of Change	Date	Description of Change

BLOOD TRANSFUSION POLICY
CONTENTS PAGE

ABBREVIATIONS

ALS	Applied Language Solutions
BCSH	British Committee for Standards in Haematology
BMA	British Medical Association
BMS	Biomedical Scientist
DHTRs	Delayed haemolytic transfusion reactions
FNHTR's	Febrile non-haemolytic transfusion reactions
FFP	Fresh Frozen Plasma
HTG	Hospital Transfusion Group
HTT	Hospital Transfusion Team
MHRA	Medicine and Health products Regulatory Authority
NHSBT	National Heath Service Blood & Transplant
NICE	National Institute for Health and Care Excellence
ODP	Operating Department Person
PTP	Post Transfusion Purpura
SABRE	Serious Adverse Blood Reaction and Events
SaBTO	Safety of Blood, Tissue and Organs
SHOT	Serous Hazards of Transfusion
TACO	Transfusion Associated Circulatory Overload
TA-GvHD	Transfusion Associated Graft-Versus-Host Disease
TRALI	Transfusion Related Acute Lung Injury

Burton Hospitals NHS Foundation Trust

BLOOD TRANSFUSION POLICY

1. KEYWORD SEARCH

Blood transfusion, consent, blood components, red blood cells, platelets, plasma, FFP, emergency, declining blood products, documentation, prescribing, blood products, plasma derivatives, anti-d, immunoglobulin, Prothrombin complex concentrate (PCC), coagulation factors.

2. SUMMARY

Transfusion of blood components is a common procedure that has significant benefits but is also associated with serious risks. Patients needing blood transfusion require full information on these benefits and risks in order to provide informed consent. The policy discusses the process of gaining consent and the resources available to support patients and health professionals. It is relevant for adults and paediatrics, and also for the administration of blood components in routine and emergency situations. The standards identified in the policy relate to the administration of blood components including red blood cells, platelets, fresh frozen plasma and cryoprecipitate. An additional section relates to the administration of blood products / plasma derivatives including albumin, coagulation factors (PCC/Octaplex) and immunoglobulin's (including Anti-D). This policy should be read in conjunction with the Trusts Consent Policy.

3. 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. It is a general legal and ethical principle that valid consent should be obtained from a patient before they are treated. Doctors need to be satisfied that they have consent from a patient, or other valid authority before providing any treatment (GMC, 2008).

The government's vision for the NHS is one that puts patients first, where "no decision about me, without me" is the norm. This puts the patients experience first, safeguarding the patient and person centred care. At the same time, patients increasingly wish to be active participants in their own care.

The National Institute for Health and Care Excellence (NICE, 2012) recommends that "patients are supported by healthcare professionals to understand relevant treatment options, including benefits, risks and potential consequences"; this includes blood transfusion. Patients should be given oral and written information as well as support to allow them to actively participate in their care and self-management. This principle is at the heart of the National Blood Transfusion Committee's principals and Patient Blood Management initiative (NHSBT 2014).

The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO, 2011 and 2014) recommends that “valid consent” for blood transfusion should be obtained and documented in the clinical records. This should include;

- The reason for transfusion
- The risks and benefits
- The transfusion process
- Any transfusion needs specific to the patient
- Any alternatives that are available, and how they might reduce their need for transfusion

In 2011, the Advisory Committee for the Safety of Blood, Tissues and Organs (SaBTO) announced their recommendations following a consultation exercise for Consent for Blood Transfusion. Their key recommendations, which state that valid consent for blood transfusion should be obtained and documented in the patient's clinical record by the healthcare professional, is already a recommendation made in the British Committee for Standards in Haematology (BCSH) Guideline on the Administration of Blood Components (2009). However, SaBTO also made the following recommendations which relate directly to clinical care. The BCSH Transfusion Task Force endorses these recommendations:

- There should be a modified form of consent for long term multi-transfused patients, details of which should be explicit in an organisation's consent policy.
- There should be a standardised information resource for clinicians indicating the key issues to be discussed by the healthcare professional when obtaining valid consent from a patient for a blood transfusion.
- There should be a standardised source of information for patients who may receive a transfusion in the UK.
- Patients who have received a blood transfusion and who were not able to give valid consent prior to the transfusion should be provided with information retrospectively.

4. PURPOSE AND AIM

The purpose of the Blood Transfusion Consent Policy is to ensure the process of involving patients in their care, informing them of the risks, benefits and alternatives to transfusion, and then obtaining consent for treatment (including the right to refuse), is a routine part of clinical care.

The aim of the Policy is to provide staff with the knowledge/information/tools required to obtain valid consent for blood products.

5. POLICY STATEMENT

The Trust will provide guidance to staff to ensure valid consent for blood products is obtained.

6. SCOPE

The Policy applies to all Trust staff in all locations involved in transfusion of blood components for transfusion. This includes, but is not exhaustive to include Nurses, Midwives, Doctors, locum Doctors, Operating Department Practitioners (ODP) and other Trust employees. This policy relates to the provision of blood components to both adults and children. When administering blood products to children, also refer to the Paediatric Blood Transfusion Policy. The blood components discussed include red blood cells, plasma, platelets and cryoprecipitate. Section 26 relates to the administration of blood products / plasma derivatives including albumin, coagulation factors and immunoglobulin's (including Anti-D).

7. KEY CONTACTS

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	Via switchboard
Haematology Specialist Practice Registrar	4394, Bleep 423
Blood Bank Manager	4126
Transfusion Practitioner	4126
Senior BMS Blood Bank	4087
Legal Services Department	5929

The Blood Bank is staffed Monday to Friday, 0900 – 1700. Outside of these hours contact the on-call Haematology Biomedical Scientist (BMS) via internal bleep 367.

8. DUTIES / ROLES AND RESPONSIBILITIES

8.1 All staff involved in the prescribing and administration of blood transfusion have a duty to ensure the components are administered safely. This includes obtaining valid consent for blood components. Such staff will have an awareness of the Blood Transfusion Consent Policy and where it is located.

8.2 The Trust Board has a corporate responsibility for ensuring;

- The Trust provides a safe environment and systems of work for staff, patients and visitors, as far as reasonable practicable.
- Overall responsibility of compliance with, and effectiveness of the administration of blood components/blood products and the Blood Transfusion Consent Policy.

- The Trust adheres to all statutory regulations and national recommendations relating to blood transfusion.

8.3 Associate Directors are responsible for:

- Ensuring staff who are involved in the blood transfusion process are competent through mandatory training and completion of competency requirements.
- Ensuring that staff follow policies and procedures for consent for blood components.

8.4 The Medical Director, Chief Nurse / Chief Operating Officer, Head Nurses and Matrons working with the Hospital Transfusion Team (HTG), are responsible for ensuring that health care professionals are informed of and adhere to the Trust policy.

8.5 The Hospital Transfusion Group (HTG) has delegated responsibility, on behalf of the Risk and Compliance Group, to implement the Trust's policies and procedures related to blood transfusion. It is also responsible for identifying and managing risk associated with transfusion. The HTG meets quarterly. Minutes from the HTG are received by the Trust's Risk and Compliance Group. The work of the HTG is overseen by the Regional Transfusion Committee (RTC - NHS Blood and Transplant).

8.6 The Hospital Transfusion Team (HTT) is the operational arm of the HTG. The HTT responsibilities regarding consent to transfusion are;

- Overseeing the Trust's policies and procedures related to consent for blood components.
- Ensuring haemovigilance.
- Monitoring adverse events related to transfusion.
- Reporting near misses and Serious Hazards of Transfusion to SHOT
- Audit related to consent for Blood Transfusion.
- Reporting to the HTG.
- Providing information and support for the clinical team involved with patients refusing blood components or blood products.

8.7 The Transfusion Practitioner is responsible for:

- Endorsing national guidelines and evidence-based practice related to consent for transfusion of blood components.
- Encouraging education and training related to consent for blood transfusion.
- Facilitating transfusion audit and feedback (continuous improvement).
- Providing information and support for the clinical team involved with patients declining blood components or blood products.
- Ensuring that the approved National Heath Service Blood and Transplant (NHSBT) written information are made available to patients receiving a blood transfusion.

8.8 On Call Duty Consultant Haematologist

- Provides a 24 hour advisory service and can be contacted via the hospital switchboard.
- Providing information and support for the clinical team involved with patients declining blood components or blood products.

