BLOOD TRANSFUSION

POLICY AND PROCEDURES FOR THE PRESCRIBING, COLLECTION, STORAGE AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS

Approved By: Policy and Guideline Committee
Date Approved: September 2014
Trust Reference: B16/2003
Version:
Supersedes:
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Name of Responsible Committee / Individual: UHL Hospital Transfusion Committee
UHL Hospital Transfusion Team
Latest review Date: October 2014
Review Date: 2017
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## Change History

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<td>July 2005</td>
<td>Review led by: Dr. Hafiz Qureshi (Consultant Haematologist) Mrs. Pavlina Aneva – now Mrs. Sharp (Transfusion Practitioner)</td>
<td>The Optimal Blood Ordering Schedule has been removed from the policy and is now a separate document on DMS.</td>
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<td>June 2011</td>
<td>Review led by: Dr. Hafiz Qureshi (Consultant Haematologist) Mrs. Pavlina Aneva – now Mrs. Sharp (Transfusion Practitioner)</td>
<td>Complete review and rewrite of the previous UHL Blood Transfusion policy. It has been set up to reflect the current UHL Trust document format.</td>
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<td>June 2014</td>
<td>Review led by: Dr. Hafiz Qureshi (Consultant Haematologist) Mrs. Pavlina Aneva – now Mrs. Sharp (Transfusion Practitioner)</td>
<td>The present version is in agreed format and standardised headings have been used. The following changes have been made to:</td>
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<td>Section 5.4: Administration of blood/blood components - reiterated that the compatibility form is not a form of formal identification. Only the blood component and patient’s identification wristband are to be used as part of the final bedside check.</td>
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<td>Section 8: The process for monitoring compliance is given in a table format.</td>
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<td>Section 12: Describes the use of Sharepoint as UHL’s library and archiving system.</td>
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Key words: Blood, Transfusion, Blood Components, Cell Salvage, Consent, NPSA assessment, SHOT, MHRA.
SUMMARY OF KEY ACTION POINTS

Positive patient identification

- Positive patient identification at all stages of the blood transfusion process is essential. Patient core identifiers are: last name, first name, date of birth, unique identification number. For patients who are unable to identify themselves, e.g. paediatric, unconscious or confused patients, verification of the patient's identification may be obtained from a parent or carer (if present). This information must match exactly the information on the patient's identification band (or equivalent) and any other associated paperwork e.g. request form, blood sample tube, prescription, blood component label.

Patient information and consent to transfusion

- Where possible, patients (and/or for paediatric patients those with parental responsibility) should have the risks, benefits and alternatives to transfusion explained to them in a timely and understandable manner.

Pre-transfusion documentation

- Minimum dataset to be recorded in the patients clinical records should contain documentation of the reason for transfusion (clinical and laboratory data) and details of the information provided to the patient (risks, benefits and alternatives to transfusion) and written consent to proceed.

Prescription

- Blood and blood components must be prescribed on the Blood Transfusion Integrated Care Pathway (ICP). The prescription must contain the patient's core identifiers and must as a minimum specify what components are to be transfused, date of transfusion, the volume/number of units to be transfused, the rate of transfusion and any other clinical special instructions or requirements e.g. irradiated, CMV-seronegative, blood warmer, or any comorbid drugs required.

Requests for transfusion

- Must include patient core identifiers, gender, current diagnosis and any relevant significant comorbidities, a clear unambiguous reason for the request, type of component and volume/number of units required, any special requirements, time needed, the location of the patient (and location where transfusion will occur if known to be different), name and contact number of the requester.

Blood samples for pre-transfusion

- All patients being sampled must be positively identified. The collection of the blood sample from the patient into the sample tubes, and the sample labelling, should be performed as one continuous, uninterrupted event, involving one patient and one trained and competent healthcare worker only. Sample tubes must not be pre-labelled. The request form should be signed by the person drawing the sample.

Collection and delivery of blood component to the clinical area

- Before collecting the blood component, ensure the patient is ready to start the transfusion and has patent venous access. When collecting the blood component from the laboratory or blood refrigerator, a trained and competent healthcare worker should take authorised documentation containing the patient's core identifiers and check these with the label on the blood component. Patient information details, date and time of collection and staff identification must be provided to the person collecting blood i.e. porter. The blood track system will verify correct patient details and record time and identity of the person collecting blood. The component should be delivered directly to the clinical area.

Administration

- The final administration check must be conducted next to the patient by a trained and competent healthcare professional who also admisters the component.

- All patients receiving a transfusion must be positively identified.

- All patient core identifiers on the patient's identification wristband must match the details on the blood component label. All blood components should be administered using a blood administration set with an integral mesh filter (170-200 micron).

- Transfusion of red cells should be completed within 4 hours of leaving temperature-controlled storage.

Monitoring of the patient

- Observations should be undertaken for every unit transfused. Minimum monitoring of the patient should include:
  - Regular visual observation throughout the transfusion episode.
  - Pre-transfusion pulse (P), blood pressure (BP), temperature (T) and respiratory rate (RR). These should be taken and recorded no more than 60 minutes before starting the transfusion.
  - P, BP and T should be taken 20 minutes after the start of each component transfusion. If these measurements have changed from the baseline values, then RR should also be taken. More frequent observations may be required e.g. rapid transfusion, or patients who are unable to complain of symptoms that would raise suspicion of a developing transfusion reaction.
  - If the patient shows any signs or symptoms of a transfusion reaction, P, BP, T and RR should be monitored and recorded and appropriate action taken.
  - Post-transfusion P, BP and T should be taken and recorded not more than 60 minutes from the end of the component.

Completion of transfusion episode

- If a further blood component unit is prescribed, repeat the administration / identity check with each unit. If no further units are prescribed, remove the blood administration set. Ensure all transfusion documentation is completed, including the traceability form (orange card).
1 INTRODUCTION

1.1 This document sets out the University Hospitals of Leicester (UHL) NHS Trusts Policy and Procedures for prescribing, collection, storage and administration of blood and blood components.

1.2 The procedures set out in this document, which must be considered in its entirety, constitute the UHL NHS Trust policy for transfusion of blood and blood components. The contents of this policy are broadly based on the national guidelines, 'The administration of blood and blood components and the management of transfused patients' published in 2009. The guidelines reflect current professional opinion and have been produced by the British Committee for Standards in Haematology (BCSH), in collaboration with the Royal College of Nursing and the Royal College of Surgeons of England.


1.4 There is a separate policy for Management of Individuals Declining Blood and Blood Products (Trust Ref. B39/2010)

2 POLICY AIMS

2.1 Transfusion must be conducted according to the guidelines and procedures associated with this policy.

2.2 To provide a safe procedure on pre-transfusion blood sampling and prescription, requesting, collection and administration of blood components to patients.

2.3 To ensure benefits for patients are maximised and the risks minimised.

2.4 It intends to provide a safe auditable protocol to maintain patient safety and standardise practice.

3 POLICY SCOPE

3.1 This policy applies to all health care professional staff caring for patients within the University Hospitals of Leicester (UHL) NHS Trust.

3.2 This policy applies to all UHL NHS Trust employees who have involvement in the transfusion process, including individuals employed by a third party as locums or as agency staff.

3.3 This policy is supported by several appendices which must be used in conjunction with it.

3.4 Some specialist areas such as renal dialysis, ECMO, neonatal unit and obstetrics, have local transfusion protocols in use. These should be followed in conjunction with this policy.
4 DEFINITIONS

The following definitions are associated with this policy:

Serious Hazards of Transfusion (SHOT) is the United Kingdom’s independent, professionally led haemovigilance scheme.

Medicine and Healthcare products Regulatory Authority (MHRA) - is responsible for regulating all medicines and medical devices in the UK by guaranteeing they reach specific standards ensuring safety for patients.

The term of Blood Components refers to units, paedipacks or pooled units of:

- Red Cells
- Platelets
- Fresh Frozen Plasma
- Cryoprecipitate
- Granulocytes

BloodTrack refers to the electronic system used at UHL for the purpose of tracking all blood components and recording a complete cold chain audit from issue to transfusion.

Thromboelastography (TEG) is a diagnostic instrument that provides comprehensive whole blood hemostasis testing that can help assess bleeding and thrombotic risks, and also monitor antithrombotic therapies.

Prothrombin Complex Concentrate (PCC) is used to reverse the effects of oral anticoagulation therapy when bleeding occurs.

Blood Transfusion Laboratory formally known as Blood Bank.

Group and Safe (or Group and Screen) – a test to determine the blood group and antibody status of a patient prior to receiving a Blood Transfusion.

Cross-matching - refers to the testing that is performed prior to the release of blood for a blood transfusion, in order to determine if donor's unit(s) are compatible with the blood of the intended recipient.

5 ROLES AND RESPONSIBILITIES

All staff involved in any aspect of blood transfusion are responsible for:

- Adhering to this policy.
- Undertaking relevant training and competency based assessment in line with national requirement.
- Updating their knowledge on transfusion practice.
- Relevant staff groups must be trained and competent in line with national requirements.
- Reporting transfusion reactions or other incidents related to transfusion.

The individual roles and responsibilities for different professional groups are summarised below:
5.1 Executive Responsibilities

The Chief Executive has the overall legal responsibility to ensure that the Trust is fully compliant with Blood safety and Quality Regulations 2005.

The Medical Director has delegated authority for overseeing safety and quality blood transfusion practice within the Trust.

5.2 Clinical Management Group (CMG) Teams

Are responsible for ensuring that all members of their staff are fully aware of UHL Blood Transfusion Policy and guidelines.
CMG teams are also responsible for ensuring staff compliance with UHL blood training and competencies requirement.
To ensure all inpatient areas, including Emergency Department (ED), have trained and competent personnel to prescribe, sample, test, transport blood products, administer blood products and carry out patient observation.
To nominate a suitable individual to represent them on the Hospital Transfusion Committee (HTC).
To ensure that incidents are reported through the Trust Incident reporting procedure, in line with Policy for Reporting and Management of Incidents (Trust Ref. B57/2011) and to ensure there is resultant organisational learning through the CMG structure and more widely across the Trust.

5.3 Line managers

Ensure that staffs involved in the blood transfusion process are:

- Fully aware of the content of the UHL Blood Transfusion policy
- Appropriately trained and competent to perform their duties in line with the requirements of NPSA SPN 14 (2006), BSQR (SI 2005 as amended) and CQC
- Fully aware of their role in the investigation of adverse clinical incidents relating to blood transfusion and in the implementation of action plans drawn up as a result of incidents and audit.
- Ensure that evidence of transfusion is returned to the Blood Bank following the Trust procedure for compliance with legislation for blood traceability (currently using manual orange card system, which may in future be replaced with another electronic tracking system).

5.4 Hospital Transfusion Committee (HTC)

Oversee, develop, implement and review Trust policy, procedures and guidelines relating to blood transfusion.
Audit the practice of blood transfusion compared to Trust policy and national guidelines, focusing on critical points of patient safety and the appropriate use of blood.
Make recommendations regarding appropriate use of blood and blood components.
Identify and manage risk associated with blood transfusion.

5.5 Hospital Transfusion Team (HTT) including Transfusion Practitioners’ Team

Assists in the implementation of the HTC objectives.
Review and update transfusion guidelines and Trust policy.
Review adverse events including ‘near misses’
Report to SHOT and HTC adverse events related to blood transfusion.
Provide formal transfusion training within the Trust as specified in Blood Transfusion Training Policy for Clinical and Support Staff (Trust ref. B39/2009).
Investigate transfusion reactions or other clinical incidents in relation to transfusion practice.

Audit blood transfusion practice

Transfusion Practitioners’ team provide advice and support during normal working hours (Monday to Friday 9 a.m. to 5 p.m.) and can be contacted on the following numbers:
LRI – ext.7876         GH – ext. 3985                   LGH – ext.4557

5.6 Medical staff

Provide patients with all relevant information when requiring a transfusion that is based on current evidence-based practice. Explain risks and benefits of proposed transfusion therapy and obtain informed written consent.

Obtain written consent for transfusion and document it in the patient’s medical notes (i.e. indication, quantity, consent and outcome). Patients should be offered information leaflets on blood transfusion at the time of proposing this treatment. Further supply of leaflets can be obtained by contacting the UHL transfusion practitioners’ team.

Ensure samples are taken and labelled from the right patient according to this policy.

Generate all requests for Group & Save and cross matching, clearly indicating the reason for transfusion and communicating the degree of urgency to the Blood Transfusion Laboratory.

Prescribe blood, blood components and blood products.

Investigate and manage transfusion reactions.

5.7 Qualified clinical staff (excluding medical staff)

Explain the procedure to the patient using a patient information leaflet.

Ensure patient is cannulated prior to ordering blood / blood products.

Use safe techniques for obtaining blood sample.

Request collection of blood.

Perform patient ID verification

Carry out all appropriate observations before, during and after the transfusion.

Complete in full all paperwork, including the orange card, associated with the transfusion.

Commence transfusions.

Monitor patient during transfusion

Notify medical staff of any suspected transfusion reactions.

Ensure blood is transfused within appropriate timescale.

Note: Bank staff can participate in the transfusion after completing the e-learning and carry out the face to face assessment.

Agency staff can only monitor the patient during the transfusion but cannot take sample or administer blood or blood components.

5.8 Health Care Assistants

Carry out observations before, during and after the transfusion.

Notify any abnormal observations to the nursing or medical staff.

5.9 Phlebotomists

Ensure that blood samples are taken and labelled according to this policy.

Use safe techniques for obtaining blood samples.
5.10 Porters

Collect and transport blood and blood components from the blood bank refrigerator to the ward areas in appropriate transport bag and with appropriate documentation. Only collect blood components for one patient at a time. Return the blood components and traceability documentation (orange cards) from the clinical areas to the blood bank.

6 Policy Statements

6.1 Procedure for prescribing blood and blood components

The decision to transfuse a patient with any blood components is the sole responsibility of medical staff and no other member of staff are authorised to make this clinical decision. The decision to transfuse must be based on a complete clinical assessment of an individual patient. The UHL policy requires obtaining informed written consent for the transfusion of blood components and products. The procedure for obtaining written consent is detailed in Appendix 20: Procedure for informed written consent for blood transfusion.

Medical staffs are primarily responsible for prescribing blood and blood components. However in some defined clinical areas where specific written blood transfusion protocols exist, appropriately trained and certified specialist nursing staff could be approved to authorise blood components within the specified transfusion protocols for that area. CMG or clinical services must submit a case of need for nurse authorisation to the HTC for consideration and approval. The individual must then complete a nationally recognised Nurse Authorisation for Transfusion course and complete competency assessment with the UHL Transfusion team.

Medical staffs are responsible for:

6.1.1 Prescribing blood component on Blood Transfusion ICP, specifying:
- The type of blood component required.
- Volume or quantity to be transfused.
- Rate or duration of infusion.
- Special requirements such as irradiated, CMV seronegative, HLA matched etc. These specifications must always be clearly stated both on the crossmatch request form and the Blood Transfusion ICP (This information can be found on the reverse of the request form & blood transfusion ICP).
- Any medication required before or during transfusion.
- If a patient’s clinical condition requires more frequent observations during transfusion than are routinely indicated on the prescription chart.

6.1.2 Investigating and management of adverse transfusion reactions and reporting any severe adverse event to the blood transfusion laboratory.

6.1.3 Authorising the Blood Component Request Form (‘crossmatch’ form), which must contain the following information:
- Patient’s Surname.
- Patient’s Forenames (initials not sufficient).
- Patient’s Date of Birth (age not sufficient).
- Patient’s NHS number or Hospital number.
- Patient’s Gender.
- Patient’s Location.
Consultant in charge of the patient.
Time and date of request.
Time and date the blood component is required.
Relevant clinical details and precise indication for transfusion (unqualified terms such as anaemia or ↓ Hb are not acceptable).
When requesting red cells, the pre-transfusion Hb (including the date of test) should be given on the cross match form.
The requests for platelets should indicate the patient’s platelet count and the clinical indication.
The Fresh Frozen Plasma (FFP) and / or cryoprecipitate requests should include clotting screen results and clinical indication. The correct dose of FFP is based on patient’s weight in Kilograms (approx. if necessary) and this information should be provided on the request form.
Name and signature of doctor filling in the request form.
Previously determined blood group, transfusion history and atypical antibodies (if known).

NOTE: Blood component request forms for UNIDENTIFIED patients must contain a unique PATIENT IDENTIFICATION NUMBER, GENDER and approximate AGE. This information must also be present on the patient’s wristband (Trust Ref.B43/2007)

6.1.4 Ensuring appropriate documentation in the medical notes. The following information must be documented:
Precise indication for the use of blood or blood components (avoid unqualified terms such as anaemia).
Ensuring a copy of the written consent is filed in the patient’s clinical notes.

NOTE: If patients are receiving long-term transfusion therapy, the indication and explanation offered to them need not be documented for each transfusion episode, but these must be fully documented for the initial episode.

Whether or not transfusion achieved the desired effect (e.g. clinical improvement, post transfusion Hb etc).
The occurrence and management of any adverse effects.
There is a specific UHL Policy for Management of individuals declining blood or blood components (Trust Ref. B39/2010) It may also be a useful resource in situations where transfusion is refused by patients for reasons other than religious beliefs. Always seek advice from the consultant in charge of the patient.

6.2 Process for requesting group and save or crossmatch samples

6.2.1 A blood sample for Group & Save and crossmatch may be obtained by the following members of staff who have been trained and assessed for this purpose:
Medical staff
Phlebotomists
Clinical staff such as nurses, midwives and other health care professionals
Where possible, addressograph labels should be used on the request forms but never on the sample tubes.

The request forms must specify whether or not the patient requires CMV negative and or irradiated blood components. The indications for CMV negative and irradiated blood components are summarised on the blood request form and the ICP and are detailed in appendices 17 and 18.
If request forms are not fully completed and/or samples labelled incorrectly, as specified in section below, they will NOT be processed. The requesting clinician or the clinician responsible for the patient will be notified accordingly.

6.2.2 Identification of the patient – accurate identification of patients at all stages of the blood transfusion process is essential.

6.2.2.1 All patients must be positively identified against the patient identifiers on their wristband and request form. In an outpatients setting where a patient is not wearing an identification wristband at the time of taking the blood sample, the patient’s full name, date of birth and home address should be verified against the patient identifiers on the request form.

Establish patient’s full name and date of birth by asking, “what is your full name?” and “What is your date of birth?” and NOT questions such as “Are you Mr…….?”.  

6.2.2.2 If the patient is unable to confirm identification details, then two members of staff as defined in 5.4.1 should confirm identity using patient’s case notes and identification wristband.

6.2.2.3 All inpatients having a transfusion must have an identification wristband at the time of taking “Group and Save” or “cross match” samples.

6.2.2.4 Only one patient should be bled at a time to minimise the risk of error.

6.2.2.5 Adults require 1 x 7.5ml EDTA samples for Group and Save/cross match.

6.2.2.6 Children (see appendix 8).

6.2.3 Labelling of patient blood samples

6.2.3.1 The member of staff taking the blood must personally label the sample tubes at the patient’s side.

6.2.3.2 The following minimum patient identification details must be clearly written on the sample tubes:

Surname
Forenames (not initials)
Date of birth
Hospital number or NHS number
Legible signature of the person taking the sample
In case the patient is unidentified, a unique identity number, patient’s gender and approximate age.

6.2.3.3 Sample tubes must never be pre-labelled.

6.2.3.4 Sample details must be handwritten. Do not use addressograph labels on samples.

6.2.4 Timing of sample collection

6.2.4.1 In the absence of a recent transfusion or pregnancy within the last 3 months, samples may be taken up to 3 months prior to plan transfusion. Samples are then valid for 3 days from the start of transfusion.

6.2.4.2 If the event of a transfusion or pregnancy within the last 3 months, samples should be taken no more than 3 days in advance of the completion of the planned transfusion.
6.2.4.3 For neonates under the age of 4 months, samples are required from the baby and the mother on the initial request only.

6.2.5 Transport of specimens to blood transfusion laboratories

6.2.5.1 The requesting clinical team is responsible for ensuring that cross match samples for urgent requests are taken to the blood transfusion laboratory in a safe and timely manner.

6.2.5.2 Samples from hospital inpatients or outpatients are normally conveyed to the laboratory specimen reception by the hospital porters. These are then passed on to the Blood Transfusion department on a regular basis. By the nature of the system there are time delays and samples can take a number of hours to get from the ward to the laboratory.

