Reference Number: UHB 348 **Version Number:** 6	**Date of Next Review: 31/07/2029** **Trust/LHB Reference Number:**

Blood Component Transfusion Procedure

Introduction and Aim

Donated blood is an essential adjunct to health care but is also a limited resource. It is increasingly expensive, subject to public health concerns and can present a source of risk for patients. It is recommended that blood/component transfusion should be an integral part of care and clinical governance responsibilities in order to make transfusion safer. It is important to provide relevant information for patients relating to transfusion and avoid unnecessary use of blood/component in clinical practice [(1)]. This document includes the principles described in the NHS Wales Blood Health Plan [(2)], to avoid unnecessary intervention, use evidence and data to improve practice and consistency within healthcare and reduce inappropriate use of blood components.

The aim of this procedure is to enable blood/components to be transfused safely, in particular to minimise the risk of giving blood/components of the wrong group to a patient in error and to avoid unnecessary transfusion in general. It is based on national multidisciplinary guidelines and informed by local experience. Red cells are the most transfused blood component; however, the principles described in the procedure apply to all blood components (e.g. platelets and plasma) [(2)].

This procedure also seeks to ensure that transfusion activities within the UHB are compliant with Blood Safety and Quality Regulations[(4)] as determined by the Medicines and Healthcare products Regulatory Agency (MHRA) who have been designated the competent authority to monitor compliance on behalf of the Department of Health (DOH). It will also incorporate some of the recommendations following the Infected Blood Inquiry (IBI) reported published in 2024[(20)]

This procedure supports the Blood Component Transfusion Policy and promotes safe and appropriate transfusion practice.

Objectives

The objectives of this policy are to provide a rational and practical framework on which to maximise patient safety during blood/component transfusion by:

- Assisting clinical staff to minimise avoidable risks of transfusions by providing clarity to the critical points of the process, namely pre-transfusion blood sampling, removal of blood components from blood fridges, transfer of blood components across clinical areas (including to satellite fridges) and administration of blood components. An understanding of the policy and procedure will provide the basis of knowledge required to comply with the National Patient Safety Agency (NPSA) (2006) Safer Practice Notice (SPN) 14 Right Patient Right Blood [(3)].
- Managing, investigating and reporting adverse events and reactions.

- Encouraging clinical staff to consider the appropriateness of transfusion and to explore alternatives.
- Promoting safer transfusion as part of clinical governance responsibilities and highlighting Good Manufacturing Practice (GMP) and the organisation's regulatory responsibilities
- Working within scope of professional practice

Scope

The procedure applies to all UHB staff involved at any stage in the transfusion process and is applicable to both children and adults. A copy of the policy and procedure will be issued by the Blood Transfusion Laboratory Manager with the Technical Service Level Agreement(s) held between the UHB and relevant third parties.

Equality and Health Impact Assessment	An Equality and Health Impact Assessment (EHIA) has been completed as part of the Blood Component Transfusion Policy and this found there to be a positive impact
Documents to read alongside this Procedure	Provision of Intra-Operative Cell Salvage Policy (UHB030) Blood and Platelet Shortage Planning Procedure (UHB285) Consent to Examination or Treatment Policy (UHB100) Labelling of specimens submitted to Medical Laboratories Policy (UHB017) Parenteral Infusion Pumps Policy (UHB081) Waste Management Policy Blood Component and Transfusion Policy (UHB068)
Approved by	UHB Transfusion Group

Accountable Executive or Clinical Board Director	Medical Director
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Disclaimer

If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the Governance Directorate.

Summary of reviews/amendments			
Version Number	**Date of Review Approved**	**Date Published**	**Summary of Amendments**

1	21/02/2017	15/03/2017	From the previous revision of the Transfusion Policy the following have been included: 1 Updated the special requirement section following updated recommendations from SaBTO 2 Updated the indications for platelet transfusion in line with updated BCSH guidelines 3 Updated the Massive Haemorrhage Protocols in line with recent BSH guidelines and clinical collaboration 4 Updated transfusion documentation
2	09/10/2020	09/10/2020	Update in accordance with SaBTO recommendations, those born after 01/01/1996 may now receive both apheresis (single donor) and pooled platelets Update in accordance with SaBTO recommendations, those born after 01/01/1996 may receive FFP rather than Octaplas Competences for Pre-transfusion sampling and Administration have been amended to be in line with All Wales strategy for competency assessment The use of O D positive blood for unknown male patients in massive haemorrhage Removal of internal Transport boxes Updated All Wales Transfusion Record E-Learning and Blood Component App added
3	June 2021	09/07/2021	Reflective of changes made to the Blood Transfusion Laboratory Computer System (LIMS) to be able to use the last 10-year history on patient for electronic issue (previously only had 6 months) Bring procedure in line with BSH compatibility guidelines irradiated guidelines Added Key words to be added onto request form SHOT TACO checklist Sample acceptance criteria regarding confirmatory sample

			New All Wales Pre-Transfusion Sampling Request form and indication codes for transfusion New Traceability label preview
4	January 2022		Updated to reflect SHOT 10 steps for transfusion pathway Updated massive haemorrhage links for obstetrics and for paediatrics definitions re: baby, infant and child
5	July 2025		Acknowledgement of Infected Blood Inquiry report Updated the removal of first line of address being mandatory in transfusion Updated e-learning details Update documentation associated with transfusion Update porter collection information (Synbiotix) Update unknown patient information Provision of blood in an emergency for patients with complex antibodies Update Major Haemorrhage protocols Updated Jehovah Witness information Updated urgent blood guidance
6	May 2026		Included e-learning for taking pre-transfusion samples Terminology changed from special requirements to specific transfusion requirements Updated to reflect historical sample valid from 01/01/2010 rather than ’10 years’ Changed timing from 2 hours to 30 minutes for confirmatory sample Reinforced independent confirmatory sample Welsh Health Circular (WHC) Reference made to additional medication may be prescribed on ePMA or medication chart. Updated to reflect 1st line of address not a requirement for zero tolerance and not printed on issue records or traceability labels Included information regarding turnaround times for provision of routine blood Additional information and guidance for patients who refuse blood components and products

Content Page

Appendices

Introduction

This procedure has been produced using the Serious Hazards of Transfusion [SHOT] guidance regarding the 10 steps of transfusion and where errors occur.

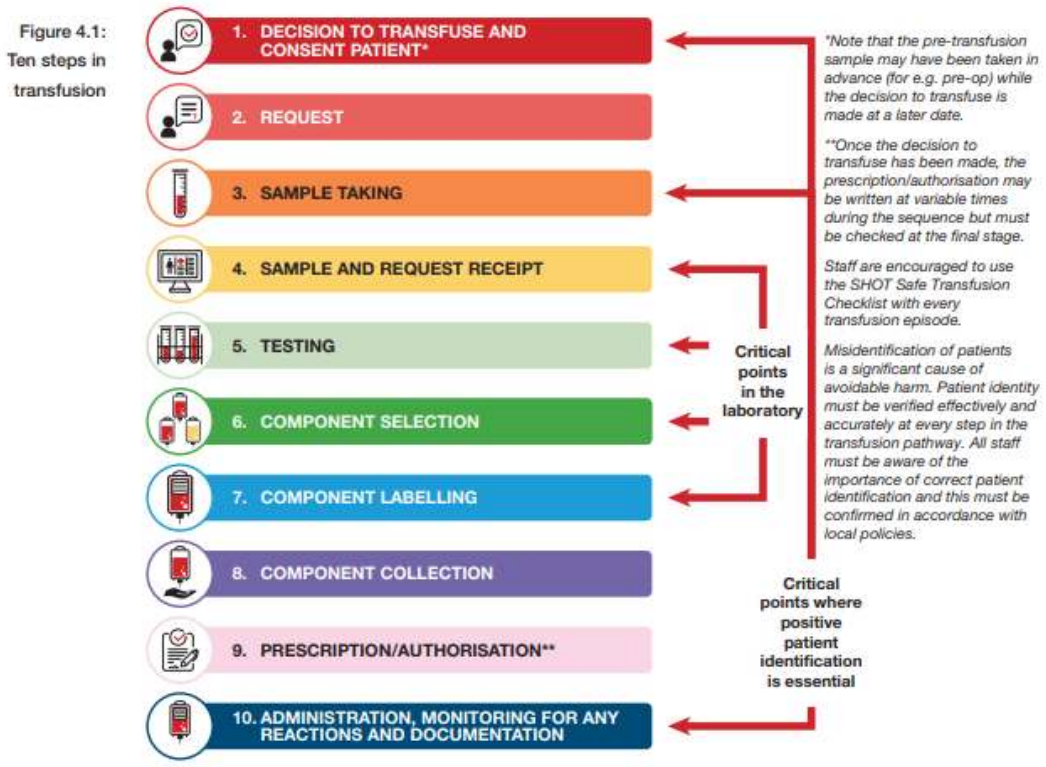


Figure 4.1: Ten steps in transfusion

SHOT[19]

ROLES AND RESPONSIBILITIES

To comply with the organisation's regulatory requirements, the Blood Transfusion Laboratory (BTL) must ensure that they have a robust Quality Management System (QMS). The organisation supports and promotes quality within the field of transfusion and the principles must be adhered to both in the BTL and clinical environments. This includes the reporting of incidents, accidents and near misses in relation to transfusion, the investigation of their cause and the implementation of corrective and preventative actions.

The UHB is ultimately responsible for ensuring that the health care professionals it employs are informed of, and have access to, UHB policies on blood transfusion. In addition, it is responsible for ensuring the BTL complies with the Blood Safety and Quality Regulations (BSQR) (SI 2005 No. 50 as amended) [4]. Further specific responsibilities have been defined as:

Transfusion Group, in conjunction with the Hospital Transfusion Team (HTT), are responsible for:

Reviewing transfusion policies and procedures on a three yearly basis or as the law, National Regulations or Guidelines change.