8.9 The Legal Services Department is responsible for the provision of legal advice during normal working hours and ensuring effective arrangements are in place to enable legal advice out of normal working hours via the On-Call Hospital Manager

8.10 Medical staff are responsible for:

- Assessing the patient to ensure that the administration of blood components or blood products are appropriate for the patient.
- Explaining the risks and benefits of blood transfusion to patients and providing approved NHS Blood and Transplant (NHSBT) patient Information as appropriate.
- Recoding verbal consent to receive the blood components has been obtained and documented within the patient's medical notes. If consent cannot be obtained, it is good practice to record this and the reason why in the medical notes.
- Documentation of indications for transfusion, number of units administered and treatment efficacy within the medical notes.
- Prescribing blood components or blood products
- To ensure that they maintain their own training requirements related to transfusion as per this policy.

8.11 Nursing and midwifery staff, ODP's and anaesthetists involved in the administration of blood components or blood products are responsible for:

- Crucial role in ensuring that valid consent has been obtained prior to administering the blood components.
- The clinician who eventually administers the blood product must confirm that valid consent has been obtained, and that the patient still agrees to have the blood transfusion.
- Escalating concerns regarding consent for blood components to the relevant medical team.
- To ensure that they maintain their own training requirements related to blood transfusion as per this policy.

8.12 All staff involved in the transfusion of blood components are responsible for maintaining and updating their knowledge and practice, and ensuring that adverse incidents and reactions are reported.

9. CONSENT FOR BLOOD TRANSFUSION

9.1 The principles governing the requirement for explanation and discussion, obtaining the patients consent and documenting this information in the medical records are the same for transfusion of blood components as for any other therapeutic intervention.

9.2 Wherever possible, a trained and knowledgeable practitioner should inform the patient (and/or for paediatric patients those with parental responsibility) of the reason for and the risks, benefits and alternatives to blood transfusion (BCSH, 2009).

9.3 This should be done in a timely manner and in a way that they can understand, as recommended by the Health Service Circular HSC 2007/001 Better Blood Transfusion Safe and Appropriate Use of Blood. Informed consent, either verbal or written, should be obtained (wherever possible) and documented in the patient's clinical notes.

9.4 The provision of information is central to the consent process. Before patients can come to a decision about blood transfusion, they need information about their condition and about possible treatments and the risks and benefits (including the risks/benefits of doing nothing). Any misrepresentation of these elements will invalidate consent.

9.5 It is advisable that healthcare professionals give information about all significant possible adverse outcomes and make a record of the information given. For this reason, to enable clinicians to provide the relevant information to the patient to provide valid consent for treatment, a consent form for blood components is to be used at the time of planning the administration of the blood transfusion.

9.6 Signed written consent by the patient for blood transfusion is not, at present, a legal requirement within the UK. At the time of writing this policy, the Advisory Committee for the Safety of Blood, Tissues and Organs (SaBTO) is reviewing patient consent for blood transfusion.

9.7 The Trust requires formal documentation in the medical notes that the patient has been involved in the decision to transfuse blood components. There are several consent forms that facilitate this. The forms are discussed in more detail in section 18 – 21: Consent Forms for Blood Transfusion.

10. WHO SHOULD OBTAIN CONSENT FOR BLOOD COMPONENTS?

10.1 The clinician prescribing the blood transfusion is responsible for ensuring that the person has given valid consent before treatment begins, although the consultant responsible for the person's care will ultimately remain responsible for the quality of medical care provided.

10.2 The GMC guidance states that the task of seeking consent may be delegated to another person, such as a junior Doctor, as long as they are suitably trained and qualified. In particular, they must have sufficient knowledge of the proposed investigation or treatment, and understand the risks involved, in order to be able to provide any information the patient may require.

10.3 The clinician who eventually administers the blood product must confirm that valid consent has been obtained, and that the patient still agrees to have the blood transfusion. This is then documented on front page of the Transfusion Integrated Care Pathway (observation chart).

11. VALID CONSENT

Valid consent implies that the patient has also had the opportunity to refuse treatment or change their mind prior consent. Where transfusion of all, or specific blood components are refused, or an Advance Directive exists, this should be documented in the patient's clinical records and communicated to all relevant healthcare professionals.

Refer to the Trusts Consent Policy regarding who has the capacity to consent.

12. WHEN SHOULD CONSENT BE SOUGHT?

12.1 Consent for blood transfusion may take place at one time, or over a series of meetings and discussions, depending on the seriousness of what is proposed and the urgency of the patient's condition. There are several forms available in the Trust to facilitate consent for blood components. These are discussed in more detail in section 18 - 21.

12.2 Clinicians should check before commencing the blood transfusion that the person still consents, and whether they have any further concerns and whether their condition has changed. This is particularly important where there has been a significant lapse of time between the form being signed and the procedure. When confirming the patient's consent and understanding, it is advisable to use a form of words which requires more than a yes/no answer from the patient: for example beginning with "tell me what you're expecting to happen", rather than "You're going to have a blood transfusion, all right?"

12.3 While administrative arrangements will vary, it should always be remembered that for consent to be valid, the patient must feel that it would have been possible for them to refuse, or change their mind.

13. PROVISION OF INFORMATION

13.1 Once a decision to have a particular blood product has been made, patients need information about what will happen:

- What components they will receive
- How many components they will receive
- The risks and benifits
- Treatment options (including valid alternatives to transfusion)
- How and when it will be administered
- How they will feel afterwards

13.2 Patients and those close to them will vary in how much information they want: from those who want as much detail as possible, including details of rare risks, to those who ask health professionals to make decisions for them. There will always be an element of clinical judgement in determining what information should be given. However, the *presumption* must be that the patient wishes to be well informed about

the risks and benefits of the various options. Where the patient makes clear (verbally or non-verbally) that they do not wish to be given this level of information, this should be documented.

13.3 Sometimes blood transfusions are administered during major procedures. Bearing this in mind, the information shared with the patient related to the transfusion should be in proportion to the nature of the condition, the complexity of the proposed investigation or treatment, or the seriousness of the condition.

13.4 In considering what information to provide, the health practitioner should try to ensure that the person is able to make an informed judgement on whether to give or withhold consent. It is advisable to inform the person of any 'material' or 'significant' risks or unavoidable risks, even if small, in the proposed treatment; any alternatives to it; and the risks incurred by doing nothing.

13.5 However, it is possible that individuals' wishes may change over time, and it is important to provide opportunities for them to express this. GMC and BMA guidance encourages doctors to explain to patients the importance of knowing the options open to them while respecting a person's wish not to know, and states that basic information should always be provided about what the treatment aims to achieve and what it will involve.

13.6 Details of information supplied to the patient (verbally and/or in other formats) must be documented on the consent form or health record.

14. PATIENT INFORMATION LEAFLETS

14.1 Leaflets explaining the risks and benefits of, and alternatives to, transfusion are to be provided to patients to support this discussion. Patient information leaflets, produced nationally by the NHSBT, are available for adult and paediatric transfusion. Where possible it is recommended that a leaflet is provided to assist in obtaining informed consent. The are available in the clinical areas, and further copies can be obtained from the Blood Bank (next to the Blood Bank fridge), or from the Trusts Transfusion Practitioner.

14.2 For patients undergoing elective surgical procedures, the pre-operative assessment clinic is an ideal opportunity to initiate this process.

14.3 At the time of writing the policy, the following leaflets are available;

- Will I Need a Blood Transfusion?
- Will I Need a Platelet Transfusion?
- Information for patients who have received an unexpected blood transfusion
- Information for Patients Needing Irradiated Blood
- Blood Groups and Red Cell Antibodies in Pregnancy Patents Guide
- Will Your Baby Need a Blood Transfusion?
- Will Your Child Need a Plasma Transfusion?
- Will Your Child Need a Blood Transfusion pack
- Patient Blood Management

- Iron in Your Diet
- Anaemia Patient Information Leaflet

14.4 Electronic copies of the leaflets can be printed via the following web address http://hospital.blood.co.uk/patient-services/patient-blood-management-resources/patient-information-leaflets/

14.5 Patients may sometimes request more detailed information about their transfusion beyond that provided in general leaflets. Additional information regarding the risks of blood transfusion are available in appendix D. Please contact the Transfusion Practitioner or On-call Haematology Consultant if further assistance is required.

Provision for Patients who's first language is not English

14.6 Burton Hospitals NHS Foundation Trust is committed to ensuring that patients whose first language is not English receive the information they need and are able to communicate appropriately with healthcare staff. It is not appropriate to use children, or other family members, to interpret for patients who do not speak English.