6.2.5.3 The system for transporting routine samples should not be used for urgent requests. If the sample is urgent it can be hand delivered directly to the laboratory by a member of the ward staff or if available (at the LRI and GH) by the air tube system. In addition the requesting clinical team should contact the blood transfusion laboratory in the event of an urgent request for blood components in order that it can be prioritised.

6.2.5.4 Samples from the Community can be sent via the daily pathology collection runs or in an emergency can be hand delivered by a taxi or a relative.

6.2.5 Transport of Specimens (Health & Safety)

The following guidance should be adopted by Hospital Staff and serious breaches should be reported to relevant Managers as a Datix incident:

6.2.5.1 All specimens to be carried upright in trays and a secondary bag or in individual sealed leak proof bags. The specimens are to be in a separate pocket to request form to avoid accidental contamination of form. Known or query high risk; hazard group 3 or derogated group 3 as Advisory Committee Dangerous Pathogens (ACDP) classification, should be delivered in a clearly labelled leak proof biohazard bag with request form labelled appropriately with relevant information for biological risk. This may also include relevant clinical details e.g. travel abroad, febrile etc.

6.2.5.2 All specimens should be transported on/in an appropriate trolley and tray or receptacle that would contain leaks and spills. It is recommended that all trolleys used for conveyance of specimens have available spill kits, including an approved disinfectant and absorbent mopping up material.

6.2.5.3 Leaking specimens must not leave the treatment area and should be immediately retaken.

6.2.5.4 Specimens should be transported in such a way to maintain patient confidentiality.

6.2.5.5 All specimens to be taken directly from source (or distribution route) to laboratory or laboratory specimen reception area so to be delivered in a timely manner.

6.2.5.6 If a specimen leaks into the tray or box, report to the nearest Pathology laboratory reception for assistance, if required.

6.2.5.7 If a specimen is dropped and spilt, and if a spill kit is not readily available, it must not be touched or left unattended. Send a messenger to the nearest Pathology laboratory reception for assistance.

6.2.5.8 All spillages must be reported as an incident using the Datix reporting system on INsite.
6.2.6 Points to remember when using the air tube system

6.2.6.1 The air tube systems in UHL are maintained by the local Facilities Departments and may only be used by authorised members of staff.

6.2.6.2 It is the responsibility of the ‘sender’ to operate the system correctly, and to have back-up systems in place for when the system is unavailable, or not performing normally.

6.2.6.3 Steps must be taken to ensure the health and safety of the recipient and anyone who works on the system.

6.2.6.4 Glass containers must not be sent in the air tube.

6.2.6.5 Specimens must be placed into a sealed plastic bag (specimen bag) before sending in an air tube carrier.

6.3 Process for collection and return of blood components

This section describes procedures for the collection of blood or blood components from their storage locations e.g. refrigerator or platelet incubator and its delivery to wards, operating theatres or other clinical area where transfusion is to be given.

6.3.1 The collection must be authorised by a member of staff who is suitably qualified to administer prescribed blood components, i.e. a doctor, registered nurse, registered midwife, registered operating department practitioner or a perfusionist. Staff responsible for the administration of blood component must ensure that a suitable intravenous access, patient’s consent and pre-transfusion observations have been secured and recorded prior to authorising collection of blood.

6.3.2 Staff collecting blood or blood components may be from a variety of backgrounds e.g. nursing, medical, portering. However, these staff must be trained and assessed to be competent users of BloodTrack™ (electronic blood tracking) system. After successful assessment a unique bar code will be issued to each individual.

6.3.3 The staff member authorising the collection must complete the Receipt for Transfusion Fluids Form. The porter/collector must collect the receipt form from the ward/theatre before collecting the blood component. Alternatively, the staff member authorising the collection must carefully provide all of the following details to the porter over telephone. The porter/collector must be able to transcribe these details onto the specified Receipt Form or pocket sized patient identification / collection form prior to collecting the blood component.

- Patients Full Name
- Date of birth
- A unique patient identification number (NHS number or Hospital number)
- Specify whether it is the first unit of blood, as this will be accompanied with the cross match report
- Where the blood or blood component is to be delivered
- Name of the person authorising the collection

6.3.4 The person collecting the blood component must check all patient identification details on the Receipt for Transfusion Fluid form, or the pocket-sized patient identification, or collection form, against the compatibility label on the blood component bag to be collected.

6.3.5 If there is discrepancy between the supplied details and the label on the blood or component then advice should be sought from the laboratory staff.
6.3.6 The receipt form should be left in the designated place near the blood bank refrigerator. Blood and blood products should be transferred to ward or theatre using red plastic carrier bags provided (except for platelets). To avoid wastage of red cells, only one unit should be collected from the blood bank refrigerator at a time unless, exceptionally, the clinical urgency is such that more than one unit of blood is to be transfused simultaneously through separate IV lines.

6.3.7 The collector must deliver the blood component to the requested location without delay and hand the component to a qualified member of the nursing staff. The blood component must not be left on the ward/theatre without the knowledge of the qualified staff who is expecting its delivery. The qualified member of staff who is responsible for the administration of blood component must check all patient identification details on the delivered blood component and the crossmatch report before accepting its delivery.

6.3.8 The collection of blood or blood component must only be requested immediately prior to administration and the administration must be commenced as soon as possible after its arrival on the ward or theatre, ideally within 30 minutes. However, transfusion may be commenced after more than 30 minutes at room temperature providing transfusion of that unit is completed within 4 hours of it’s removal from a blood fridge. For adult patients, under normal circumstances a unit of red cells can be safely given over a period of 2 to 3 hours. If significant delays occur the blood transfusion laboratory must be informed, and arrangements made for returning the component to the Blood Transfusion Laboratory. The time of return must be documented.

6.3.9 Red cells must only be stored in a designated blood bank refrigerator and NEVER in a drug or any other refrigerator.

6.3.10 Platelets must NEVER be stored in any refrigerator.

6.3.11 If unused, cross matched red cells will only remain available until 0900hrs on the day after the planned date of transfusion, unless special arrangements have been agreed with the laboratory. It is therefore essential that surgical teams must notify Blood Bank of any cancellations or revision of theatre lists.

6.4 Process for administration and traceability of blood and blood products

Blood components must only be administered by a registered healthcare professional that is trained and assessed as competent in both transfusion and IV administration in accordance with the UHL Transfusion Training Policy for Clinical and Support Staff (Trust Ref. B39/2010)

6.4.1 The following members of staff are authorised to administer the prescribed blood or blood components:

- Doctor
- Registered nurse
- Registered midwife
- Registered operating department practitioner (ODP) Perfusionist

6.4.2 The members of staff listed under 6.4.1 must be trained and assessed as competent in the administration of Blood components.

6.4.3 Immediately before setting up the transfusion, two healthcare professionals listed above must perform the final administration check at the patient’s bedside.
The unit of blood component to be transfused
The Blood Transfusion Integrated Care Pathway
Patient identification band

The alert and conscious patient must be positively identified by asking his/her surname, first name and date of birth, and crosschecking with the information on the patient ID band and blood component tag.

6.4.4 For patients who are unconscious or otherwise compromised the identification must be confirmed by two healthcare professionals (see 6.4.1) using the documentation outlined above.

6.4.5 In case of an unidentified patient, minimum details that need to be checked are the unique patient identity number and gender on all documents and the patient’s wristband.

**IMPORTANT:** It is essential that any patient having a blood transfusion has an identification band, or equivalent e.g. photo ID card with unique patient identifiers. For patients in operating theatres it may be necessary to fit identification wristbands on more than one limb. In any case, if it is necessary to remove the wristband in theatre, it is the anaesthetist’s responsibility to ensure that a replacement wristband is fitted on a more accessible limb. If wristbands are removed it is essential that alternative measures be put into place to ensure that patient details can be verified.

6.4.6 The compatibility tag and the label on the blood pack must also be checked and found identical with the prescription details on the integrated care pathway with respect to the following details:
- The blood pack number.
- The component type.

The need for any special requirement such as irradiation, CMV-negative must also be checked on the blood transfusion integrated care pathway.

Ensure ALL equipment is taken to the patient’s bedside. This should include the blood component, ICP, drip stand and blood component giving set.

6.4.7 The label on the blood component pack must be checked for the EXPIRY DATE prior to commencement of transfusion to ensure the transfusion of blood component is completed before it’s expiry date and time.

The expiry date of red cells and platelets is at midnight on the expiry date stated on the blood component pack. The transfusion of FFP and Cryoprecipitate must be completed within 4 hours of thawing time stated on the component pack. If however, thawed FFP is not transfused, it can be returned to Blood Transfusion Laboratory within 30 minutes of its receipt. Once returned, FFP accepted by Blood Transfusion Laboratory may be stored in the Blood Bank fridge for a subsequent issue within 24 hours of the stated thawing time.

6.4.8 Red cells must be ABO compatible with the recipient and should be RhD matched to the recipient. If the blood group of red cells units and the blood group of the patient are not identical and the sticker shown in the section below is not on the compatibility report, DO NOT START TRANSFUSION, AND IMMEDIATELY CONTACT BLOOD TRANSFUSION LABORATORY FOR ADVICE.
6.4.9 Occasionally the blood group of platelets, FFP and cryoprecipitate may not be identical to the patient’s blood group. This will be stated on the crossmatch report. Units may be issued by the blood bank with the following stickers where products with alternative blood group are issued (if in doubt contact the Blood Transfusion Laboratory).

6.4.10 After ALL bedside checks have been satisfied, BOTH qualified staff members must sign the ICP, documenting the date and start time, against the blood unit being transfused. In the event of any discrepancy, transfusion must not proceed and further advice must be obtained from the Blood Transfusion Laboratory. The START and END times of each unit of blood component transfused must be documented on the ICP.

6.4.11 It is absolutely essential that both members of staff carrying out the bedside check are vigilant and that one does not rely upon the other to be rigorous. Each member of staff is individually accountable for their actions.

6.4.12 The person attaching the unit of blood component to the patient must also sign the ICP and enter the start time and date.

6.4.13 Check the prescription chart to ascertain the prescribed blood component and its infusion rate, whether any pre-medications or diuretic need to be given, or if there are any special requirements, such as CMV-seronegative or irradiation.

6.4.14 The flow rate must be adjusted according to the prescription.

6.4.15 The same bedside check procedure is required for each subsequent unit of blood. The crossmatch report accompanies the first unit only, and during the transfusion it must be secured to the adhesive mount sheet within the ICP.

6.4.16 After completion of the transfusion procedure, the ICP along with the crossmatch report and any additional observation chart used for monitoring transfusion must be filed in patient’s case notes as a permanent record.

6.4.17 The fate of all blood products must be traceable from donor to recipient and vice versa - THIS IS A LEGAL REQUIREMENT. Orange cards must be completed at the start of the transfusion and sent immediately back to blood bank via the sample collection box to ensure that traceability records of each component are maintained.

**NOTE:** It is the responsibility of the person administering the blood component to complete and return the orange card.

Any wholly unused products must be returned to the blood bank. All wastage must be reported to the laboratory to complete audit trail.

Partial transfusions, however small, should be recorded as transfused and be documented accordingly.

Please refer to the flow chart overleaf for UHL Blood Product Traceability Procedure for clinical areas:
It is mandatory that this procedure is followed for administering each unit of blood or blood component.

**ACTION:** All blood components are issued with a tag which includes the orange traceability card

**RESPONSIBILITY:** Blood Transfusion Laboratory member of staff issuing blood component

**ACTION:** As soon as transfusion of a unit of blood component begins, complete the details on the orange traceability card that came with the blood component.

*Do not wait until the transfusion is complete. Each orange card must be completed as soon as the transfusion of the corresponding unit starts.*

**RESPONSIBILITY:** Nurse or other healthcare professional administering the transfusion.

**ACTION:** Return orange traceability card to Blood Transfusion Laboratory following your local procedure. *Do not send via the internal post.*

**RESPONSIBILITY:** Nurse or other healthcare professional carrying out transfusion

Completed orange cards must be returned promptly to Blood Transfusion Laboratory. Orange cards received in Blood Transfusion Laboratory will be checked and reconciled daily against the issue records. All incomplete cards will be returned to place of origin for correction and/or completion. If a correctly completed orange card is not received within 7 calendar days of date of issue, an incident form will be completed and referred to the appropriate CMG Patient Safety leads to investigate the reasons for non-compliance.

100% compliance is mandatory for all clinical areas and is monitored by the Trust board. Completed and matched orange card receipt forms will be filed on a blood bank database. 100% compliance is a legal requirement and is the responsibility of Directors/Managers of each CMG where blood products are used.

6.4.18 **General instructions**

6.4.18.1 Drugs must NOT be added to blood components under any circumstances.

6.4.18.2 Blood component packs should be visually inspected prior to transfusion for integrity of the pack, evidence of any leaks at the ports and seams and for the presence of clots or other contraindications such as platelets clumping or abnormal colour change. If any of these apply the component must not be used and clinical staff should contact the blood bank for further instructions.

6.4.18.3 The transfusion of a unit of red cells should be completed within 4 hours of removal from the controlled temperature environment.
6.4.18.4 Transfusion of Fresh Frozen Plasma (FFP) should be commenced as soon after thawing as possible and the transfusion must be COMPLETED within 4 hours. FFP may be stored for up to 24 hours providing it has been stored in an appropriate blood fridge immediately following the thawing process.

6.4.18.5 Cryoprecipitate must not be stored in the fridge and must be transfused within 4 hours of thawing.

6.4.18.6 Transfusion of platelets should be commenced immediately upon their receipt and completed within 4 hours.

NOTE: platelets are kept at room temperature and must never be placed in a fridge.

6.4.18.7 Blood/blood components can be administered via any sized cannula. The blood giving set must be changed after two units of the same blood/blood component, after 8 hours, or if the filter is found to be blocked, whichever occurs first.

Blood/blood components must not be transfused through a giving set which was used for the infusion of other intravenous fluids or a different type of blood component. It is not necessary to prime the giving set with 0.9% Normal Saline; the giving set should be primed with the blood component only.

All blood components should be administered using a blood component administration set which incorporates 170-200 micron filter.

Platelet concentrates should be transfused through a standard blood or a platelet administration set.

Platelet concentrates should not be transfused through administration sets which have already been used to administer other blood components.

6.4.18.8 If an electronic pump is to be used for the transfusion of blood/blood component, the person administering blood must ensure that such infusion pumps have been approved and validated by the UHL Hospital Transfusion Team for the transfusion of blood components.

6.4.18.9 Generally, it is not necessary to warm blood before transfusion. However, there are specific indications for warming blood and these include:
- At flow rate of greater than 50 ml/kg/hour in adults.
- At flow rate of greater than 15 ml/kg/hour in children.
- When transfusing patients with clinically significant cold agglutinins (Cold Haemagglutinin Disease).
- When performing exchange transfusions.
- Active peri-operative warming techniques may be necessary for some patients during anaesthesia. If blood warming is considered essential, then it must be achieved using approved blood warming apparatus.

IMPORTANT: Blood must only be warmed using approved and validated blood warming equipment with built in thermostat and an audible alarm.

Blood warming sets should not be routinely flushed with 0.9% Normal Saline solution but exceptions can be made if using High Flow Sets where the priming volumes exceed 65mls.

Blood must never be warmed on radiators, in hot water, microwaves or other heating equipment not specifically designed for this purpose. Failure to comply with this
requirement is likely to result in severe red cell haemolysis with potentially lethal consequences.

6.4.18.10 An indication of whether or not the transfusion achieved the desired effect (either post transfusion increment or improvement in the patient symptoms) and details of any reaction to the transfusion should be documented in the patient notes.

6.4.18.11 Overnight transfusions should be avoided whenever possible, for reasons of patient safety.

6.4.18.12 Once transfusion is set up, the patient must not leave the ward or clinical area without nursing supervision. If a patient needs to go out of the ward for an investigation or procedure, he/she should be accompanied by a healthcare professional; the transfusion must not simply be discontinued and resumed afterwards as this could increase the risk of a serious infective complication.

6.4.18.13 Always wear gloves when handling blood components. Administration of blood components is governed by the use of ANTT (Aseptic Non-Touch Technique).

6.5 Monitoring of patient during transfusion

6.5.1 Baseline vital signs i.e. PULSE, BLOOD PRESSURE, RESPIRATORY RATE AND TEMPERATURE must be checked immediately before the collection of the Blood Component from the Blood Fridge; then again between 15 to 20 minutes after the start of transfusion, 60 minutes after the start of transfusion, and on completion of the transfusion of each unit. These observations apply for EACH UNIT of blood or blood component this information must be recorded on the UHL Blood Transfusion ICP or equivalent, however if an equivalent chart is used for this purpose it is the responsibility of the health care professional administering blood/blood component to ensure that the above observations are recorded as an absolute minimum.

It should be noted that the above requirements for clinical observations are an absolute minimum. There will be situations where more frequent observations are necessary e.g. unconscious or heavily sedated patients and patients with heart failure, these should be recorded on a separate observations chart which is clearly timed and dated. This can then be attached to the ICP.

6.5.2 Most serious transfusion reactions tend to occur within the first 15 to 20 minutes of starting a new blood or blood component unit and the patient must therefore receive very close visual observation during this time. Watch the patient closely for any of the following symptoms or signs:

- Shivering
- Flushing
- Shortness of breath
- Pain in the chest, back, loin or extremities
- Pain or burning sensation at the drip site
- A feeling of apprehension or “something wrong”
- Unexplained drop in blood pressure
- Collapse
- A rise in temperature of 1.5°C or more from the baseline observations
- Skin rash or urticaria
- Anaphylaxis
- Haemoglobinuria
- Bleeding from venepuncture sites
- Non-specific deterioration in the patient’s condition
Inpatients should be observed for late reactions during the subsequent 24 hours. Day case and short-stay transfusion patients should be warned about the possibility of late adverse reaction(s) and a relevant contact number supplied.

**IMPORTANT:**

*If the patient shows any of the above signs or symptoms transfusion must immediately be stopped and the giving set disconnected from the cannula. Medical staff responsible for the patient must be contacted immediately. The cannula end of the giving set should be sealed with an appropriate bung. The giving set must not be disconnected from the blood component pack. The cannula should be kept patent with a slow running drip of Sodium Chloride 0.9% until medical staff has reviewed the patient.*

### 6.5.3

The patients should be made aware of the importance of reporting any unusual symptoms to their health care professional

### 6.5.4

The management of severe transfusion reactions should be discussed with the senior haematology medical staff.

**NOTE:** Appendix 15 describes investigation and management of transfusion reactions.

### 6.5.5

Vital signs related to transfusion should be recorded on the UHL Blood Transfusion ICP. If more frequent observations are required (e.g. unconscious or heavily sedated patients and patients with heart failure), these should be recorded on a separate observations chart which is clearly timed and dated. This can then be attached to the ICP.

### 6.5.6

All transfusion reactions must be recorded in the patient’s notes.

### 6.5.7

The blood transfusion laboratory must be notified of all adverse reactions to transfusion of blood or blood components. The laboratory may request the return of the units of blood component and request additional samples from the patient for appropriate serological and microbiological investigations.

### 6.5.8

Following discussion with laboratory staff the unit of blood component, with attached administration set must be returned to the blood bank for further investigation. Please note that when returning a blood component with the attached administration set a sterile bung is used to prevent spillage and contamination.

**NOTE:** The flow chart for management of transfusion reaction can be found within the Blood Transfusion Integrated Care Pathway (see appendices 20 and 21).

### 6.6 Reporting adverse events

### 6.6.1

The UK Blood Safety and Quality Regulations (2005, as amended) make it a legal requirement that all serious blood related adverse reactions and events are reported to the MHRA within 7 days. It is therefore mandatory for health care professionals to immediately report such reactions or events to the blood bank who will then report these to the MHRA.

### 6.6.2

A Datix incident form must be completed. This includes ‘near miss’ episodes involving procedural errors that were detected in time to prevent a serious complication of blood transfusion.

### 6.6.3

Transfusion incidents are investigating by the HTT and reported periodically to the HTC.
6.6.4 The HTT review incident trends and formulate action plans where appropriate.