- Promoting continuing education in transfusion medicine for all members of staff.
- Reviewing the arrangements for providing continuing education and training of staff in transfusion policies and procedures and the law.
- Reviewing adverse transfusion events including “near misses”.
- Reviewing the appropriateness of blood/component transfusion and making recommendations about the proper use of blood and blood components.
- Recommending corrective action in transfusion practice, where indicated.
- Promoting continuing education in transfusion medicine for all members of staff.
- Informing the UHB via the Quality and Safety Committee of the Transfusion Group activity by submission of a quarterly report or escalating individual issues as appropriate.

The Blood Transfusion Laboratory staff are responsible for:

- Ensuring the labelling of request forms and blood samples comply with local guidelines.
- Blood grouping and compatibility testing.
- Checking computer records for any special transfusion requirements when blood or blood components are requested.
- Cross checking against previous blood group and antibody status.
- Error reporting.
- Ensuring that blood and blood components are properly labelled, and the identification details of the patient and the blood component transfused are the same on the traceability label attached to the pack and the blood transfusion issue record.
- The investigation and reporting of transfusion reactions or other incidents related to transfusion [17].
- Ensuring adequate blood stock management and invoking the Blood and Platelet Shortage Planning Procedure when appropriate.

The Clinical Areas and Senior Nurses and Ward Managers are responsible for:

- Ensuring training in blood/component transfusion policies and procedures and law is included in induction programmes for new staff in the relevant areas.
- Ensuring all clinical staff involved in the blood/component transfusion process are aware of UHB transfusion policies and procedures, have undergone relevant training and are deemed competent to undertake the procedures in those areas of transfusion where they are authorised to practice and are able to evidence this under the VBA process.
- Ensuring adverse transfusion events including “near misses” are identified, documented, reported, investigated and appropriate action taken, this includes the timely implementation of CAPA.
- Ensuring all traceability labels are returned within 48 hours of transfusion for all blood/components.

Clinical areas that house satellite fridges do so under a locally documented agreement managed by the BTL and compliance is mandatory.

The Medical staff/ Independent Authorisers of Blood Components are responsible for:

- Prescribing/authorising blood, blood components and blood products.
- Ensuring special requirements are requested appropriately
- Ensuring adequate documentation of blood/component transfusion in the medical notes.
- Ensuring that informed consent has been obtained.
- Where capacity to consent is in doubt, complying with the Mental Capacity Act 2005.

The Medical staff/appropriately trained registered Nurses and Midwives are responsible for:

- Requesting blood, blood components and blood products.
- Taking blood samples for compatibility testing.
- Explaining the risks and benefits of blood transfusion to patients, considering everyone’s individuality in accordance with their fundamental Human Rights 1998, and complying with the consent process.
- Carrying out the procedure for the administration of blood and blood components.

- Monitoring patients during transfusion and carrying out the appropriate actions in the event of adverse effects.
- Reporting of transfusion reactions or other incidents related to transfusion.

Unregistered nursing staff, e.g. student nurses and health care support workers, may be involved in the transfusion process under the close supervision of the Registered Nurse/Midwife. Unregistered staff cannot be involved in the pre-administration checking procedure or connection of the administration line to the patient's cannula. Student midwives can undertake pre-transfusion sampling, under direct supervision providing they have undertaken the necessary training and competency assessment.
The Registered Nurse/Midwife remains responsible for ensuring transfusion policies and procedures are adhered to at all times.

The Phlebotomists are responsible for:

- The collection of blood samples for compatibility testing, provided they are aware of UHB transfusion policies and procedures, have undergone relevant training and are deemed competent to do so.
- Ensuring that they only collect samples where there is a correctly completed transfusion request form, and the patient can be correctly identified.
- Reporting to the nursing and medical staff responsible for the patient where these conditions are not satisfied.

The Portering staff are responsible for:

- The collection of blood, blood components and blood products, provided they are aware of the UHB transfusion policies and procedures.
- Have undergone the relevant training and they are deemed competent to carry out the collection procedures and complete the relevant documentation.

The UHB has a Transfusion Practitioner Team, their overall responsibilities are:

- To report to the Blood Transfusion Laboratory Management Team.
- To report to the Transfusion Group as defined in their terms of reference.
- To act as the UHB contact point for transfusion advice.
- To lead on education and audit appropriateness of blood usage.

- To support the clinical areas in identifying, training and educating a suitably experienced practitioner to represent the area and to be trained as an assessor in line with NPSA SPN 14[3].

It is the responsibility of everyone involved in the blood transfusion process to report any adverse incidents, accidents or near-misses in accordance with regulatory requirements to SABRE and SHOT [4]. The BTL will investigate all reported adverse incidents, accidents or near-misses related to transfusion. Incidents that are deemed as having patient or organisational risk will be reported in accordance with the UHB Incident Reporting Procedure via Datix. It is the responsibility of all Cardiff and Vale UHB employees to participate in/facilitate this process.

E-learning is available to facilitate staff knowledge and can be accessed via ESR. This should be updated every two years and links for appropriate modules to be completed are listed below:

E-learning for medics: Medics e-learning

E-learning for nurses: Nurses e-learning

E-Learning for staff who just take pre-transfusion samples: Pre-Tx sampling e-learning

Assistance to register can be sought from the Transfusion Practitioner Team on Ext. 44594 or 24360.

REQUEST

When the decision to transfuse blood/component is made, this should be clearly documented in the medical notes together with the reason for transfusion, including a note of the haemoglobin level or platelet count when this has been the trigger for transfusion [11]. (See appendix for indication for transfusion).

The patient should be provided with written documentation explaining their transfusion needs, as part of the informed consent procedure. Where capacity to consent is in doubt the Mental Capacity Act 2005 and its Code of Practice must be followed. There are specific checklists available for Jehovah's Witness patients and patients 18 years and over, who refuse blood transfusion. These should be utilised in patients care were appropriate. If the transfusion is for a child, then the child's parents/carers should be given relevant information.

A suitably trained doctor, nurse, midwife, should complete the request form and at the same time a doctor or independent authoriser of blood components must authorise the blood / components on the All-Wales Transfusion Record. The request form should specify quantity and any specific transfusion requirements (e.g. Irradiated, CMV negative, – see appendix). Any specific transfusion requirements **must** be communicated to the BTL. Key words are also in the appendix. The organisation endorses the completion of the request form prior to the collection of the pre-transfusion sample for blood group and antibody screen and/or compatibility testing as per National Guidelines. This form must be used as part of the **positive patient identification** check in the pre-transfusion sampling procedure.

The request form must be complete and legible, failure to comply with these standards will result in the sample being rejected and a new sample requested. The information required, see below, is in accordance with guidelines published by the BSH (2012) [5] which do not require information regarding the patient's ethnicity, disability, origin or religion. Addressograph labels are acceptable on request forms, but caution must be taken to ensure they belong to the correct patient. There is advice on how to complete the request form in the appendices

The first part of the request form MUST contain the following details, and an addressograph is acceptable on the request form:

- First name
- Last name
- Date of birth
- Hospital/NHS number
- Name and signature of requesting doctor/nominated deputy

Other fields to be completed on the form in line with best practice:

- Gender
- Location (e.g. ward)
- Consultant
- Date that the blood sample was requested
- Ext/Bleep number of the requester
- Reason for transfusion/relevant transfusion history
- Number and type of blood components required (if any)
- The date and time that blood components are required

Positive patient identification is essential, and the person taking the pre-transfusion sample is responsible for the completion of the declaration part of the request form. The signature on this part of the form and on the sample, confirms the person signing has followed the correct procedure, and they accept responsibility that the sample was taken from the patient

identified on the request form. The person taking the sample must print their name, add a signature, and specify the date and time the sample was taken. If any of these details are missing, the sample is not suitable for processing and must result in rejection and a new sample requested. Please note: the declaration does not need to be filled in when a form is sent for subsequent requesting of components as no sample is taken.

The request form can be used in two ways:

- used to order blood/components and sent with the patient's blood specimen to the BTL or
- used to request a blood group and antibody screen test (sent with patient's blood specimen) where there may be a future requirement for blood/components.

Pre - Transfusion Sample

An appropriately trained doctor, nurse, midwife, phlebotomist or health care support worker should draw the pre-transfusion blood sample. The NPSA recommends that all staff are trained, and competency assessed in pre-transfusion sampling procedures. The organisation requires that these competency assessments are completed and evidenced during individuals VBAs. It is the individuals' responsibility to ensure they are competent to undertake this task. **Positive Patient Identification** of the patient is essential. Patients must be asked to state their full name, address and date of birth before the sample is drawn. This is in keeping with the organisation's patient identification procedure. Those details, and the hospital number, must be checked against the patient wristband and request form [6, 7]. If there are any discrepancies or the patient does not have a wristband (with the exception of out-patient areas), do not proceed until the issue is resolved. It is acknowledged that in certain extreme emergency situations this may not be possible, for example, newborn babies being transfused as part of resuscitation procedures. However, due regard must be applied to positive patient identification in all circumstances.

Extra care must be taken when drawing blood samples from patients unable to participate in a verbal identification check, i.e. children, confused patients, unconscious patients or anyone with any disability that prevents them from verbally identifying themselves. In these circumstances, in addition to checking the wrist band the patient's identity can be checked, where possible, with a third party at the bedside i.e. a relative, friend or colleague. Positive identification is recorded on the request form by the person collecting the sample, by completing the declaration section of the request form.

The label on the blood sample tube must be handwritten legibly, using a ball point pen by the person who took the blood immediately after it is taken, beside the patient. Labelling for each patient should be completed before the next patient is bled. Sample labels must never be filled in before the specimen is drawn, as this is a leading cause of transfusion incidents. Addressograph labels are not acceptable on sample labels. Take care to ensure that the details on the sample correspond exactly with the details on the request form as any discrepant forms and samples will be rejected by the BTL. This could result in delay in provision of components and in patients being re-bled unnecessarily.

The UHB accepts that there may be clinical situations where it may be difficult for the person taking the sample to label the sample, e.g. femoral stab. In these situations, it is the responsibility of the person labelling the sample to ensure they have positively identified the patient and to sign the request form and sample.

The sample label must include the following information:

First name	Date of birth
Last name	Hospital number or (NHS Number)
Gender	Location (e.g. Ward)
Signature of person taking blood (must be legible)	

The person taking the sample must complete the declaration section on the request form, completing the date and time the sample was taken, and by printing, signing and adding their contact details to the form.