14.7 Information leaflets translated into several languages for adults, children and parents are available from NHSBT. These can be printed from the following web-site. http://hospital.blood.co.uk/patient-services/patient-blood-management-resources/patient-information-leaflets/

14.8 The Trust has a contract with Applied Language Solutions (ALS) to provide our interpreting service; there is a back up telephone interpreting service through Language Line if ALS cannot provide an interpreter. Staffordshire ASSIST provide British Sign Language interpreting. All wards and departments have an Interpreting folder giving guidance on booking interpreters. This information is also available for staff on the PALS intranet page along with other guidance to support staff in caring for patients with different communication needs. http://queensintranet/directorates/Corporate/pals/interpreter.asp

15. INFORMATION RELATING TO TRANSFUSION RISKS

15.1 The risk of harm occurring as a result of a blood transfusion is very low. Compared with many medical and surgical procedures modern blood transfusion is extremely safe but deaths and major morbidity still do occur. Errors in the identification of patients, blood samples and blood components are the root cause of many preventable serious adverse events. Around 1 in 13 000 blood component units are transfused to the wrong patient (not always with adverse consequences) and up to 1 in 1 300 pre-transfusion blood samples are taken from the wrong patient. Transfusion related deaths can also occur due to transfusion associated circulatory overload (TACO) and transfusion-related acute lung injury (TRALI) (SHOT 2013).

15.2 Transfusion risks are discussed in more detail in Appendix D. The NHSBT patient information leaflets explains some of the risks for the patient, but the clinician may need to discuss further risks for the individual patient based on the patient

assessment. Note that SHOT have reported that most transfusion related deaths occur as a result of Transfusion Associated Circulatory Overload (SHOT 2011, 2012, 2013).

16. INFORMATION RELATING TO TRANSFUSION ALTERNATIVES

The Trust actively supports the principles of Patient Blood Management (National Blood Transfusion Society 2014) which state that everyone involved in blood transfusion needs to take responsibility for ensuring that blood components are used appropriately for the benefit of patients. On some occasions, there are alternative treatments available to transfusing blood components. These include the use of;

- Iron supplements (oral, intramuscular or intravenous iron) for the treatment of iron deficiency anaemia.
- Vitamin B12 or folic acid may be given if these vitamins are deficient.
- Erythropoietin (stimulates the bone marrow to produce red cells)
- Prothrombin complex concentrate to reverse the effects of oral anticoagulation therapy when bleeding occurs requiring rapid action to accelerate coagulation.

For more information refer to the Blood Transfusion Policy or contact the On-Call Haematology Consultant.

17. DOCUMENTATION IN THE MEDICAL NOTES

17.1 As per the Blood Transfusion Policy, clinical assessment should include an evaluation of the patient's age, body weight and concomitant medical conditions that predispose to Transfusion Associated Circulatory Overload (TACO): cardiac failure, renal impairment, hypoalbuminaemia and fluid overload. These factors should be documented in the patients' clinical notes and should be considered when prescribing the volume and rate of the transfusion, and in deciding whether diuretics should be prescribed.

17.2 The rationale for the decision to transfuse and the specific components to be transfused must be documented in the patients' clinical records. This is in addition to completing the relevant Consent checklist. The following information must be documented:

- Clinical assessment for suitability for transfusion
- Clinical indication for transfusion
- Date of the proposed transfusion
- Type of blood product for transfusion
- The number of units to be transfused

18. CONSENT FORMS FOR BLOOD TRANSFUSION

18.1 The Trust also requires formal documentation for transfusion of blood components. There are several consent forms that facilitate this.

Form Title	When to use	Print Ref No.
Consent Checklist for Blood Transfusion	Consent Checklist for transfusion of blood components for planned transfusions of red blood cells, platelets, plasma or cryoprecipitate. (See Appendix B)	QHB785A
Consent Checklist for Blood Transfusion (For patients requiring regular transfusions of blood components)	Consent Checklist for transfusion of blood components for patient's receiving multiple transfusions. (See Appendix C)	QHB786A
Consent form 1: Patient Agreement to Investigation or Treatment (adult)	When unplanned blood transfusion may become necessary during a procedure (adults). Refer to the Trusts Consent Policy.	WKZ991A
Consent Form 2: Parental agreement to investigation or treatment for a child or young person	When unplanned blood transfusion may become necessary during a procedure (paediatrics). Refer to the Trusts Consent Policy.	WKZ992A
Consent form 5: Jehovah's Witnesses Excluding Blood Components	Refer to the Trusts Consent Policy and Blood Transfusion -Declining Blood Components Policy	QHB272A

The Consent for Blood Components checkllist does not require a patient signature, but Consent Forms 1, 2 and Consent Form 5 (Excluding Blood Components) do require patient signatures. Completed forms must be completed in full and filed in the patient's medical records.

18.2 **Consent Checklist for Blood Transfusion (General) Prospective and Retrospective**

Planned transfusion of blood components will usually require the full Consent Form for Blood Transfusion (general) to be completed and written patient information provided (NHSBT leaflet). Where possible, discussion should take place to include appropriate information regarding the benefits and risks of transfusions and specific relevant. Refer to appendix D for a summary of transfusion risks. The lower section of this form will be used in the event of an unplanned transfusion during a care event that does not allow for discussion e.g. during a surgery or an emergency event (refer to section 19). If the patient is unable to consent, refer to section 20.

18.3 **Consent Form 1 – Patient Agreement to Investigate or Treatment (adults), Consent Form 2 - Parental agreement to investigation or treatment for a child or young person** (for use when unplanned blood transfusion may become necessary during a planned procedure)

The GMC guidance states that it is good practice to seek the views of the patient on possible additional procedures including transfusion when seeking consent for the original intervention. In the case of planned surgical procedures, the Trust consent forms WKZ991A (Form 1) – "Patient agreement to investigation or treatment", and WKZ992A (Form 2) "Parental agreement to investigation or treatment for a child or young person", requires that blood transfusion is discussed if it is an extra procedure that may become necessary during the investigation or treatment. Again, the discussion should include what the blood transfusion involves, the benefits and risks and any available alternative treatments, and any particular concerns of this patient. If blood transfusion may be needed, or is anticipated during a surgical procedure, the Consent for Blood Transfusion Checklist should be completed.

During an operation it may become evident that the person could benefit from a blood product that was not within the scope of the original consent. If it would be unreasonable to delay the procedure until the person regains consciousness (for example because there is a threat to the person's life) it may be justified to administer the blood product on the grounds that it is in the person's best interests. However, the administration of the blood product should not be merely because it is convenient.

18.4 **Modified Consent Checklist for Blood Transfusion (For patients requiring Regular Transfusion of RBC, FFP, Platelets or Cryo)**

Long-term transfusion-dependent patients will not require the consent form to be completed at each transfusion episode. For this purpose a modified consent form is to be used.

When obtaining consent for the first transfusion regime, the full Consent Form for Blood Transfusion will be completed at this stage and written patient information provided (NHSBT leaflet). Where possible, discussion should take place to include appropriate information regarding the benefits and risks of multiple transfusions and specific relevant issues e.g. iron overload, risk of allo-immunisation including haemolysis risks (red cells) and platelet refractoriness (HLA antibodies), infective risks and other transfusion reactions.

Subsequent transfusions administered where there is no change in treatment or risk will require completion of the Modified Consent for Blood Components (Transfusion Dependent Patients) form. Patient information leaflets are not required to be given to the patient again unless it is felt appropriate for the individual patient.

If the patient's condition alters significantly to require a change to the treatment plan, or the risks to the patient alter, the full consent form for blood components will need to be completed again.

19. RETROSPECTIVE DOCUMENTATION OF CONSENT IN EMERGENCY SITUATIONS

19.1 In emergency situations, the clinician has a duty of care and should act to preserve life. Unless the patient explicitly refuses transfusion or carries an Advance Directive, transfusion that is considered to be in their best interests should be carried out and the decision and rationale documented in the patients clinical records.

19.2 Clearly in emergencies, the two stages (discussion of options and confirmation that the patient wishes to go ahead) will follow straight on from each other, and it may often be appropriate to use the patient's notes to document any discussion and the patient's consent, rather than using a form.

19.3 The urgency of the patient's situation may limit the quantity of information that they can be given, and the documentation recorded, but should not affect its quality. Where possible, a statement should be recorded confirming the reason for the transfusion, the transfusion plan, and any possible risks (e.g. TACO). The documentation should also include if the patient has provided verbal consent for the transfusion and alternatives that may have been offered.

19.4 Patients who unknowingly received blood components should be informed that they have received a blood component transfusion prior to (e.g. transfused during surgery or emergency situations). It is the responsibility of the prescribing Doctor to ensure that this takes place.

