

	2330 - Guideline for authorisation and the	
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	components	
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This guideline has been registered with the trust. However, clinical guidelines are guidelines only. The interpretation and application of clinical guidelines will remain the responsibility of the individual clinician. If in doubt contact a senior colleague or expert. Caution is advised when using guidelines after the review date or outside of the Trust.

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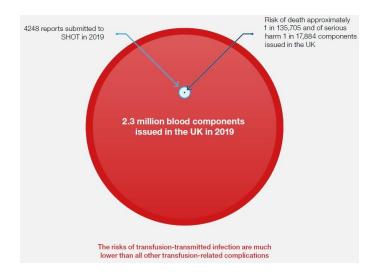
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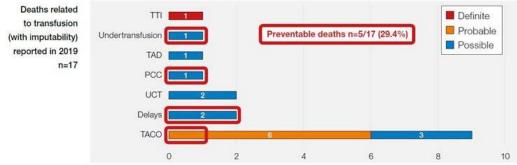
1 Introduction

This guideline is intended to support the current Trust Transfusion Policy CL/CGP/008. In 2019, approximately 2.5 million units were transfused in the UK. NUH currently transfuses approximately 31,000 units of blood/blood components annually.

This guideline aims to promote and support best evidence-based transfusion practice at NUH to provide our patients with timely, appropriate, and safe transfusion therapy. Overall, transfusion components themselves are very safe, but significant numbers of errors in transfusion practice continue to occur causing actual and potential patient harm.



All accredited blood transfusion laboratories must report to a national haemovigilance scheme. In the U.K., this is the Serious Hazards of Transfusion (SHOT). Since 2010, there have been 176 reported deaths related to transfusion. In 2019, there were 17 reported deaths, 5 of which were preventable.



TTI=transfusion-transmitted infections; TAD=transfusion-associated dyspnoea; PCC=prothrombin complex concentrate; UCT=uncommon complications of transfusion: TACO=transfusion-associated circulatory overload

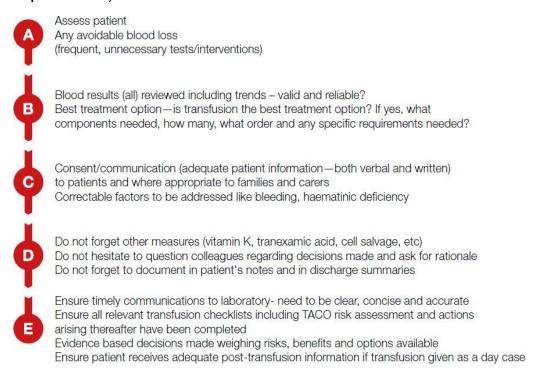
2 Decision to Transfuse

In 2018, SHOT received 3326 reports, 1451 (43.6%) of which related to errors. This included 272 reports of incorrect blood components transfused comprising special requirements not met. There were 106 reports of avoidable transfusions, 8 of which were patients with severe anaemia from haematinic deficiency, where the decision to transfuse was flawed based on "poor knowledge, communication failures, incorrect decisions or poor prescribing."

It is essential that when blood is authorised for a patient the full clinical picture is taken into consideration and not just the laboratory results. When an unexpected abnormal FBC or clotting result occurs, always repeat the result. If confirmed, then the cause of the abnormality must be determined before deciding if transfusion is an appropriate treatment.

Along with the specific components to be transfused, the rationale for the decision to transfuse should be documented clearly in the patient's clinical records.

The following A-E decision tree can facilitate decision-making in transfusion (SHOT report 2019):

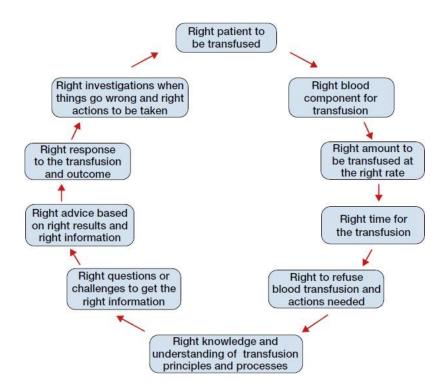


Certain patient groups may be at higher risk of being adversely affected by transfusions. This includes all patients being considered for solid organ transplantation and females of child-bearing potential. These patients may develop immune complications that will adversely affect their clinical outcome, specifically graft rejection and haemolytic disease of the newborn.

Exclusion from donation

Patients who are transfused are excluded from blood donation in the future. It is in the health community's interest to ensure that every transfusion is appropriate.

The 2019 SHOT report recommends that all staff involved in the transfusion process should consider the 10 "rights" for a safe transfusion:



3 Consent

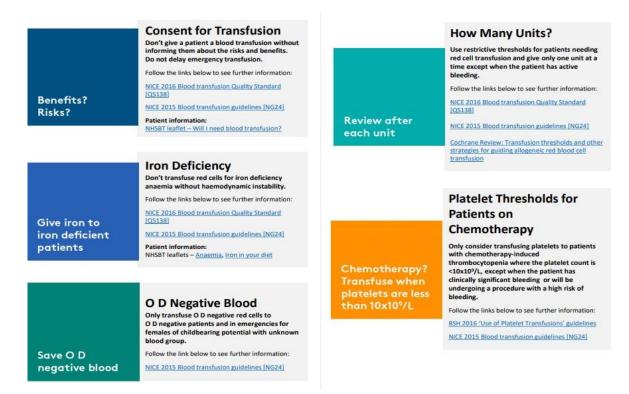
It is the responsibility of the authoriser to ensure that the risks, benefits and alternatives to transfusion with the patient and to record the detail of the discussion in the clinical notes (consent forms 1, 2 or 3 can be used for this purpose) as per the Consent to Examination or Treatment Policy CL/CGP/020.

All patients, whenever possible, must give informed consent for transfusion and must be provided with information to allow them to make an informed decision. Copies of "Will I need a blood transfusion?" leaflet are available in all clinical areas, from the Transfusion Practitioner (TP) Team and online on the NHS Blood and Transplant (NHSBT) website https://hospital.blood.co.uk/patient-services/patient-blood-management/patient-information-leaflets/ which also includes other useful patient information relating to transfusion.

3.1 Choosing Wisely Initiative

In 2016, the first Choosing Wisely UK principles were published online with further principles in transfusion added in 2018: https://www.choosingwisely.co.uk/shared-decision-making/

For Blood Transfusion this involves the Royal College of Pathologists: https://www.rcpath.org/profession/patient-safety-and-quality-improvement/patient-safety-resources/choosing-wisely/recommendations-for-transfusion-medicine.html



Click picture for leaflet

4 Authorisation

Blood components are excluded from the legal definition of medicinal products (Human Medicines Regulations, 2012) and must be 'authorised' rather than 'prescribed' (Pirie & Green, 2008). As such, this guidance refers to authorisation of blood components and not prescription.