6.7 Disposal of used blood packs and blood giving sets

6.7.1 On completion of uncomplicated transfusion administration the packs must then be retained and kept in a designated area on each ward/theatre for at least 24 hours. All used blood component packs must be placed in an orange polythene bag used for disposal of clinical waste or in a red transport bag. The bag must then be sealed, labelled with the patient name and the date of transfusion. If a transfusion is completed in theatre, the empty packs must accompany the patient to the ward. This will make it possible to investigate any adverse event that may have been attributed to blood transfusion. After 24 hours, the bags should be disposed of as per the Waste Management Policy (Trust Ref. A15/2002).

6.7.2 The giving sets are disposed of into a sharps bin.

6.7.3 In the event of a serious transfusion reaction, the implicated blood component pack should be sent to the blood transfusion laboratory, with the giving set still attached to the blood component pack, and the cannula end of giving set sealed using an appropriate bung.

6.7.4 Partially transfused units that are no longer required must be sealed using an appropriate bung and discarded as per the clinical waste policy.

6.7.5 It is not necessary to flush the giving set/blood warmer with Sodium Chloride 0.9% solution following transfusion. The giving set should be disconnected and the IV access flushed with a bolus of Sodium Chloride 0.9% solution.

7. Education and Training Requirements

All relevant staff must have read and understood this policy and procedures therein. Training on transfusion is provided during Trust induction and thereafter through annual updates. Staff involved in the process of blood transfusion (including prescribing blood, obtaining a sample, collecting or returning and transporting blood, administering blood and caring for patients undergoing a transfusion) must have received relevant to their role training. This is done by on mandatory training sessions delivered by Transfusion Practitioners.

7.1 All existing staffs need to do the e-learning for transfusion relevant to their role within UHL every 3 years. This can be accessed via www.euhl.org.uk

7.2 New staff to the Trust must attend induction session on transfusion.

7.3 New staff to the Trust must have a one off face to face competency assessment relevant to their role in transfusion recorded on the eUHL system, in addition to the e-learning. A valid competency assessment within the last two years from previous employer will be accepted.

8. Policy Statements and Procedures

This policy is supported by the following procedures and guidelines which must be used in conjunction with this policy:
### 9 Process for Monitoring Compliance

The following table lists the monitoring arrangements for this policy:

<table>
<thead>
<tr>
<th>Element to be monitored</th>
<th>Lead</th>
<th>Tool</th>
<th>Frequency</th>
<th>Reporting arrangements</th>
<th>Acting on recommendations and Lead(s)</th>
<th>Change in practice and lessons to be shared</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive patient identification prior to transfusion</td>
<td>Lead TP</td>
<td>As part of the ICP audit</td>
<td>Annual spot checks audit in different clinical areas.</td>
<td>Hospital Transfusion Committee (HTC) to receive and approve audit reports and action plans.</td>
<td>Hospital Transfusion Committee (HTC)</td>
<td>If changes are required these would be endorsed by the UHL Executive Quality Board (EQB) and CMGs informed of changes required. EQB would maintain oversight of implementation by CMGs.</td>
</tr>
<tr>
<td>Minimum dataset of pre-transfusion documentation recorded</td>
<td>Lead TP</td>
<td>As part of the ICP audit</td>
<td>Every two years</td>
<td>HTC to receive and approve audit reports and action plans</td>
<td>HTC</td>
<td>If changes are required these would be endorsed by the UHL Executive Quality Board (EQB) and CMGs informed of changes required. EQB would maintain oversight of implementation by CMGs.</td>
</tr>
<tr>
<td>in the patients clinical records.</td>
<td>Deputy Service Manager Blood Bank</td>
<td>Audit of transfusion request document</td>
<td>Annual audit of completion of BT request forms.</td>
<td>HTC to receive and approve audit reports and action plans</td>
<td>HTC</td>
<td>If changes are required then these would be endorsed by the UHL Executive Quality Board (EQB) and CMGs informed of changes required. EQB would maintain oversight of implementation by CMGs.</td>
</tr>
<tr>
<td>Requests for transfusion include minimum dataset on the request forms.</td>
<td>Lead TP</td>
<td>As part of the ICP audit</td>
<td>Every two years</td>
<td>HTC to receive and approve audit reports and action plans</td>
<td>HTC</td>
<td>If changes are required then these would be endorsed by the UHL Executive Quality Board (EQB) and CMGs informed of changes required. EQB would maintain oversight of implementation by CMGs.</td>
</tr>
<tr>
<td>Accurate completion of BT Integrated care Pathway (ICP)</td>
<td>Lead TP</td>
<td>As part of the ICP audit</td>
<td>Every two years</td>
<td>HTC to receive and approve audit reports and action plans</td>
<td>HTC</td>
<td>If changes are required then these would be endorsed by the UHL Executive Quality Board (EQB) and CMGs informed of changes required. EQB would maintain oversight of implementation by CMGs.</td>
</tr>
<tr>
<td>Minimum monitoring of patient during transfusion</td>
<td>Lead TP</td>
<td>As part of the ICP audit</td>
<td>Every two years</td>
<td>HTC to receive and approve audit reports and action plans</td>
<td>HTC</td>
<td>If changes are required then these would be endorsed by the UHL Executive Quality Board (EQB) and CMGs informed of changes required. EQB would maintain oversight of implementation by CMGs.</td>
</tr>
<tr>
<td>Compliance with traceability of all blood and blood components.</td>
<td>HTC Chair</td>
<td>Ongoing audit</td>
<td>Quarterly reports prepared for the HTC meetings and monitored</td>
<td>HTC to receive and approve audit reports and action plans</td>
<td>HTC</td>
<td>If changes are required then these would be endorsed by the UHL Executive Quality Board (EQB) and CMGs informed of changes required. EQB would maintain oversight of implementation by CMGs.</td>
</tr>
</tbody>
</table>
10 **EQUALITY IMPACT ASSESSMENT**

The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.

As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

11 **LEGAL LIABILITY**

The Trust will generally assume vicarious liability for the acts of its staff, including those on honorary contract. However, it is incumbent on staff to ensure that they:

- Have undergone any suitable training identified as necessary under the terms of this policy or otherwise.
- Have been fully authorised by their line manager and their Directorate to undertake the activity.
- Fully comply with the terms of any relevant Trust policies and/or procedures at all times.
- Only depart from any relevant Trust guidelines providing always that such departure is confined to the specific needs of individual circumstances. In healthcare delivery such departure shall only be undertaken where, in the judgement of the responsible clinician it is fully appropriate and justifiable - such decision to be fully recorded in the patient’s notes.

It is recommended that staff have Professional Indemnity Insurance cover in place for their own protection in respect of those circumstances where the Trust does not automatically assume vicarious liability and where Trust support is not generally available. Such circumstances will include Samaritan acts and criminal investigations against the staff member concerned.

Suitable Professional Indemnity Insurance cover is generally available from the various royal colleges and professional institutions and bodies.
12 SUPPORTING REFERENCES, EVIDENCE BASE AND RELATED POLICIES


British Committee for Standards in Hematology Blood Transfusion Taskforce (2007) *Addendum to the Guidelines for the use of fresh-frozen plasma, cryoprecipitate and cryosupernatant, 2004*


Fowler, K et al. *The outcome of congenital cytomegalovirus infection in relation to maternal antibody status* New England Journal of Medicine, 326, 663-667


Serious Hazards of Transfusion (SHOT) scheme (1996-2012) *SHOT Annual Reports* SHOT Office. Manchester  
http://www.shotuk.org

The NHS Blood & Transplant [http://www.blood.co.uk/hospitals](http://www.blood.co.uk/hospitals)

Guidelines for compatibility procedures in blood transfusion laboratories. BCSH Transfusion Medicine, 2004, 14, 59-73

13 PROCESS FOR VERSION CONTROL, ARCHIVING AND REVIEW OF THE DOCUMENT

Once this Policy has been approved by the UHL P&G Committee, Trust Administration will allocate the appropriate Trust Reference number for version control purposes. The updated version of the Policy will then be uploaded and available through INsite.

Documents and the Trust’s externally-accessible Freedom of Information publication scheme.
It will be archived through the Trusts SharePoint system.
Accompanying letters will be sent to clinical directors, service managers, lead nurses, HTT members and via the monthly HTT newsletter.

This Policy will be reviewed every three years or more frequently if required so that current evidence continuous to underpin policy statements, guidelines and procedures.
It is the responsibility of the UHL Hospital Transfusion team to commission the review.
# Introduction / Scope

The guideline is intended for adult patients only. A separate guideline is available for children and neonates (see Appendix 8).

These guidelines are aimed at clinical staff responsible for making a decision to transfuse red cells for transfusion.

The information contained in these guidelines is based on national guidelines published by the British Committee for Standards in Haematology (2008) and The Association of Anaesthetists of Great Britain and Ireland (2001).

## The Main Body of the Guideline / Procedure

### 2.1 Background

There are significant concerns about the safety of blood transfusion with regard to both infectious and non-infectious complications of transfusion, and the theoretical risk of transmission of variant Creutzfeldt-Jakob disease (vCJD).

Additional safety requirements are increasing the cost of blood components.

There is no universal trigger for red cell transfusion. The decision to transfuse a patient should be based on haemoglobin level and a careful clinical assessment, indicating that transfusion is necessary to save life or prevent major morbidity.

There are serious concerns relating to the sufficiency of blood supply in the future.

### 2.2 General principles

- **2.2.1** Decision to transfuse should be based on a careful assessment of patient's clinical state and haemoglobin.
- **2.2.2** Blood transfusion must be justified as essential to prevent major morbidity or mortality.
- **2.2.3** Alternatives to allogeneic red cells should be considered where appropriate.
- **2.2.4** Document precise indication for transfusion in case notes.
- **2.2.5** Risks and benefits of transfusion should be explained to patients and their informed consent obtained. This should be clearly documented in case notes.
- **2.2.6** Patients should be offered an information leaflet (the leaflets are available in all clinical areas and further supplies can be obtained from blood bank).
- **2.2.7** Preoperative assessment should include diagnosis and treatment of iron deficiency anaemia with iron supplements.
- **2.2.8** The following table 1 summarises current local guidelines for all indications of red cell transfusions.

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**NB:** Paper copies of this document may not be most recent version. The definitive version is held on INsite Documents.
Table 1

<table>
<thead>
<tr>
<th>Haemoglobin</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hb less than 70 g/L</td>
<td>Transfuse 2 units of Red Cells and aim to maintain Hb around 90 g/L (90-100 g/L in patients &gt; 70 or with significant IHD)</td>
</tr>
<tr>
<td>Hb 70 -90 g/L, in a patient who is otherwise stable and no further blood loss is anticipated.</td>
<td>Transfusion is not generally indicated unless patient is symptomatic of anaemia.</td>
</tr>
<tr>
<td>Hb 90 g/L or above</td>
<td>No red cells transfusion required in stable patients with no anticipated blood loss</td>
</tr>
</tbody>
</table>

2.3 Indications for the use of red cell transfusion

To treat acute blood loss:

2.3.1 Assessment of acute blood loss

It is often difficult to estimate the amount of blood loss in this situation. Reference to the following table (Basket et al 1990) may be useful for clinical assessment.

In acute blood loss, crystalloids and/or colloids may be sufficient to replace up to 20% blood volume (effects of hypovolaemia vs. anaemia).

15% loss (750 ml in adult) – crystalloids only may be sufficient unless pre-existing anaemia or cardio-respiratory compromise, or further blood loss anticipated.

15-30% loss (800–1500ml in an adult) – crystalloids or synthetic colloids. Need for red cell transfusion unlikely unless pre-existing anaemia or cardio-respiratory compromise or further blood loss anticipated.

30-40% loss (1500–2000ml) – rapid volume replacement with crystalloids or synthetic colloids – red cell transfusion will probably be required.

>40% blood loss – refer to protocol for management of massive haemorrhage. Fresh Frozen Plasma, cryoprecipitate and / or platelets may be necessary to correct coagulation abnormalities.

Aim to maintain Hb > 90 g/L.

Inform blood bank of the degree of urgency.

See Table 2 for a classification of hypovolaemic shock according to percentage blood loss, and the associated clinical signs (Basket 1990):

Table 2

<table>
<thead>
<tr>
<th>Blood loss</th>
<th>Class I</th>
<th>Class II</th>
<th>Class III</th>
<th>Class IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percentage:</td>
<td>&lt;15 %</td>
<td>15-30 %</td>
<td>30-40 %</td>
<td>&gt;40 %</td>
</tr>
<tr>
<td>Volume (ml):</td>
<td>750 ml</td>
<td>800-1500 ml</td>
<td>1500-2000 ml</td>
<td>&gt;2000 ml</td>
</tr>
<tr>
<td>Blood pressure</td>
<td>Unchanged</td>
<td>Normal</td>
<td>Reduced</td>
<td>Very low</td>
</tr>
<tr>
<td>Systolic:</td>
<td>Unchanged</td>
<td>Raised</td>
<td>Reduced</td>
<td>Unrecordable</td>
</tr>
<tr>
<td>Diastolic:</td>
<td>Unchanged</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
2.3.2 Peri-operative transfusion

Wherever possible, the objective should be to manage the patient so that transfusion of allogeneic blood is not required.

Pre-operative considerations:

2.3.2.1 The Optimal Surgical Blood Order Schedule – OSBOS (ID: 4978447288) should be used for patients undergoing surgery that would normally require blood transfusion.

2.3.2.2 Patients should have a full blood count and group & antibody screen performed when placed on the waiting list for elective surgical procedure that is likely to require red cell transfusion (See DMS reference number 56978).

2.3.2.3 Patients with microcytic anaemia should be investigated for iron deficiency. Iron deficiency anaemia should be corrected during the pre-operative period.

2.3.2.4 Stop aspirin or other anti-platelet therapy one week pre-operatively where possible.

2.3.2.5 Pro-active management of anticoagulated patients.

2.3.2.6 Consider alternatives to allogeneic blood wherever appropriate.

2.3.2.7 Consider Peri-operative red cell salvage where relevant (anticipated blood loss = / > 1 Litre and no contraindication such as malignancy or contaminated field). The cell salvage machines are available in theatres at all three sites and the majority of ODPs have been trained in their use. See appendices 12 and 13 for more detailed information.

2.3.3 Anaemia in critical care

Over-transfusion may increase mortality in this group.
Decision to transfuse should be based on assessment of clinical and laboratory parameters. See Table 1 on p. 29

2.3.4 Chronic anaemia

In patients without significant symptoms of anaemia, avoid transfusion and establish underlying cause.
Investigate and treat haematonic deficiency.
Consider erythropoietin (e.g. in anaemia associated with chronic renal failure).

2.3.5 Anaemia associated with malignancy

Currently, there is no consensus on transfusion triggers in patients with anaemia associated with haematological or non-haematological malignancy. In patients with haematological malignancy, the majority practice in the UK is aimed at maintaining Hb levels around 100 g/L.

3 References


Herbert et al 1999 – Canadian Critical Care Trial Group, randomised, controlled (n=838) NEJM, 340, 409-417.


Serious Hazards of Transfusion, Annual Reports 1996-2013 (www.shotuk.org).


4 Legal Liability Statement

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1 **Introduction / Scope**

The purpose of these guidelines is to give clear instructions to clinical staff responsible for the prescription, administration and issue of platelets for transfusion. They are based on the current national guidelines published by the British Committee on Standards in Haematology (BCSH).

2 **The Main Body of the Guideline / Procedure**

As with other blood components, transfusion of Platelets must be prescribed and fully documented on the Blood Transfusion Integrated care pathway.

2.1 **Clinical indications for platelet transfusions**

Therapeutic platelet transfusions are indicated for patients with active bleeding associated with thrombocytopenia, although serious spontaneous haemorrhage due to thrombocytopenia alone is unlikely to occur at platelet counts above $10 \times 10^9/L$.

The cause of thrombocytopenia should be established (where possible) before a decision about the use of platelet transfusion is made.

Any decision must also be based on an assessment of risk versus benefit. Risks associated with platelet transfusions include allo-immunization, transmission of infection, allergic reactions and transfusion-related acute lung injury; potential benefits include reducing morbidity associated with minor haemorrhage and reducing morbidity/mortality resulting from major bleeding.

2.1.1 **Prophylactic platelet transfusions**

Prophylactic platelet transfusion is currently a standard practice for patients with bone marrow failure (due to bone marrow disease, cytotoxic therapy or irradiation).

2.1.1.1 **Acute leukaemia (excluding promyelocytic leukaemia)**

A threshold for prophylactic platelet transfusion of $10 \times 10^9/L$ should be used, unless severe sepsis &/or minor haemorrhage warrants a higher threshold of $20 \times 10^9/L$.

2.1.1.2 **Acute promyelocytic leukaemia**

There are no studies that specifically address the threshold for platelet transfusion in this condition. The presence of a coagulopathy would be expected to increase the likelihood of haemorrhage at any given platelet count. As a minimum, the platelet count should be kept above $30 \times 10^9/L$ in patients who are haemorrhagic and until coagulopathy is completely resolved.
2.1.3 Haemopoietic stem cell transplantation

The risk of mucosal injury is generally higher in bone marrow transplantation than with chemotherapy for acute leukaemia. However, a small number of studies have indicated that the threshold for platelet transfusion can be safely lowered to $10 \times 10^9$/L. Peripheral blood stem cell transplantation results in a shorter duration of thrombocytopenia than bone marrow transplantation, and the threshold for platelet transfusion can be the same as for marrow transplantation and acute leukaemia.

2.1.4 Chronic stable thrombocytopenia

Patients with chronic and sustained failure of platelet production, for example some patients with myelodysplasia or aplastic anaemia, may remain free of serious haemorrhage with platelet counts consistently below $10 \times 10^9$/L.

A specific threshold for transfusion is not appropriate for patients with chronic stable thrombocytopenia and these patients are best managed on an individual basis depending on the degree of haemorrhage.

Long-term prophylactic platelet transfusions may be best avoided in these patients because of the risk of allo-immunization and platelet refractoriness, and other complications of transfusion. Therapeutic platelet transfusions should be used to treat overt haemorrhage, and such patients may require prophylactic platelet transfusions to prevent recurrent haemorrhage during unstable periods associated with infection or active treatment.

2.1.2 Prophylaxis for surgery and invasive procedures

If platelet transfusion is necessary to raise platelet count to cover an invasive procedure, it must not be assumed that the platelet count will rise just because platelet transfusions are given.

A preoperative platelet count should always be checked to ensure that the following thresholds have been reached.

2.1.2.1 Bone marrow biopsy

In patients with severe thrombocytopenia, who are not haemorrhagic and who do not have coagulopathy, bone marrow aspiration and trephine biopsy may be performed without platelet support, providing that adequate surface pressure is applied.

In the presence of haemorrhagic symptoms or significant coagulopathy, the platelet count should be raised to at least $30 \times 10^9$/L for bone marrow trephine biopsy.

2.1.2.2 Other invasive procedures

For lumbar puncture, epidural anaesthesia, gastroscopy and biopsy, insertion of indwelling lines, transbronchial biopsy, liver biopsy or similar procedures, the platelet count should be raised to at least $50 \times 10^9$/L.
2.1.2.3 Major surgery

For laparotomy, multiple trauma surgery, major cardio-thoracic surgery and operations in critical sites such as the brain or eyes, the platelet count should be raised to $100 \times 10^9$/L.

2.1.2.4 Platelet function disorders

Patients with platelet function disorders rarely need platelet transfusions. However, acquired causes of platelet dysfunction can exacerbate bleeding in patients who already have impaired haemostasis.

The following recommendations (grade C, level IV) are for the management of bleeding or for prophylaxis before invasive procedures for patients with a known or suspected platelet function disorder. It is no longer considered necessary to use HLA-matched platelet transfusions for non-alloimmunized patients.

- Withdraw drugs known to have anti-platelet activity.
- Correct any underlying condition known to be associated with platelet dysfunction, if possible.
- Correct the haematocrit to $>0.30$ l/l in patients with renal failure, either with the use of recombinant erythropoietin or red cell transfusion.
- Consider the use of DDAVP (1-deamino-8-D-arginine vasopressin, desmopressin) in patients with inherited dysfunction defects, such as storage pool disease.
- Consider the use of DDAVP or cryoprecipitate in patients with uraemia.
- Use platelet transfusions where the above methods are not appropriate or are ineffective.
- Recombinant factor VIIa, has been shown to be effective in the management of bleeding and for prophylaxis before surgery in patients with Glanzmann's thrombasthenia.