The signature on the sample tube and the signature of the person confirming positive patient identification has been completed must match for the sample to be accepted.

For unknown patients (e.g. In Emergency Unit), the request form must contain the following details

Phonic name (e.g. Sierra Zebra)	Emergency Hospital number
Presumed DOB (01.01. xxxx)	(e.g. E123456H)
Gender (Male / Female)	Location (e.g. Ward)
Name, signature and bleep	When blood components required
number of requesting	Diagnosis and reason for request
healthcare professional	Special requirements if appropriate

Timing of sample collection in relation to previous transfusions:

If stored at 4°C, EDTA whole blood samples may be used for compatibility testing for up to 7 days.
The timing of sample collection for compatibility tests must take account of previous transfusions and pregnancies.

Transfusion or pregnancy may cause a primary or secondary immune response and samples selected for cross matching or antibody screening must take account of this, so that newly developed antibodies are detected.

When a patient is being repeatedly transfused, it is not necessary to submit a daily cross match sample. Such patients should be screened for the development of irregular antibodies every 72 hours.
If a transfusion has been given more than 72 hours previously, a new sample is required according to the following guidance:

Patient transfused or pregnant:	**Sample to be taken up to:**
Within last 3 months	**48 Hours before transfusion (with a 24-hour reservation period)**
Greater than 3 months	**7 days before transfusion**

In a pregnant patient – immunisation is more likely to occur during the third trimester of pregnancy. It is advisable that a sample is taken immediately before transfusion or upon admission for an elective procedure.

Requirement for confirmatory sample and the taking of duplicate samples

In line with current BSH guidelines Cardiff and Vale University Health Board (UHB) requires a confirmatory sample to be taken.

If the patient has a blood group on record in the Laboratory information system (LIMS) for ABO/D and antibody screen since 01/01/2010, this will be used as the patient historical record. Therefore, when a known patient requires blood products, clinical staff are required to take **one** current sample [22].

If the patient is **not known** to Blood transfusion laboratory (BTL) then an additional **confirmatory** sample will be required.

- The confirmatory sample must come from **separate** venepuncture events and ideally should be carried out by two different people.

- If the same person carries out the two samples, they should be taken more than **30 minutes** apart. If this is not possible due to clinical urgency contact the BTL for advice.

- If the samples are urgent and are taken by the same person, the confirmatory sample will be held by the BTL until confirmation that the confirmatory sample was taken independently.

- In an emergency, if blood is required e.g. major haemorrhage, blood group O RhD negative or O RhD positive will be issued, so not to cause any delay to the patient. However, a confirmatory sample should be sent as soon as possible, enabling the BTL to change to group specific.

If you are unsure if Blood Transfusion Laboratory already have a historic blood group, you can check on the electronic patient records for a BBS sample within the last 10 years (rolling). If you are still unsure then please telephone Blood Transfusion Laboratory 42157 (UHW), or 25389 (UHL) to avoid unnecessary testing of patient samples. Duplicate samples will not be tested, and a free text will be added onto clinical portal to advise the clinical team that the sample will not be processed.

Care must be taken to not take both the current and confirmatory sample during the same venepuncture episode, see Welsh Health Circular/WHC.

Sample Receipt

In line with the Clinical Advisory Group of the Welsh Government's Guidelines the UHB has introduced a Zero Tolerance Policy on the acceptance of pre-transfusion blood samples in April 2011. This means that any inaccuracies on either the sample request form or the sample bottle will lead to the sample being discarded and the patient being re-bled. Once the sample and form have left the clinical area there will be no opportunity to amend form or sample. See appendix – sample acceptance zero tolerance.

Testing

Historically blood has been issued only after serological compatibility testing, a process where the patient's plasma is tested directly against a sample of the

red cells from the donor unit. Currently this process has a routine turnaround time of two hours, and the compatible units are reserved for an individual patient for up to 48 hours.

Group and Screen turnaround times in routine cases

40-60 minutes from sample receipt for patients who are suitable for electronic issue.

1 to 2 hours from sample receipt for patients with grouping discrepancies e.g. Allogeneic BMT patient

2 to 6 hours from sample receipt for patients with allo or autoantibodies. This testing includes, a group, screen then antibody identification, additional panels if needed and compatibility testing.

4 to 8 hours from sample receipt for patients with complex antibody profiles, pan-reactive autoantibodies, monoclonal antibody treatment e.g. daratumumab. This time includes transport time to refer samples to WBS if needed. Urgent transport is guaranteed within 90 minutes one way.

With the introduction of automation to the BTL it is now possible to issue selected units without serological compatibility testing i.e. electronic issue or EI.

Patients are eligible for Electronic Issue (EI) provided the following criteria are met:

- The ABO and RhD blood group results on the current sample and any historical record must be identical.
- The ABO and RhD results of the current sample are authorised.
- A record must exist of 2 fully automated ABO/D groups and antibody screens where results have been transferred electronically (and are unedited). A minimum of one historical record (within the last 10 years) and the current sample.
- There is no outstanding antibody screen registered for the patient.
- The patient's plasma ***does not contain and has not been known to contain***, clinically significant alloantibodies reactive at 37^0C.
- The antibody screen on the current sample is negative.

Patients not eligible for EI will have serological compatibility testing performed on receipt of the initial request and blood will be reserved appropriately for that patient.

In emergency situations it is essential that the BTL is contacted immediately to ensure that blood is available for collection at the agreed appropriate time.

It is a clinical decision to transfuse blood components when the patient is not eligible for EI and there has been insufficient time to complete full compatibility testing as this may result in adverse events (immediate or delayed transfusion reactions) as the patient may have unidentified antibodies or develop significant antibodies [e.g. maternal sensitisation to rhesus antigens].

O RhD Negative / O RhD Positive units

A stock of O RhD negative and O RhD positive blood for emergency use is maintained by the BTL at UHW and UHL. This must only be used when delay in transfusion will jeopardise the patient's life.

ABO and RhD group specific uncrossmatched units

On receipt of a valid sample blood can be issued which is ABO and RhD group specific uncrossmatched within 15 minutes, if blood group is known historically. This preserves the stock of O RhD negative blood.

Fully compatible (cross matched) units

The patient is required to have an historical sample and a current valid sample to comply with the BSH guidelines to issue blood components. The BTL must be informed by the clinical area of the urgency.

Patients with atypical antibodies

The patient's plasma is screened to identify any atypical red cell antibodies of potential clinical significance. These usually occur after sensitising events and are directed against other blood group antigens (e.g. Kell, Duffy, Kidd) on the surface of red cells. If such antibodies are identified every effort is made to provide blood which is negative for the corresponding antigen to avoid the risk of haemolytic transfusion reactions. This is a time-consuming process and will delay the provision of blood. If a patient should need blood urgently the Consultant Haematologist can advise on the severity of risk if blood is given that is not fully compatible. This risk must be balanced with the risk of delaying transfusion.

The BTL must be informed of any changes to the patient's clinical condition that may be significant to their transfusion requirements.

Platelets may be issued immediately on a confirmed blood group, but it should be noted that the availability of this resource is limited, and they may need to be ordered from the WBS.

Pre thawed Fresh Frozen plasma (FFP) is available within the UHB. However, it must be noted if additional is required it takes 20 minutes to thaw.

Provision of emergency blood for patients with complex antibodies.

Blood components that do not conform to specified requirements may be issued for therapeutic use when any benefits of giving the component outweigh the risks as assessed by a medical practitioner on behalf of the patient.

The concessionary release procedure can be found on SharePoint Concessionary release

Component Selection

See appendix for guidance on component selection including special requirements.

Labeling of blood components

All blood components have a traceability label attached giving patient details. The bag label contains a tear-off section that must be returned to the BTL to ensure compliance with the legal traceability requirements of the BSQR confirming that the component has been transfused. Additionally, an adhesive strip containing the required information for recording the transfusion is supplied on the traceability label which must be adhered to the All-Wales Transfusion Record (AWTR).

Bag identifier – label on blood/component bag bearing blood group of donors, 14-digit unique donation numbers should match the donation numbers on the traceability label. The expiry date and additional information such as CMV negative/irradiated/ should also be checked.

It should be noted that laboratory documentation related to transfusion episodes is scanned and retained for a period of up to 30 years or longer to allow a full audit trail of donations from donor to patient.

COLLECTION AND DELIVERY OF BLOOD/BLOOD COMPONENTS

The blood/component should not be collected until the blood/component has been prescribed/authorised and the required equipment is available. The blood/component must be prescribed/ authorised on the All-Wales Transfusion Record and any associated medication prescribed on the All-Wales inpatient medication chart or ePMA. The patient must have patent intravenous access. The baseline observations must be undertaken. These are temperature, pulse, blood pressure, respiratory rate and oxygen saturation as a minimum. All observations must be recorded on the All-Wales Transfusion Record (AWTR) within an hour of the transfusion starting. In addition, the overall patient's condition should be noted so significant clinical changes can be detected.

Care should be taken with regard to the timing of transfusions, e.g. are there sufficient staff to undertake the appropriate supervision and appropriately timed for patient needs. Transfusion at night should be avoided unless the patient is symptomatic.

A member of staff from the appropriate clinical area should complete a collection slip or enter details onto Synbiotix with the patient identification information listed below. Addressograph labels are acceptable on collection slips. Staff must indicate the component or product type to be collected and quantity. Abbreviations must be avoided.

First name
Last name
Gender
Date of Birth
Hospital number (NHS Number)
Location (e.g. Ward)

The suitably trained person retrieving the blood/component should take the collection slip from the ward or print out from Synbiotix to the BTL. The details on the collection slip/print out, the traceability label and the bag identifier must be checked against the BTL issue record when the component is collected. The BTL issue record must be signed, dated and timed when blood/components are removed.

Synbiotix

Synbiotix is the system used within Cardiff and Vale UHB for requesting a porter to collect blood components.

Units of blood should be removed from the issue fridge in the BTL or satellite fridge individually, as they are required. All blood components must be carried in a plastic blood carrier bag to ensure the patient's details remain confidential throughout the transportation process. This also enables minimal handling. Blood taken in a bag must be returned within 30 minutes of removal from the fridge for it to be returned to stock. If blood is not returned within 30 minutes, it will be disposed of.