There are no legal barriers to any appropriately trained, competent, locally designated and approved registered regulated health care professional (HCP) being able to authorise blood component administration.

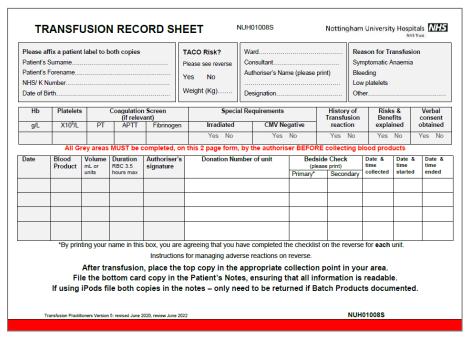
Blood components should only be authorised by an appropriately trained, competent and locally authorised registered practitioner using a transfusion record sheet (NUH01008N, in date version).

All staff should be trained and competency assessed via staff's own ESR record.

Advance clinical practitioners must also have completed the East Midlands Regional Transfusion Committee (RTC) Non-Medical Authorisation course and signed off as competent by their clinical supervisor and the Hospital Transfusion Committee (HTC).

4.1 Authorising the transfusion

The authorisation should be recorded on a Transfusion Record Sheet (TRS) NUH01008S. This is an A4 carbonated form.

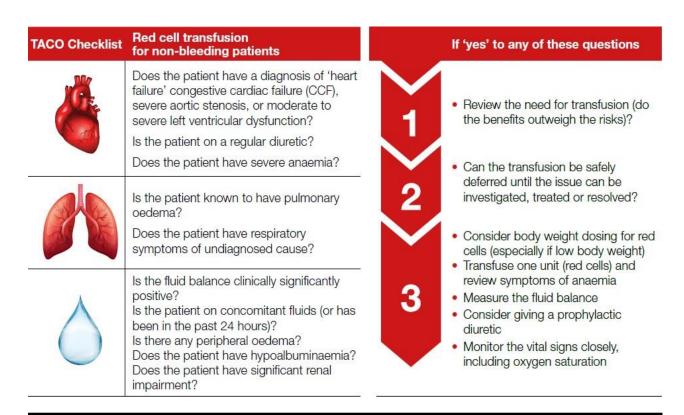


Grey sections are mandatory. Important information regarding transfusion management can be found on the reverse of this form.

The TRS **must** include the following information:

- Patient core identifiers; first name, surname, date of birth and unique identification number (K or NHS number). These must match EXACTLY the details on the patient's wristband for the transfusion to proceed.
 Patient ID label can be affixed to top and bottom copies.
- Location and consultant
- Name and designation of the authoriser
- Clinical rationale for the transfusion
- Completion of Transfusion-Associated Circulatory Overload (TACO) risk assessment and preventative actions (see below)
- Any clinical special transfusion requirements e.g. irradiated, CMV seronegative
- Indication of transfusion history and consent
- Date the blood component/product transfusion is required.

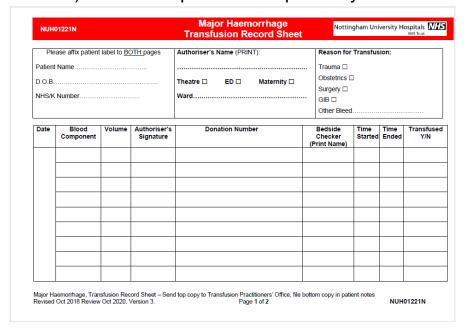
- Do NOT add further days on to the TRS after initial authorised transfusion is complete
- Type of blood component/product to be administered
- Volume or number of units to be transfused (volume in mLs for paediatric transfusions)
- Rate of transfusion
- Blood results for the product or component you are authorising
- Do NOT add extra lines to a TRS that has been completed by another authorise, i.e., only one authoriser for each TRS



Due to the differences in adult and neonatal physiology, babies may have a different risk for TACO. Calculate the dose by weight and observe the notes above.

Annual SHOT Report 2019

During a major haemorrhage, the major haemorrhage transfusion record sheet (NUH01221N) can be completed retrospectively.



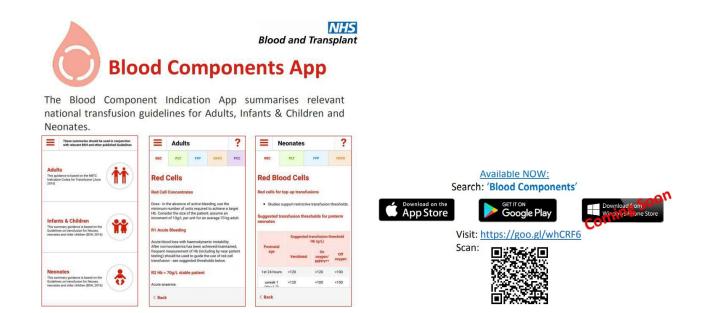
4.2 Previous transfusion reactions

If the patient reports a previous transfusion reaction to any blood component OR the clinical alert "transfusion risk-previous transfusion reaction" appears on the patient's electronic clinical record (Medway/Notis), the patient will require a full assessment of risks and benefits to decide on the appropriate transfusion regime and any mitigating measures. Contact Haematology medical staff for advice.

5 Blood Components and Products

The NHSBT Blood Component Indication App summarises relevant guidelines to act as a prompt for clinicians to facilitate appropriate use of blood and enable robust documentation of indications.

The app is based on the National Blood Transfusion Committee (NBTC) codes for transfusion and the British Society of Haematology "Guidelines on transfusion for foetuses, neonates and older children" (2016). The app should be used in conjunction with the full national and local guidelines.



5.1 Red Cells

The decision to transfuse blood must balance the need to provide adequate tissue oxygenation against the potential risks of transfusion and the appropriate use of a limited resource. It should be based on clinical judgement according to the individual patient's needs and the clinical situation.

A red cell transfusion may be indicated to:

- Replace acute blood loss due to haemorrhage, trauma or surgery
- Increase the oxygen carrying capacity of the blood.

There is no universal trigger or target haemoglobin for transfusion.

Anaemias should be investigated and the cause determined if possible before deciding to transfuse.

Do NOT transfuse patients with haematinic deficiency regardless of the haemoglobin in the absence of significant organ compromise. These patients have an increased risk of TACO.

Restrictive red cell transfusion strategies have been shown to be safe and reduce the length of the patients hospital stay (Handbook of Transfusion Medicine, 2013).