2.2 Massive transfusion

A platelet count of around $50 \times 10^9$/l is expected when red cell concentrates equivalent to approximately two blood volumes have been transfused. There is consensus that the platelet count should not be allowed to fall below $50 \times 10^9$/l in patients with acute bleeding.

A higher target level of $100 \times 10^9$/l has been recommended for those with multiple trauma or central nervous system injury.

Please refer to the UHL massive haemorrhage protocol.

2.3 Disseminated intravascular coagulation (DIC)

Platelet transfusions are a part of the management of acute DIC, where there is bleeding associated with thrombocytopenia, in addition to management of the underlying disorder and coagulation factor replacement.

Frequent estimation of the platelet count and coagulation screening tests should be carried out.

Aim to maintain the platelet count $> 50 \times 10^9$/l, as in massive blood loss. In chronic DIC, or in the absence of bleeding, platelet transfusions should not be given merely to correct a low platelet count.
2.4 Cardiopulmonary bypass (CPB)

Where possible, consider stopping anti-platelet drugs at least a week pre-op in patients attending for elective surgical revascularization.

Where it is not safe or possible to discontinue anti-platelet drugs before surgery, consider using aprotonin.

Microvascular bleeding, as indicated by continued oozing from surgical incisions and venous cannulation sites, may occur as a consequence of either thrombocytopenia (usually platelet counts < $50 \times 10^9/l$) or acquired (transient, reversible) platelet dysfunction due to CPB.

The use of the Thromboelastography (TEG - Rotem) and platelet function tests using multiplate should be carried out whenever possible to guide clinical decision for prescribing platelet transfusion.

The use of platelet transfusion should be reserved for those patients who are experiencing excessive postoperative bleeding and in whom a surgical cause has been excluded.

There is no indication for prophylactic transfusion of platelets in patients undergoing CPB.

2.5 Neonatal alloimmune thrombocytopenia (NAIT)

The optimal approach to the postnatal management of NAIT suspected on clinical grounds is to transfuse compatible platelets as soon as possible, as delay in the provision of effective treatment may result in an increased risk of severe haemorrhage.

It is not necessary to wait for laboratory confirmation of the diagnosis.

The transfusion of human platelet antigen (HPA)-1a-negative, HPA-5b-negative platelet concentrates will result in least delay in providing treatment and will be effective in around 95% of cases of NAIT.

If there is no response to HPA-1a negative, HPA-5b negative platelet concentrates, or if the HPA incompatibility is known to be for HPAs other than HPA-1a or HPA-5b, consideration should be given to the use of a platelet concentrate prepared from the mother. Such concentrates should be gamma irradiated and washed, in order to minimize the transfusion of maternal platelet allo-antibodies that may otherwise prolong the neonatal thrombocytopenia.

Intravenous immunoglobulin infusion for the postnatal management of NAIT is effective in 75% of cases but increase in platelet count is delayed for 24–48 h, during which time the infant remains at risk of intracranial haemorrhage. HPA 1a- and 5b-negative platelets should be transfused without undue delay.

2.6 Post-transfusion purpura

High-dose intravenous immunoglobulin (total dose of 2 g/kg in divided doses given over a period of 2 to 3 days) is the current treatment of choice and has 85% response rate.

High dose (2 or more adult doses) platelet transfusions may be required to control severe bleeding before there has been a response to high-dose intravenous immunoglobulins.

There is no evidence that platelet concentrates from HPA-1a-negative platelets are more effective than those from random donors in the acute thrombocytopenic phase, and the dose of platelets may be more important than the type of the donor platelets. It is not known whether random transfusions in the acute phase prolong the duration or severity of thrombocytopenia.
2.7 Autoimmune thrombocytopenia (ITP)

Platelet transfusions are generally ineffective in ITP and are reserved for patients with life-threatening bleeding from the gastrointestinal or genitourinary tracts, bleeding into the central nervous system or other sites associated with severe thrombocytopenia.

In these situations, intravenous methylprednisolone 500 mg to 1 g (adult dose) and / or high dose IV immunoglobulins (1 g/Kg body weight /day for 2 days) should be given at the same time to maximize the chances of stopping the haemorrhage and raising the platelet count.

3 Contraindications

Please note that platelet transfusions are not indicated in all cases of thrombocytopenia and may indeed be contraindicated in certain conditions, such as TTP (Thrombotic Thrombocytopenic Purpura). If in doubt, please seek advice from haematology on-call team.

4 Administration and rate of transfusion

When Platelets are given prophylactically to adults, it is recommended that one adult therapeutic dose (ATD) is given. This should increase the platelet count by at least 20-40x10^9/l.

When platelets are given therapeutically to treat active bleeding, a larger dose of platelets maybe indicated, the dose and frequency of administration depends on the individual circumstances.

Platelets must be administered immediately on delivery to the clinical area. Delay in administration increases the risk of transfusion reaction.

It is recommended that platelet concentrate is administered over a 30 minute period (BCSH, 1992, 1999, 2009) in an adult, through a standard blood administration set or platelet administration set. Do not give through a set that has already been used for red cells.

For children (< 20kg), the dose is 10-15 ml/kg. The rate of transfusion should be 20-30 ml/kg/h.

For adverse effects, refer to the Handbook of Transfusion Medicine.

5 References


British Committee for Standards in Hematology (1999) Guidelines for the Administration of Blood and Blood Components and the management of Transfused Patients. Transfusion Medicine, 9, 227-238


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1 **Introduction / Scope**

1.1 The purpose of these guidelines is to assist clinical decisions about the transfusion of Fresh Frozen Plasma (FFP) and Cryoprecipitate. It is targeted to all clinical staff responsible for the prescription, administration and issue of these products.

The guidelines are based on the current national guidelines published in 2004 by the British Committee for Standards in Haematology (BCSH).

1.2 The indications for the transfusion of Fresh Frozen Plasma (FFP), cryoprecipitate and cryosupernatant plasma (plasma depleted in FVIII and fibrinogen) are very limited. The risks of transmitting infections are similar to those of other blood components but when transfused they can have unpredictable results which include anaphylaxis, transfusion related acute lung injury (TRALI) and haemolysis from transfused antibodies to blood group antigens, especially A and B.

1.3 As with other blood components, transfusion of FFP must be prescribed and fully documented on the Blood Transfusion Integrated care pathway.

2 **The Main Body of the Guideline / Procedure**

2.1 **Clinical indications for the use of FFP and Cryoprecipitate**

2.1.1 **Multiple coagulation factor deficiencies; disseminated intravascular coagulation (DIC)**

FFP and platelets are indicated when there are demonstrable multi-factor deficiencies (e.g. DIC) associated with severe bleeding. Aim to maintain platelet count >50 and INR and APTT ratios <1.5.

Cryoprecipitate is indicated if the plasma fibrinogen is less than 1.5 g/L, AND the patient is bleeding.

FFP is NOT indicated in DIC with no evidence of bleeding – there is NO evidence that prophylactic replacement regimes prevent DIC or reduce transfusion requirements in these situations.

FFP is NOT indicated for volume replacement.

2.1.2 **Thrombotic thrombocytopenic purpura (TTP)**

Single to 1.5x volume plasma exchange should commence as soon as possible within 6 - 8 hours of first presentation.

Refer to BCHS Guideline on the diagnosis and management of thrombotic thrombocytopenic purpura and other thrombotic microangiopathies (2012).

2.1.3 **Reversal of warfarin effect**

FFP is **NOT** the first line treatment of choice where a rapid reversal of anticoagulation with warfarin (or other Coumarin derivatives) is required to control severe, life threatening haemorrhage.

FFP Should **NOT** be used for reversal of warfarin anticoagulation in the absence of bleeding.

FFP should only be considered for the reversal of Warfarin where either the patient is bleeding or requires emergency surgery and the first line treatment,
Prothrombin Complex Concentrate (Beriplex or Octaplex) is contraindicated (See UHL PCC guidelines – ID: 4051709675).
If FFP needs to be administered in these situations where PCC (Octaplex / Beriplex) is contraindicated, Vit K 5 mg should also be administered by slow intravenous route.
Refer to UHL Guidelines on Management of Warfarin Overdose (Trust Ref. C2/2001); See also Appendix 5 of this policy.

2.1.4 Vitamin K deficiency in intensive care (ICU)
Prolonged clotting times in ICU patients should be corrected with vitamin K (e.g. 5mg by slow intravenous injection) where appropriate.

FFP is NOT routinely indicated in this situation.

2.1.5 Liver disease
There is no evidence to support routine use of FFP in patients with chronic liver disease, in the absence of bleeding associated with significant abnormal coagulation parameters i.e. INR >1.5 and/or APTT ratio >1.5. Prophylactic use of FFP is therefore not routinely indicated in these patients.
There is no evidence that prophylactic use of FFP reduces the risk of severity of bleeding during or following invasive procedures in patients with chronic liver disease.
FFP may be only administered as part of the management of active bleeding in patients with liver disease and significant coagulopathy.

2.2 Dosage
The volume of FFP in each pack is stated on the label (usually 270-280 ml in Adult pack).
The recommended dose is 10-15 ml/kg – may need to be repeated after 4-6 hours if bleeding continues or more frequently in patients with massive haemorrhage. The repeat doses should be guided by coagulation tests.
Cryoprecipitate: Single adult dose is 10 units. Paediatric dose is 1 unit per 5-7 Kg body weight. A single dose should raise plasma fibrinogen level by 1 g/L.
Dosage and frequency of administration should be guided by Point of Care Thromboelastography (TEG) for laboratory coagulation parameters wherever possible

2.3 Type of FFP
There are 3 types of FFP available in the UK:

Standard FFP for adults (from UK donors)
Imported Methylene Blue treated FFP (used for children up to age of 16)
Solvent detergent-treated FFP (which is currently mainly used for plasma exchange in Thrombotic Thrombocytopenic Purpura (TTP) and Haemolytic Uraemic Syndrome (HUS)).

2.4 FFP is also NOT indicated in the following:

Hypovolaemia
Fresh-frozen plasma should never be used as a simple volume replacement in adults or in children. Crystalloids are safer, cheaper and more readily available.

Plasma exchange (except for TTP and possibly for plasma exchange, additional risk factor bleeding such as patients with Goodpasture’s syndrome)
Although using plasma-free replacement fluids results in the progressive reduction of coagulation factors, immunoglobulins, complement and fibronectin; haemorrhage and/or infections are not encountered. In the rare event that haemorrhage occurs, a platelet count check before giving FFP is advisable. There may be a problem with pseudocholinesterase levels being low as a result of many plasma exchanges with saline/albumin if the patient then needs an anaesthetic. This can be corrected with FFP, although alternative drugs are available that can be used providing the anaesthetist is aware.

**Reversal of prolonged INR in the absence of bleeding**

There is no justification for using FFP to reverse a prolonged INR in the absence of bleeding.

### References


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PROTOCOL FOR USE OF RECOMBINANT COAGULATION FACTOR VIIa (NovoSeven)

**UHL Protocol for use of Recombinant Coagulation Factor VIIa (NovoSeven ®) in uncontrolled haemorrhage**

Massive uncontrolled haemorrhage defined as:
1. Consider after 6 units of blood have been given
2. Define after 9 units of blood have been given

-rVB not indicated

No

- All accepted and available surgical measures to control bleeding attempted, or surgical measures impossible/prohibited
- Correct pH > 7.2
- Aim for Core Temperature > 35°C

Yes

-rVB not indicated unless/x until surgical control attempted

No

- Is TEG trace normal using standard and heparinised cups (patient received heparin)?

Yes

- Give appropriate blood components, protamine and/or tranexamic acid given as per TEG protocol and reassess (See TEG Protocol overlay)
- Is repeat TEG normal and patient still bleeding?

Yes

- RECONSIDER AND EXCLUDE SURGICAL CAUSE OF BLEEDING

No

Contact blood bank and give first dose of rVIIa (NovoSeven) and reassess bleeding after 15-20 minutes

If bleeding uncontrolled 20 minutes after the first dose of NovoSeven, discuss repeat doses with on-call haematologist

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**The process for obtaining and administration of rVIIa (NovoSeven) from blood bank**
1. Contact Haematology SP or Consultant on call for Blood Transfusion and Haemostasis role for authorisation of rVIIa
2. Telephone (day, on call hours) your site Blood Bank
3. Provide patient’s name, DOB, hospital number, weight, location and name of authorising haematologist and prescribe authorised/agreed dose
4. Immediately send someone to Blood Bank to collect NovoSeven pack, which will include instructions and mandatory audit form
5. Complete the audit form and return to Emma Yates, Blood Transfusion, Level 2, Sandringham Building, UHL
6. UHL Therapeutic Advisory Service will be notified of all failures to complete the mandatory audit form

**Base by W/Hz (see product insert for instructions on reconstitution and administration)**
- 60kg = 80 micrograms/kg to nearest combination 1.0, 2.0, or 5.0 mg vials
- 56-59kg = 7.0 mg (5mg + 2mg vials)
- 38-55kg = 0.0 mg maximum (5mg + 2mg vials)

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**Cautions**
- Recent thrombosis, high risk (e.g. PE, MI, thrombolytic stroke in last 6 months, prosthetic heart valve), history of significant thrombogenic

Please note that there has been an important change in the Novoseven SPC (Summary of Product Characteristics). In view of the significant risk (approx. 5%) of major and potentially fatal thrombotic events associated with the use of NovoSeven, the manufacturer now clearly states against using this drug for unlicensed indications, including its use in acquired vasculopathy of trauma or major surgery.

The choice of justifiable use entirely on the prescribing clinician, who will need to consider risks versus benefits and, whenever possible, inform patient / relatives of the significant risk (approx. 5%) of major, potentially fatal, thrombotic complications associated with its use. If in doubt, please discuss with the on call consultant haematologist.

For the same reason, NovoSeven must not be used concurrently with other potentially thrombogenic factor Xa inhibitors such as Novatis or Arixtra.
Please note that there has been an important change in the Novoseven SPC (Summary of Product characteristics). In view of the significant risk (approx. 5%) of major thrombotic events associated with the use of Novoseven, the manufacturers now clearly advise against using this drug for unlicensed indications, including its use in acquired coagulopathy of trauma or major surgery.

This places the onus of justifiable use entirely on the prescribing clinician, who will need to consider risks versus benefits and, wherever possible, inform patient / relatives of the significant risk (approx. 5%) of major, potentially fatal, thrombotic complications associated with its use. If in doubt, please discuss with on-call Consultant haematologist.

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1 **Introduction / Scope**

Various coagulation factors concentrates used for treatment of Haemophilia patients are prescribed and administered by the Haemostasis Clinical Nurse Specialists or trained haematology medical staff. The relevant protocols and guidelines are kept in the Haemostasis department, Osborne Building, LRI.

2 **The Main Body of the Guideline / Procedure**

2.1 **Reversal of Warfarin in life threatening haemorrhage**

The Prothrombin Complex Concentrate (PCC), (Octaplex or Beriplex), is available from Blood Transfusion Laboratory at LRI, LGH and GGH for immediate reversal of oral anticoagulation with Warfarin or other Coumarin derivatives in patients with intracranial haemorrhage or other life threatening bleeding. The use of Fresh Frozen Plasma (FFP) is unsatisfactory in this situation as it does not achieve immediate and complete reversal of anticoagulation.

Intravenous vitamin K (5 mg to 10 mg) will be necessary in addition to Prothrombin Complex Concentrate.

*Octaplex or Beriplex can be obtained from blood transfusion laboratory after discussion with on-call haematology Specialist Registrar or Consultant who will advise on the appropriateness of its use and instructions on dose calculations.*

For further information see UHL PCC guidelines(ID: 4051709675).

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ALBUMIN SOLUTIONS AND IV IMMUNOGLOBULIN PREPARATIONS

Appendix Six

1 Introduction / Scope

These are blood products and are all provided with batch numbers which must be documented in patient’s case notes. These products do not need to be ABO compatible.

Human albumin is available in three different formulations:
- 500ml bottles of 4.5% solution
- 100ml bottles of 4.5% solution (for paediatric use)
- 100ml bottles of 20% solution

2 The Main Body of the Guideline / Procedure

All enquiries regarding albumin solutions must be directed to the Blood Transfusion Laboratory.

Except for certain high user wards (special arrangements will be made with these wards), albumin will only be issued on a named patient basis upon receipt of correctly completed request form.

All issued albumin will need to be collected from the blood bank.

Albumin solutions may be stored for short periods on the ward or theatre providing the storage temperature is not exceeded (+2°C to +25°C).

Albumin solutions are made from pooled Human Plasma (blood product), transfusions need to be monitored and supervised as per Hospital Transfusion Policy.

The reason for transfusion must be documented in the patient’s notes.

All unused product should be promptly returned to blood bank.

NOTE: Use only for patients prescribed. Do NOT use for other patients, as the Blood Transfusion laboratory must be able to trace the batch number of product to individual patient. Failure to comply is a CRIMINAL OFFENCE.

2.1 Administration and rate

REMEMBER: Albumin is a human derivative and therefore carries many potential risks.

Human Albumin Solution (HAS) is dispensed on a named patient basis. Documentation of its use and corresponding batch numbers etc must be strictly upheld. It is given as an intra-venous infusion and administered at room temperature. It must be administered using a standard blood giving set at the rate specified by the prescribing clinician.

There are specific instructions in the IV drug monograph (available through Medusa online) for the administration of high dose IV Immunoglobulin.

The administration of 20% solutions of albumin requires more frequent patient monitoring with hourly observations of pulse, blood pressure and respiratory rate.

Plasma volume replacement – crystalloid solutions are safe and effective for resuscitation in traumatic and haemorrhagic shock. Colloid solutions may help to maintain haemodynamic stability when vascular permeability is increased; however albumin has no specific benefit over colloid solutions but is much more expensive. There is no evidence that the administration of albumin reduces the risk of death in critically ill patients with hypovolaemia, burns, or hypoalbuminaemia. A low plasma albumin is indicative of a poor prognosis, but raising it by albumin infusion does not improve the outcome.
NO OTHER MEDICATION OR SUBSTANCE(S) SHOULD BE ADDED TO HAS.

2.1.1 Unless otherwise prescribed, HAS is given by intravenous infusion at a rate of:

- **20% HAS** 1 – 2 ml per minute (60 – 120ml/hr and must not exceed 2ml/min)
- **4.5% HAS** 5ml per minute (300ml/hr)

   In severe cases this may be increased to 1,000ml/hr

   For patients undergoing plasma exchange the rate may be increased to 1,800ml/hr

2.1.2 **Immunoglobulin preparations**

   (Refer to UHL Immunoglobulin I.V. monogram on Medusa).

2.2 **Disposal of empty glass Albumin bottles**

   Any unused bottles of HAS should be returned to the blood bank to be wasted as store conditions outside of the department are not qualified.

   Any bottles with residual unused product and / or empty glass bottles must be disposed of as per Waste Management Policy (Trust Ref. A15/2002).

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1 Introduction / Scope

The decision to administer O Neg Blood is entirely the responsibility of the clinician concerned.

Blood transfusion laboratory must be immediately informed of the degree of urgency and anticipated blood component requirement.

Uncrossmatched, O-Negative blood must only be used when there is life threatening blood loss and where the degree of urgency allows no time to wait for the arrival of group specific or cross-matched blood from the blood transfusion laboratory.

2 The Main Body of the Guideline / Procedure

2.1 Group specific blood can normally be made available for collection from the blood transfusion laboratory within 20 minutes of receiving patient’s blood sample. Crossmatched blood can be made available for collection within 40-45 minutes of the receipt of samples; unless atypical antibodies are detected when further laboratory tests will be necessary, involving further delay. Crossmatched or group specific blood must be used in preference to O-Negative blood whenever possible.

2.2 Units of uncrossmatched, O-Negative blood are available for use in extreme emergency, in each of the following UHL blood bank refrigerators:

2.2.1 Leicester Royal Infirmary (LRI)
   Blood bank refrigerator, Level 2, Sandringham Building (2 units).
   Blood bank refrigerator in the Maternity unit (2 units).
   Blood bank refrigerator in Central Operating Department (2 units).
   Blood bank refrigerator in A&E (4 units).

2.2.2 Glenfield Hospital (GH)
   Main blood bank refrigerator in Pathology (4 units).

2.2.3 Leicester General Hospital (LGH)
   Main blood bank refrigerator in Pathology (4 units).
   Blood bank refrigerator in Maternity Unit (2 units).