19.5 The Blood Transfusion Consent Form (appendix B) includes a section for retrospective transfusions. Only this lower section of the form requires completion.

19.6 The patient will need to be given an NHSBT patient information leaflet relevant to the blood product received, and also a copy of the NHSBT leaflet "information for Patients Who Have Received an Unexpected Blood Transfusion". The later provides information to the patient stating that they can no longer be a blood donor, and where to find out additional information about blood transfusion.

20. DOCUMENTATION OF CONSENT WHEN PATIENTS ARE UNABLE TO CONSENT

20.1 The relevant consent for blood components form must be used unless the patient is unable to consent.

20.2 When it is felt the patient has no capacity to consent, the doctor must ensure compliance with the Trust's Consent Policy. All decisions made on behalf of the person who lacks capacity need to be made in the person's best interest. It is important to document this in the medical notes. Records should show what the decision was, why the decision was made, how the decision was made, who was involved (recording names where possible) and the outcome of the capacity assessment. Further advice regarding consent can be obtained from Legal Services or the Safeguarding Matron.

20.3 The principles of the Mental Capacity Act (DoH, 2005) must be adhered to. The five principles outlined in the Section 1 of the Act are designed to protect people who lack capacity to make particular decisions, but also to maximise their ability to make decisions, or to participate in decision-making, as far as they are able to do so.

- A person must be assumed to have capacity unless it is established that he/she lacks capacity.
- A person is not to be treated as unable to make a decision unless all practicable steps to help him/her to do so have been taken without success.
- A person is not to be treated as unable to make a decision merely because he/she makes an unwise decision.
- An act done, or decision made, under this Act for or on behalf of a person who lacks capacity must be done, or made, in his/ her best interests.
- Before the act is done, or the decision is made, regard must be had to whether the purpose for which it is needed can be as effectively achieved in a way that is less restrictive of the person's rights and freedom of action.

21. DURATION OF CONSENT

21.1 When a person gives valid consent for transfusion of blood components, in general that consent remains valid for an indefinite duration, unless it is withdrawn by the person.

21.2 However, if new information becomes available regarding the blood transfusion (for example new evidence of risks or new treatment options) between the time when consent was sought and when the intervention is undertaken, the GMC guidance states that a doctor or member of the healthcare team should inform the patient and reconfirm their consent. In the light of this, the clinician should consider whether the new information should be drawn to the attention of the patient and the process of seeking consent repeated on the basis of this information. Similarly, if the patient's condition has changed significantly in the intervening time it may be necessary to seek consent again, on the basis that the likely benefits and/or risks of the transfusion may also have changed.

21.3 It is good practice to confirm that the person who has given consent (assuming that they retain capacity) still wishes to have the blood components immediately prior to administration. Where possible, the Nurse, Midwife, ODP or Anaesthetist administering the blood component must ensure that consent has been obtained prior to administration, and that the patient is aware of what blood components they are to receive. The Blood Transfusion Care Pathway (QHB695A) includes a check for this for the clinician to record that they have undertaken this. If there is any doubt regarding consent, this needs to be addressed by the Doctor and the prescribing Doctor must be informed.

22. DECLINING BLOOD TRANSFUSION

22.1 If the process of seeking consent is to be a meaningful one, refusal must be one of the patient's options. Refer to the Trust's Consent Policy and the Declining Blood Transfusion Policy for further information.

22.2 Declining of blood components may occur for many reasons such as fear of errors, infection transmission or because of religious beliefs. The decision to not allow people to donate blood if they have received a blood transfusion since 1990 has further increased the occurrences of declining blood components. It is important to understand why the patient is declining, and it is necessary to record this and the reason why in the medical notes.

22.3 If a person has declined certain blood components before an anaesthetic, then this must be respected if the refusal is applicable to the circumstances. The patients Lead Consultant and Consultant Anaesthetist must be informed as soon as this is known. Further discussions and investigations will need to take place before the Consultants and the patient decide if undergoing the procedure is in the patient's best interest. Refer to the Declining Blood Transfusion Policy for further information.

22.4 Where a patient has refused to have a transfusion of a blood component, ensure that the patient realises they are free to change their mind. Where delay may affect their treatment choices, they should be advised accordingly. Refer to the Trust's Consent Policy and the Blood Transfusion - Declining Blood Policy for further information.

23. WITHDRAWAL OF CONSENT

A person with capacity is entitled to withdraw consent at any time, including during the administration of the blood component. Where a person does object during treatment, it is good practice for the practitioner, if at all possible, to stop the procedure, establish the person's concerns and explain the consequences of not completing the procedure. This must be recorded in the patient's records.

24. CONSENT FOR CHILDREN AND YOUNG PEOPLE

The legal position concerning consent and refusal of treatment by those under the age of 18 is different from the position for adults. For the purposes of this Policy 'children' refers to people aged below 16 and 'young people' refers to people aged 16–17. Reference must also be made to the Trust's Consent Policy and the Declining Blood Components Policy.

24.1 **Consent for Children (up to 16)**

Only people with 'parental responsibility' are entitled to give consent on behalf of their children. You must be aware that not all parents have parental responsibility for their children (for example, unmarried fathers do not automatically have such responsibility although they can acquire it). If you are in any doubt about whether the person with the child has parental responsibility for that child, you must check.

A child under 16 may have the capacity to consent to some interventions but not to others. The child's capacity to consent should be assessed carefully in relation to each decision that needs to be made. It is, however, good practice to involve the child's family in the decision-making process, if the child consents to their information being shared.

Although a child or young person may have the capacity to give consent, this is only valid if it is given voluntarily. This requirement must be considered carefully. Children and young people may be subject to undue influence by their parent(s), other carers or a sexual partner (current or potential), and it is important to establish that the decision is that of the individual him or herself.

Refer to the Declining Blood Transfusion Policy for information related to children and/or parents declining blood components

24.2 **Consent for Young People (16-17)**

By virtue of section 8 of the Family Law Reform Act 1969, people aged 16 or 17 are presumed to be capable of consenting to their own medical treatment, and any ancillary procedures involved in that treatment, such as blood transfusions. Consent will be valid only if it is given voluntarily by an appropriately informed young person capable of consenting to the particular intervention. However, unlike adults, the refusal of a competent person aged 16–17 may in certain circumstances be overridden by either a person with parental responsibility or a court.

25. CONSENT FOR BLOOD PRODUCTS / PLASMA DERIVATIVES

25.1 Plasma derivatives include albumin, coagulation factors (Prothrombin Complex/Octaplex) and immunoglobulin's (Anti-D/Rophylac). They are manufactured from pooled plasma donations in plasma fractionation centres. Such blood components are not considered to be a blood component, and therefore do not come under MHRA's remit for the Blood Safety Quality Regulations.

25.2 The manufacture of plasma derivatives, including anti-D immunoglobulin, is strictly controlled. All donors are screened for hepatitis B, hepatitis C and HIV. Since 1999, as a vCJD risk-reduction measure, all plasma derivatives used in the UK are manufactured using donations from countries with a low risk of vCJD. The end product is also treated to deactivate any viruses, so the risk of contracting a virus through plasma derivatives is extremely low.

25.3 Plasma derivatives are covered by the Medicines Act and, like any other drug, must be prescribed by a licensed practitioner. Verbal consent for these blood products is required, but unlike transfusions of blood components such as red blood cells or plasma, a consent form is not required to be completed. Verbal consent is appropriate, but the consent process must be documented. Documentation should include the patient's decision to either accept or decline the product, and if relevant, the reason for declining should also be recorded. The documentation

should also include the date when the blood product is to be given the strength of dose and route of administration. It is good practice to also state what written information has been provided

25.4 All pregnant women must be offered written and verbal information about anti-D immunoglobulin to inform their decision about receiving anti-D immunoglobulin. NICE guidance recommends that choice is offered at the time of recording blood group in her antenatal healthcare records. This should be clearly recorded by the healthcare professional, both in the woman's 'handheld' and the hospital records (BCSH, 2014). It is good practice to also state what written information has been provided to the lady.

25.5 The information leaflet "Blood Groups and Red Cell Antibodies in Pregnancy" is available for pregnant women to help with the informed consent process which is produced by NHSBT. Additional copies are available from the Trusts Transfusion Practitioner.

26. REPORTING INCIDENTS

26.1 Any unexpected transfusion event related to consent that has an actual or potential short term or long term detrimental effect on a patient must be reported using the Trust's Safeguard adverse incident reporting system under the category patient incident/transfusion. Incident reporting should include "near miss" episodes involving procedural errors which were detected in time to prevent a serious complication of blood transfusion. All incidents related to transfusion graded 3 to 5 must be discussed with the patient or their representative. The Transfusion Practitioner or Blood Bank must be informed of any grade 3 to 5 incident relating to transfusion as soon as is possible.