Single-unit red blood cell transfusions are widely recommended [National Institute for Health and Care Excellence (NICE) 2015, Choosing Wisely UK 2018] for adults (or equivalent volumes calculated based on body weight for children or adults with low body weight) who do not have significant, active bleeding and are otherwise clinically stable, with further clinical assessment to determine whether additional transfusion is required

A dose of 4ml/Kg raises the Hb concentration by approximately 10 g/l in adults. The average volume of an adult red cell unit is 280 ml. One RBC unit raises the Hb by 10 g/l ONLY for patients weighing approximately 70 kg in weight; it is not applicable to patients of lower body weight.

Warning:

- Neonates and small children require doses calculated in ml of blood (up to 5 ml/kg/hr.).
- Children weighing >40 kg should have their doses calculated similarly to adults—a formula to achieve a target Hb should NOT be used, as this results in overtransfusion.
- Point of care testing results should not be used in isolation, and low results should be double checked with the full blood count sent to the laboratory if the clinical situation permits.

5.1.1 Chronic Anaemias

In chronic anaemia without significant symptoms or haemodynamic compromise, **establish and treat the underlying cause** before considering transfusion. If transfusion is necessary, the **minimum** number of red cell units should be transfused to achieve symptom control.

Single unit transfusions are recommended in inpatient settings. **Do not transfuse to achieve a target Hb**. However, in outpatient settings, a more liberal and pragmatic approach might be required though the Hb threshold should still be individualised.

Transfusions of more than 2 units of red cells in a single setting are discouraged in patients at increased risk of TACO.

5.1.2 Nutritional Deficiencies

- Patients with B12, folate, or iron deficiencies, regardless of the haemoglobin level, should NOT be transfused if there is no significant organ compromise. These patients may have only minor symptoms, even at very low Hb levels (<50 g/L). The deficiency should be treated with the appropriate supplement, i.e., B12, folate, or iron.
- These patients are at high risk of TACO. If transfusion is indicated because of significant organ compromise, then a single unit can be authorised and the patient clinically reassessed after transfusion.
- Further transfusions should be based on the patient's clinical condition, not the post-transfusion haemoglobin.

SHOT Recommendations 2019

Learning points

- Medical staff, particularly those working in emergency departments, need better education about anaemia, in particular how to recognise iron, B12 and folate deficiency which can often be treated with the missing vitamin alone, but when an elderly patient has severe symptoms a limited (usually single unit) transfusion may be indicated
- Primary care physicians have a responsibility to understand and manage haematinic deficiencies appropriately
- The transfusion-related 'choosing wisely' recommendations should be widely promoted, and patients should be encouraged to discuss the appropriateness of their transfusions

5.1.3 Acute Blood Loss, including Massive Haemorrhage

In patients with haemorrhage and haemodynamic instability, estimation of blood loss may be difficult, and haemoglobin (Hb) is a poor indicator of the need for transfusion. The effects of hypovolaemia and anaemia should be considered separately. Empirical decisions about the immediate use of red cell transfusion are required by clinicians experienced in resuscitation.

In acute blood loss, the following guidelines have been suggested once normovolaemia is achieved:

- Hb > 100 g/L: No indication for transfusion
- **Hb < 70 g/L:** Transfusion probably indicated and should be assessed on an individual basis. The minimum number of units should be transfused and the patient reassessed.

- **Hb 70-90 g/L:** In otherwise fit & stable patients with no anticipated further blood loss then transfusion may only be indicated if symptomatic to maintain Hb >70 g/L.
- Older patients or those with significant cardiovascular or respiratory disease may not tolerate anaemia, and clinicians may need to aim for an Hb>80 g/L.

For massive haemorrhage refer to 'Transfusion Management of Massive Haemorrhage Procedure' (CLGPP046) for details.

- The recommended haemoglobin range to maintain is Hb 70-90 g/L.
- Tranexamic acid should be considered EXCEPT for acute GI bleeds.
 - Tranexamic acid does not improve outcomes in acute GI haemorrhage and can cause harm by increasing venous thromboembolic risk (HALT-IT, Lancet 2020).
- The use of intra-operative cell salvage should be considered.

5.1.4 Surgery/Medicine/Critical Care

In all cases of surgical planning, if the procedure entails a >10% risk of requiring a transfusion, the patient's Hb should be optimised before the procedure. See Appendix 2 Patient Blood Management for further recommendations.

Generally, an Hb <70g/L can be used to guide the use of red cell transfusion if the patient is normovolaemic.

If the patient has cardiovascular disease, transfusion may be considered at an Hb of <80g/L with a threshold of >90 g/L if the patient has acute coronary syndrome.

For patients who are not actively bleeding, single unit transfusions should be given and the Hb rechecked.

5.2 Platelets

Platelets for transfusion are usually only issued after consultation with Haematology medical staff.

Platelet transfusions may be indicated for the prevention and treatment of haemorrhage in patients with thrombocytopenia or platelet function defects. Platelet transfusions are not indicated in all types of thrombocytopenia and in some situations are contra-indicated, notably in thrombotic thrombocytopenic purpura (TTP) and heparin-induced thrombocytopenia (HIT).

The underlying cause of the thrombocytopenia should be identified and expert advice sought.

Dose:

- One adult therapeutic dose for adults and older children (> 15 kg).
- 10-15 ml/kg for children ≤ 15 kg

Requests for >1 bag of platelets will not be processed without discussion with the transfusion consultant (or deputy).

The platelet count should be checked 10-30 minutes post transfusion to ascertain the increment achieved by the transfusion. If the desired count is not achieved, **DO NOT request further bags**; they will be ineffective. Discuss with Haematology medical staff.

5.2.1 Prophylactic platelet transfusions

5.2.1.1 Bone Marrow Failure

Platelet transfusion may be required to prevent spontaneous bleeding in patients with reversible bone marrow failure when the platelet count <10 x 109/l.

Use a 'no prophylactic platelet transfusion' strategy for asymptomatic patients with chronic bone marrow failure (including those taking low dose oral

chemotherapy or azacitidine) unless there is ongoing bleeding or a history of bleeding.

In patients with additional risk factors, platelet transfusion may be indicated at a platelet count <20 x 109/l

5.2.1.2 Acute Promyelocytic Leukaemia(APL)

Patients with newly diagnosed APL often present with bleeding and/or coagulopathy. They are at high risk of life-threatening haemorrhage when they present and throughout their initial treatment. Therefore, it is recommended that platelet transfusions are given to maintain a platelet count 30-50 x 109/L (along with FFP and cryoprecipitate if required to maintain a fibrinogen 1 to 1.5 g/dL—see Section 5.3) throughout their induction therapy until the resolution of all clinical and laboratory signs of coagulopathy.

5.2.1.3 Surgery and Invasive Procedures

All requests for prophylactic platelets prior to invasive procedures must be authorised by haematology medical staff.