2.3 The blood transfusion laboratory must be immediately notified by telephone or bleep during out of hours, if O-Negative blood is removed from any of the above blood bank refrigerators, to facilitate prompt replacement of emergency O-Negative units.

2.4 On admission the patient must be fitted with a wristband with all patient identity details, or if the patient is unidentified, then the unique identity number and gender must be used. These details should be quoted on requests for urgent blood.

2.5 The documentation form supplied with each emergency O negative unit must be accurately and fully completed then immediately returned to Blood Bank. This information should also be recorded in the patient’s notes (a peel off label is provided on the O-Negative blood documentation form).
NOTE: It is a legal requirement to ensure traceability of blood from donor to recipient.

2.6 Extra care should be taken to monitor the patient closely to detect any evidence of acute reactions.

3 Legal Liability Statement

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1 Introduction / Scope

Transfusion of infants and neonates presents some unique considerations not only in relation to product specification and transfusion procedures but also the fact that there are special hazards of transfusion in this age group.

The information herein is aimed at all Healthcare Professionals undertaking any aspect of a Paediatric and/or Neonatal transfusion episode. It provides information and detailed instructions for transfusion practice in children and neonates. It should however be followed in conjunction with the main UHL Blood Transfusion policy.

These guidelines are based on the Transfusion Guidelines for Neonates and Older Children published by the British Committee on Standards in Haematology (2004) and amendments 2005 & 2007.

2 The Main Body of the Guideline / Procedure

2.1 Special requirements

All red cells and platelets for transfusion are leucodepleted. There are specific indications for the use of CMV-seronegative blood components and/or gamma irradiated cellular blood components, which are summarised in Appendices 17 and 18. Children with special requirements must have this clearly indicated, and signed by the consultant, on the inside front cover of their medical notes (see appendix 19 for Notification of patients who require CMV Neg or Irradiated products). Notification of any special requirements must also be made to blood bank by the child’s clinical team. The Prescription must also clearly state the special requirement where indicated on the UHL Blood Transfusion Integrated Care Pathway.

2.2 Blood sampling

Obtaining a Blood Sample from a neonate in particular must be given careful consideration. Due to the circulating volume, the quantity and frequency of blood taken must be kept to a minimum and excessive/unnecessary sampling should be avoided.

Sample Requirements for G+S and or Cross-Match:

- **Neonates** - <4months of age require a 1.2ml EDTA sample (together with maternal samples; at first presentation only)
- **Children <10kg** – require a 1.2ml EDTA sample for G+S or Cross-match
- **Children >10kg** – require a 7ml EDTA sample for G+S or Cross-match

2.3 Administration

2.3.1 Red cell transfusions

2.3.1.1 Indication
The indications for red cell transfusion will be according to the specific, local guidelines in use in the unit caring for the child. The indication for transfusion must be clearly documented in the patients’ medical notes; similarly it is important to document any benefit the transfusion made to the patients’ clinical outcome.

While the beneficial effect of transfusion or lack there may be known empirically at the time the patient is being managed, it is not always evident in the medical notes.

**2.3.1.2 Calculation of red cell transfusion volume**

**Children <10kg weight**

Total volume (ml) = (desired Hb g/dl – actual Hb g/dl) x child’s weight (kg) x 4.

*Aliquot containing the nearest volume required will be issued*

**Children >10kg weight**

Transfuse 3 – 4ml/kg/g rise of Hb required using complete units. Use table below to calculate the amount of blood required:

1. Find the weight of the child in kg along the top row
2. Look down the column below this to find the nearest rise in Hb required (measured in g)
3. The figure in the units needed (left hand) column tells you how many units will achieve that rise, e.g. Child of 14kg with Hb 7.5g. 1 unit will raise the child’s Hb by 5g i.e. to 12.5g/dl.

<table>
<thead>
<tr>
<th>Weight in kilograms</th>
<th>Units needed</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>11</td>
</tr>
<tr>
<td>0.5</td>
<td>3.5</td>
</tr>
<tr>
<td>1.0</td>
<td>7.0</td>
</tr>
<tr>
<td>1.5</td>
<td>10.0</td>
</tr>
<tr>
<td>2.0</td>
<td></td>
</tr>
<tr>
<td>3.0</td>
<td></td>
</tr>
<tr>
<td>4.0</td>
<td></td>
</tr>
</tbody>
</table>

**Children >45kg weight**

- 1 unit of red cells will increase Hb by ~1 g.
- Transfusion Rate: 3 – 5 ml/kg/hour

**2.3.2 Platelet transfusions**

**2.3.2.1 Indication**

Platelet transfusions are indicated for the prevention and treatment of haemorrhage in patients with thrombocytopenia or platelet function defects.
However platelet transfusions are not indicated in all causes of thrombocytopenia and may be contraindicated in certain conditions. The need for platelet transfusion in an individual child will depend on the cause of the thrombocytopenia, the presence and risks of bleeding and the necessity of any invasive procedures. Transfusion will be according to the relevant guidelines in use in the unit caring for the child.

### 2.3.2.2 Calculation of requirements

**Dose:**
- Children <15kg: 10-20ml/kg
- Children >15kg: 1 single apheresis pack

**Rate of infusion:**
It is recommended that platelets be administered over a 30 to 60 minute period. In the paediatric setting, this approximates to a rate of 20-30ml/kg/hour. Increased rates of administration, especially in neonates, may lead to vasodilatation and hypotension.

### 2.3.3 Fresh Frozen Plasma and Cryoprecipitate

#### 2.3.3.1 Indication

The indications for the transfusion of fresh frozen plasma (FFP) and cryoprecipitate are very limited.

FFP and cryoprecipitate are indicated when there are demonstrable multiple coagulation factor deficiencies (e.g. disseminated intravascular coagulation (DIC)) associated with severe bleeding.

#### 2.3.3.2 Administration

**Aim to maintain:**
- platelet count >50
- INR and APTT ratios <1.5
- Fibrinogen >1g/l

Cryoprecipitate is only indicated if plasma fibrinogen is <1g/L, and patient is bleeding. This is now supplied as Methylene Blue pooled donations (1st April 2014).

**NOTE:** Requests for FFP and Cryoprecipitate must be made via the haematology medical staff and indications for use can be discussed.

#### 2.3.3.3 Calculation of Requirements

- **FFP Dose:** 10 – 15 ml/kg
- **Cryoprecipitate:** 5-10mls/kg.

Will raise fibrinogen by 0.5-1.4g/l. Measure level post transfusion to confirm the outcome.

FFP and cryoprecipitate are thawed in blood bank. They cannot be re-frozen once thawed. Transfusion of FFP and cryoprecipitate should be commenced as soon after thawing as possible and must be completed within 4 hours of thawing.
2.3.4 Vitamin K

2.3.4.1 Indication

Vitamin K is required for normal function of factors II, VII, IX and X.
In Vitamin K deficient coagulopathy without bleeding give IV Vitamin K.
Vitamin K deficient coagulopathy with bleeding give IV Vitamin K & FFP.

2.3.4.2 Dose

300 micrograms/kg (max 10mg) single dose, repeat as necessary.
Response within 30 – 120 minutes.

2.3.5 Human Albumin Solution (HAS)

2.3.5.1 Indication

Albumin is a blood product and issued via the Blood Transfusion Laboratory
on a named patient basis.
There are specific indications for the use of human albumin solution, which
will be according to the policy of the specialist unit caring for the patient.

2.3.5.2 Calculation of requirements

<table>
<thead>
<tr>
<th>Albumin Concentration</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>20% HAS</td>
<td>2 – 5ml/kg</td>
</tr>
<tr>
<td>4.5% HAS</td>
<td>10 – 20ml/kg</td>
</tr>
</tbody>
</table>

For information relating to the rate of infusion, please refer to the
manufacturers recommendations; to be found on the information leaflet inside
the HAS packaging.

2.3.6 Immunoglobulin

Refer to IV drug monograph for the individual named product for administration
guidance.

2.3.7 Adverse events including ‘near miss’ events

All adverse incidents and ‘near miss’ events must be reported as per UHL Policy for

2.3.8 Investigation and management of transfusion reactions

Transfusion reactions are discussed at length in Appendix 15. However, for more
detailed information about Anaphylaxis go directly to UHL Childrens’ Medical

3 References

Transfusion Guidelines for neonates and older children, British Journal of Haematology,
124, 433-453

British Committee for Standards in Hematology Blood Transfusion Taskforce (2005)
Guidelines for the use of fresh-frozen plasma, cryoprecipitate and cryosupernatant
The British Society for Haematology, 126, 11-28
4 Legal Liability Statement

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1 **Introduction / Scope**

Patients with renal disease are particularly vulnerable with regard to fluid overload and therefore require careful assessment of their fluid status. Whilst there is a need to correct anaemia, it is also vital that renal and transplant patients have a thorough and accurate clinical assessment of their fluid status prior to the prescribing and administration of blood and blood products. It is essential that each unit of blood or blood product is recorded on the fluid balance chart in order to maintain an accurate record of the fluid balance. In addition, consideration must be given to the patient’s fluid management, specifically with regard to whether or not the transfusion is included into their overall fluid intake allowance.

Where patients are not receiving renal replacement therapy, consideration must be given to whether or not the standard frequency of observations of vital signs is increased in line with the patient assessment/condition.

2 **The Main Body of the Guideline / Procedure**

2.1 **Administration of blood during haemodialysis or haemofiltration**

2.1.1 **Prescribing of blood transfusions**

Blood transfusions for haemodialysis and haemofiltration patients should always be given whilst the patient is on haemodialysis or haemofiltration unless otherwise prescribed by medical staff during which, the harmful effects of the associated volume and potassium load can be rectified (Daugirdas & Ing 2001).

All blood transfusions for patients on haemodialysis or haemofiltration should be prescribed by medical staff. Registered nursing staff must ensure that the additional fluid gain caused by the transfusion is calculated into the prescribed weight loss on haemodialysis or haemofiltration respectively.

2.1.2 **Administration of blood during haemodialysis or haemofiltration**

Codan blood administration set must be used for the transfusion as the filter in the bubble trap of the dialysis machine is not sufficient to stop small clots passing through.

A maximum of one unit of blood can be transfused over an hour on haemodialysis or haemofiltration. Unless otherwise prescribed, a patient can receive a maximum of 2 units of packed cells during a 4-hour haemodialysis treatment.

Prior to the commencement of the blood transfusion, the standard patient identification checks for transfusion of blood components should be performed as per UHL policy.

The patient’s baseline temperature, respiration, pulse and blood pressure must be checked just prior to commencing the prescribed transfusion. If vital signs are within the patient’s ‘normal limits’, the transfusion can begin.

Blood must be administered by intermittent bolus doses only. AT NO TIME SHOULD THE TRANSFUSION BE LEFT TO INFUSE UNATTENDED.

The volume of blood administered as a bolus can be measured using the blood pump of the haemodialysis machine.
For example:

To infuse 100mls of blood as a bolus, ensure the blood pump speed is set at 200mls/min, clamp the arterial line from the patient and open fully the roller clamp on the blood giving set for 30 seconds. The patient will receive 100mls of blood. Adjust the calculation accordingly if the blood pump speed is slower or faster.

To start the transfusion, the first bolus of blood should be 50mls. Observation for the patient’s reaction to the blood should be measured in the usual way, i.e. recording patient’s temperature, pulse and blood pressure prior to each bolus and observing for transfusion reactions.

If the patient’s temperature, respiration, pulse and blood pressure are satisfactory and there are no signs of transfusion reactions or fluid overload, the transfusion can continue with the bolus dose increasing to 100mls every 15 minutes. This procedure is repeated with the second unit of blood.

In the event of a severe reaction, transfusion must be discontinued immediately. Medical staff responsible for the patient must also be contacted immediately as per UHL policy.

2.2 Administration of blood during peritoneal dialysis (ambulatory or continuous cycling)

2.2.1 Prescribing of blood transfusions

In all cases, patients receiving peritoneal dialysis must have their fluid status assessed and treatment regime prescribed accordingly by medical staff prior to the administration of a blood transfusion.

All blood transfusion for patients on peritoneal dialysis should be prescribed by medical staff on an intravenous prescription chart.

2.2.2 Administration of blood to patients on Peritoneal Dialysis

The patient’s baseline temperature, respiration, pulse and blood pressure must be checked just prior to commencing the prescribed transfusion. If vital signs are within the patient’s ‘normal limits’, the transfusion can begin.

The patient’s temperature, respiration, pulse and blood pressure must be checked every 15 minutes for the first hour of the transfusion. If vital signs are within normal limits, the patient’s temperature, pulse, respiration and blood pressure can be recorded hourly until the unit of packed cells is completed. For every subsequent unit of packed cells that is administered, the frequency of the recordings of temperature, respiration, pulse and blood pressure must follow the same pattern: i.e. every 15 minutes for the first hour, and hourly thereafter until the unit of packed cells is complete.

In the event of a severe reaction, transfusion must be discontinued immediately. Medical staff responsible for the patient must also be contacted immediately as per UHL policy.

3 References

Daugirdas J. T., Blake P. G. & Ing T. S. (2001). The Handbook of Dialysis, Lippincott Williams & Wilkins

Dr J. Medcalf Guidance for Fluid Management in Patients following Renal Transplantation (Dec 2010), Within the UHL Transplant Unit Handbook

4 Legal Liability Statement

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1 Introduction / Scope

The purpose of this guideline is to provide health professional staff with instructions for inter-hospital transfer of patients whilst receiving blood transfusion.

2 The Main Body of the Guideline / Procedure

2.1 Transfer of patients whilst receiving blood transfusion between hospitals within the Trust

2.1.1 If a patient has to be transferred from one hospital to another within the Trust while transfusion is in progress, a registered nurse or midwife, or a member of medical staff must remain with the patient until transfer is complete.

2.1.2 The registered nurse or midwife responsible for the patient must inform the technical staff in their blood transfusion laboratory giving full details of the transfer.

2.1.3 The Blood Transfusion laboratory will arrange urgent transportation of unused blood components to appropriate blood bank refrigerator making sure that the blood component packs are transported in controlled storage conditions. This procedure ensures safe transfer of blood components and must be discussed with blood bank staff for all movement of blood between hospitals. The expiry time for the transfer box must be checked prior to use.

2.1.4 The Blood Transfusion laboratory receiving the blood components will notify the responsible registered nurse or midwife on the destination ward/theatre of the availability of patient-specific blood components.

2.2 Transfer of blood with a patient to a hospital outside the Trust (see Appendix 11)

The ward must not send blood outside the Trust without informing Blood Transfusion laboratory. The Blood Transfusion laboratory needs to know where it is sent so they can inform the receiving hospital and provide accompanying documentation. The Blood Transfusion Laboratory will package the blood appropriately and make it available to the ward for transport with the patient (See Appendix 11 for summary of East Midlands Regional Procedure for the Emergency Transfer of Blood and Components with Patients between Hospitals).

2.3 Receipt of blood with a patient from a hospital outside the Trust (see Appendix 11)

All blood products received with a patient from outside of the Trust must be processed through the Blood Transfusion Laboratory to be correctly documented and integrity checked before use. Contact blood bank immediately on patient’s arrival. Be aware there is a time limit on transport. The blood must be received by Blood Transfusion within the time limit or it will have to be wasted (See Appendix 11).
3 **Legal Liability Statement**

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The transfer documents stated in this procedure can be found in the following policy:

East Midlands Regional Transfusion Committee Procedure for the Emergency Transfer of Blood and Components with Patients between Hospitals

1 Introduction/ Scope

The purpose of this guideline is to help ensure the following:
- Blood is only transferred in the appropriate clinical scenario.
- Blood is transported and packaged in accordance with validated procedures to ensure quality and safety.
- The transfer of blood is correctly documented to maintain proof of the cold chain of blood storage.
- Vein-to-vein traceability is maintained.
- The roles and responsibility of the dispatching and receiving hospitals are clearly defined.
- Transport of blood is optimally managed by transfer from one transfusion laboratory to another transfusion laboratory.
- Wastage of blood is minimised.

2 The Main Body of the Guideline / Procedure

The need to transfer blood with a patient should be a rare occurrence in modern practice, but two scenarios were considered to be an exception:
- Blood allocated to a specific patient who was actively bleeding and in whom the risk of transfer to a specialist unit was considered appropriate. Such patients would require a medical and/or nursing escort.
- Patients being transferred who have special transfusion requirements such as complex phenotyped blood, irradiated blood or HLA matched platelets. However, these blood components should be transferred directly to the laboratory in the receiving hospital.

2.1 Procedure for the Dispatching Hospital laboratory

2.1.1 Initial documentation

2.1.1.1 Blood / blood components accompanying the patient

Document the transfer information details from the requesting clinical area using the correct transfer form (see top of appendix for location of forms).

Obtain full patient identification (full name, DOB, unique hospital/NHS number).

Document on the transfer form the receiving hospital and clinical area including the approximate time of departure.

Identify the blood/blood components issued to the patient.
2.1.2 Blood / blood components transferred to a satellite Blood Bank

Identify the allocated/issued blood/blood components requested for specific patient

or

Identify the blood/blood components agreed for stock transfer
Document information on the appropriate transfer form
Transfer of Blood/Blood Components between Hospital Blood Banks

2.1.2 Blood / blood component packaging and final documentation

2.1.2.1 Complete the transfer documentation and attach a record of the unit donation numbers & prepare the transit box, packaging material & labels.

2.1.2.2 Place the blood/blood components IMMEDIATELY BEFORE dispatch in a transit box surrounded by cool packs that have been equilibrated to the appropriate storage temperature. Put the cool packs on the bottom and sides of the box as well as on the top.

2.1.2.3 Ensure there is no free air space in the transit box.

2.1.2.4 Ensure the correct document is place in the transfer box and retain a copy.

2.1.2.5 Replace the transit box lid and seal using appropriate ties.

2.1.2.6 Complete and attach a dispatch label to the transit box.

2.1.3 Dispatch of blood / blood components

On dispatch contact the receiving hospital to inform of dispatch. Outside normal hours contact the Biomedical Scientist (BMS) on call in the laboratory in each hospital:

LRI – ext. 6605                GH – ext.3577                   LGH – ext. 4564

or via switchboard.

Information must be provided on time of dispatch, mode of transport, estimated time of arrival and the number and type of units dispatched. Patient identification should also be provided.

2.2 Procedure for the receiving hospital when components taken immediately to the laboratory

2.2.1 The receiving Blood Transfusion Laboratory should document the time of delivery and where applicable notify the clinical area.

2.2.2 On arrival the transit box should be checked for integrity, examine the storage conditions, verify the units, complete the transfer documentation & send the documentation to blood bank.

2.2.3 Transfer the units to suitable storage conditions.

2.2.4 The receiving Blood Transfusion Laboratory must ensure the transferred units are entered into stock. This includes any that are disposed of due to poor storage conditions to ensure full traceability.

2.2.5 The receiving Blood Transfusion Laboratory must notify the transferring hospital of the fate of the units which should include units transfused to the patient, disposal and units entered into stock.

2.2.1 Procedure for the receiving hospital when components taken immediately to the clinical area
Nursing staff should notify blood bank of any blood/blood components that arrive with the patient to the clinical area. Blood bank staff will advise further.

3 References


NHSBT Appropriate use of blood group & National laboratory managers group (2011) Guidance for the Emergency Transfer of Blood and Components with patients between Hospitals

East Midlands Regional Transfusion Committee Procedure for the Emergency Transfer of Blood and Components with Patients between Hospitals (Adapted from: Guidance for the Emergency Transfer of Blood and Components with Patients between Hospitals NHSBT Appropriate Use of Blood Group & National Laboratory Managers Group of the CMO’s National Blood Transfusion Committee)

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1 Introduction

Whilst allogeneic (donated) blood is an essential adjunct to health care, it is a limited resource, increasingly expensive and can present a source of risk for patients, in particular the risk of "wrong blood" incidents as reported by the Serious Hazards of Transfusion steering group.

The Health Service Circular Better Blood Transfusion recommended that effective alternatives to allogeneic blood transfusion are explored, including appropriate use of autologous blood transfusion techniques such as Intra operative Cell Salvage (ICS).

National guidelines for appropriate use of blood and blood components have been developed by the British Committee for Standards in Haematology (BCSH) to ensure blood and blood components are prescribed effectively.

NOTE: This guideline should be used in conjunction with Appendix 13, UHL Guidelines for the Use of Intra-operative Cell Salvage in Obstetrics.