26.2 Incidents requiring reporting on Safeguard include;

- Valid consent for blood components has not been obtained.
- An individual has taken formal consent for a procedure which they are not appropriately trained.
- Clinical audit has identified non compliance with the requirement that staff should be appropriately trained to take consent.

26.3 The Blood Bank Manager and Transfusion Practitioner will be notified of all incidents entered with a Transfusion category. Subsequently, as part of the Adverse Incident investigation, a Root Cause Analysis will be undertaken and any risk issue identified will be addressed, including a review of the requirement and appropriateness of that individual to take Consent. An action plan will be agreed and monitored.

26.4 The Clinical Risk Manager provides the Transfusion Practitioner with a monthly report of transfusion related incidents. This is then reported to the HTT, HTG and Risk and Compliance Group.

26.5 The Trust actively reports to both Serous Hazards of Transfusion (SHOT) and Serious Adverse Blood Reaction and Events (SABRE). The HTT will investigate all

adverse incidents relating to blood transfusion and submit the required external report to SHOT or SABRE. Significant incidents are reported to the HTG.

27. TRAINING NEEDS ANALYSIS

27.1 As per the Blood Transfusion Policy, it is essential that staff involved in the transfusion process are sufficiently educated in transfusion matters and assessed as competent to perform critical tasks.

27.2 The Medicines & Healthcare Regulatory Authority (MHRA) dictate that all staff involved in the prescribing of blood components undertake dedicated, mandatory blood transfusion training on a regular basis. Doctors are required to undertake BT6 every two years.

27.3 The Trust's Mandatory Training Matrix is maintained within the Electronic Staff Record and will identify all individual staff roles required to complete the individual blood training course.

27.4 The training allows practitioners to:

- Meet national training requirements for staff involved in blood transfusions
- Develop the technical/theoretical knowledge required to underpin new and existing clinical skills.
- Review and update their knowledge to inform their practice.

27.5 Clinicians are responsible for knowing the limits of their own competence, and should seek the advice of appropriate colleagues when necessary.

28. MONITORING COMPLIANCE

28.1 It is good practice for each clinical area to self-audit their compliance with the Blood Transfusion Consent Policy.

28.2 The Transfusion Practitioner will undertake an annual audit which will focus on the administration of the blood product in clinical practice and consent. Ten patient records will be reviewed using a standard audit tool (appendix E).

28.3 The Trust will participate in relevant national audits relating to consent for transfusion as agreed by the HTT/HTG.

28.4 Audit findings will be reported to the HTT/HTG.

28.5 Audit findings and analysis of adverse incident reports are used to inform teaching programmes and ward / department based education.

29. POLICY EFFECTIVENESS

The effectiveness of this policy will be measured in the following ways:

- Adherence to the policy will be monitored on an on-going basis by the Transfusion Practitioner (internally).
- Level of consultation (internal and external)

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Appendix A

GUIDANCE FOR CLINICAL STAFF TO SUPPORT PATIENT CONSENT FOR BLOOD TRANSFUSION

Patient may require Blood / Blood Component Transfusion

Patients receiving a blood transfusion (red cells, platelets plasma or cryoprecipitate) whether for a medical or surgical cause should be informed of the indication for the transfusion including risks, benefits and alternatives. A record of this discussion should be documented in the patient s clinical records.

Ideally the decision to transfuse should be made with the patient or parent/carer in advance of any planned transfusion.

In the emergency setting, the information will need to be given retrospectively.

Prospective Information

Valid consent* should be obtained prior to any planned transfusion and documented in the patients clinical record.

* Valid consent entails the provision of information on risks, benefits and alternatives available before asking the patient to give consent. This does not have to include a signature from the patient.

Retrospective Information

Patients treated in emergency setting where it was not possible to obtain valid consent pre-transfusion. Patients who were told pre-procedure (e.g. preoperatively) that they *might* require a transfusion then need to be informed whether they did/did not receive a transfusion.

Key issues to be discussed when obtaining valid consent

1. The following information must be discussed and recorded on the relevant Consent Form
   - Blood component to be transfused
   - Indication for transfusion
   - Benefits of the transfusion
   - Risks of transfusion
   - Possible alternatives to transfusion
   - How the transfusion is administered and the importance of correct patient identification
   - Inform patient that following a blood transfusion they can no longer be a blood donor.
2. Provide written information (NHSBT leaflets).
3. Check if patient needs time to consider or requires further information.
4. Document the discussion in the patient's clinical records/File the relevant Consent Form.

At discharge

1. If patient has had a transfusion, ensure that they have been informed.
2. Record information about the transfusion in the discharge summary, also stating that the patient has been informed.

Appendix B

Burton Hospitals NHS
NHS Foundation Trust

Patient ID Sicker
Hospital Number: _____
Surname: _____
Forename: _____
Date of Birth: _____

CONSENT FOR BLOOD TRANSFUSION
(General) Prospective and Retrospective Checklist
Transfusion of RBC, FFP, Platelets or Cryo

This checklist must be completed in full prior to prescribing blood components (prospectively), or retrospectively when blood components have been administered in an emergency situation. Medical staff are to complete the checklist.

Key issues which must be discussed and agreed, with the patient, when obtaining valid verbal consent. Please tick all to indicate the following have been discussed.
Please put N/A if not applicable.

Product to be Transfused; _____ Quantity _____
Indication for transfusion; _____
Date of proposed transfusion; _____

Note: Specific blood components/products must be prescribed along with the special requirements, if applicable (e.g. irradiated, CMV negative, HLA matched). If a blood warming device is required, please specify in the prescription.

Prospective Consent Checklist for Blood Transfusion – to be discussed with the patient

	tick
1. Type of blood component to be transfused	☐
2. Number of units to be administered	☐
3. Indication for transfusion	☐
4. Predicted benefits of the transfusion	☐
5. Risks of the transfusion	☐
6. Possible alternatives to transfusion	☐
7. How the transfusion is administered	☐
8. The importance of correct patient identification.	☐
9. The relevant patient information leaflet must be provided (NHSBT)	☐
10. Does the patient need more time to consider or require further information?	Yes/No
11. Has the patient given verbal consent if able?	Yes/No
12. Unable to complete all of the above as the patient falls under the mental capacity act/confused/unconscious or other situation _____	Yes/No

Retrospective Checklist Blood Transfusion

	tick
1. Type of blood component administered	☐
2. Number of units administered	☐
3. Indication for transfusion	☐
4. Risks of the transfusion	☐
5. Inform the patient that following a blood transfusion they can no longer be a blood donor.	☐
6. The relevant patient information leaflet must be provided including Information for Patients Who Have Received an Unexpected Blood Transfusion (NHSBT)	☐

Completing Doctor - Ensure all boxes have been ticked or where not applicable, put N/A. Print and sign your name below and file in the patient's medical records when complete.

Discussed with (name)_____
Print name_____ Grade_____ Speciality_____
Signed_____ Date_____ Time _____

Guidance

This document has been developed in line with SaBTO and NICE guidance for clinical staff to support patient consent. These also reflect the GMC guidance *Consent: Patients and Doctors Making Decisions Together* and *Good Medical Practice*. For further information, please refer to the Trusts Blood Transfusion - Consent Policy and the Trusts Consent Policy.

Type of blood component to be transfused (e.g. red cells, plasma, platelets, cryoprecipitate)
Indication for transfusion (e.g. low HB, symptomatic anaemia, low platelet count etc.)
Predicted benefits of the transfusion (e.g. symptomatic relief, desired HB etc.)
Risks of the transfusion (see below)
Possible alternatives to transfusion (e.g. oral/IV iron, withhold transfusion with possible delayed recovery etc.)
How the transfusion is administered. (e.g. IV also duration, special requirements such as blood warmer etc.)
The importance of correct patient identification. It is important for the patient to know that for safety reasons, they will be asked several times to confirm their name and date of birth to ensure the right blood is given to the right patient.
Inform the patient that following a blood transfusion they can no longer be a blood donor. Since 1980 people who have received blood transfusions can no longer donate blood. This is to minimise the vCJD risk in this country.
The relevant patient information leaflet must be provided (NHSBT). These are available in every relevant clinical area (further stocks can be obtained from next to the Blood Bank Fridge).