The recommended platelet thresholds depending on the cause of the thrombocytopenia are:

- >20x10⁹/L Venous central lines (both tunnelled and un-tunnelled), inserted by experienced staff using ultrasound guidance techniques
- ≥40x10⁹/LLumbar puncture
- ≥80x10⁹/L Epidural catheter (insertion and removal)
- >100x10⁹/L Neurosurgery or ophthalmic surgery involving the posterior segment of the eye
- >50x10⁹/L Major surgery
 - Percutaneous liver biopsy consider trans-jugular biopsy if the platelet count is below this level
 - Renal biopsy (see below)

5.2.1.4 Interventional Radiology Procedures

The platelet threshold desired depends on the bleeding risk of the procedure AND the cause of the thrombocytopenia.

Please refer to: 'Society of Interventional Radiology Consensus Guidelines for the Periprocedural Management of Thrombotic and Bleeding Risk in Patients Undergoing Percutaneous Image-Guided Interventions – Part II: Recommendations' and local guidelines for advice. https://www.jvir.org/action/showPdf?pii=S1051-0443%2819%2930407-5

Do not give platelet transfusions routinely prior to:

- bone marrow aspirate or trephine biopsy
- peripherally inserted central catheters (PICCs)
- traction removal of tunnelled central venous catheters
- cataract surgery

Do not use platelet transfusions pre-procedure if antiplatelet agents have not been discontinued. They will be ineffective.

Platelets should be administered shortly before the procedure, and an **FBC** must be checked pre-procedure to ensure the desired threshold has been achieved. If the platelet count has not risen sufficiently, discuss with Haematology medical staff as to whether further platelet transfusions are indicated.

5.2.2 Bleeding

Consider platelet transfusion thresholds in the following situations:

- <20-30 x 10⁹/L bleeding that is not severe or life-threatening, though lower levels may be sufficient to control bleeding.
- >50 x 10⁹/L severe bleeding
- >75-100 x 10⁹/L massive haemorrhage, multiple trauma, traumatic brain injury or spontaneous intracerebral haemorrhage.

5.2.2.1 Massive Haemorrhage

A platelet count of 50x10⁹/L is expected when red cell concentrates equivalent to approximately two blood volumes have been transfused.

- Maintain platelet count ≥75 x 10⁹/L.
- Platelets should be requested if there is ongoing bleeding and the platelet count is <100 x 10⁹/L.
- See Major haemorrhage Policy CL/CGP/046_ http://nuhnet/nuh_documents/Documents/Transfusion%20Management %20of%20Massive%20Haemorrhage%20Procedure.doc

5.2.3 Platelet Function Disorders (Acquired and Congenital)

- Do not use prophylactic platelet transfusions when antiplatelet agents have not been discontinued
- Stop drugs with anti-platelet activity and consideration of the use of prohaemostatic agents, e.g. tranexamic acid
- Platelet transfusions may be necessary as an additional measure for critical bleeding, when the above methods are ineffective or inappropriate
 - Spontaneous intracerebral haemorrhage Platelet transfusions have been shown to be ineffective and harmful in patients and so are not recommended in this situation. (Baharoglu, *Lancet* 2016)
- Renal failure—avoid platelet transfusions. Infused platelets will acquire a dysfunction from uraemia. Patients have a higher risk of platelet alloimmunisation.
 - Additional treatment with desmopressin should be considered preprocedure and for bleeding.
 - All patients with congenital platelet function disorders MUST be discussed with the Haemophilia team before any intervention, including potential platelet transfusions.

5.2.4 Disseminated Intravascular Coagulation (DIC)

The cornerstone of DIC treatment is the treatment of the underlying condition. Transfusion of platelets or plasma components in patients with DIC should not primarily be based on laboratory results and should in general be reserved for patients who present with actual bleeding or a high risk of bleeding, or prophylactically only if an invasive procedure is required

Check a platelet increment, as it may not be possible to achieve the desired target. If this occurs, the clinical team must make a risk/benefit assessment of proceeding with the procedure despite a suboptimal platelet count. Haematology medical staff can advise further.

5.2.5 Liver Disease

Patients with liver disease are often thrombocytopenic because of portal hypertension/hypersplenism. Moderate levels of thrombocytopenia are generally not associated with an increased bleeding risk even during invasive procedures

These patients frequently do not respond to platelet transfusions because of hypersplenism. If a transfusion is deemed appropriate, the platelet count should be checked after transfusion. However, the likelihood that the desired increment will not be achieved is high, and so it is advisable to have a contingency plan in place PRIOR to transfusion. This should involve discussion between the clinical team and the patient (or representative) of the risks/benefits of proceeding with the procedure despite a suboptimal platelet count. Haematology medical staff can provide further advice.

For planned major procedures in patients with liver disease-related thrombocytopenia of platelet count <50 x 10⁹/L, consider the use of a thrombopoeitin agonist. Refer to the hepatology team via: nuhnt.nottinghamhepatology@nhs.net.

Tranexamic acid may be indicated for specific invasive procedures and can be given as per usual (see section 7.4).

5.3 Fresh Frozen Plasma (FFP) and Cryoprecipitate

The indications for transfusing FFP and cryoprecipitate are very limited. When transfused, they can have unpredictable adverse effects including allergic reactions, including anaphylaxis.

Do **NOT** use FFP for:

- Volume replacement.
- Routine correction of abnormal clotting tests in the absence of bleeding, including prior to invasive procedures. Identify the cause of the abnormality to establish the correct management.

Dosing

FFP: 12 to 15ml/kg body weight. The maximum single dose is 1000-1200 ml, equivalent to approximately 4 bags of FFP as increased doses in patients with high body mass index may be associated with circulatory overload.

Octaplas: only to be used for plasma exchange to treat patients with confirmed or suspected thrombotic thrombocytopenia purpura (TTP). Must be approved by Haematology medical staff and requested on a paper BT request form.

Cryoprecipitate: Adults and children >50 kg: two pooled units, equivalent to ten individual donor units; this contains approximately 3 gm of fibrinogen and will raise the fibrinogen by 1 g/L.

Children: <50 kg: 5-10 mg/kg. Maximum dose is 2 pools or 10 bags of neonatal cryoprecipitate.

5.3.1 Factor Deficiency and Anticoagulation "Reversal"

FFP may be used as replacement of single coagulation factor deficiencies, where a specific or combined factor concentrate is unavailable, e.g. factor V.

Oral or parenteral Vitamin K is the treatment of choice and should be given to patients in whom this is suspected because of a prolonged PT/aPTT or who are at high risk of developing Vitamin K deficiency, e.g. patients on ICU, postop, on antibiotic therapy.

5.3.1.1 Vitamin K Deficiency Not Related to Warfarin Use

Do **NOT** use FFP to treat Vitamin K deficiency.