If the clinical area does not have a satellite fridge, the BTL should be contacted if the clinical area requires more than one unit of red cells.

No blood component should be stored in a ward drugs fridge

Any member of staff who undertakes blood/component collection from the BTL or satellite fridge must be trained to do so to comply with the legislation. In addition, staff who undertake collection of blood/components must be trained and competency assessed in line with the NPSA SPN 14[(3)].

Collecting blood in an emergency is discussed in appendix.

Prescription/Authorisation

The All-Wales Transfusion Record (AWTR) – includes a section on consent, specific transfusion requirements, Transfusion Associated Circulatory Overload (TACO), risk assessment and a pre administration checklist. The observations should also be recorded on the AWTR. Any specific transfusion requirements (e.g. irradiation of blood/component or cytomegalovirus (CMV) negative must be indicated on the prescription section of the record and special requirements are discussed in appendix. Any transfusion-related drugs must be prescribed on the All-Wales in-patient medication chart or ePMA.

Blood components can only be prescribed/authorised on The All-Wales Transfusion Record by Doctors and staff who have successfully undertaken the independent authorisation of blood components.

Administration

Pre-Administration Checklist

As detailed on the All-Wales Transfusion Record pre administration checks must be completed by the person administering immediately prior to the transfusion AT **THE PATIENTS SIDE** prior to the commencement of the blood component. All checks should be undertaken for each unit at the time of administration. The temperature, pulse, blood pressure, respiratory rate and

oxygen saturations as a minimum should be recorded on the All-Wales Transfusion Record before each unit of blood is requested to be collected.

- Patient is wearing identification (ID) band, or approved alternative in use
- Patient identifiers on ID band are correct (confirmed by PPI where possible)
- Patient identifiers on compatibility label match those on ID band and AWTR
- Donation number on compatibility label and component are identical
- Patient's blood group is compatible with component blood group
- Component is within expiry date/time
- Visual check of component completed (leaks, discolouration, clumping)
- Component is correct (I.e. red cells, platelets, FFP, or cryoprecipitate)
- Concomitant medication administered (if required)
- Specific requirements met (if any indicated)

One appropriately trained member of staff, who may be a Doctor, RN, RSCN, RMN or an ODP, is responsible for checking each unit of blood/component before administration. If local policy advocates a double person checking procedure for blood components it must be performed as a double independent check.

The transfusion should take place in a clinical area where the patient can be closely observed by clinical staff. Care should be taken with regard to the timing of transfusions, taking into consideration patient's individual needs and requirements.

Routine, non-urgent transfusion activity should be avoided out of hours [15]. Decisions to transfuse out of hours should be based on an individual patient risk assessment and documented accordingly in the medical records. Naturally, patients who require transfusion in an emergency situation out of hours must be transfused appropriately according to their clinical need.

Administration

Bed Side Checks

Positive Patient Identification [PPI] is essential. Patients must be asked to state their full name, address and date of birth, in line with the organisations patient identification procedure. The patient identification details, and the hospital number, must be checked against the patient wristband, traceability label and All Wales Transfusion Record. If there are any discrepancies, or the patient does not have a wrist band, **do not proceed** until the issue is resolved. Extra care must be taken when administrating blood/components to patients unable to participate in verbal identification check, i.e. children, confused patients, unconscious patients. In these circumstances, in addition to checking

the wristband the patient's identity should be checked, where possible, with a third party at the bedside i.e. a relative, friend or colleague.

The bedside check must occur at the patient's bedside. The NPSA SPN 14[3] recommends that all staff are trained, and competency assessed in the administration of blood components. The organisation requires that these competency assessments are evidenced under VBAs.

The following details must be checked and found to be identical on the patient wristband, traceability label and the All-Wales Transfusion Record:

First name	Date of Birth
Last name	Hospital Number or (NHS number)

The blood unit number (14-digit unique donation number) must be checked and found to be identical on the bag identifier and bag label. Care should be taken if using paediatric RBC or apheresis platelets as there may be multiple packs with the same unit number as they are sourced from the same donor. The packs are differentiated by the 'pack' number.

The blood transfusion should be commenced as soon as possible after removal from the BTL issue/satellite fridge (not exceeding 30 minutes). Blood must never be stored in the clinical area, especially in ward fridges. Blood may only be stored in a clinical area if it has a designated blood satellite fridge.

In certain circumstances, blood that has been out of a temperature-controlled environment for more than 30 minutes but is still intended to be transfused can be administered as long as the transfusion is complete within 4 hours of the blood leaving controlled refrigeration, i.e. removal from the BTL issue/satellite fridge/blood. Staff must be certain that the blood has been stored appropriately in the meantime and at suitable temperatures (i.e. it must not have been artificially cooled or warmed). If the transfusion is in progress at 4 hours, it must be immediately stopped and discarded.

Blood / components should be transfused through a designated sterile blood giving set. It should not be left to 'warm up'. Blood components are now leucodepleted at source, and there is no need for the use of an additional leucodepletion filter. There is no requirement to prime the giving set with an alternative fluid or to flush the giving set post-transfusion.

At the start of the transfusion the patient should be asked to report any symptoms of fever, rigor, rash, flushing, and shortness of breath or pains in the loin or the extremities. Other signs and symptoms of transfusion reaction may also occur (see appendix). Staff should be mindful of communication issues and understanding if English is not the patient's first language.

It is strongly advised, that where possible, only one blood/component is transfused at any given time, however depending on the clinical situation it may be necessary for patients that have multiple intravenous access, e.g. a double lumen line, to enable multiple blood/components to be transfused at the same time. Care must be taken, as if the patient had a transfusion reaction it would be difficult to ascertain the contributing blood/component.

Drugs must never be added to blood. Dextrose solution (5%) can cause haemolysis and solutions containing calcium may cause clotting of citrated blood.

If the transfusion is required to be temporarily stopped, the giving set should be closed off and the intravenous access suitably flushed to avoid any clot formation. On restarting the transfusion, the intravenous access site and giving set line must be observed to ensure that there are no clots, and the line is fully patent.

Electronic pumps may damage red cells and should only be used if verified as safe for this purpose by the manufacturer, and the user is trained and competency assessed in line with the UHB Infusion Pumps Policy. The sterile blood transfusion giving set should be compatible with the pump, as defined by the manufacturer.

Giving sets previously used for blood should not be used to administer platelets. Platelets should be administered via a platelet giving set or a standard blood giving set. The giving sets must be changed between each unit of platelets.

The giving set should be changed every 12 hours during transfusion of red blood cells or after two units. If there is a significant delay in between units being transfused, it is advisable to change the giving set. Change the giving set if there is a change in the group of transfused blood (e.g. from group O to group specific in an emergency) and dispose of it at the end of the transfusion episode.

The warming of blood and blood components is generally not recommended as it is of limited benefit and can be dangerous. If indicated, blood warmers must always be used and maintained according to the manufacturer's guidelines. All devices should be CE serviced as per hospital Health and Safety and Clinical Engineering policies, Medicines and Healthcare Products Regulatory Agency (MHRA) and manufacturers' guidelines.

Blood warmers are only indicated when:

a) Massive, rapid transfusion could result in cooling of cardiac tissue, causing potentially fatal dysrhythmia. If the rate of transfusion is greater than 100 mL per minute blood warming devices should be used.
b) Transfusion is required by patients with cold agglutination disease.
c) Exchange transfusion is indicated in the newborn.
d) Designated blood warmers should be used at flow rates of > 50 mL/kg/hour in adults (15 mL/kg/hour in children); for exchange transfusion in infants and for patients with cold agglutinins.

Blood should be transfused at a rate determined by clinical circumstances. This may be as quickly as possible in a case of trauma but is usually at a rate of one unit every 90 – 120 minutes in adults [(2)], with diuretic cover where necessary. Transfusion can go over a longer period of time, relating to individual patients' risk factors, however transfusion of red cells **must** be completed within 4 hours of the component leaving controlled refrigeration 'fridge to finish time'.

Platelets and FFP should be transfused over a 30-minute period.

The temperature, pulse, blood pressure, respiratory rate and oxygen saturations as a minimum should be recorded on the All-Wales Transfusion Record before each unit of blood is transfused (up to an hour prior to transfusion), fifteen minutes after the start of the transfusion of each unit, and at the end of transfusion of each unit. Further transfusion observations are only required if the patient is unwell or has a reaction and should be based on an individual patient assessment.
Particular care should be taken in monitoring unconscious patients, particularly during the first fifteen minutes of the transfusion.

The person checking the blood should enter the time and date the transfusion commenced on the All-Wales Transfusion Record and sign that they have administered it. The 14-digit unique donation number must be entered on the All-Wales Transfusion Record. An adhesive strip containing this number is provided on the bag label for convenience.

Used blood/component bags and giving sets can be discarded, provided the patient is well, at the end of the transfusion in accordance with UHB Waste Management Policy. It is not necessary to return the blood bag to the BTL unless a reaction has occurred.

For further information of the safe administration and use of Immunoglobulin, advice can be sought from the Advanced Nurse Practitioner – Immunology and Allergy on (029) 2184 8380.

Traceability

If for any reason the blood/component or any blood product is not transfused it must be returned to the BTL immediately to ensure compliance with legislation. Any unused blood/component that has been out of the BTL a temperature-controlled environment in excess of 30 minutes must be brought to the attention of the BTL staff, whether routine or out of hours. The blood must be returned as soon as possible to the BTL to be discarded as it is unsuitable for restocking into the BTL fridges. Blood left on the ward without being transfused for long periods is at risk of being administered to the patient by accident.

A component is considered transfused even if a patient receives only a few millilitres of the transfusion.
If a component is pierced with a giving set but nothing is transfused to the patient, that is the primed line has not been attached to the patient's intravenous access, the component must be disposed of with the giving set safely in the clinical area. In these circumstances it is inappropriate on health and safety grounds due to the risk of a needlestick injury, to return the non-transfused component to the BTL. However, the BTL staff must be informed that the component has not been transfused so it can be marked as disposed. This can be indicated on the returned traceability label.