Risks of Transfusion

The NHSBT leaflet "Will I Need a Blood Transfusion" discusses the safety of blood transfusions. The current blood donation testing strategies in the UK minimise the risk of transfusion transmitted infections. The likelihood of getting an infection is therefore very low as noted below.

- Hepatitis B – 1 in 1.3 million blood donations
- HIV – 1 in 6.5 million
- Hepatitis C – 1 in 28 million

Non-infectious acute transfusion reactions (ATR's) include;

- Febrile non-haemolytic transfusion reactions – usually clinically mild – likely to continue the transfusion after symptomatic treatment.
- Allergic transfusion reactions – ranging from mild urticaria to life-threatening angioedema or anaphylaxis.
- Transfusion-associated circulatory overload (TACO) – cardiac, renal, low BMI increased risk.
- Transfusion-related acute lung injury (TRALI).
- Acute haemolytic transfusion reactions – e.g. ABO incompatibility.

- Bacterial contamination of blood unit – range from mild pyrexial reactions to sepsis.

Severe ATRs occur in about 1 in 7000 units transfused.
Patients should be asked to report symptoms that arise during the transfusion and for at least the next 24 hours.
Refer to the Blood Transfusion – Consent Policy for additional information.

FILE IN MEDICAL NOTES WHEN COMPLETE

Appendix C

Burton Hospitals NHS
NHS Foundation Trust

CONSENT FOR BLOOD TRANSFUSION (REGULAR TRANSFUSIONS)

Patient ID Sicker
Hospital Number: _____
Surname: _____
Forename: _____
Date of Birth: _____

Checklist for patients requiring regular transfusion
Transfusion of RBC, FFP, Platelets or Cryoprecipitate

Consent for Blood Transfusion (General) form has been completed for the first transfusion. Since the previous transfusion episode, there has been no change in the treatment plan or risk to the patient that would warrant completion of the Consent for Blood Transfusion (General) form.

Today I have discussed the following with the patient;

Indication for transfusion	
Type of blood component to be transfused (include special requirements)	
Number of units to be administered	
Proposed transfusion date	

The patient has previously been informed of the benefits and risks of the transfusion, possible alternatives to transfusion, how the transfusion is administered and the importance of correct patient identification. The relevant patient information leaflet has been provided (NHSBT) and the patient is aware that following a blood transfusion they can no longer be a blood donor. The patient has consented to the on-going transfusion programme.

Completing Doctor

Print name _____ Grade _____ Speciality _____

Signed _____ Date _____ Time _____

FILE IN MEDICAL NOTES WHEN COMPLETE

Appendix D

Information for Clinicians - Transfusion Risks

Compared with many medical and surgical procedures modern blood transfusion is extremely safe but deaths and major morbidity still do occur. Errors in the identification of patients, blood samples and blood components are the root cause of many preventable serious adverse events. Around 1 in 13 000 blood component units is transfused to the wrong patient (not always with adverse consequences) and up to 1 in 1 300 pre-transfusion blood samples are taken from the wrong patient.

Serious acute transfusion reactions are often unpredictable but patients are put at unnecessary risk by inappropriate decisions to transfuse. In 2013 Annual Report, the UK Serious Hazards of Transfusion haemovigilance scheme (SHOT – http://www.shotuk.org/) described 247 incidents of 'incorrect blood component transfused' (each underpinned by 100 near misses).

Twelve ABO-incompatible transfusions (all due to clinical errors) and 161 incidents of 'avoidable, delayed or under-transfusion' were reported. There were twenty two transfusion-related deaths (twelve associated with transfusion-associated circulatory overload) and 143 cases of major morbidity (most often following acute transfusion reactions).

Transfusion-transmitted infection is now a rare event but there is no room for complacency as the emergence of new infectious agents requires constant vigilance.

Non-Infectious Hazards of Transfusion

Acute transfusion reactions

Acute transfusion reactions (ATRs) present within 24 hours of transfusion and vary in severity from mild febrile or allergic reactions to life-threatening events. They include:

- Febrile non-haemolytic transfusion reactions – usually clinically mild
- Allergic transfusion reactions – ranging from mild urticaria to life-threatening angio-oedema or anaphylaxis.
- Acute haemolytic transfusion reactions – e.g. ABO incompatibility.
- Bacterial contamination of blood unit – range from mild pyrexial reactions to rapidly lethal septic shock depending on species.
- Transfusion-associated circulatory overload (TACO).
- Transfusion-related acute lung injury (TRALI).

Patients should be asked to report symptoms that arise during the transfusion and for at least the next 24 hours.

Severe ATRs occur in about 1 in 7000 units transfused. Patients may present suddenly with cardiovascular collapse and the underlying cause may not be immediately apparent. The differential diagnosis of severe, life-threatening ATRs includes bacterial transfusion-transmitted infection, acute haemolytic reactions (usually due to ABO-incompatible transfusion), anaphylaxis, TRALI and TACO.

Severe and Life-Threatening Reactions

Acute Haemolytic Reactions

The most serious reactions are caused by transfusion of ABO-incompatible red cells which react with the patient's anti-A or anti-B antibodies. There is rapid destruction of the transfused red cells in the circulation (intravascular haemolysis) and the release of inflammatory cytokines. The patient often quickly becomes shocked and may develop acute renal failure and disseminated intravascular coagulation (DIC). Transfusion of less than 30 mL of group A red cells to a group O patient has proven fatal. Acute haemolysis may also, rarely, be caused by transfusing plasma-rich blood components, such as platelets or FFP (usually group O) containing high-titre or high-potency anti-A or anti-B antibodies to a patient with group A, B or AB red cells. This has mainly been reported in infants and small children. The 2013 annual report for SHOT includes one case of fatality due to an acute haemolytic reaction.

ABO-incompatible transfusion occurs in around 1 in 180 000 red cell units transfused. It is usually caused by human error when taking or labeling pre-transfusion blood samples, collecting components from the blood bank or satellite refrigerator and/or failing to perform a correct identity check of blood pack and patient at the bedside. If red cells are transfused to the wrong patient, there is around a 30% chance they will be ABO incompatible. Major morbidity (requiring intensive care or renal dialysis) occurs in up to 30% of cases and 5–10% of episodes contribute to the death of the patient.

Transfusion-associated circulatory overload (TACO)

TACO is defined as acute or worsening pulmonary oedema within 6 hours of transfusion. Typical features include acute respiratory distress, tachycardia, raised blood pressure and evidence of positive fluid balance. It has probably been significantly under-reported in the past and may now be the most common cause of transfusion-related death in developed countries.

TACO causes significant morbidity and mortality. In 2013 SHOT received 96 reports of TACO. It contributed to the death of twelve patients and was responsible for 34 cases of major morbidity. Elderly patients with low a low body mass index are at particular risk. Predisposing medical conditions can also include the risk of circulatory overload. These include heart failure, renal impairment and low albumin concentration. Small patients, such as the frail elderly and children, are at increased risk of receiving inappropriately high volume and rapid blood transfusions. Most reported cases involve red cell transfusions but high-volume FFP transfusions, sometimes given inappropriately for reversal of warfarin, have been identified as a risk. Poor pre-transfusion clinical assessment, failure to administer a diuretic and inadequate monitoring during transfusion is a common feature of reported cases.

Transfusion of a blood component contaminated by bacteria

Although rare, this more often occurs with platelet components (which are stored at 22–24°C) than with red cells refrigerated at 2–6°C and can rapidly be fatal. Measures to reduce bacterial contamination from the donor arm have significantly reduced this risk but awareness and rapid response are important. The transfusion of a pack contaminated with highly pathogenic bacteria often causes an acute severe reaction soon after the

transfusion is started. Initially, this may be indistinguishable from an acute haemolytic reaction or severe allergic reaction. Typical symptoms and signs include rigors, fever (usually >2°C above baseline), hypotension and rapidly developing shock and impaired consciousness. The 2013 annual report for SHOT states that there were no proven bacterial incidents in 2013.

Severe allergic or anaphylactic reactions

Shock or severe hypotension associated with wheeze (bronchospasm), stridor from laryngeal oedema or swelling of face, limbs or mucous membranes (angioedema) is strongly suggestive of anaphylaxis – an acute, life-threatening emergency. Other skin changes may include flushing and urticaria ('nettle rash' or hives) that also occur in less severe allergic reactions. Severe allergic and anaphylactic reactions may occur with all blood components but are most commonly reported with plasma-rich components such as platelets or FFP. The 2013 annual report for SHOT reported that there were no transfusion related deaths as a result of severe allergic or anaphylactic reactions.