5.3.1.2 Vitamin K Antagonists

- Do not use FFP routinely for urgent reversal of warfarin or other Vitamin K antagonists. It contains insufficient concentrations of the vitamin K dependent factors (especially FIX) to achieve physiological correction of anticoagulation.
- Over-anticoagulation with vitamin K antagonists can be reversed by a range of measures depending on the urgency of the clinical situation. See Haemostasis and Thrombosis guidelines_
 <a href="http://nuhnet/nuh_documents/Lists/Clinical%20A%20to%20Z/AK5.aspx?R_ootFolder=http%3a%2f%2fnuhnet%2fnuh%5fdocuments%2fLists%2fClinical%20A%20to%20Z%2fHaematology%2fhaemostasis%20and%20thrombosis&FolderCTID=0x0120000A04A8C608278A4C87397FA7D0D7D31E
- Vitamin K 10 mg IV should always be given first in the case of severe bleeding or if an invasive procedure is required. Do not wait for an INR result.
- Prothrombin complex concentrates (PCC) may be appropriate for life or limb-threatening situations. Do not use to enable elective procedures.

For further information see:

http://nuhnet/nuh_documents/Guidelines/Cancer%20and%20Associated%20Specialties/Clinical%20Haematology/2401.pdf

5.3.1.3 Direct Oral Anticoagulants (DOACs)

FFP will NOT reverse the action of these drugs. Guidelines for the management of bleeding in patients on individual DOACs are available here: http://nuhnet/nuh_documents/Guidelines/Cancer%20and%20Associated%20S pecialties/Clinical%20Haematology/2805.pdf

5.3.2 Disseminated Intravascular Coagulation (DIC)

FFP may be useful in patients with either a prolonged PT/aPTT (>1.5xcontrol) AND if the patient is actively bleeding, at high risk of bleeding, or requires an invasive procedure.

Cryoprecipitate may be used to enhance the fibrinogen levels if hypofibrinogenamia persists (<1.0 g/L) despite FFP replacement.

Discuss with Haematology medical staff.

5.3.3 Liver Disease

Patients with liver disease often have abnormal PT/aPTTs. However, this does not correlate with an increased bleeding risk, as they have "balanced haemostasis".

There is no evidence of benefit for FFP in non-bleeding patients regardless of the PT ratio. The available evidence suggests that patients with liver disease do not benefit from FFP as prophylaxis before invasive procedures. The effect of administration of FFP is unpredictable and complete normalisation of the PT does not occur.

FFP and cryoprecipitate should not be transfused prophylactically for low bleeding risk procedures, such as paracentesis.

There is no good evidence to support a role for prophylactic FFP to reduce the risk of bleeding from percutaneous liver biopsy. An alternative procedure with a lower bleeding risk, e.g., transjugular liver biopsy, should be considered.

If FFP is deemed appropriate, coagulation tests should be repeated post infusion to guide decision-making. As the likelihood of the desired correction will not be achieved is high, it is advisable to have a contingency plan in place PRIOR to transfusion. This should involve discussion between the clinical team and the patient (or representative) of the risks/benefits of proceeding with the procedure in the event the clotting doesn't correct. Haematology medical staff can provide further advice.

<u>5.3.4</u> <u>Abnormal Clotting Tests Prior to Invasive Procedures in a Non-Bleeding Patient NOT on Anticoagulation</u>

There is no target threshold of PT/aPTT or fibrinogen below which the bleeding risk for an invasive procedure is "safe".

- Prolonged coagulation screens or low fibrinogen levels are NOT an indication to transfuse.
- A normal clotting screen or fibrinogen is not a prerequisite for invasive procedures.
- The use of prophylactic FFP in this setting is not supported by good quality evidence and is not recommended.
- If the fibrinogen is <1.0 g/L and the assessment indicates a significant bleeding risk for the procedure, then transfusion with one adult dose (or paediatric equivalent) of cryoprecipitate can be considered.

Transfusion of FFP only results in minimal or no correction of PT. An abnormal PT/aPTT does not predict periprocedural bleeding. Most prolonged coagulation screens are clinically insignificant. **However, if an abnormality is identified, the cause MUST be established well in advance of the procedure** to ensure correct management.

A detailed personal family history of bleeding, drug history, and knowledge of the bleeding risks associated with each surgical or other invasive procedure are more important than clotting test results when assessing the likelihood of clinically significant bleeding

5.3.5 Surgical Bleeding and Massive Haemorrhage

Transfusion of FFP and cryoprecipitate in the management of major haemorrhage should be guided by timely tests of coagulation and viscoelastic haemostatic assays, such as TEG[®], if available. Formulae to guide replacement strategies are not recommended unless these tests are unavailable.

FFP and cryoprecipitate should be given to maintain a PT/APTT<1.5xcontrol and fibrinogen >1.5-2.0 g/L.

5.3.6 Neonatal & Paediatric FFP

The normal range for coagulation test results varies with the age and gestational age at delivery of the neonate.

Routine prophylactic administration of FFP is NOT indicated to prevent peri or interventricular haemorrhage (PVH) in preterm infants, as a volume replacement or to correct clotting abnormalities.

Please refer to Trust neonatal guidelines on haemostasis http://nuhnet/nuh_documents/Guidelines/Family%20Health/Neonatal%20Unit/2767.pdf

5.4 Granulocytes

Granulocytes are available as pooled granulocytes or leukocyte buffy coats. The latter will be supplied by NHSBT only if the former is unavailable. All requests must be discussed with the duty NHSBT consultant.

Granulocytes are produced for a named patient, so the BT laboratory and NHSBT must be informed when they are no longer required.

A valid group sample is required because they are cross-matched before issue.

All granulocyte components are irradiated prior to issue.

Patients who are known to be CMV negative or whose CMV status is unknown MUST receive CMV negative granulocytes.

5.4.1 Clinical Indications:

Patients with severe neutropenia who fulfil **ALL** of the following criteria:

- 1. Severe neutropenia (<0.5 x 10⁹/L) due to congenital or acquired bone marrow failure syndromes
- 2. Receiving active treatment in an attempt to achieve disease remission.
- 3. Proven or highly probable fungal or bacterial infection that is unresponsive to appropriate antimicrobial therapy.
- 4. In whom neutrophil recovery is expected in the near future and/or in whom definitive therapy of curative potential is planned.

OR

Patients with a known congenital disorder of neutrophil function **regardless of neutrophil count** with proven or highly probable fungal or bacterial infection unresponsive to appropriate antimicrobial therapy.

Granulocyte transfusions should not be used in:

- Patients with bone marrow failure where neutrophil recovery is not anticipated to recur spontaneously and no further active treatment is planned.
- Sepsis in the absence of either neutropenia or known neutrophil dysfunction
- Pyrexia of unknown origin

Transfusion may continue until one of the following events occurs:

- Clear evidence of endogenous recovery based on neutrophil count
- Resolution of infection
- Clinical deterioration despite a minimum of 3 days of transfusion
- Severe reactions to granulocyte transfusions

5.4.2 Cautions:

Adverse events such as febrile reactions, HLA alloimmunuisation and transfusion related acute lung injury (TRALI) are well recognised complications; and therefore granulocyte transfusions should only be used where the possible benefits outweigh the hazards.