The BTL must receive positive confirmation that a component has been transfused to ensure compliance with the legislation. A system of return of the traceability label to the BTL has been implemented to meet this statutory requirement of the BSQR (SI 2005 No. 50 as amended) [(4)]. Ensuring that all blood and blood components are traceable from donor to recipient and that traceability records are maintained for a minimum of 30 years is a requirement of the legislation. It is the responsibility of clinical staff to return the labels to the BTL within 48 hours of completion of the transfusion and if the label is not returned alternative evidence will be accepted (either a copy of the All-Wales Transfusion Record or Anaesthetic chart with the appropriate affixed sticker attached). This affects all blood components (e.g. red cells; fresh frozen plasma; platelets; cryoprecipitate). It is recommended for all other blood products (e.g. Anti-D; Prothrombin Concentrate Complex (PCC); albumin, immunoglobulin). Adverse incidents will be raised via the Clinical Governance department if the clinical area fails to return the traceability labels to the BTL, additionally repeated non-compliance will be escalated through the organisational structure.

Occasionally, a patient may be admitted with blood components that have been prepared for transfusion at another hospital. In this circumstance, blood received with the patient from elsewhere must be sent to the BTL in the receiving hospital prior to being re-issued for transfusion. Caution must be taken when the patient and/or blood components have been subject to an inter-hospital transfer as hospital identification numbers may have changed. The BTL

will ensure cold chain requirements are maintained and log the transferred blood/components into the Laboratory IT system to ensure full traceability.

Appendix 1: INDICATIONS FOR RED CELL TRANSFUSION

The main indications for red cell transfusions are bone-marrow failure, transfusion programs for chronic diseases and surgical indications for acute or perioperative blood loss, either measured or estimated, or acute blood loss due to trauma. There is increasing evidence that a conservative policy of perioperative red cell transfusion does *not* compromise clinical outcome, and some evidence that it may improve outcome in certain circumstances. The following recommendations are based on guidelines published by the British Committee for Standards in Haematology (BSH) [(2)], which are reviewed by the Royal College of Surgeons of England, the Royal College of Physicians and the Royal College of Anaesthetists and are the **suggested** standards for audit locally.

Acute or perioperative blood loss where the decision to transfuse is based on an estimate of circulating volume lost:

- Blood loss should be treated with crystalloid infusion initially
- For blood loss of <15% of circulating volume blood transfusion is not generally indicated.
- Blood loss of 15–30% of circulating volume is not an automatic indication for transfusion of red cells, unless the patient was previously anaemic, or unless there is cardiopulmonary compromise.
- Blood loss of >30% of circulating volume generally requires the transfusion of red cells.

Acute or perioperative blood loss where the decision to transfuse is based on the measured haemoglobin IN ADULTS:

- When the haemoglobin is >100g/L blood transfusion is not generally indicated.
- When the haemoglobin is 70–100g/L blood transfusion may be indicated, but the decision to transfuse should not be based on the measured haemoglobin alone.
- When the haemoglobin is <70g/L (or 80g/L in patients with cardiopulmonary compromise) transfusion of red cells is generally indicated, however consideration should be given to all clinical signs and symptoms.

Consideration should be given regarding the quantity of blood given to obtain the required transfusion targets and improve patient symptoms – this may involve single unit transfusion. The checking of Hb levels prior to subsequent unit transfusions is recommended.

Patients on transfusion programs and patients with bone marrow failure:

- A clinical team experienced in their care should manage these patients.
- The transfusion threshold should be determined by an assessment of the patient's symptoms of fatigue in the absence of clinical indicators.

- Alternatives to red cell transfusion (e.g. Iron, Erythropoietin) should be considered where appropriate.

Indications – guidance regarding the use and administration of RBC, platelets, FFP, PCC and Cryo can be found here and compatibility of components can be checked here

Appendix 2: THE USE AND ADMINISTRATION OF PLATELETS

The following recommendations are based on the guidelines published by the BSH (2016) [10].

Risk / Monitoring
There are risks associated with platelet transfusions. The decision to transfuse should include an assessment of risk versus benefit. The risks include:

- Alloimmunization
- Allergic reactions
- Transfusion-related acute lung injury
- Transmission of infection
- As platelets are stored at room temperature they are more often implicated in adverse events due to bacterial contamination than other blood components

The patient should be informed of possible complications of transfusion.

Administration

Only staff members who have passed NPSA competency assessment for the administration of blood components.

A confirmed blood group is required to issue platelets.

The same procedure should be undertaken as described in the administration of blood. The nurse or doctor should ensure that the details on the platelet pack traceability label correlate with those on the patient's wrist band and the All-Wales Blood Transfusion Record. Utilisation of the pre-administration check list on the All-Wales Transfusion Record is essential. The bag should be inspected for any discolouration. Platelets may appear to be tinged 'green'. This is usually due to the donor taking the oral contraceptive or hormone replacement therapy. If there are any concerns, please contact the BTL.

Platelets must be administered through a platelet giving set or a standard blood giving set. The platelet giving set must be changed between each

unit of platelets. Platelets must not be transfused through giving sets that have been used for blood.

Platelets must be transfused as soon as possible after reaching the clinical area and should be administered within 30 minutes.

Platelets must not be refrigerated or stored for any time in the clinical area.

Monitoring follows the same baseline; 15 minute and post transfusion observation checks as for red cell transfusions.

Indications – guidance regarding the use and administration of RBC, platelets, FFP, PCC and Cryo can be found here and compatibility of components can be checked here

Platelets are indicated for the prevention and treatment of haemorrhage in patients with thrombocytopenia or platelet function defects. Platelets are not indicated in all cases of thrombocytopenia and may indeed be contraindicated in certain conditions. Please refer to specific local guidelines where available.

The most common cause of platelet dysfunction is acquired secondary to patient medication including the use of Aspirin and Clopidogrel. These both have prolonged effects on platelet function. The action of Clopidogrel is not readily reversed by platelet transfusion.

Selection of Platelet Products

Platelet concentrates are prepared from either whole blood donations (a pool of 4 donors), or by plateletpheresis (single donor). Platelets are leucodepleted at source by filtration or centrifugation/elutriation.

- Volume 150-300mL for apheresis platelets
  150-450mL for pooled platelets
- Platelets count >240 $x10^9$ per adult dose

Storage/Shelf life – 5 - 7 days stored at room temperature with continual gentle agitation.

The shelf life and requirements for standard microbiological testing prior to release may cause temporary shortages especially following holiday periods.

ABO compatibility

Platelets of the same ABO group as the patient are the components of choice. Best practice would indicate group O products are not selected for non-group O patients.

Indications – guidance regarding the use and administration of RBC, platelets, FFP, PCC and Cryo can be found here and compatibility of components can be checked here

ABO non identical transfusions may result in poorer platelet increments but this has not been shown to be clinically significant and such transfusions are acceptable.

Group O platelets must be labelled as negative for high titre anti-A and anti-B antibodies if given to group A, B and AB patients this should be given if there is no suitable alternative.

Mismatched platelet transfusions may lead to low level haemolysis.

RhD compatibility

There are no RhD antigens on platelets; however, there is a small amount of red cell contamination in platelet components. Therefore, some precautionary measures are required.

RhD negative platelet components should be administered where possible to RhD negative patients.

If RhD positive platelets are administered to RhD negative women of childbearing potential, then anti-D prophylaxis should be administered. A dose of 500 iμ anti-D given subcutaneously in a thrombocytopenic patient should cover up to 5 platelet transfusions over a 6-week period.

Specific transfusion requirements

Please see appendix on special transfusion requirements regarding CMV status/ component. Additional information regarding special transfusion requirements can be found here

All platelets supplied by the Welsh Blood Service (WBS) are irradiated at source and can be given to patients at risk of Transfusion Associated Graft versus Host

disease (TA-GVHD), however caution is needed if the platelets have been imported from England/Scotland.

Human Leucocyte Antigen (HLA) matched platelets may be required in cases of platelet refractoriness secondary to HLA antibodies. Such cases should be guided by specialist haematological advice. Due to the specialist nature and limited resource issues surrounding the provision of HLA platelets the requesting clinician must agree to provide regular platelet increments post transfusion to the Transfusion Service to ensure optimised patient and donor care.

Indications – guidance regarding the use and administration of RBC, platelets, FFP, PCC and Cryo can be found here and compatibility of components can be checked here

Neonatal platelet packs will always be CMV negative and irradiated but will only be provided group O or A D negative as available from WBS.

In accordance with SaBTO recommendations those patients born after 01/01/1996 may now receive both apheresis (single donor) and pooled platelets [10,13].

Platelets with neonatal specification and HLA/HPA selected platelets will remain apheresis derived.

Appendix 3: THE USE AND ADMINISTRATION OF FRESH FROZEN PLASMA (FFP)

The following recommendations are based on the guidelines published by the BSH, 2018[11].

Plasma components (fresh frozen plasma (FFP) and cryoprecipitate (cryo)). The SaBTO recommendations mean that it is no longer necessary for those born after 1st January 1996 to receive pathogen reduced FFP. This will effectively remove the current distinction for selection of plasma components [13].

Risk / Monitoring

There are risks associated with FFP transfusions. The decision to transfuse should include an assessment of risk versus benefit.

The risks include:

- Fluid overload
- Allergic reactions and anaphylaxis
- FFP contains a large volume of plasma proteins. Allergy resulting in urticaria has been reported in 1-3% of transfusions, whilst anaphylaxis is rare.
- Patients who are IgA deficient are at increased risk of anaphylaxis. In patients who have proven IgA sensitivity specialist advice must be obtained.
- Transfusion related acute lung injury (TRALI) - TRALI is associated with the presence of leucocyte alloantibodies in donor plasma. TRALI presents clinically as severe respiratory distress with hypoxia, pulmonary oedema similar to adult respiratory distress syndrome (see transfusion reactions for more details)
- Transmission of infection
- Haemolysis due to transfused antibodies

Administration

Only staff members who have passed NPSA competency assessment for the administration of blood components should administer FFP.