Severe allergic reactions associated with IgA deficiency

Only a small minority of patients with IgA deficiency are at risk of developing severe allergic reactions to blood components. Those at most risk have severe IgA deficiency (<0.07 g/L), often with anti-IgA antibodies in their plasma. Even then, most such patients do not react to blood transfusion. Patients with less severely reduced IgA levels as part of a more generalised (e.g. common variable immunodeficiency or secondary to a lymphoproliferative disorder) antibody deficiency disorder and the frequent mild cases picked up when screening for IgA coeliac antibodies are not at risk. Patients with no history of severe reactions to blood transfusion should be transfused with standard blood components. The small group of patients with severe IgA deficiency and a clear history of serious allergic reaction to blood components should be discussed with a specialist in transfusion medicine and/or clinical immunologist.

Transfusion-related acute lung injury (TRALI)

Classical TRALI is caused by antibodies in the donor blood reacting with the patient's neutrophils, monocytes or pulmonary endothelium. Inflammatory cells are secluded in the lungs, causing leakage of plasma into the alveolar spaces (non-cardiogenic pulmonary oedema). Most cases present within 2 hours of transfusion (maximum 6 hours) with severe breathlessness and cough productive of frothy pink sputum. It is often associated with hypotension (due to loss of plasma volume), fever and rigors and transient peripheral blood neutropenia or monocytopenia. Chest X-ray shows bilateral nodular shadowing in the lung fields with normal heart size.

SHOT data suggest an approximate incidence of TRALI of 1 in 150 000 units transfused. It is most common after transfusion of plasma-rich blood components such as FFP or platelets and implicated donors are usually females sensitised during previous pregnancy. Since the UK Blood Services switched to using male donors for producing FFP, re-suspending pooled platelets in male plasma and screening female apheresis platelet donors for leucocyte antibodies, SHOT has documented a significant fall in both reported cases and mortality from TRALI. The 2013 annual report for SHOT reported ten cases of TRALI, including one death.

Hypotensive reactions
Hypotensive reactions are indicated by an isolated fall in systolic blood pressure of 30 mm Hg or more (to <80 mm Hg) during, or within one hour of, transfusion with no evidence of an allergic reaction or haemorrhage. Most are transient but they occasionally progress to shock and organ dysfunction. The cause of most of these reactions is unknown, although they may be more common in patients taking ACE inhibitors.

Iron Overload
Iron overload can be a problem for people who receive multiple transfusions. As red cells break down over time, the iron in the haemoglobin is released and extra iron is stored in body tissues. Extra iron that is not immediately needed to make new blood cells is normally stored in the liver, spleen, and bone marrow and also in other organs that don't normally store iron. Iron overload can cause no symptoms, or it can cause non-specific symptoms that are also seen in other conditions. Some of these symptoms include tiredness or weakness, loss of libido, weight loss, abdominal pain, or joint aches or pain. This can be identified by undertaking Serum transferrin saturation and serum ferritin.

Less Severe Acute Transfusion Reactions

Febrile non-haemolytic transfusion reactions (FNHTRs)
FNHTR are characterised by fever, sometimes accompanied by shivering, muscle pain and nausea. These are much less common since leucodepleted blood components were introduced. They can occur up to 2 hours after completion of the transfusion and are more common in multi-transfused patients receiving red cells.

Mild allergic reactions
Symptoms are confined to itching (pruritus) and/or skin rash (‘nettle rash’ or hives) with no change in vital signs. They are most common in patients receiving plasma-rich components such as FFP or platelets.

Delayed Transfusion Reactions

Delayed haemolytic transfusion reactions (DHTRs)
DHTRs occur more than 24 hours after transfusion in a patient who has previously been ‘alloimmunised’ to a red cell antigen by blood transfusion or pregnancy. The antibody may have fallen to a level that is undetectable by the pre-transfusion antibody screen and the patient is then inadvertently re-exposed to red cells of the immunising group. Antibodies to the Kidd (Jk) blood group system are the most common cause of DHTRs reported to SHOT, followed by antibodies to Rh antigens. There were no deaths reported to SHOT in the 2013 annual report.

Transfusion-associated graft-versus-host disease (TA-GvHD)
This rare and almost always fatal complication occurs when viable lymphocytes in a blood donation engraft in the patient and mount an immune response against the recipient’s cells of a different HLA type. At-risk patients usually have impaired cell-mediated immunity and are unable to reject the foreign cells. There were no deaths reported to SHOT in the 2013 annual report.

Post-transfusion purpura (PTP)
Affected individuals develop a very low platelet count and bleeding 5 to 12 days after transfusion of red cells. The typical patient is a parous female who is negative for a common platelet antigen, most commonly HPA-1a, and may have been initially sensitised by carrying a HPA-1a positive fetus in pregnancy. PTP is caused by re-stimulation of platelet-specific alloantibodies in the patient that also damage their own (antigen-negative) platelets by an 'innocent bystander' reaction. This severe, and potentially fatal, complication has become rare since the introduction of leucodepleted blood components. The 2013 annual report for SHOT includes one death caused by post transfusion purpura.

Infectious Hazards of Transfusion

Historically, transfusion-transmitted infections dominate the transfusion safety agenda but they are now rare in developed countries. However, constant vigilance is required to counter the risk from established and newly emergent pathogens in the era of mass international travel.

Viral infections
With modern donor selection and testing, hepatitis B, hepatitis C and HIV transmission are now very rare in the UK (Table 5.3). The current risk of an infectious donation entering the UK blood supply is now <1 in 1.2 million donations for hepatitis B, <1 in 7 million for HIV and <1 in 28 million for hepatitis C.

With the exception of hepatitis B, conventional screening tests were traditionally based on the detection of viral antibodies in donor blood. There is a small risk of infectious components entering the blood supply if a donation is made during the window period early in the course of infection before a detectable antibody response. These window periods have been much reduced by the addition of antigen testing and nucleic acid testing. Donations from new donors carry a slightly higher risk of viral positivity than repeat (previously tested) donors. The following table summarises the 23 confirmed viral transmissions (28 affected recipients) reported to the UK Blood Services between 1996 and 2012.

Estimated risk per million blood donations of hepatitis B virus, hepatitis C virus and HIV entering the blood supply due to the window period of tests in use, UK 2010–2012 (data and information collected by the NHSBT/Public Health England Epidemiology Unit)

	Hepatitis B Virus	**Hepatitis C**	**HIV**
All donations	0.79	0.035	0.14
Donations from repeat donors	0.65	0.025	0.14
Donations from new donors	2.23	0.133	0.18

Confirmed viral transfusion-transmitted infections, number of infected recipients and outcomes reported to UK Blood Services 1996–2012 (extracted from SHOT Annual Report 2012).

Infection	No. of incidents	No. of infected recipients	Deaths related to infection	Major morbidity	Minor morbidity
Hepatitis A	3	3	0	2	1
Hepatitis B	11	13	0	13	0
Hepatitis C	2	2	0	2	0
Hepatitis E	2	3	0	1	2
HIV	2	4	0	4	0
HTLV	1	2	0	2	0
Parvovirus B19	1	1	0	1	0

Hepatitis A
This is primarily an acute enteric infection spread by the faeco-oral route (contaminated food or water). Transmission by transfusion is very rare as affected individuals are usually unwell and deferred from donation. There is no carrier state and blood donations are not screened for hepatitis A antibody or antigen. As a non-enveloped virus it is resistant to methods of pathogen inactivation such as solvent detergent treatment.

Hepatitis B
The hepatitis B virus (HBV) is readily transmitted by infectious blood or body fluids, including sexual intercourse and parenteral drug use, and perinatal transmission is common in endemic areas such as the Far East and China. Most patients recover after the initial episode of acute hepatitis but some develop a chronic carrier state, estimated at 350 million individuals worldwide, with long-term risk of cirrhosis of the liver and hepatocellular cancer. Hepatitis B remains the most commonly reported viral transfusion transmitted infection in the UK because of window period transmissions but more sensitive screening tests for blood donations, such as HBV NAT, are increasingly effective. The 2013 annual report for SHOT includes one probable transfusion-transmitted incident investigated in 2013 following a transfusion in 2012.

Hepatitis C
There are around 170 million affected individuals worldwide. Initial infection is often symptomless but around 80% of patients develop a chronic carrier state with long-term risk of cirrhosis, liver failure and liver cancer. Hepatitis C was formerly a major cause of transfusion transmitted infection, known as ‘non-A non-B hepatitis’, but the risk of transmission by blood transfusion has fallen dramatically since the introduction of antibody screening in 1991 and progressively more sensitive tests for hepatitis C antigen and RNA since 1999. There were transfusion transmitted incidents reported to SHOT in the 2013 annual report.