Pooled granulocytes and leucocyte buffy coats are also red cell and platelet contaminated. Buffy coats, in particular, will significantly increase the patient's Hb/hct, and so venesection may be required if granulocytes are given daily to patients who are not red cell transfusion-dependent. Similarly, an adult dose (2 pools or 10 bags) contains the equivalent of 2.5 ATDs of platelets, so additional platelet transfusion requirements might decrease.

5.4.3 Dosing:

	<30 kg	<50 kg	>50 kg or adults
Pooled 10-20 ml/kg		2 pools	
granulocytes	Maximum 2		Each pool 200-250
granulocytes	pools		ml.
Leucocyte buffy		10-20 ml/kg	10 bags
coats		Maximum 10	
Coals		bags	

Granulocytes should be infused as soon as possible after collection as they only have a 24 hour expiry shelf life. The entire dose should be infused over 1-2 hours.

6 Special Requirements

Some patients may have additional requirements depending on their clinical circumstances or previous reactions to transfusions. Some of the commonly encountered requirements include:

- Irradiated cellular components
- CMV negative cellular components
- HLA or HPA-matched platelets
- Washed cellular components
- Sickle negative/phenotyped units

An alert may show on the patient's Medway/Notis record. Patients requiring irradiated components might carry a card.



6.1 Irradiated Cellular Components

Transfusion-associated graft-versus-host disease (TA-GvHD) is a rare, usually fatal, complication of transfusion of blood components containing lymphocytes. The condition was first recognised in immunocompromised recipients transfused with cellular blood components (red cells, platelets, granulocytes) containing viable lymphocytes. Subsequently it was evident that non-immunosuppressed patients could also develop the condition, particularly if the blood components transfused derived from a human leucocyte antigen (HLA) -haploidentical unrelated donor or family member.

Various strategies exist to reduce the number of contaminating lymphocytes. Since 1999, all components in the UK are leucocyte depleted (LD) before storage. Standardised pre-storage LD is sufficient to prevent or markedly reduce TA-GvHD at least in the immune-competent non-HLA-matched recipients. Component storage time is also an important determinant, with no components > 14 days old implicated in the development of TA-GvHD. Finally, to further minimise the risk for susceptible patients, irradiation remains the main method of inactivating lymphocytes in the transfused component.

Only red cells and platelets require irradiation; FFP and cryoprecipitate do not require.

All HLA-matched platelets, units supplied for intra-uterine transfusion, and granulocytes are irradiated.

6.1.1 Emergency Situations

NUH typically carries enough irradiated red cell (adult and neonatal) and platelet (adult only) stock to supply at short notice for emergencies, but if irradiated components are unavailable, **the provision of red cells or platelets must not be delayed** to enable at-risk patients to receive irradiated components. The BT lab can preferentially issue red cells >14 days. If non-irradiated components are used in this setting because of urgency, this should be recorded and clinical observation made for any evidence of TA-GvHD over the next 6 weeks.

6.1.2 Patient Categories requiring Irradiated Cellular Components

6.1.2.1 Allogenic Haematopoietic Stem Cell Transplant

Irradiated components should be started on **initiation of conditioning and continued until all of the following criteria are met**:

- 1. >6 months have elapsed since the transplant date
- 2. The lymphocyte count is $>1.0 \times 109/l$
- 3. The patient is free of active chronic GvHD
- 4. The patient is off all immunosuppression

If chronic GvHD is present or continued immunosuppressive treatment is required, irradiated blood components should be given indefinitely. Treatment with irradiated blood components should continue indefinitely if this is required based on transplant conditioning, underlying disease or previous treatment, e.g. previous diagnosis of HL or previous purine analogue treatment.

<u>6.1.2.2</u> <u>Autologous Stem Cell Transplantation</u>

Irradiation should start from **7 days prior to harvest** to 3 months post-transplant

6.1.2.3 Chimeric Antigen Receptor T-Cell (CAR-T) Therapy

CAR-T therapy is a complex and innovative treatment and it is currently approved in the UK for the treatment of some cases of lymphoma and acute

leukaemia. A patient's own T cells are collected and genetically altered to recognise target antigens expressed on the cell surface of specific neoplastic cells. CAR-T therapy can lead to significant immunosuppression, but also the autologous lymphocyte collection may contain viable lymphocytes that can cause TA-GvHD.

Patients undergoing peripheral blood lymphocyte collections for future CAR-T cell re-infusion should receive irradiated cellular blood components for 7 days prior to and during the harvest, to prevent the collection of viable allogeneic T lymphocytes.

6.1.2.4 Lymphocyte-Depleting Drugs

Some immunosuppressive drugs cause profound T-cell lymphopenia, which can predispose the recipient to developing Ta-GVHD. These include:

- Purine analogues (e.g. fludarabine, nelarabine, deoxycoformycin, clofarabine, bendamustine
- Alemtuzumab (Campath, anti-CD52)
- Antithymocyte globulin (ATG)

Irradiation should be continued indefinitely for patients receiving these drugs.

6.1.2.5 Hodgkin Lymphoma (HL) - Suspected or Confirmed

All adults and children with HL at any stage of the disease should have irradiated red cells and platelets indefinitely.

If the diagnosis is excluded, contact the BT laboratory to remove the irradiated requirements.

6.1.2.6 Congenital Primary T-Lymphocyte Immunodeficiencies in Infants and Children – Suspected or Confirmed

All severe congenital T-lymphocyte immunodeficiency syndromes with significant qualitative or quantitative T-lymphocyte deficiency should receive irradiated components.

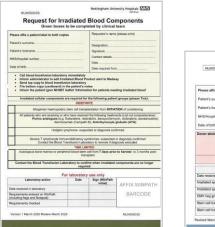
If the diagnosis is excluded, contact the BT laboratory to remove the requirement.

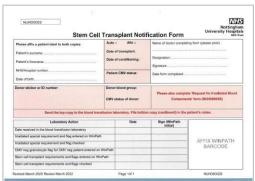
6.1.3 Requesting Irradiated Cellular Components

The patient should be informed that they require irradiated components and receive a copy of the NHSBT leaflet 'Information for patients needing irradiated blood', complete the card inside and present to the patient. (https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/14672/160509-27091-irradiated-blood-blc6082p-final.pdf)

Complete:

- NUH05003S Request for Irradiated Blood Components
- NUH05002S Stem Cell Transplant Form (for haematopoietic stem cell transplant patients only).





Forms can be obtained from the BT laboratory.