A confirmed blood group is required to issue FFP.

The same procedure should be undertaken as described in the administration of blood. The nurse or doctor should ensure that the details on the FFP traceability label correlate with those on the patient's wrist band and the All-Wales Transfusion Record. The bag should be inspected for any discolouration.

FFP should be transfused as quickly as the patient's condition permits at a rate prescribed by the attending doctor. If unused it must be returned to the BTL.

Monitoring follows the same baseline; prior to commencing, 15 minutes after commencement and post transfusion observation checks as for red cell transfusions.

Indications

FFP is required for:

- Replacement of single factor deficiencies when a suitable specific or combined factor concentrate is not available.
- Acute disseminated intravascular coagulation (D.I.C)
- Thrombotic thrombocytopenic purpura (T.T.P)

Conditional use:

- Immediate reversal of Warfarin - in the presence of life or limb threatening bleeding. The Prothrombin Complex Concentrate is the component of first choice in these circumstances (see section on PCC)
- FFP is not indicated for the routine reversal of Warfarin
- Major transfusion (see Major haemorrhage appendix)
- Liver disease

Note for hypofibrinogenaemia cryoprecipitate or fibrinogen concentrate is likely to be indicated. Please seek specialist advice.

Selection of FFP

U.K sourced FFP from single donors:

- Donors are predominately male with no transfusion history (to reduce the risk of TRALI) and virally tested as per red cell components.
- There is no pathogen reduction process.
- This is the standard FFP component available for adults.
- Volume 180-300mL
- Contains all coagulation factors
- Usual dose 15mL/kg

Storage / Shelf-life

FFP is stored frozen. It takes 20 minutes to defrost and be available for transfusion. After defrosting it may be kept for up to 5 days if stored at 4ºc within the laboratory.

Indications – guidance regarding the use and administration of RBC, platelets, FFP, PCC and Cryo can be found here and compatibility of components can be checked here

Group AB FFP is often in short supply

Group O FFP must only be given to group O recipients

The RhD status of the FFP is unimportant due to the lack of red cell contamination and RhD positive FFP can safely be given to D negative recipients, including women of childbearing age.

Specific transfusion requirements

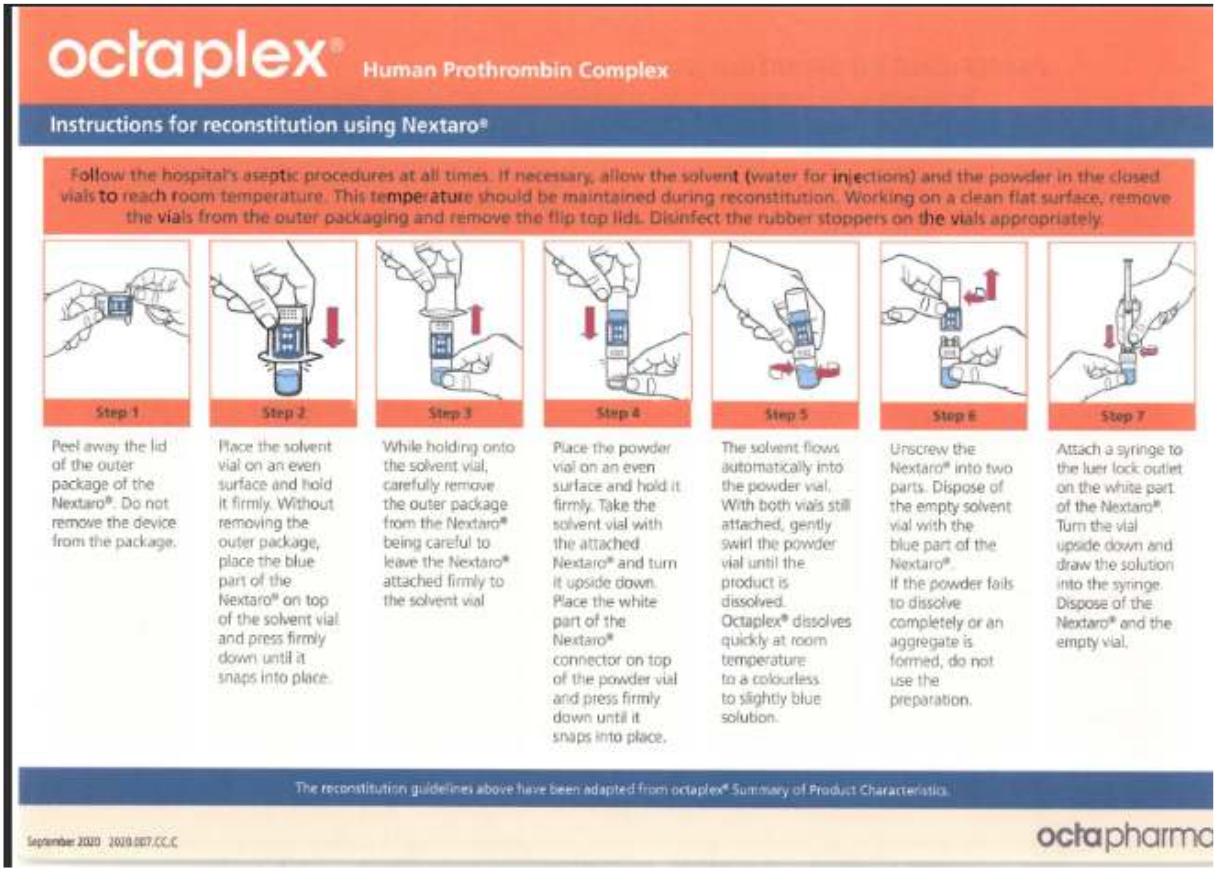
There are no reported cases of graft versus host disease or cytomegalovirus with FFP. Therefore, FFP does not need to be irradiated or CMV tested.

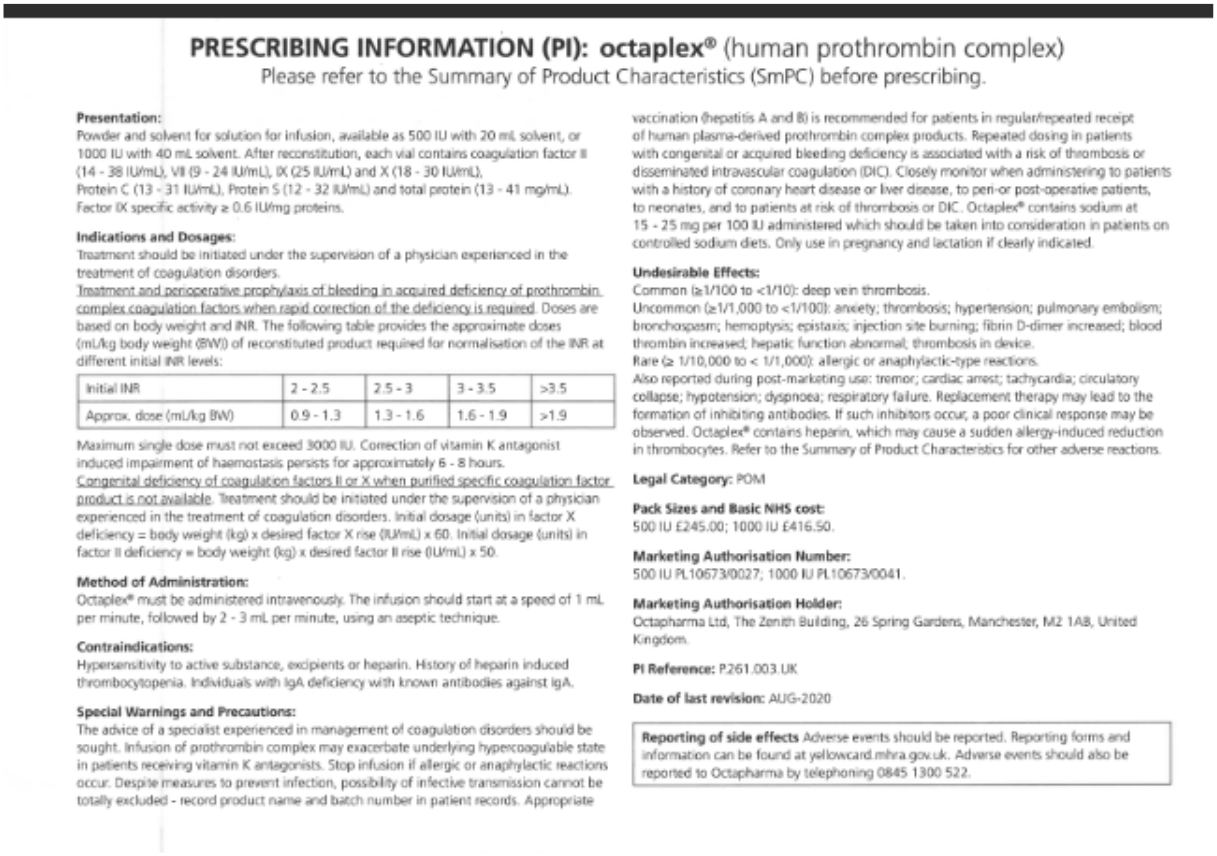
Appendix 4: THE USE AND ADMINISTRATION OF PROTHROMBIN COMPLEX CONCENTRATE (PCC).

Prothrombin complex concentrates (PCC) are concentrates of Factors II, VII, IX and X. The available products are used for the emergency reversal of Warfarin therapy. PCC will be issued from the BTL following consultation with the Haematology SPR / Consultant. The administration should be under the direction of a doctor belonging to the team looking after the patient.

Only staff members who have passed NPSA competency assessment for the administration of blood components and have the competency recorded on ESR, should administer blood components.

PCC is issued in 500 iμ vial sizes, with a diluent 20mL (water for reconstitution) and a factor concentrate in powder form. Dosing will be advised by the haematologist providing support and the dose is rounded up to the nearest 500 iμ vial as part vials are not given.