2 Statement of intent

These guidelines set out the way in which intra-operative cell salvage is implemented, and monitored across the UHL Trust.

This guideline applies to all health care staff involved in Intra-operative Cell Salvage for patients within the University Hospitals of Leicester (UHL) NHS Trust.

This guideline does not relate to the use of unwashed postoperative autologous blood collected from wound drains.

3 Responsibilities associated with ICS include:

3.1 Prescribing responsibilities

Salvaged blood needs to be prescribed by the medical staff on the UHL Trust transfusion prescription/ICP form. Checks remain mandatory and should be in accordance with the Trust transfusion policy for positive patient identification.

3.2 Labelling responsibilities

The re-infusion bag should be labelled with the Green Autologous Transfusion labels supplied by the machine manufacturers as soon as is reasonably practical (i.e. when the patient is in theatre or as soon as the processing set is loaded if a "collect only" system has been used initially. The patient details should be handwritten and must include the following:

- full name
- date of birth
- hospital number
- collection start date and time
- expiry date and time
Addressograph labels SHOULD NOT be used because of the known associated risks of using a wrong patient’s label. All salvaged blood must be labelled clearly to include the patient’s name, hospital number, date of birth, the date and time of collection, expiry time (6 hours from commencement of collection) and the name of the person carrying out the procedure. The volume of salvaged blood processed by cell salvage machine, and the volume of packed cells prepared for re-infusion must also be recorded.

3.3 Individual responsibilities

Use of cell salvage should be discussed with the patient in advance (when possible) and this must be documented on the anaesthetic chart or in the patient notes.

Individual staff should ensure that they are adequately trained and competent in the use of the ICS system and their individual responsibilities according to their area of work, i.e. operator, anaesthetics, scrub, recovery and ward staff. Individual staff should ensure they are adequately trained and competent in the use of ICS in each of the specialities they work in.

The cell salvage operator must be named for each individual case. The operator must have received specific training and be named on a theatre register of trained operators.

Unregistered staff will only be able to set up the collection set after completing training, if processing of salvaged blood is required a registered member of staff will need to be called.

The responsible medical officer must be named for each individual case and should be familiar with the clinical aspects of cell salvage.

3.4 Documentation responsibilities

Staff should ensure that documentation (including all appropriate labelling) accurately reflects the ICS process. The documentation record should include:

6.2.2 The ICS patient record form.
6.2.3 The Green autologous transfusion label should be completed and attached to the re-infusion bag.
6.2.4 At the time of re-infusion of the salvaged blood, the peel off section on the autologous transfusion label should be completed and attached in the appropriate place in the patients’ clinical records or ICP.
6.2.5 Appropriate labelling of heparin saline anticoagulant at the start of the procedure.
6.2.6 Bedside pre-transfusion checks and patient observations should be performed and recorded during autologous blood re-infusion in the same way as for the transfusion of allogeneic blood.
6.2.7 Additional observations are at the discretion of the clinical staff based on an individual patient assessment.
6.2.8 Adverse incidents should be documented in the patients’ clinical records and reported per UHL incident reporting procedure (DMS reference number 26535).
6.2.9 For each individual case the bar-code data for the patient, operator, surgeon, anaesthetist, procedure and disposables used must be scanned into the Cats machine using the bar code scanner attached to each machine. (This includes collection only cases)

4 Conditions for use

Use of intra operative cell salvage is a clinical decision and each case should be considered individually. Whilst it is expected that these guidelines are adhered to, there may be
individual circumstances where the risk benefit ratio for using intra-operative cell salvage may be considered to be in the best interests of a patient, and a senior clinician may decide to proceed outside these guidelines.

5 **Indications for use**

Any surgery in a clean operative field when the anticipated blood loss will require the patient to need a blood transfusion or anticipated loss is greater than 20% of blood volume or approximately one litre in an adult.

Patients with a low Hb or increased risk factors for bleeding.
*Patients with multiple antibodies or rare blood types.*
*Patients with objections to receiving allogeneic (donor blood).*

5.1 **Procedures and situations which are considered suitable for ICS** (This is not an exhaustive list)

<table>
<thead>
<tr>
<th>Vascular Surgery, Trauma &amp; Orthopaedics</th>
<th>Open aortic aneurysm repair - (elective and emergency)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Splenic/liver trauma</td>
</tr>
<tr>
<td></td>
<td>Spinal surgery</td>
</tr>
<tr>
<td></td>
<td>Revision hip replacement</td>
</tr>
<tr>
<td></td>
<td>Pelvic and femoral fractures</td>
</tr>
<tr>
<td></td>
<td>(In primary hip and knee replacement it may be better to consider post operative drainage systems)</td>
</tr>
<tr>
<td>Urology</td>
<td>Radical cystectomy</td>
</tr>
<tr>
<td></td>
<td>Radical prostatectomy</td>
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<tr>
<td></td>
<td>Nephrectomy</td>
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<td></td>
<td>Pelvic clearance</td>
</tr>
<tr>
<td>General Surgery</td>
<td>Hepatectomy</td>
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<tr>
<td></td>
<td>Abdominal/thoracic trauma</td>
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<tr>
<td></td>
<td>Emergency laparotomy</td>
</tr>
<tr>
<td>Cardiac</td>
<td>All major procedures (post-op drainage may be of use if mediastinal drainage is of high volume).</td>
</tr>
<tr>
<td>Obstetric</td>
<td>Emergency use: Major obstetric haemorrhage at caesarean section, laparotomy for postpartum haemorrhage genital tract trauma, etc.</td>
</tr>
<tr>
<td></td>
<td>Elective use: Anticipated haemorrhage at caesarean section, e.g. placenta praevia/accreta, large fibroid uterus, etc.</td>
</tr>
<tr>
<td>Gynaecology</td>
<td>All major procedures e.g. pelvic clearance.</td>
</tr>
<tr>
<td>Head and Neck</td>
<td>Major procedures</td>
</tr>
<tr>
<td>Jehovah's Witnesses or any patient refusing a blood transfusion</td>
<td>Consideration should also be given to post-op drainage and re-infusion where indicated</td>
</tr>
<tr>
<td></td>
<td>All surgical procedures where blood loss is expected to have an impact</td>
</tr>
</tbody>
</table>
Maximum benefit of cell salvage can be gained by capture of emergency cases which often require large volume blood component support.

6 General instructions

Strict sterility must be maintained at all times. Salvaged cells should preferably be re-infused within six hours of the commencement of collection, in order to minimize the risk of infection.

Blood filters should be used according to the guidelines / manufacturer’s instructions (see note A/B).

Ensure wash fluid used with processing of blood is isotonic (0.9%) saline only, this also includes any wash used at the operation site.

Ensure anticoagulant solutions are stored separately from fluids for intravenous infusion

Cell salvage of blood from swabs is only recommended in certain cases and when scrub staff have experience of the technique.

Beware dilutional coagulopathy and anaemia with large volume losses. Measure haematocrit / haemoglobin / coagulation profile during the procedure.

Bear in mind that salvaged blood will not have been screened for viruses and take standard precautions.

Salvaged blood should under no circumstances be stored in a blood fridge; salvaged blood should be kept within the theatre.

Cell Salvage in Obstetric Cases should only be performed by multidisciplinary teams who develop regular experience of intra-operative blood cell salvage. (Nice guidelines Nov 2005)

Suction tips should be single lumen, wide bore and ideally not less than 4mm diameter, to ensure minimum cell damage.

6.1 Contraindications

6.1.1 Contamination of the surgical field with faeces, urine.

6.1.2 Infection at the site of the wound

6.1.3 Patients with sickle cell disease, trait.

6.2 Special considerations

6.2.1 The presence of Amniotic Fluid in the operative field *(see NOTE A).

6.2.2 The presence in the operative field of malignant tumours with the potential for metastatic spread *(see NOTE A&B).

NOTE A

UHL guidelines now recommend against routine use of leucocyte filter in obstetrics or in malignancy in view of the clinical risks associated with the use of such filters (see section 6.4 below).

NOTE B

Intra-operative cell salvage is now increasingly used in patients with malignancy although there is still controversy in view of the possibility that intra-operative cell salvage may encourage metastatic spread of malignant cells present in the surgical field. In many cases, the clinical benefits of intra-operative cell salvage may outweigh this risk which remains theoretical and unquantifiable. The routine use of leucocyte filter is no longer recommended (see section 6.4 below)

6.3 Cautions
6.3.1 In general, use of intra-operative cell salvage is not recommended if the surgical field contains any of the following:

- Betadine / Chlorhexidine
- Hydrogen peroxide
- Alcohol
- Distilled water
- Antibiotics not for parenteral use.
- Fibrin adhesives

6.3.2 AVOID aspirating into the collection set:

- Topical clotting agents (e.g. collagen, thrombin), bone cement

It is possible to avoid some of these issues by using two sets of working suction apparatus – one to the cell salvage collection reservoir and the other to unsterile collection for disposal.

6.4 Revised UHL guidance on the use of Leucocyte filters for re-infusion of salvaged blood:

Previously the UHL (and national) guidelines recommended routine use of leucocyte filters for re-infusion of autologous blood collected using intra-operative cell salvage in patients with malignancy or when used in obstetrics. However, in the last few years, there has been an increasing number of reports, both locally and nationally, of severe hypotension observed during re-infusion of salvaged blood using leucocyte filters, particularly (but not exclusively) when a pressure device is concurrently used to speed up transfusion through such filters. The MHRA have also recently produced a safety alert regarding the use of leucocyte filters in cell salvage (“One Liners”, Issue 82, January 2011, www.mhra.gov.uk).

In view of the risk of severe hypotension and possibly cardiac arrest associated with the use of leucocyte filters, a formal risk assessment has been undertaken within UHL regarding the use such filters during intra-operative cell salvage in pregnancy, and in the presence of malignancy.

The following points have also been considered when producing this local guideline. The currently available leucocyte filters:

- Are not validated for effective removal of amniotic fluid or malignant cells
- Are not licensed for use with pressure devices
- Slow down the rate of re-infusion of salvaged blood, particularly when used in conjunction with a fluid warmer

The agreed UHL guidance now warns against routine use of leucocyte filters for cell salvage in general, and against concurrent use of a pressure device in particular.

When using intra-operative cell salvage in Obstetrics, consideration should be given to using two suctions to remove amniotic fluid and meconium via a separate suction to waste. This should be considered on an individual patient basis taking into account:

- The amount of amniotic fluid expected
- The stage at which massive haemorrhage is expected
- Patient factors e.g. religious beliefs, presence of antibodies limiting the use of donor blood etc
There is evidence that cell salvage machines remove virtually all amniotic fluid contaminants when used on a quality wash cycle, hence the use of the quality wash cycle is mandatory in all but exceptional circumstances (e.g. uncontrollable massive haemorrhage in a JW patient).

(H Qureshi / Rob Powell / Helen Brooks / Malcolm Chambers – July 2011)

7 Further Information

7.1 Quality assurance

The manufacturer of the CATS cell salvage machine (Fresenius Hemocare) states in its Operating Instructions (4/10.97) the CATS Cell Salvage machine produces Blood for re-infusion with a high Haematocrit. Each machine will have a sample of blood from the re-infusion bag tested at three monthly intervals to ensure the blood for re-infusion has a Hct of >50%. If the Hct should fall below this level it indicates a malfunction of the machine and will be taken out of the clinical area until the machine has been checked and the fault rectified. All quality assurance records for each machine will be monitored and held by the Transfusion Team.

7.2 Record keeping

A patient record form must be completed – this is the shared responsibility of the anaesthetist and the cell salvage operator. The original of the Patient record form (white form) for all cases where salvaged blood has been processed for re-infusion will be filed in the patient’s notes. A copy of the Patient record form (pink form) will be stored in the file with each machine.

For cases where collection only has taken place there is no need for a copy to be placed in the patients notes, just place the original form in the file with the machine. This form will contain details of the cell saver used, the type and amount of anticoagulant used, the volume of blood processed, the volume of blood re-infused, the operator name, procedure, date, and any complications or comments relating to the use of cell salvage. For audit and quality assurance purposes, this data will also be entered into a database.

7.3 Training

All members of staff must have received formal training prior to performing Intra-operative cell salvage. All members of staff are required to undertake the online e-learning package (learn cell salvage) prior to attending a formal UHL course and be able to demonstrate that they have attended an annual half day update to ensure continuing good practice.

The Main Theatre Departments across the three hospitals will hold the training records.

8 References

Intraoperative blood cell salvage in obstetrics

9 Legal Liability Statement

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1 Introduction / Scope

Intra operative cell salvage is a technique that involves the collection of a person’s own (autologous) blood from the surgical field, its processing using specialised cell salvage equipment and re-infusion back to the same person.

These guidelines set out the way in which intra-operative cell salvage is implemented in Obstetric cases across the UHL Trust.

NOTE: This guideline should be used in conjunction with Appendix 12, UHL Guidelines for the use of Intra-operative Cell Salvage

2 Indications for Use

Cell salvage in obstetric cases should only be performed by multidisciplinary teams who develop regular experience of intra-operative blood cell salvage.
(Nice guidelines Nov 2005)

The decision to use cell salvaged blood should be made by the senior members of the medical team caring for the woman. This decision should take into account the requirement for blood transfusion and the risks/benefits of using cell salvaged blood rather than allogeneic transfusion. It must not be used if staff are inexperienced in its use.

Cell salvage should be considered in the following circumstances for caesarean section or post-partum procedures:
1) Where major haemorrhage is on-going or anticipated
2) The woman has signed an advance directive refusing autologous blood products
3) Cell salvage should be considered for all emergency sections where time and staffing allows.

The setting up of cell salvage must not detract from either maternal resuscitation and care or the need to expedite delivery of the baby

2.1 Pre-operative counselling

In elective cases the use of cell salvage should be explained to the woman and the risks and benefits of both cell salvaged blood and allogeneic transfusion explained.

In emergency cases verbal consent should be obtained prior to the infusion of salvaged blood and the risks and benefits explained as appropriate

2.2 Set up

Under normal circumstances the collection reservoir and patient suction line only needs to be set up. The processing unit can then be set up as needed. Occasionally the whole circuit will be required to be set up on continuity but women should be advised that this takes time and may not always be possible.

Two suction systems may be used but is not essential:
1) Cell salvage suction
2) Normal surgical suction – ‘waste’ suction
The cell salvage suction should be used from the beginning of the case to salvage blood. The ‘waste’ suction may be used to remove meconium and frank amniotic fluid.

If there is significant bleeding then the cell salvage suction should be used accepting that some amniotic fluid may be mixed with the blood.

Amniotic fluid should be eliminated by the quality wash cycle programme (Fresenius CATS Plus).

The first suction may also be used if the degree of haemorrhage is such that full power suction is required. This should be in addition to the cell salvage suction.

2.3 Processing

The decision to use cell salvaged blood should be made by the senior members of the medical team caring for the woman. This decision should take into account the requirement for blood transfusion and the risks/benefits of using cell salvaged blood rather than allogeneic transfusion.

1) The salvaged blood must be processed using the ‘quality’ wash cycle programme unless in exceptional circumstances (such as major haemorrhage) when a consultant anaesthetist may decide to use a rapid wash cycle.

2) The UHL local guidance has recently changed and routine use of leucocyte filters is no longer recommended in view of the associated risk of severe hypotension. The agreed UHL guidance now warns against routine use of leucocyte filters for cell salvage in general, and against concurrent use of a pressure device in particular.

See below:

Revised UHL guidance on the use of Leucocyte filters for re-infusion of salvaged blood:

Previously the UHL (and national) guidelines recommended routine use of leucocyte filters for re-infusion of autologous blood collected using intra-operative cell salvage in patients with malignancy or when used in obstetrics. However, in the last few years, there has been an increasing number of reports, both locally and nationally, of severe hypotension observed during re-infusion of salvaged blood using leucocyte filters, particularly (but not exclusively) when a pressure device is concurrently used to speed up transfusion through such filters. The MHRA have also recently produced a safety alert regarding the use of leucocyte filters in cell salvage (“One Liners”, Issue 82, January 2011, www.mhra.gov.uk).

In view of the risk of severe hypotension and possibly cardiac arrest associated with the use of leucocyte filters, a formal risk assessment has been undertaken within UHL regarding the use such filters during intra-operative cell salvage in pregnancy, and in the presence of malignancy.

The following points have also been considered when producing this local guideline. The currently available leucocyte filters:

- Are not validated for effective removal of amniotic fluid or malignant cells
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- Slow down the rate of re-infusion of salvaged blood, particularly when used in conjunction with a fluid warmer
When using intra-operative cell salvage in Obstetrics, consideration should be given to using two suctions to remove amniotic fluid and meconium via a separate suction to waste. This should be considered on an individual patient basis taking into account:

- The amount of amniotic fluid expected
- The stage at which massive haemorrhage is expected
- Patient factors e.g. religious beliefs, presence of antibodies limiting the use of donor blood etc

There is evidence that cell salvage machines remove virtually all amniotic fluid contaminants when used on a quality wash cycle, hence the use of the quality wash cycle is mandatory in all but exceptional circumstances (e.g., uncontrollable massive haemorrhage in a JW patient).

(H Qureshi / Rob Powell / Helen Brooks / Malcolm Chambers – July 2011)

3) In cases of continuing haemorrhage where clinicians are sure that all amniotic fluid, membranes etc have been removed consideration to using emergency wash cycles and pressurising blood through normal blood giving sets may be considered.

4) A patient record form must be completed – this is the shared responsibility of the anaesthetist and the cell salvage operator.

5) A Kleihauer should be performed on Rh-D negative women and prophylactic anti-D given if the baby is Rh-D positive, and where the woman does not have history of immune anti-D antibody. The blood sample for Kleihauer test should be taken approximately 30 minutes after the re-infusion of salvaged blood is completed, and a minimum of 1,500 units anti-D administered (pending the need for any further anti-D as determined by subsequent Fetal Red Cell Quantitation (FMH).

2.4 Swab washing

Swabs can be gently washed by the following process:
1) Put swabs into sterile bowl with normal saline or anticoagulant fluid
2) Leave for a minimum of 10 minutes
3) Gently squeeze swabs
4) Salvage the liquid

3 Further Information

The decision to use cell salvage and how it is used intra-operatively is the responsibility of the senior clinicians.

The use of cell salvage in obstetrics remains unlicensed and the presence of amniotic fluid or meconium is contra-indicated in the operating manual. However it’s use as described above is supported by:
1) National use in other units
2) NICE guidelines
3) Current research
4) UK Cell Salvage Action Group and AAGBI Intra-operative Cell Salvage Working Party

4 References


MHRA (MDA/2010/001) www.mhra.gov.uk
NICE guideline IPG 144 *Intra-operative cell salvage in obstetrics* November 2005


BCSH guidelines on the Use of Prophylactic anti-D Immunoglobulin (2011 rewrite, final draft, Qureshi H et al)

5 **Legal Liability Statement**

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1 Introduction and Scope

UHL in conjunction with the DoH have produced this contingency plan for blood component shortage. The DoH paper set out an integrated plan for the National Health Service Blood and Tissue (NHSBT) to work with hospitals to ensure that if blood stocks fall to low levels, blood will be available for essential transfusions and priority will be given to the most urgent cases.

The red cell and platelet shortage plans operate in similar ways, describing three phases dependent on NHSBT stock levels - Green, Amber and Red. The green phase (normal blood stocks) is focused on compliance with the recommendations of the HSC 2007/001 Better Blood Transfusion – Safe and Appropriate use

NHS emergency planning requires the development of contingency plans to ensure the effective use of available blood and blood components when blood stocks have fallen to very low levels, and will be critical to ensuring transfusion support remains available for patients who needed most. The UHL performs practice exercise to test this contingency plan on a regular basis

For detailed information, see the complete document (Trust Ref. B16/2011).
1 Introduction / Scope

A reaction to the transfusion of blood products may be mild or severe and life threatening e.g. a haemolytic reaction due to ABO incompatibility, or sepsis because of bacterially contaminated blood products. Adequate management depends on the likely nature of a transfusion reaction. It will be frequently necessary to seek specialist advice from senior haematology medical staff.