Phone the BT laboratory when submitting the form.

This will ensure there is no delay in applying the irradiated flag to the patient's BT record in whilst awaiting the form to arrive in the laboratory.

 If a patient's irradiated requirements change, a new form MUST be sent and the laboratory notified.

6.1.4 Authorising Irradiated Cellular Components

- Complete the special requirements section. This is mandatory.
- Ensure the request is accurate. If there is a discrepancy between the request and the laboratory record, you will be contacted to confirm the irradiation requirements and submit a new request.

Complete the Transfusion Record Sheet:

Special Re	equirements
Irradiated	CMV Negative
Yes No	Yes No

A reminder to confirm any special requirements is included in the bedside administration transfusion checklist.

6.2 Cytomegalovirus (CMV) Negative Cellular Components

CMV negative units will be automatically provided for the following patients:

- Intra-uterine transfusions
- Neonates (up to 4 months of age). ALL neonatal units will be CMV negative
 - N.B. CMV unselected units are suitable for neonates over 28 days post EDD.
- Pregnant women, regardless of CMV status, who require elective antenatal transfusions. CMV negative units are NOT required during labour and delivery
 - Please state in clinical details that patient is pregnant.
- Granulocyte components for CMV negative and CMV status unknown patients.

No other patients require CMV negative components.

In instances when CMV negative units are not available and transfusion is urgent, transfusion should not be delayed: CMV unselected units will be issued.

6.3 Haemoglobinopathies

Discuss with Haematology and the BT laboratory as patients may require phenotyped or Hb S (sickle) negative units. These units may have to be ordered from NHSBT.

<u>6.4</u> Other Requirements (HLA or HPA matched Platelets, Washed Components)

Additional requirements such as HLA or HPA-matched platelets must be discussed with and agreed by Haematology.

A minimum of 24 hours' notice is required for these components. Insufficient noticemay result in:

- a less well matched unit being provided, as the unit may need to be selected from local stock
- an ad-hoc delivery charge

Please discuss requirements with the BT laboratory.

An HLA-type is required. If this is not available already, please complete HLA request form (3a) and send samples as required. https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/20470/2021-0010-3a a4 specimenbagformzxu1064.pdf

Once the samples are received, NHSBT will require an order form (FRM 558) to be completed and faxed to them either directly or via the BT laboratory. This *must* be received before NHSBT will issue HLA-matched platelets.

After each HLA-matched platelet transfusion:

- Check a platelet increment to ensure the transfusion is effective and to optimise future matches.
- Complete and return the NHSBT "Selected Platelets Follow-Up Form". Failure to monitor the patient's response to HLA matched platelets compromises patient care with potentially inappropriate transfusions

Please see the following link for details.

https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/18079/inf1328-v12.pdf

Washed components must be discussed with and authorised by the transfusion consultant.

7 Patient Blood Management (PBM)

Patient Blood Management (PBM) is a multidisciplinary, evidence-based approach to optimising the care of patients who might need a blood transfusion.

NHS Blood and Transplant

Patient Blood Management

Optimising the care of patients who may need transfusion

What is Patient Blood Management (PBM)?

PBM is an evidence-based, multi-disciplinary approach to optimising the care of patients who may need a blood transfusion.

PBM puts the patient at the heart of decision making. **PBM** represents an international initiative in best practice for transfusion medicine.

Why is PBM needed?

Improve patient outcomes.

Reduce healthcare costs.

Avoid inappropriate use of blood – blood is then available for those who really need it.

Further information can be found:

https://www.transfusionguidelines.org/uk-transfusion-committees/national-blood-transfusion-committee/patient-blood-management

Aspects of PBM include:

- 1. Identifying and correcting the underlying cause of the anaemia before considering transfusion whenever possible
- 2. Avoiding transfusion for managing anaemia if alternatives are available e.g. oral iron for iron deficiency anaemia, intravenous iron for functional iron deficiency; B12 and folate supplementation
- 3. Individualised planning for patients needing regular transfusion and considering the potential for complications of transfusion such as red cell alloimmunisation and iron overload

4. Optimising haemostasis in bleeding medical and surgical patients by reviewing the need for anticoagulation and antiplatelet drugs.

PBM is integral to the care of the surgical patient from preoperative assessment onward. Timely identification and correction of anaemia and thrombocytopenia prior to surgery (and other invasive procedures) will reduce unnecessary transfusions and has been linked to improved patient outcomes.

Appropriate pre-operative assessment is essential to identify and correct any anaemia prior to surgery. The recommended Hb levels prior to surgery, depending on the overall bleeding risk, are:

- Female 115 g/L*
- Male 130 g/L

To avoid causing unnecessary delay to patients, anaemia screening should take place **when referral for surgery is first made**, in order to allow investigation and correction if appropriate.

- Where surgery is urgent, whatever time is available before operation should still be used for anaemia investigation and treatment initiation
- Elective surgery should be scheduled to allow optimisation of patients' haemoglobin and iron stores.
- For all cases of surgical planning, if the procedure entails a >10% risk of requiring a transfusion, the patient's Hb should be optimised. For patients undergoing surgery with a higher risk of bleeding, a haemoglobin lower than these levels are more likely to require transfusion support. This has been associated with a poorer postoperative outcome.
- Review of medications which increase the risk of bleeding, such as anticoagulants and antiplatelet agents. The use of these drugs must be assessed and managed to reduce the risk of bleeding in surgery.
- Autologous blood alternatives to the transfusion of allogeneic blood should be encouraged whenever appropriate – particularly the use of intraoperative salvage for some surgical and trauma patients. The use of antifibrinolytic drugs or tissue sealants should be used if appropriate.

^{*}WHO guidelines state120 g/L, but local reference ranges apply.

7.1 Iron Therapy

Patients with ferritin below the lower range of normal (absolute deficiency) or with normal ferritin but transferrin saturation <20% (functional deficiency) should treated with preoperative iron replacement. This can be either oral or parenteral depending on the timing of the operation: oral iron therapy is sufficient for patients with iron deficiency anaemia and whose surgery is not urgent.

Patients with functional iron deficiency are more likely to respond to parenteral iron replacement.

Intravenous iron also to be given if:

- the interval between the detection of the anaemia and surgery is predicted to be short
- o if the patient is intolerant of or doesn't respond to oral iron.

7.2 Erythropoietin-Stimulating Agents (ESAs)

Agents available to stimulate erythropoiesis in clinical practice are all recombinant variants of the naturally occurring hormone erythropoietin, including agents such as erythropoietin alpha and darbepoetin. These agents are most commonly used in renal medicine but are also licensed for use in chemotherapy-induced anaemia. In addition, erythropoietin alpha is also licensed for peri-operative use, although there is no biological effect difference between different ESAs. In addition to their effects on red cell mass, ESAs may also protect against tissue ischaemia by anti-oxidative and anti-inflammatory mechanisms, and promoting small vessel angiogenesis.