Hepatitis E
Caused by a small non-enveloped RNA virus, hepatitis E was formerly believed to be most prevalent in warmer climates and less developed countries where it is mainly spread by

the faeco-oral route. In Western countries, recent studies have indicated large numbers of asymptomatic infections and up to 13% of individuals in England are seropositive for hepatitis E antibodies. Hepatitis E usually produces a self-limiting acute hepatitis but can lead to chronic infection, especially in immunocompromised patients, and may cause cirrhosis of the liver. An increase in the frequency of diagnoses of hepatitis E in patients in the UK has been seen in recent years. Blood Services are monitoring the situation closely, and working to establish the risk to transfusion recipients. The 2013 annual report for SHOT includes one possible transfusion-transmitted incident pending investigation.

Human immunodeficiency virus (HIV) 1 and 2
Transfusion transmission by both single-donor and pooled blood components was common early in the course of the 1980s epidemic of acquired immunodeficiency syndrome (AIDS). Modern donor selection and screening has made transmission a rare event in the UK. The two incidents identified since SHOT reporting began (1996 and 2003) were both from HIV antibody negative window period donations before the introduction of HIV RNA screening.

Cytomegalovirus (CMV)
Cytomegalovirus is a common herpes virus that causes asymptomatic infection or a mild glandular fever-like illness in most healthy individuals. Despite an antibody response (seroconversion), the virus persists in blood monocytes and 50–60% of adults in the UK, including blood donors, are lifelong carriers of the virus. It can be transmitted by transfusion of cellular blood components although this may be difficult to distinguish from reactivation of previous infection. CMV can cause severe, sometimes fatal, infection in fetuses, neonates and immunocompromised adults. There has long been debate about the relative merits of donor CMV antibody screening (CMV negative components) or routine pre-storage leucodepletion in preventing transmission to patients at risk. At the time of writing this policy, Blood Bank will provide CMV negative blood for neonates (up to 28 days after expected date of delivery) and pregnant women.

Human T-cell lymphotropic virus types I and II
These T-cell-associated RNA retroviruses are endemic in southwest Japan, the Caribbean Basin, sub-Saharan Africa and parts of South America, where they affect 15–20 million people. They are transmitted by sexual contact, breastfeeding, shared needles and blood transfusion. The clinical significance is uncertain but is associated with a 1 to 4% lifetime risk of developing adult T-cell leukaemia/lymphoma. The combination of donor screening for antibodies to HTLV I and II plus leucodepletion of cellular blood components has virtually eliminated transmission by transfusion in the UK.

Human parvovirus B19
Infection with this common, seasonal, non-enveloped DNA virus is often asymptomatic and there is no chronic carrier state. It causes the childhood illness erythema infectiosum (‘slapped cheek syndrome’). The virus can be transmitted by cellular blood components or frozen plasma. Although routine blood donor testing is not performed, only one incident was reported to SHOT between 1996 and 2013. Components manufactured from large donor plasma pools, such as immunoglobulins and clotting factor concentrates, are screened for high titres of Human Parvovirus.

West Nile Virus

This mosquito-borne flavivirus has spread from its traditional distribution in Africa, western Asia, southern Europe and Australia in recent years and now produces seasonal epidemics across the United States and Canada, usually between May and November. Most infections are mild or asymptomatic, but around 0.5% of patients develop severe encephalitis that may be fatal. Blood donors may transmit the infection during the 3- to 15-day incubation period; therefore, individuals returning from affected areas are deferred from donation for 28 days or may be accepted for donation with the added precaution of WNV NAT screening.

Bacterial infections

Syphilis

All donations are routinely screened for antibodies to *Treponema pallidum*. Transmission is now extremely rare and no cases have been reported since SHOT surveillance began in 1996.

Other bacterial infections

Blood components may be contaminated by bacteria, most often derived from the donor arm at the time of collection, which can proliferate on storage and harm the recipient. Bacteria from the normal skin flora, such as the coagulase negative staphylococci rarely produce severe infections although febrile reactions may occur. More pathogenic gram positive bacteria, such as *Staphylococcus aureus*, and gram negatives, such as *E. coli*, *Klebsiella* spp. and *Pseudomonas* spp., may produce life-threatening reactions. The 2013 annual report for SHOT includes no deaths as a result of bacterial contamination.

Bacterial transfusion transmitted infections are more common with platelet components because of their storage at 20–24°C. The risk increases with storage time after donation and is the main reason for the short shelf life of platelet components.

Adverse Effects of Transfusion

Preventing bacterial transmission

Improved techniques for cleaning/decontamination of the donor arm and diversion of the first 20–30 mL of the donation into a side-pouch (this blood is used for donor testing) have produced a marked fall in the reports of bacterial transfusion transmitted infections in the UK. No cases were reported to SHOT between 2009 and 2013. As an additional safety measure, the UK Blood Services have introduced automated culture of all platelet donations and this may allow the safe extension of their shelf life from 5 to 7 days.

Protozoal Infections

Malaria

Despite increasing international travel, transfusion-transmitted malaria remains a rare event in the UK. There have been two cases reported to SHOT (both *Plasmodium falciparum*) since 1996, the last in 2003, one of which was fatal. A policy of taking a travel history at the time of donation combined with deferral and, where indicated, testing for malarial antibodies has proved effective.

Chagas disease
This serious multi-system disease, caused by *Trypanosoma cruzi*, is endemic in Central and South America and may be transmitted by blood transfusion. No transfusion transmitted cases have been recorded in the UK and precautions centre on donor history of residence/travel and, where appropriate, testing for antibodies to the parasite.

Variant Creutzfeldt–Jakob disease (vCJD)
This fatal neurological disease, due to the same agent (abnormal variant of prion protein) as bovine spongioform encephalopathy (BSE) in cattle and caused by eating beef from affected animals, was first identified in the UK in 1996. By the end of 2013 there had been 174 cases in the UK, peaking in 2000. Four cases of transfusion-transmitted vCJD infection have been identified, from three apparently healthy donors who later developed vCJD. All occurred with non-leucodepleted red cells donated before 1999. Three of the four recipients died of vCJD a few years after the implicated transfusion. The fourth recipient died of unrelated causes but had abnormal prion protein in the spleen at post-mortem examination (significance uncertain). There are still many uncertainties around the pathogenesis and epidemiology of vCJD and no practical screening test for blood donors has yet been developed. The vCJD risk-reduction measures introduced in the UK include:

- Importation of plasma for fractionated blood components (1998)
- Leucodepletion of all blood components (1999)
- Importation (and viral inactivation) of fresh frozen plasma for all patients born on or after 1 January 1996 (when dietary transmission of vCJD is assumed to have ceased) (2002)
- Exclusion of blood donors who have received a blood transfusion in the UK since 1980 (2004)
- Importation of solvent detergent plasma for adult patients undergoing plasma exchange for thrombotic thrombocytopenic purpura (2006).

Adapted from *The Handbook of Transfusion Medicine* (2013) NHSBT

Appendix E

Audit Tool – Blood Transfusion Audit Assessment Form

Date of audit-	Time of audit-	Dept-	Pt No-
Product-	Component No.-	Date of transfusion- Time of transfusion-	Planned Tx- Transfusion Dep. Pt -

Ref	Criteria – Operational procedure	Yes, No n/a	Comment
1	Is the blood prescribed?		
2	Evidence of a medical assessment prior to planning the transfusion		
3	Was a consent form used? (state what form)		
	Indication for Transfusion		
	Date of planned transfusion		
	Is consent documented in the medical notes?		
	States that consent has been obtained/patient unable to consent		
	Benefits were discussed with the patient		
	Risks were discussed with the patient		
	Alternatives were offered to the patient		
	Patient information leaflet provided		

	If an Integrated Care Pathway is used, has the administrator confirmed that consent has been obtained?		
4	Was written patient information provided?		
5	Is an appropriate Observation chart in use?		
6	Has the G number been entered on the chart?		
7	Have baseline observations been recorded up to 1 hour prior to commencing the transfusion?		
8	Have 15 minute obs been recorded (+/- 5mins)		
9	Has the temperature and pulse been recorded (minimum) one hourly?		
10	Has a final set of observations been recorded?		
11	Has the Unit Issue Card been completed correctly?		
12	Has the white unit issue card been returned to Blood Bank?		
13	Post transfusion - Has the transfusion been documented in the medical notes?		
14	Does the GP letter state that the patient received a blood transfusion?		

Auditor-	Signature-	Reported to-	Date reported