2 Summary of key recommendations from BCSH guidelines 2012 for the Investigation and Management of Acute Transfusion Reactions

<table>
<thead>
<tr>
<th>Summary of Key Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Recognition of acute transfusion reactions (ATR)</strong></td>
</tr>
<tr>
<td>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 the results of investigations are available.</td>
</tr>
<tr>
<td>All patients should be transfused in clinical areas where they can be directly observed, and where staff are trained in the administration of blood components and the management of transfused patients, including the emergency treatment of anaphylaxis.</td>
</tr>
<tr>
<td>The recognition and immediate management of ATR should be incorporated into local transfusion policies and there should be mandatory transfusion training requirements for all clinical and laboratory staff involved in the transfusion process.</td>
</tr>
<tr>
<td>Patients should be asked to report symptoms which develop within 24 hours of completion of the transfusion.</td>
</tr>
<tr>
<td><strong>Immediate management of ATR</strong></td>
</tr>
<tr>
<td>If a patient develops new symptoms or signs during a transfusion, this should be stopped temporarily, but venous access maintained. Identification details should be checked between the patient, their identity band and the compatibility label of the blood component. Perform visual inspection of the component and assess the patient with standard observations.</td>
</tr>
<tr>
<td>For patients with mild reactions, such as pyrexia (temperature of &gt; 38°C and rise of 1-2°C), and/or pruritus or rash but without other features, the transfusion may be continued with appropriate treatment and direct observation.</td>
</tr>
<tr>
<td>Patients with mild isolated febrile reactions may be treated with oral paracetamol (500-1000mg in adults). Patients with mild allergic reactions may be managed by slowing the transfusion and treatment with an antihistamine.</td>
</tr>
<tr>
<td>Anaphylaxis should be treated with intramuscular adrenaline (epinephrine) according to UKRC guidelines. Patients who are thrombocytopenic or who have deranged coagulation should also receive intramuscular adrenaline if they have an anaphylactic reaction.</td>
</tr>
<tr>
<td>If a patient being transfused for haemorrhage develops hypotension, careful clinical risk assessment is required. If the hypotension is caused by haemorrhage, continuation of the transfusion may 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.</td>
</tr>
<tr>
<td>If a patient develops sustained febrile symptoms or signs of moderate severity (temperature &gt; 39°C or a rise of &gt; 2°C and/or systemic symptoms such as chills, rigors, myalgia, nausea or vomiting), bacterial contamination or a haemolytic reaction should be considered.</td>
</tr>
<tr>
<td><strong>Laboratory Investigations</strong></td>
</tr>
<tr>
<td>In all moderate and severe transfusion reactions, standard investigations, including full blood count, renal and liver function tests and assessment of the urine for haemoglobin should be...</td>
</tr>
</tbody>
</table>
performed.

If febrile symptoms of moderate severity are sustained implicated units should be returned to the laboratory for further investigation, the blood service contacted immediately so that associated components from the implicated donation can be withdrawn and the patient sampled for repeat compatibility and culture.

Patients who have experienced moderate or severe allergic reactions should have IgA levels measured. Low levels found on screening, in the absence of generalised hypogammaglobulinaemia, should be confirmed by a more sensitive method and IgA antibodies should be checked.

Patients with IgA deficiency diagnosed after an ATR should be discussed with an allergist or immunologist regarding future management.

In the absence of platelet or granulocyte transfusion refractoriness, or acute post-transfusion thrombocytopenia or leucopenia, investigation of the patient with ATR for leucocyte, platelet or neutrophil-specific antibodies is not indicated.

**Subsequent management of the patient**

Patients who have experienced an anaphylactic reaction associated with transfusion must be discussed with an allergist or immunologist, in keeping with UKRC guidelines.

For patients with recurrent febrile reactions, we recommend a trial of premedication with oral paracetamol given one hour before the reaction is anticipated (or non-steroidal anti-inflammatory drugs in patients with predominant chills or rigors - but an assessment of the risks of medication against the severity of reaction should be made in each case).

Patients who continue to react should have a trial of washed blood components.

For recurrent mild allergic reactions, there is no evidence to support routine prophylaxis with antihistamines or steroids. Alternative causes such as allergy to drugs or latex gloves should be excluded.

For patients with recurrent moderate or severe allergic reactions, other than those in which the patient is IgA deficient, options for further transfusion include:

- Use of directly monitored transfusion of standard components in a clinical area with resuscitation facilities. Consider antihistamine prophylaxis (although the evidence for efficacy is low, the risks are also low). This may be the only option when further transfusion is urgent and withholding blood is a greater risk.
- Transfusion of washed red cells or platelets.
- The use of pooled solvent-detergent treated FFP when there are recurrent allergic reactions to FFP in patients undergoing plasma exchange.

Patients with confirmed IgA deficiency and a history of reaction to blood should be transfused with components from IgA-deficient donors (first choice) or washed red cells (second choice) if time allows.

Life-saving transfusion should not be denied or delayed if these are not immediately available but the facilities and skills to manage severe allergic reactions must be present. Patients with known IgA deficiency (IgA <0.07g/l) and no history of reactions to blood must be assessed on an individual basis, taking into account the urgency of transfusion, the indication for IgA testing, the anticipated frequency of transfusion and history of allergy/anaphylaxis in other settings. Most will receive standard components without problems, but discussion with a transfusion medicine or clinical immunology or allergy specialist is advisable if time allows.

**Reporting of ATR**

All transfusion reactions except mild febrile and/or allergic reactions must be reported to appropriate regulatory and haemovigilance organisations (MHRA and SHOT) and should also be reviewed within the hospital.
3. The Main Body of the Guideline / Procedure

3.1 Haemolytic transfusion reaction

“Haemolytic transfusion reaction is one in which signs of increased red cell destruction are produced as a result of transfusion.”

A distinction is made between an immediate reaction and one in which destruction begins only after there has been an immune response provoked by the transfusion.

3.1.1 Acute haemolytic reaction

“This may be caused by the transfusion of incompatible red cells, bacterially contaminated or thermally damaged blood.”

Incompatible red cells react with the patient's own anti-A or anti-B, activating complement, causing intravascular haemolysis and disseminated intravascular coagulation (DIC). Transfusion of ABO incompatible blood almost always arises from errors in labelling the sample or from inadequate pre transfusion bedside checks. If a unit is mistakenly transfused to a patient other than the one from whom the sample was received the chances of ABO incompatibility are about 1 in 3. The reaction is usually most severe when group A red cells are given to a group O patient. In a conscious patient, only a few mls may be needed to cause a severe reaction within minutes of commencing transfusion. In an unconscious patient some of the symptoms will not be evident.

3.1.1.1 Clinical features of a haemolytic reaction

- Fever, chills or rigor.
- Tachycardia.
- Hypotension and circulatory collapse.
- Severe pain at drip site.
- Pain in back or chest.
- Dyspnoea.
- Haemoglobinaemia.
- Acute oliguria, renal failure and collapse.
- Disseminated intravascular coagulation (DIC).

3.1.1.2 Management

- Stop the transfusion without delay.
- Resuscitate the patient.
- Seek advice from Consultant Haematologist, Intensive Care Specialist and Renal Physician.
- Maintain blood pressure with artificial plasma expanders.
- Return all blood packs and the drip set to the Blood Transfusion Laboratory.
- Take samples for:
  - FBC
  - Coagulation screen
  - LFTs
  - Haptoglobin
  - Blood culture
  - U&E
  - Re-group, antibody screen, direct anti-human globulin test, re cross-matching and, if necessary, for further units to be cross-matched
  - Test all urine passed for haemoglobin
Treat DIC.
Maintain a strict fluid balance sheet.

### 3.1.2 Delayed haemolysis

The titre of an antibody in a recipient's plasma may be too low to be detected in the pre-transfusion tests. However, if incompatible red cells are transfused a secondary response may be provoked. A few days after transfusion there is a rapid increase in antibody with consequent destruction of transfused red cells.

#### 3.1.2.1 Clinical features

- Fever (not always present).
- Fall in haemoglobin level.
- Jaundice (often not before day 5 post-transfusion and can be as late as day 10).
- Haemoglobinuria (a mean of 8 days post-transfusion).

#### 3.1.2.2 Management

Take samples for:
- FBC
- LFT
- Direct Antiglobulin Test (Coombs test)
- Antibody screening

Inform Blood Transfusion Laboratory staff and discuss with senior haematology medical staff.

### 3.2 Febrile Non-Haemolytic Transfusion Reactions (FNHTR)

Mild febrile reactions are often caused by cytokines in blood components or patient antibodies to donor leucocyte antigens. These often occur towards the end of the transfusion and there are no clinical signs other than a rise in temperature and non-specific accompaniments of any pyrexia. FNHTRs are now seen relatively less frequently because of universal leucodepletion of blood components. FNHTRs are unpleasant but not life threatening. Paracetamol is often all that is required.

However, it is important to remember that a mild febrile reaction may be the early stages of an acute haemolytic transfusion reaction caused by incompatible or bacterially contaminated blood. If a patient becomes unwell or hypotensive, transfusion must not be restarted and blood transfusion laboratory must be informed who will arrange the return of the blood component pack and additional blood samples from patient for necessary serological and microbiological investigations.

### 3.3 Allergic Reactions

Caused by antibodies in the patient to infused plasma proteins or infusion of allergens, which react, with patient’s IgE antibodies; more likely to occur with platelets and plasma than red cell concentrates.

#### 3.3.1 Clinical features (within minutes of the transfusion)

- Urticaria.
- Itching.

Symptoms usually subside if the transfusion is slowed and antihistamine (e.g. Chlorphenamine 10mg i.v.) is given by slow injection. Hydrocortisone 100mg i.v. may also be used.

### 3.4 Anaphylaxis
This is a very rare but life-threatening complication. The onset is rapid and often dramatic. Immediate action is required. In some cases this is associated with antibodies against IgA in patients who have severe IgA deficiency. Antibodies to other plasma proteins may be implicated in other cases.

For Paediatric Guidelines related to Anaphylaxis, please see DMS No 20241(UHL Childrens Medical Guideline).

### 3.4.1 Management

- Discontinue transfusion.
- Maintain airway and give oxygen (40-100%).
- Give Adrenaline 0.5 to 1.0 mg (0.5 to 1.0 ml of a 1 in 1000 solution) intramuscularly.
- Attach patient to cardiac monitor.
- Epinephrine may need to be repeated after 10-20 minutes according to response in blood pressure and pulse rate.
- Hydrocortisone 100-200 mg intravenously should be given to prevent later recurrence or biphasic reaction.
- Nebulised Salbutamol +/- IV Aminophylline infusion may be necessary for persistent bronchospasm.
- Chlorphenamine 10 to 20 mg IV over at least 5 minutes.
- Promptly seek advice from intensive care physician and Consultant Haematologist.
- Inform the Blood Transfusion Laboratory.
- Under no circumstances should transfusion be restarted.

### 3.4.2 Future transfusions

Washed cellular blood components or selected blood components from IgA deficient donors may be needed for future transfusion.

### 3.5 Septic Shock

Although this complication is extremely rare with a reported incidence of two cases per million blood components transfused, the mortality remains very high. This is caused by bacterial contamination of red cells or platelets.

#### 3.5.1 Clinical features

- Usually acute with rapid onset.
- Pyrexia.
- Hypotension.
- Tachycardia.
- Collapse.

#### 3.5.2 Management includes

- Discontinuation of transfusion
- Promptly seek advice from Consultant Haematologist, microbiologist and intensive care physician, as rapid intensive care support is likely to be required.
- Blood cultures.
- Microbiological investigations of the remaining blood components.
- Immediate resuscitation with intravenous fluids and IV antibiotics. Intravenous Ciprofloxacin is an appropriate initial choice.
- Inform the Blood Transfusion Laboratory.
3.6 Transfusion Related Acute Lung Injury (TRALI)

This rare but life-threatening complication manifests as features of non-cardiogenic pulmonary oedema, either during or soon after transfusion.

The cause is usually donor plasma that contains antibodies to the patient's leucocytes and is a serious condition with a high mortality rate.

3.6.1 Clinical features include
- Chill
- Fever
- Non-productive cough
- Breathlessness
- Hypoxia
- Interstitial shadowing on chest x-ray

3.6.2 Management is that of acute respiratory distress syndrome
- Stop transfusion
- Immediately seek advice from senior haematology medical staff and ITU physician

3.7 Fluid Overload

This can occur when correcting chronic anaemia in elderly patients or those with pre-existing cardiac disease.

3.7.1 Clinical features
- Dyspnoea.
- Tachycardia.
- Hypotension.

3.7.2 Management
- Stop the transfusion.
- Give furosemide 40mg IV in the first instance.
- Arrange chest X-ray and ECG.

3.8 Late Complications of Transfusion

3.8.1 Iron overload
Transfusion dependent patients receiving red cells over a long period become overloaded with iron. Chelation therapy with Desferrioxamine or Deferasirox may be indicated. Such patients should be referred to a haematologist.

3.8.2 Graft versus host disease (GvHD)
This is a rare but often fatal complication of transfusion caused by T-lymphocytes. Immunodeficient patients e.g. recipients of an allogeneic bone marrow transplant, foetal intrauterine transfusions, patients with Hodgkin's disease, patients undergoing specific chemotherapy including fludarabine, cladribine, clofarabine, campath (alemtuzumab), Deoxycoformycin (DCF, Pentostatin), Nellarabine or AntiThymocyte Globulin (ATG) and patients with suspected or confirmed congenital cellular immune deficiency such as DiGeorge Syndrome are at risk of this disease. It has also occurred in immunologically normal patients after transfusion of a first or second degree relative's blood (from shared HLA haplotypes). It is prevented by irradiation of cellular blood components given to patients at risk.
3.8.3 Post-transfusion purpura (PTP)

PTP is a rare but potentially life threatening complication of red cell or platelet transfusion, most often seen in female patients. It is caused by platelet-specific alloantibodies. Typically 5-9 days after transfusion the patient develops an extremely low platelet count with bleeding. Refer to a Consultant Haematologist for treatment advice. High dose IV Immunoglobulin is the treatment of choice. Plasma exchange may be required. If platelet transfusion is absolutely essential, platelets compatible with the patient's antibody should be used. Likewise any red cell transfusions should be from donors negative for the implicated platelet antigen.

4. Further Information / References

BCSH (2012) *Investigation and Management of Acute Transfusion Reactions*

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Massive haemorrhage – UHL policy

NB: includes massive obstetric haemorrhage

Blood product volumes and drug doses are stated for ADULTS

In CHILDREN, involve senior anaesthetist from the start to advise on the appropriate drugs and doses

Major bleeding

- ABCDE approach in appropriate environment
- Ensure suitably senior staff is involved NOW
- Give appropriate warmed IV crystalloid bolus
- Request / transfuse red cells if indicated, using O negative emergency blood if necessary (NB: Blood Bank must be informed if emergency blood is used to ensure re-supply)
- Immediate haemorrhage control measures, e.g.
  - Direct pressure on wounds / nose if epistaxis
  - Pelvic binder for suspected unstable pelvic frac
  - Tourniquet when indicated
- Reverse any Warfarin anticoagulation as per ‘FCC clinician pack’; Islate document UHLS-P-600-6102
- Consider antifibrinolytic measures (see box 1)
- Arrange cell salvage where available (see box 2)

Senior decision maker decides to declare massive haemorrhage (see box 3)

Policy not applicable; revisit later if indicated

Campus

Inform your consultant NOW
Nominate a Blood ‘Bank co-ordinator’ for the duration of the incident (inform laboratory if this changes)
- Coordinator dials 2222 and says ‘fast-bleed Blood Bank’
- When Blood Bank staff call back, coordinator will say ‘Massive haemorrhage DECLARED’ and give details of Coordinator’s own name
- Incident location (e.g. ED resuscitation room)
- Extension number (ideally including one alternative)
- Patient’s details (if already known)
- Ensure required blood samples have been sent (see box 4)
- Beware hypothermia - use fluid warming devices and forced air warming blanket (e.g. ‘Bair Hugger’)

Send ‘runner’ to Blood Bank NOW to wait for MHP

Blood Bank immediately prepare MHP (massive haemorrhage pack – see reverse / next page)

Bleeding controlled?

Y

Request next MHP

Give MHP

(whole or partially as per senior clinical judgment)

Follow through bleeding control measures (see box 5)
- Repeat laboratory test bundle (see box 4)
- Beware hyperkalaemia if >6units of red cells transfused
- Make goal-directed adjustments (see box 6)

Bleeding controlled?

N

Involve duty haematology doctor

University Hospitals of Leicester

Appendix Sixteen

Antifibrinolytic measures

Consider tranexamic acid (IVA) in adults, give
- 1G (i.e. 10mL) neat as slow bolus over 10mins
- 2G (20mL) in 10% saline 50mL over 8h (i.e. set infusion pump to deliver 2.5mL/h)
- In children, give a 15mg/kg bolus (max 1G), then 2mg/kg/h for 8h in a convenient volume of 6% saline

NB: In obstetrics, give only if still bleeding after obstetric pharmacological first line techniques
- In trauma, use with caution if >3h from injury

Cell salvage

Cell salvage machines are available from
LRI
- Equipment room near Theatre 6 (Obstetric/General Building)
- Obstetric theatre (Kensington building)
GGM
- Cardiac theatres and orthopaedic theatres
LGH
- Main theatres and obstetric theatres

NB: For every 1L of salvaged red cells ensure balanced replacement of other blood components as follows:
- 2units (3 units)
- Platelets 1 ADT +
- Cryoprecipitate 2 poools (after 2L)
- Adult Therapeutic Dose

When to declare

Typical scenarios include (but are not limited to)
- Clinically obvious severe traumatic bleeding or collapse
- Haemorrhagic shock (e.g. systolic BP <70 initially or <90 after fluid bolus)
- 2x units in (in children: 2x20ml/kg) red cells transfused within an hour AND similar further needs anticipated
- Bleeding rate 150mL/min
- 50% total blood volume loss in 3h

Laboratory test bundle

Near-patient tests
- Venous blood gases – machines available in LRI ED AMU ITU GGH CDU CEC ITU LGH depending on local availability also
- FBC or HB (HemoCUE)
- Thromboelastography (TEG)
- Laboratory tests
- FBC, U&Es, ionized Calcium, INR, APTT and fibrinogen
- LFT and G&Es only initially

Bleeding control measures

For obstetric haemorrhage
See Islate documents UHLS-P-600-6660 and UHLS-P-600-7067

For gynaecological haemorrhage
See Islate document 3989179481

For acute upper GI bleeding
See Islate document 8244594488

Consider interventional radiologist advice (e.g. for arterial embolization in pelvic fractures)

Consider ‘damage control surgery’

Haematology duty doctor can advise if the following products are indicated
- Recombinant activated Factor VII (rFVIIa) – see Islate document UHLS-P-600-5023
- Prothrombin Complex Concentrate (PCC)

Goal-directed adjustments

- If fibroglobinogen <1 (<1.5 in obstetrics) give Cryoprecipitate 2 units
- If ionized Calcium <1 GIVE Calcium Chloride 10% 10ml. IV over 10mins
- If platelets <80
  - Give 1 adult therapeutic dose (ATD) of platelets; give 2 ATD if platelets <50
  - If TEG trace abnormal
    - Give appropriate products as guided by TEG treatment algorithm
  - If INR or APTT >1.5 (NB: use these only in those areas where no TEG available)
    - Give FFP 4 units

Massive haemorrhage – UHL policy

Massive haemorrhage pack (MHP) release sequence
For action by Blood Bank staff (Clinicians: for information only)

'Massive haemorrhage declared'

Any red cells transfused already?

Y

Equivalent of MHP 1 (see left) transfused already?

N

Release the equivalent of MHP 1 and also release next pack straight away

Is this trauma?