PRESCRIBING INFORMATION (PI): octaplex® (human prothrombin complex)

Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

Presentation:
Powder and solvent for solution for infusion, available as 500 IU with 20 mL solvent, or 1000 IU with 40 mL solvent. After reconstitution, each vial contains coagulation factor II (14 - 38 IU/mL), VII (9 - 24 IU/mL), IX (25 IU/mL) and X (18 - 30 IU/mL), Protein C (13 - 31 IU/mL), Protein S (12 - 32 IU/mL) and total protein (13 - 41 mg/mL). Factor IX specific activity ≥ 0.6 IU/mg proteins.

Indications and Dosages:
Treatment should be initiated under the supervision of a physician experienced in the treatment of coagulation disorders.
Treatment and perioperative prophylaxis of bleeding in acquired deficiency of prothrombin complex coagulation factors when rapid correction of the deficiency is required. Doses are based on body weight and INR. The following table provides the approximate doses (mL/kg body weight (BW)) of reconstituted product required for normalisation of the INR at different initial INR levels:

Initial INR	2 - 2.5	2.5 - 3	3 - 3.5	>3.5
Approx. dose (mL/kg BW)	0.9 - 1.3	1.3 - 1.6	1.6 - 1.9	>1.9

Maximum single dose must not exceed 3000 IU. Correction of vitamin K antagonist induced impairment of haemostasis persists for approximately 6 - 8 hours.
Congenital deficiency of coagulation factors II or X when purified specific coagulation factor product is not available. Treatment should be initiated under the supervision of a physician experienced in the treatment of coagulation disorders. Initial dosage (units) in factor X deficiency = body weight (kg) x desired factor X rise (IU/mL) x 60. Initial dosage (units) in factor II deficiency = body weight (kg) x desired factor II rise (IU/mL) x 50.

Method of Administration:
Octaplex® must be administered intravenously. The infusion should start at a speed of 1 mL per minute, followed by 2 - 3 mL per minute, using an aseptic technique.

Contraindications:
Hypersensitivity to active substance, excipients or heparin. History of heparin induced thrombocytopenia. Individuals with IgA deficiency with known antibodies against IgA.

Special Warnings and Precautions:
The advice of a specialist experienced in management of coagulation disorders should be sought. Infusion of prothrombin complex may exacerbate underlying hypercoagulable state in patients receiving vitamin K antagonists. Stop infusion if allergic or anaphylactic reactions occur. Despite measures to prevent infection, possibility of infective transmission cannot be totally excluded - record product name and batch number in patient records. Appropriate vaccination (hepatitis A and B) is recommended for patients in regular/repeated receipt of human plasma-derived prothrombin complex products. Repeated dosing in patients with congenital or acquired bleeding deficiency is associated with a risk of thrombosis or disseminated intravascular coagulation (DIC). Closely monitor when administering to patients with a history of coronary heart disease or liver disease, to peri-or post-operative patients, to neonates, and to patients at risk of thrombosis or DIC. Octaplex® contains sodium at 15 - 25 mg per 100 IU administered which should be taken into consideration in patients on controlled sodium diets. Only use in pregnancy and lactation if clearly indicated.

Undesirable Effects:
Common (≥1/100 to <1/10): deep vein thrombosis.
Uncommon (≥1/1,000 to <1/100): anxiety; thrombosis; hypertension; pulmonary embolism; bronchospasm; hemoptysis; epistaxis; injection site burning; fibrin D-dimer increased; blood thrombin increased; hepatic function abnormal; thrombosis in device.
Rare (≥ 1/10,000 to < 1/1,000): allergic or anaphylactic-type reactions.
Also reported during post-marketing use: tremor; cardiac arrest; tachycardia; circulatory collapse; hypotension; dyspnoea; respiratory failure. Replacement therapy may lead to the formation of inhibiting antibodies. If such inhibitors occur, a poor clinical response may be observed. Octaplex® contains heparin, which may cause a sudden allergy-induced reduction in thrombocytes. Refer to the Summary of Product Characteristics for other adverse reactions.

Legal Category: POM

Pack Sizes and Basic NHS cost:
500 IU £245.00; 1000 IU £416.50.

Marketing Authorisation Number:
500 IU PL10673/0027; 1000 IU PL10673/0041.

Marketing Authorisation Holder:
Octapharma Ltd, The Zenith Building, 26 Spring Gardens, Manchester, M2 1AB, United Kingdom.

PI Reference: P.261.003.UK

Date of last revision: AUG-2020

Reporting of side effects Adverse events should be reported. Reporting forms and information can be found at yellowcard.mhra.gov.uk. Adverse events should also be reported to Octapharma by telephoning 0845 1300 522.

Octaplex reconstitution video

The BTL also supplies Berinert (C1 esterase Inhibitor) which is different from Beriplex (PCC), and care must be taken not to confuse the two different products. It is important to ensure that the correct concentrate is used.

Reconstitution:

- Where possible, allow the product to reach room temperature before reconstitution is commenced.
- PCC powder is dissolved with 20mL water for injection using the transfer device supplied, using an aseptic technique. The diluent should be added slowly to the powder to avoid frothing of the concentrate. It may take several minutes before the powder is completely dissolved and free from particles.
- Do not use solutions which are cloudy or contain particles.
- Once dissolved the prepared product should be drawn up into a syringe.

- Prepared product should be administered immediately after reconstitution. Do not refrigerate product after reconstitution.

Administration:

- The prepared product should be administered by slow intravenous injection. Manufacturers' guidelines recommend a rate of 1mL/minute, but the rate of administration should be orientated to the degree of urgency. For life or limb threatening bleeding episodes the recommended rate of administration is 10-15 minutes per whole infusion.
- Routinely there are no specific side effects expected. However, very occasionally and in rare cases, hypersensitivity or allergic reactions may occur. These should be managed by discontinuing the PCC infusion and administering intravenous steroids and antihistamines. PCC should only be administered in areas where acute anaphylaxis can be managed.
- Take care that no blood enters the syringe filled with concentrate to prevent precipitation occurring.
- After administration any unused solution and administration equipment must be discarded appropriately.
- The batch number of each infusion should be recorded in the patient's notes.
- Any unused PCC should be returned to the BTL immediately.

Indications – guidance regarding the use and administration of RBC, platelets, FFP, PCC and Cryo can be found here and compatibility of components can be checked here

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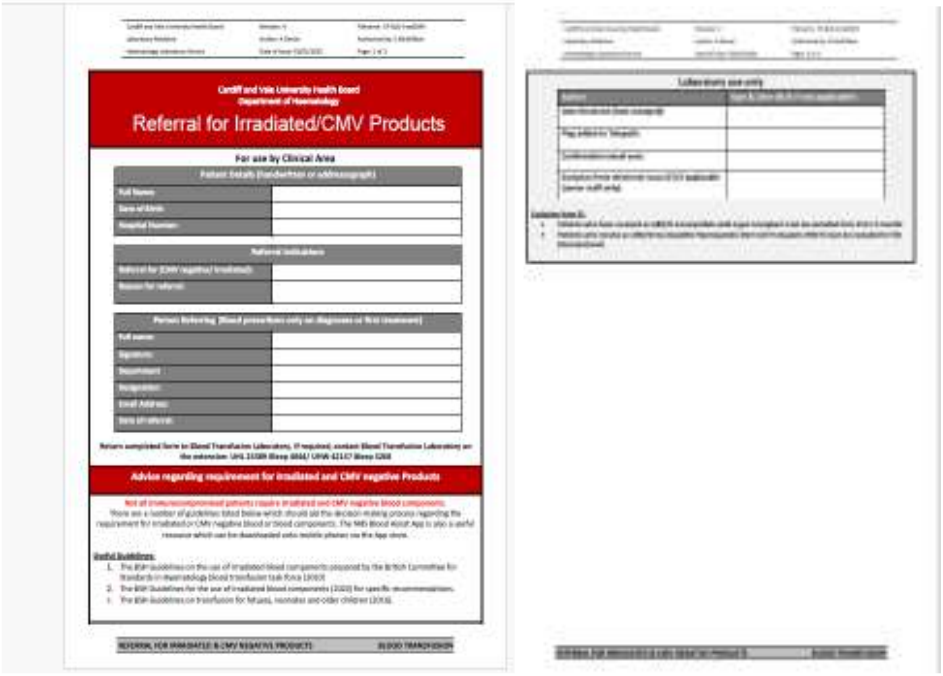
Appendix 5: SPECIFIC TRANSFUSION REQUIREMENTS

There are certain specific transfusion requirements that may need to be fulfilled to ensure safe transfusion practice for a particular patient, which can be checked using the link below or on SharePoint (blood transfusion page). NHS Blood Assist

Special Requirements Referral form


Referral for Irradiated/CMV Products

This form can be downloaded from: Referral for irradiated/CMV products and returned to blood bank.

Appendix 6: MAJOR HAEMORRHAGE

Critically ill patients requiring massive transfusion require the rapid availability of blood components, laboratory investigations and expert haematological advice. Massive blood loss may be defined as the replacement of a patient's total blood volume with stored blood in less than 24 hours, although alternative definitions allowing more anticipation (such as 50% blood volume loss within 3 hours, or a loss of 150 mL/min) may be a more useful clinical guide. The importance is to recognise blood loss early and institute effective action promptly to prevent the onset of shock and its consequences in the patient. [8, 9]

Patients with massive blood loss are not a homogenous group. They present in a range of specialties and the UHB has developed local major haemorrhage protocols with adaptions for specific clinical areas see hyperlinks listed below for specific MHP protocols:

All medical, nursing, laboratory and support staff must know where to find the haemorrhage protocol in relevant areas and be familiar with their contents. It is recommended that their knowledge should be supported by training and regular drills.

Within all of these protocols a successful outcome requires prompt action and good communication between various clinical specialties, diagnostic laboratories and Blood Transfusion Laboratory staff. Involvement with specialist coagulation either by agreed replacement protocols or bespoke advice will allow the optimal use of blood product and pharmacological agents.

Thromboprophylaxis should be given after major haemorrhage and should be started as soon as possible after bleeding ceases.

There are specific procedures for obtaining blood in an emergency for neonatal patients and these are displayed locally within the relevant clinical areas as a controlled document.

The major haemorrhage protocols are currently going through a PDSA cycle to update them with work ongoing. At present the documents listed below remain fit for purpose but are due to be updated once the PDSA cycles have been completed. The changes include one number to activate the major haemorrhage, both in hours and out of hours.