ESAs should be used where transfusion avoidance is desirable, particularly in patients who:

- Decline blood
- Have complex red cell antibodies

ESAs appear effective in reducing the need for transfusion in other patient groups, but an individual risk-benefit assessment should be made, as while rare, there are potential side effects, including an increased thrombotic risk.

The role of ESAs on tumour progression or reduced progression-free survival cannot be excluded. Relative contraindications include uncontrolled hypertension and patients who cannot receive adequate thromboprophylaxis.

Review of the product literature and consultation with Haematology is advised.

7.3 Top Up Transfusions

There is no good evidence to support pre-operative transfusion to normal or near normal in anticipation of bleeding to improve surgical outcomes.

- Pre-emptive transfusion does not reduce total transfusion requirements in the absence of other PBM measures.
- Preoperative transfusion does not protect against the deleterious effects of preoperative anaemia
- Anaemia should be corrected by the evidence-based treatments above, if possible

In situations where transfusion is likely to be unavoidable despite optimal PBM, the question of whether pre-operative transfusion is superior to intra-operative transfusion is unknown, and the need for preoperative transfusion should be assessed on an individual case basis. However, it should be emphasised that if appropriate pathways are followed for non-emergency or urgent surgeries, these situations should be uncommon.

7.4 Cell Salvage and Tranexamic Acid

- Offer tranexamic acid to adults undergoing surgery who are expected to have at least moderate blood loss (greater than 500ml).
- Consider tranexamic acid for children undergoing surgery who are expected to have at least moderate blood loss (greater than 10% blood volume).
- Do not routinely use cell salvage without tranexamic acid.
- Consider intra-operative cell salvage with tranexamic acid for patients who are expected to lose a very high volume of blood (for example in cardiac and complex vascular surgery, major obstetric procedures, and pelvic reconstruction and scoliosis surgery).

8 References

- Clinicians Check List © World Health Organization, 2000.
 WHO/EHT/06.02:
 - https://www.who.int/bloodsafety/clinical_use/ClinicalUseBInfoSheetEn.pdf?ua=1
- NICE guideline (NG24): Blood transfusion, November 2015: https://www.nice.org.uk/guidance/ng24
- Handbook of Transfusion Medicine 5th Edition (D Norfolk Ed), 2013. The Stationery Office, London:
 - https://www.transfusionguidelines.org/transfusion-handbook
- Advisory Committee on the Safety of Blood, Tissues and Organs, SaBTO (2011a) Patient Consent for Blood Transfusion:
 https://www.gov.uk/government/publications/patient-consent-for-blood-transfusion
- Advisory Committee on the Safety of Blood, Tissues and Organs, SaBTO (2011b) Consent for Blood Transfusion. Retrospective Patient Information

 Good Practice Guidance:
 Little March
 - http://www.transfusionguidelines.org.uk/transfusion-practice/consent-for-blood-transfusion-1
- SHOT Annual Reports and Summary: https://www.shotuk.org/shot-reports/report-summary-and-supplement-2019/

British Society of Haematology guidelines

- Administration of blood components:
 https://b-s-h.org.uk/guidelines/guidelines/administration-of-blood-components/
- Guidelines on the management of anaemia and red cell transfusion in adult critically ill patients:
 https://b-s-h.org.uk/guidelines/guidelines/guidelines/management-of-anaemia-and-red-cell-transfusion-in-adult-critically-ill-patients/
- Red blood cell specifications for patients with hemoglobinopathies: a systematic review and guideline (ICTM Collaboration):

- https://b-s-h.org.uk/guidelines/guidelines/red-blood-cell-specifications-for-patients-with-hemoglobinopathies-a-systematic-review-and-guideline-ictm-collaboration
- Guidelines for the use of platelet transfusions:
 https://b-s-h.org.uk/guidelines/guidelines/guidelines/guidelines/use-of-platelet-transfusions/
- Guidelines for the use of fresh-frozen plasma, cryoprecipitate and cryosupernatant: http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2141.2004.04972.x/full
- Guidelines on the spectrum of fresh frozen plasma and cryoprecipitate products: their handling and use in various patient groups in the absence of major bleeding:
 - https://b-s-h.org.uk/guidelines/guidelines/spectrum-of-fresh-frozen-plasma-and-cryoprecipitate-products/
- Transfusion for fetuses, neonates and older children:
 https://b-s-h.org.uk/guidelines/guidelines/transfusion-for-fetuses-neonates-and-older-children/
- Guidelines for the diagnosis and management of disseminated intravascular coagulation: https://b-s-h.org.uk/guidelines/guidelines/guidelines/diagnosis-and-management-of-disseminated-intravascular-coagulation-1/
- Guidelines on the use of irradiated blood components: https://b-s-h.org.uk/guidelines/guidelines/guidelines-on-the-use-of-irradiated-blood-components/
- Identification and Management of Pre-Operative Anaemia
 https://b-s-h.org.uk/guidelines/guidelines/identification-and-management-of-pre-operative-anaemia/

Further guidelines

- NHSBT: Guideline for the use of granulocyte transfusions:_ <u>https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/14874/inf2764-clinical-guidelines-for-the-use-of-granulocyte-transfusions.pdf</u>
- DIC subcommittee of the Scientific and Standardization Committee of the International Society on Thrombosis and Haemostasis: Guidance for diagnosis and treatment of disseminated intravascular coagulation from harmonization of the recommendations from three guidelines:

http://onlinelibrary.wiley.com/doi/10.1111/jth.12155/pdf

- Society of Interventional Radiology Consensus Guidelines for the Periprocedural Management of Thrombotic and Bleeding Risk in Patients Undergoing Percutaneous Image-Guided Interventions – Part II: Recommendations:
 - https://www.jvir.org/action/showPdf?pii=\$1051-0443%2819%2930407-5.
- Association of Anaesthetists: Regional anaesthesia and patients with abnormalities of coagulation:
 - http://www.aagbi.org/sites/default/files/rapac_2013_web.pdf
- SaBTO report of the Cytomegalovirus Steering Group, March 2012: https://www.gov.uk/government/publications/sabto-report-of-the-cytomegalovirus-steering-group

Trials

- HALT-IT: Effects of a high-dose 24-h infusion of tranexamic acid on death and thromboembolic events in patients with acute gastrointestinal bleeding (HALT-IT): an international randomised, double-blind, placebo-controlled trial, The HALT-IT Collaborators, *Lancet* 2020
- PATCH: Platelet transfusion versus standard care after acute stroke due to spontaneous cerebral haemorrhage associated with antiplatelet therapy (PATCH): a randomised, open-label, phase 3 trial, Baharoglu, et al., Lancet 2016