N

Y

MHP 1

Red cells

>50kg 4 units
31-50kg 3 units
10-30kg 2 units
<10kg 1 unit

MHP 2

Red cells

>50kg 4 units
31-50kg 3 units
10-30kg 2 units
<10kg 1 unit

FFP

3 units
2 units
2 units
1 unit

MHP 3

Red cells

>50kg 4 units
31-50kg 3 units
10-30kg 2 units
<10kg 1 unit

FFP

3 units
2 units
2 units
1 unit

Platelets

1 ATD
1 ATD
1 ATD
1 ATD

MHP 4 and all further packs

Red cells

>50kg 4 units
31-50kg 3 units
10-30kg 2 units
<10kg 1 unit

FFP

3 units
2 units
2 units
1 unit

Platelets

1 ATD
1 ATD
1 ATD
1 ATD

Cryoprecipitate

2 pools
5 paediatric units
2 paediatric units
1 paediatric unit

Notes to clinicians

- If cross-matched blood not yet available, red cells will be provided as
- O negative (women and children) or O positive (men)
- Group specific
- FFP and cryoprecipitate both require defrosting – this takes about 20min
- In children, transfusion of 5mL/kg red cells will typically raise Hb by 10g/L

Hashi Qureshi / Pavlim Anena / Martin Wiece – Aug 14 – Version 32
1 **Further Information / References**

http://www.nrls.npsa.nhs.uk/resources/type/alerts/?entryid45=83659

2 **Legal Liability Statement**

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1 Introduction / Scope

The objective of this guideline is to provide clinicians with information when the use of irradiated blood components is appropriate. It is broadly based on the British Committee for Standards in Haematology (BCSH) guidelines (2009), the American Association of Blood Banks (AABB) recommendations and the European Blood and Marrow Transplantation handbook (European School of Haematology, revised edition 2008).

2 The Main Body of the Guideline / Procedure

2.1 Introduction

Transfusion-associated graft-versus-host disease (TA-GvHD) is a rare but usually fatal complication following transfusion of lymphocyte-containing blood components.

When allogeneic lymphocytes remain viable, they are able to engraft in the transfused recipient and attack and reject the host tissue because of the immunological differences between recipient and donor tissues. The risk associated with an individual transfusion depends on the number and viability of contaminating lymphocytes, the susceptibility of the patient's immune system to their engraftment and the degree of immunological (HLA) disparity between donor and patient. It is thought that the clinical manifestations of GvHD are due to the effects of pro-inflammatory cytokines released by the engrafting donor lymphocytes (Hill et al., 1997, Williamson & Navarette., 2001).

At present the major technology for preventing TA-GvHD is irradiation of blood components to inactivate residual lymphocytes.

2.2 Clinical indications for irradiated blood components

Table 1 below summarises where irradiated blood components should be used.

Table 1

<table>
<thead>
<tr>
<th>Clinical category</th>
<th>Recommended duration of gamma irradiated blood component therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recipients of allogeneic bone marrow and PBSC transplant</td>
<td>From the start of conditioning therapy to 6 months post transplant or until the peripheral blood lymphocyte count is ≥ 1 x 10^9/L, in the absence of chronic GvHD. Patients with chronic GVHD should continue to receive irradiated blood components. The BMT Consultant to notify the blood bank when irradiated blood components are no longer necessary for an individual patient in this category.</td>
</tr>
<tr>
<td>Allogeneic bone marrow or PBSC donors</td>
<td>From 7 days before harvest until completion of harvest.</td>
</tr>
<tr>
<td>Recipients of autologous bone marrow and PBSC transplants</td>
<td>From 7 days before harvest until the harvest is complete and then from 7 days before transplant till 3 months post transplant. Patients receiving TBI should continue to receive irradiated blood</td>
</tr>
<tr>
<td>Condition</td>
<td>Duration</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>Hodgkin’s disease (any stage)</td>
<td>Continue indefinitely</td>
</tr>
<tr>
<td>Recipients of Fludarabine, Clolarabine, Nelarabine, Deoxycoformycin (DCF, Pentostatin), Campath (Alemtuzumab) and anti-Thymocyte Globulin (ATG)</td>
<td>Continue indefinitely If Fludarabine given as part of BM/PBSC transplant conditioning regimen, the duration for irradiated blood requirement should be as for post-autologous or allogeneic BMT categories above.</td>
</tr>
<tr>
<td>Intrauterine transfusions (IUT) of red cells or platelets</td>
<td>Start at first IUT and continue to irradiate any red cell or platelet transfusions until 6 months of age (including top up transfusions). Transfuse blood component within 24 hours of irradiation.</td>
</tr>
<tr>
<td>All exchange transfusions for neonates and infants</td>
<td>Continue until 6 months of age. Transfuse blood component within 24 hours of irradiation.</td>
</tr>
</tbody>
</table>
| HLA Matched platelets and red cell, platelets or granulocyte donations from first or second degree relatives | On all occasions | 2.3 Communication with blood bank

2.3.1 The blood transfusion laboratory will irradiate all cellular blood components once it has been notified of a clinical indication.

_NOTE:_ If blood transfusion laboratory is not notified of this requirement, it has no means of knowing that irradiated components are required.

2.3.2 Once notified, the blood transfusion laboratory will continue to provide gamma irradiated cellular blood components throughout the specified duration of the need to transfuse irradiated components.

2.3.3 In the case of recipients of allogeneic bone marrow or PBSC transplants, the blood transfusion laboratory will continue to provide irradiated blood components until a transplant consultant has given a clear instruction that irradiation is no longer required.

2.3.4 The ultimate responsibility to notify blood transfusion laboratory of an indication for gamma irradiation of blood components lies with the clinician. The blood bank must
be notified of this requirement by completing a blood bank request form with the appropriate clinical details.

**NOTE:** For haematology and oncology patients (adults and children) who require irradiated and/or CMV Neg blood components the clinician must notify the blood bank of this requirement using the form of notification of patient requiring CMV Neg and irradiated blood components (see appendix 20). These forms are available in all paediatric patients’ haematology and oncology clinical areas and only needs to be completed initially. When the patient is first diagnosed however, the requirements of CMV Neg and Irradiated blood must also be indicated on G&S or cross match request forms for each blood transfusion request.

### 2.3.5 A clinician who is either:

**2.3.5.1** signing the first prescription for Fludarabine, Cladribine, Clofarabine, Nelarabine, Deoxycoformycin, anti-Thymocyte Globulin (ATG) or Campath (Alemtuzumab) for any patient, or signing a subsequent prescription where it is not clear from patients notes that blood bank has previously been notified

**2.3.5.2** attending a patient with new diagnosis of Hodgkin’s disease or a congenital immunodeficiency state or other clinical categories specified in this document, must ensure that:

- the blood transfusion laboratory is notified as soon as possible,
- and
- the patient (parent where appropriate) has been made aware of this requirement and has been given the “irradiated blood components” card and information leaflet (published by National Blood Service and available through hospital transfusion team).

### 2.3.6 All requests for irradiated red cells or platelets must be clearly specified on blood bank request form as well as on the ICP.

### 2.3.7 The bone marrow transplant coordinator must:

- hand a copy of the patient’s transplant protocol to the blood bank in advance of commencing conditioning therapy, and
- notify the blood bank of all planned BM/PBSC harvests at least 7 days in advance of scheduled procedure.

### 2.3.8 On receipt of such notification, the blood transfusion laboratory must:

- immediately make a permanent entry in its records, and
- issue the ward or other clinical area with the sticker for patient’s case notes, specifying the requirement for irradiated blood components.

### 2.3.9 Clinical staff responsible for administering blood must carefully check the blood components label and the ICP to ensure compliance with the required specification.

### 2.3.10 As an additional safety measure and for the purpose of regular audit:

The Pharmacy department send weekly reports to Blood Transfusion department on all patients who have received Fludarabine, Cladribine, Clofarabine, Nelarabine, Deoxycoformycin (DCF, Pentostatin), Anti Thymocyte Globulin (ATG/ALG) and Campath (Alemtuzumab)

Once weekly the Transfusion department receive minutes from the Lymphoma MDT database and identify all new Hodgkin’s disease patients.

### 3 Further Information / References


4 **Legal Liability Statement**

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1 Introduction / Scope

The objective of this guideline is to provide clinicians with evidence based guidance for current clinical indications for the use of cytomegalovirus (CMV) negative blood components. The information contained in this guideline is based on the national guidelines published by the British Committee for Standards in Haematology and the American Association of Blood Banks, and reflects the recent position statement published by the UK Department of Health Advisory Committee on the Safety of Blood Tissues and Organs (SaBTO), in March 2012.

Transfusion Transmissible CMV (TT-CMV) can cause severe and potentially fatal CMV disease in certain at-risk patients. Those at risk include recipients of haemopoietic stem cell (HSC) transplants, neonates and recipients of intrauterine transfusions. The risk of TT-CMV has been reported to be as high as 30-40% in susceptible individuals receiving CMV-unscreened and non-leucodepleted blood. In the UK all blood components are leucodepleted at source. Leucodepletion alone has been shown to greatly reduce the risk of TT-CMV. While some European and North American HSC transplant centres now consider leucodepletion to be an acceptable alternative to CMV-seronegative blood components (the reported residual risk of TT-CMV being approximately 1-3 % with either approach), this view is not widely accepted and most authorities in this country regard CMV seronegative blood components to be superior to leucodepleted components. It would appear logical that combining these two strategies would further reduce the residual risk of TT-CMV.

2 The Main Body of the Guideline / Procedure

2.1 Indications for CMV-seronegative blood components

Patients in the following clinical categories should receive CMV Seronegative blood components unless the clinical urgency is such that provision of CMV Seronegative blood is likely to cause unacceptable delay.

- Neonates or infant up to 28 days old. For premature neonates, count 28 days cut off from their expected date of delivery
- All Intrauterine transfusions
- Planned transfusions during pregnancy, wherever clinically possible (Not necessary during or post delivery)
- CMV negative recipients of allogeneic bone marrow and/or peripheral blood stem cell transplants.
- Specific CMV-negative paediatric patients receiving chemotherapy, where the treatment protocol demands this.
- Granulocyte components should continue to be provided as CMV seronegative for CMV seronegative patients.

The above group of patients should receive CMV seronegative blood components, unless the clinical urgency is such that provision of CMV negative blood/components is likely to cause unacceptable delay. If clinical urgency makes it impossible to source / provide CMV negative blood components for these patients, please inform the patient’s clinical team that CMV unscreened, leucodepleted blood is considered CMV-safe and is clinically acceptable.
in urgent / emergency cases where appropriate CMV negative blood components are not immediately available.

**CMV negative blood components are not required for any other patient categories including newly diagnosed or suspected leukemic patients.**

Refer to Consultant Haematologist if problems.

2.2 Notification to blood transfusion laboratory of the need to transfuse CMV-seronegative blood components: communication and documentation

- The responsibility to notify the blood transfusion laboratory of a need to transfuse CMV negative blood lies with the clinician who must specify CMV Seronegative transfusion on the blood request form and the ICP for all transfusion episodes.
- Once notified, the blood transfusion laboratory must immediately make a permanent entry in its records.
- Clinical staff responsible for administering blood must carefully check the blood components label and the prescription chart to ensure compliance with the required specification before commencing transfusion.

3 Further Information / References

- Fowler, K et al. *The outcome of congenital cytomegalovirus infection in relation to maternal antibody status* New England Journal of Medicine, 326, 663-667.

4 Legal Liability Statement

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NOTIFICATION TO BLOOD TRANSFUSION OF PATIENTS WHO REQUIRE CMV NEGATIVE OR IRRADIATED BLOOD COMPONENTS

PLEASE

1. FULLY COMPLETE ALL PARTS OF BOTH THE FORM AND LABEL.
2. PEEL OFF THE LABEL AND PUT ON INSIDE COVER OF PATIENTS NOTES.
3. SEND THE COMPLETED FORM TO BLOOD TRANSFUSION WITHOUT DELAY

PATIENT’S NAME

HOSPITAL NUMBER

DATE OF BIRTH

IRRADIATED PRODUCTS NEEDED

YES [ ] NO [ ]

REASON

…………………………………………………………………………………………………..

CMV NEGATIVE PRODUCTS NEEDED

YES [ ] NO [ ]

REASON

…………………………………………………………………………………………………..

PATIENT’S CMV STATUS

Positive / Negative / Pending

(If pending add date for review)

DATE FOR REVIEW

SIGNED…………………………. DATE …………………...

PRINT NAME…………………………. GRADE…………………

CMV and Irradiated Blood Requirements

Name:………………………………………

Hosp Number: …………….. DOB:………

Irradiated Needed: Yes / No

Reason:…………………..

CMV Needed: Yes / No

Reason:….……………….

CMV status review date …………..

Signed:……………………… Date:………………

Print Name:…………………………

For lab use only

Entered into patient’s BAPEX record

By

Date

PEEL OF THE LABEL AND STICK ON THE INSIDE FRONT COVER OF THE NOTES
1. **Introduction / Scope**

Blood Transfusion carries potential risks and some of the risks may be serious or even potentially life threatening. The Department of Health’s Better Blood Transfusion 3 circular (HSC 2007/001) requires NHS trusts to implement a number of actions to improve appropriate use of blood and safety of Blood Transfusion. One of these actions is to ensure patients are well informed of the risks and benefits of Blood Transfusion and that this is clearly documented in patients’ case notes. However various local audits of Blood Transfusion show that this process is very rarely documented in patients’ case notes, and anecdotal experience suggests that patients are rarely given adequate information about risks and benefits of transfusion, and where this information is provided, its quality and content is variable.

Written consent for Blood Transfusion is included in the Blood Transfusion Integrated Care Pathway. The consent page (see below) provides guidance on the process of obtaining written consent, and the two peel off stickers, pre-printed with “risks associated with Blood Transfusion”. Each risk has a check box which should be ticked as the risk is explained. The peel off stickers should then be pasted on the Standard UHL Consent form, top copy to be filed in the case notes and bottom copy to be handed to the patient.

Patients should be offered a written information leaflet on Blood Transfusion, in addition to verbal information given during the process of obtaining written consent. These leaflets are available in various languages and can be obtained from any of three blood banks or by contacting one of the Blood Transfusion Practitioners. Parent information leaflets are available for neonates and younger children. Children’s information leaflets are also available for older children.

The Blood Transfusion team will support clinical areas and teams with the implementation of written consent for Blood Transfusion.

2. **The Main Body of the Guideline / Procedure**

**Notes for obtaining informed, written consent for blood transfusion:**

**2.1 Patients receiving regular or multiple Blood Transfusions:**

Patients requiring regular Blood Transfusions will only need to be consented once initially. Such patients are likely to include:

- Haematology patients (adult and paediatric)
- Oncology patients (adult and paediatric)
- Gastroenterology patients on regular blood transfusion support for recurrent GI bleeding

All other patients requiring occasional transfusion will need to be consented once during each admission.

The form below provides step-by-step instructions on how to obtain written consent for Blood Transfusion:
University Hospitals of Leicester NHS Trust
Informed Consent for Blood Transfusion (Red cells, Platelets, FFP or Cryo)

Step by step guide on how to obtain written consent for Blood Transfusion:

1) If a patient needs, or is likely to need Blood Transfusion, informed written consent should be obtained wherever possible.

2) Use the UHL standard consent form.

3) Explain the reasons, benefits and risks of proposed Blood Transfusion to the patient, and offer written information leaflet on Blood Transfusion. The following text may be used for this purpose:

"I/we feel that it is, or it may become, necessary for you / your child to receive a Blood Transfusion. Although Blood Transfusion is quite safe, there are some potential risks associated with this treatment. In the UK the risk of contracting a viral infection such as hepatitis or HIV from Blood Transfusion is extremely small. Very rarely patients receiving Blood Transfusion may experience an allergic reaction or develop other complications such as haemolysis (breakdown of red cells in your blood) or a bacterial infection. The actual risk of contracting vCJD through blood is unknown but is likely to be extremely small. There is also a very small risk of receiving “unsuitable” blood, however there are stringent procedures in place to minimise this risk."

In some cases, particularly for surgical patients, there may be suitable alternatives to offering donor blood. Please discuss this with your senior colleagues or a member of the Blood Transfusion team.

4) Use the peel off stickers at the bottom of this page. Tick all boxes to indicate that the listed benefits and possible risks have been explained to the patient. Affix one sticker to each copy of consent form, file the top copy in patient’s case notes and hand the bottom copy to the patient.

5) Consent for haematology and medical patients:

Patients requiring regular transfusion support will only need to be consented once, at the beginning of regular transfusion programme.

All other patients who are likely to require occasional transfusions should be consented once during each admission episode.

6) Consent for surgical procedures:

Patients undergoing Planned surgical procedures which require “Group and Save” or Cross Match (see Maximum Surgical Blood Ordering Schedule) – should be consented for Blood Transfusion at the same time as the consent is taken for the surgical procedure.

Patients undergoing emergency surgery:

Obtain written consent if time allows, otherwise obtain and document verbal consent if patient is able to give consent.

7) Emergency transfusion in an unconscious patient, or if the patient is otherwise unable to give informed consent – the clinician in charge will decide what is in the best interest of the patient and document in case notes – remember, the issue of informed consent for Blood Transfusion is no different to any other emergency treatment or intervention.

CONSENT FOR BLOOD TRANSFUSION

Benefits

I. To treat anaemia/improve delivery of oxygen to tissues

II. To replace blood loss (bleeding/haemolysis)

III. To help prevent further bleeding

Potential Risks

1. Extremely small risk of viral illness such as hepatitis or HIV or other viruses

2. Very small risk of bacterial infection

3. Risk of transfusion reaction – allergic or haemolytic

4. Unknown but probably extremely small risk of vCJD

5. Very small risk of received unsuitable blood (though procedures in place to prevent this risk)

Alternative options to blood transfusion
2.2 Neonates and young children:

Parents/ guardians will need to provide written consent/Assent. Appropriate patient / parent information leaflets should be offered. Please see the Neonatal Blood Transfusion Assent Form below.

**Documentation of Discussion of Risks and Benefits of Blood Transfusion (Red cells, Platelets, FFP or Cryo) in Neonates**

Your doctor feels that it is, or it may become, necessary for your child to receive a blood transfusion as part of your child’s treatment at the Neonatal Care Unit. Although blood transfusion is quite safe, there are some potential risks associated with this treatment. Your doctor or nurse will explain these risks to you and will offer you an information leaflet. In the UK the risk of contracting a viral infection such as hepatitis or HIV from blood transfusion is extremely small. Very rarely patients receiving blood transfusion may experience an allergic reaction or develop other complications such as haemolysis (breakdown of red cells in your blood) or a bacterial infection. The actual risk of contracting vCJD through blood is unknown but appears to be extremely small. There is also a very small risk of receiving unsuitable blood, however there are stringent procedures in place to minimise this risk.

You will be asked to read and sign this form to indicate that you understand the benefits and possible risks of blood transfusion.

**Statement of healthcare professional**

I confirm that I have explained the reason for blood transfusion including benefits and potential risks/parent, and have offered / given a blood transfusion information leaflet to parent / guardian.

Statement of Healthcare professional

Full Name........................................................... Grade ..............................................................
Signature.......................................................... Date ..............................................................

Statement of Patient / Parent/ Guardian

I confirm that benefits and potential risks of blood transfusion have been explained to me.

Name of Parent / Guardian..........................................
Signature.......................................................... Date..............................................................

**Statement of Interpreter (if applicable):** I have interpreted the above information to the parent / guardian in a way I believe he/she could understand.

Name of Interpreter ........................................ Signature ........................................ Date ....

Note: If parents wish to receive a copy of this form, please photocopy for them.
2.3 Emergency transfusion in unconscious patients or those who are unable to give informed consent:

As applies to any other emergency treatment or procedure, it is not possible to obtain patient’s written consent in these situations. Clinicians will however need to document this fact in patient’s case notes.

2.4 Emergency transfusion in conscious patients

In emergency situations it may not be possible to take informed written consent. The clinicians should, where possible, verbally inform patients/parents and document this discussion (retrospectively) in the case notes.

2.5 Consent for patients undergoing planned surgery:

The majority of patients who undergo planned surgery do not require Blood Transfusion. However patients undergoing procedures which require either ‘Group & Save’ or ‘Cross Match’ (See UHL Optimal Surgical Blood Ordering Schedule ID: 4978447288), will need to be consented for the likelihood of requiring Blood Transfusion during or after surgery. These patients should be consented for Blood Transfusion at the same time as they are consented for the surgical procedure. Simply ticking the blood transfusion box on the standard consent form is insufficient as this does not provide any evidence of the specific risks and benefits of Blood Transfusion having been explained to patients.

A tick box to confirm written consent for Blood Transfusion will be added to the pre-theatre check list.

2.6 Consent for patients undergoing emergency surgery:

Occasionally, in life threatening emergency situation, patients may need to be immediately taken to theatre and the time may not allow for informed written consent to be obtained. It is likely that in such cases there would have been no time to take other routine consents such as consent for surgical procedure etc. In these cases the reason for not obtaining consent should be clearly documented in case notes.

3. Further Information / References

SaBTO Consent task Group (2011) Patient Consent for Blood Transfusion