EU Major Haemorrhage EU MHP

EU Synbiotix EU synbiotix activation

Major haemorrhage UHW wards - CI-BLD-2MassTxGeneral.doc

Obstetric major haemorrhage - Major Haemorrhage Obstetric.pptx

Major haemorrhage UHW X-Ray CI-BLD-2MassTxXray.docx

Cardiac theatre/CITU CI-BLD-2MassTxCardiac.doc

UHW theatre/ICU CI-BLD-2MassTxThICU.doc

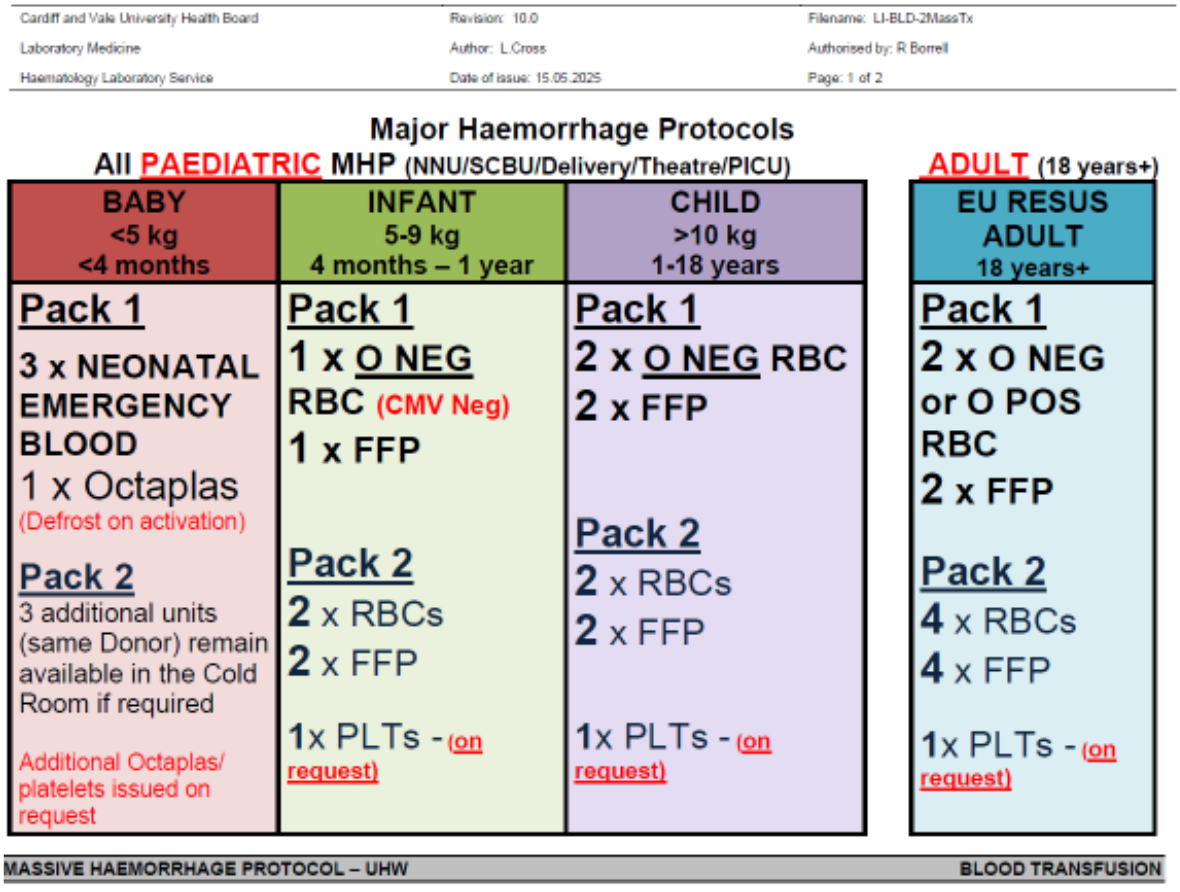
Paediatric Major Haemorrhage Paediatric Major Haemorrhage

Synbiotix MHP Synbiotix activation MHP

Major haemorrhage UHL MHP UHL

Blood components provided during major haemorrhage's are listed below.

These amounts may change due to availability of components from the Welsh Blood Service.



Cardiff and Vale University Health Board | Revision: 10.0 | Filename: LI-BLD-2MassTx
Laboratory Medicine | Author: L.Cross | Authorised by: R Borrell
Haematology Laboratory Service | Date of issue: 15.05.2025 | Page: 1 of 2

Major Haemorrhage Protocols

All PAEDIATRIC MHP (NNU/SCBU/Delivery/Theatre/PICU)

BABY <5 kg <4 months	INFANT 5-9 kg 4 months – 1 year	CHILD >10 kg 1-18 years	ADULT (18 years+) EU RESUS ADULT 18 years+
Pack 1 3 x NEONATAL EMERGENCY BLOOD 1 x Octaplas (Defrost on activation) **Pack 2** 3 additional units (same Donor) remain available in the Cold Room if required Additional Octaplas/ platelets issued on request	**Pack 1** 1 x O NEG RBC (CMV Neg) 1 x FFP **Pack 2** 2 x RBCs 2 x FFP 1x PLTs - (on request)	**Pack 1** 2 x O NEG RBC 2 x FFP **Pack 2** 2 x RBCs 2 x FFP 1x PLTs - (on request)	**Pack 1** 2 x O NEG or O POS RBC 2 x FFP **Pack 2** 4 x RBCs 4 x FFP 1x PLTs - (on request)

MASSIVE HAEMORRHAGE PROTOCOL – UHW BLOOD TRANSFUSION

Other ADULT Major Haemorrhage Protocols

General Wards including Main Theatres, ITUG	Obstetrics	Cardiac Theatres & CITU
6 x RBCs (2 in a bag) 4 will remain in the issue fridge, until required **4** x FFP (on request)	**MHP IMMEDIATE** **6** x RBCs (2 in a bag) 4 will remain in the issue fridge until required **MHP ON HOLD** **6** x RBCs (All in the issue fridge) **4** x FFP	**6** x RBCs (2 in a bag) 4 will remain in the issue fridge until required **4** x FFP (on request) **1** x Platelets (on request)
ALL requests for Fibrinogen in MHP situation (adult or paeds) – DO NOT require Haem SpR authorisation		

Appendix 7: ORDERING URGENT BLOOD/COMPONENTS

There may be occasions in non-bleeding patients where blood is required urgently but not as a major haemorrhage. In patients presenting with Hb <60g/l it is recommended that the patient is reviewed immediately and a clinical decision made regarding the urgency of transfusion. If blood/components are required urgently the BTL (UHW - ext. 42157, Bleep 5268, UHL - ext. 25389, Bleep 4844) should be contacted by the requesting clinician as soon as possible indicating the blood/component and quantity required and the level of urgency. Discussion can then take place between clinician and BTL regarding the appropriate blood/component to be provided. The time that the blood products will be available should be agreed (i.e. 3.30pm not in 2 hours). Verbal communication is vital, do not rely on the blood form stating ASAP.

The preferred working practice is for the doctor to then send a request form urgently to the BTL; if, due to the nature of the emergency, this is not a viable option, a verbal request can be taken over the telephone. The verbal request must include:

Patient's Full Name (first and surname)
Date of Birth
Hospital number or NHS Number
Gender
Patient Location
Component required and quantity
Contact details for requesting doctor

All difficult names should be spelled out phonetically to avoid confusion. These details must be read back to the person making the request for their confirmation.

If the patient is admitted as an emergency and their demographic details are unknown the verbal request or request form must contain:

Emergency Number
Phonic Name
Estimated DOB
Gender
Patient Location
Component required and quantity
Contact details for requesting doctor

Collection of blood/components in an emergency

In an emergency the porter/collector still needs patient details to ensure the right component is collected for the right patient. This can be done either by:

1. Clinical staff entering patient details onto synbiotix and calling porter to highlight the urgency of request
2. Request porter to collect a blood collection slip from the clinical area in UHL via synbiotix and give patient details over the phone
3. Clinical staff can come directly to the BTL; however, they **must** come with full patient details.

Details required:

Patient's Full Name (first and surname)
Date of Birth
Hospital number or NHS Number
Patient Location
Component required and quantity

If details are taken via telephone, the portering supervisor will record the details appropriately on the synbiotix system and then read them back to double check that they have the correct information. The portering supervisor will then allocate the task as soon as possible to the next available porter. The information will be given to the porter, and the porter will repeat the information given to them.

Any difficult names should be spelled out phonetically to avoid confusion.

If the patient is admitted as an emergency and their demographic details are unknown the verbal request or collection slip must contain:

Emergency Number
Phonic Name
Estimated DOB
Gender
Patient Location
Component required and quantity
Contact details for requesting doctor

If a current blood group and antibody screen (G&S) is not available an appropriately labelled sample must be brought promptly to the BTL.

It is a clinical decision to transfuse blood components when there has been insufficient time to complete full compatibility testing, and this may result in

adverse events (immediate or delayed transfusion reactions) as the patient may have unidentified antibodies.

O RhD Negative and O RhD Positive units

A stock of O RhD negative blood for emergency use is maintained by the BTL at UHW and UHL. This must only be used when delay in transfusion will jeopardise the patient's life.
Women of childbearing potential must have RhD negative blood issued until their RhD type is determined. If such patients are found to be RhD positive, R1R1, K- blood should be issued. If possible, until their c antigen is known.
Women without childbearing potential and males may have RhD positive blood in life threatening, major haemorrhage situations.

ABO and RhD group specific uncrossmatched units

On receipt of the sample blood can be issued which is ABO and RhD group specific uncrossmatched within 15 minutes. This preserves the stock of O RhD negative blood.

Fully compatible (cross matched) units

If the patient has not had a recent blood group and antibody screen request, blood can be issued in emergency situations with a minimum turnaround time of 60 minutes of the BTL receiving a correctly labelled sample if the antibody screen is negative (The BTL must be informed by the clinical area of the urgency).

Patients with atypical antibodies

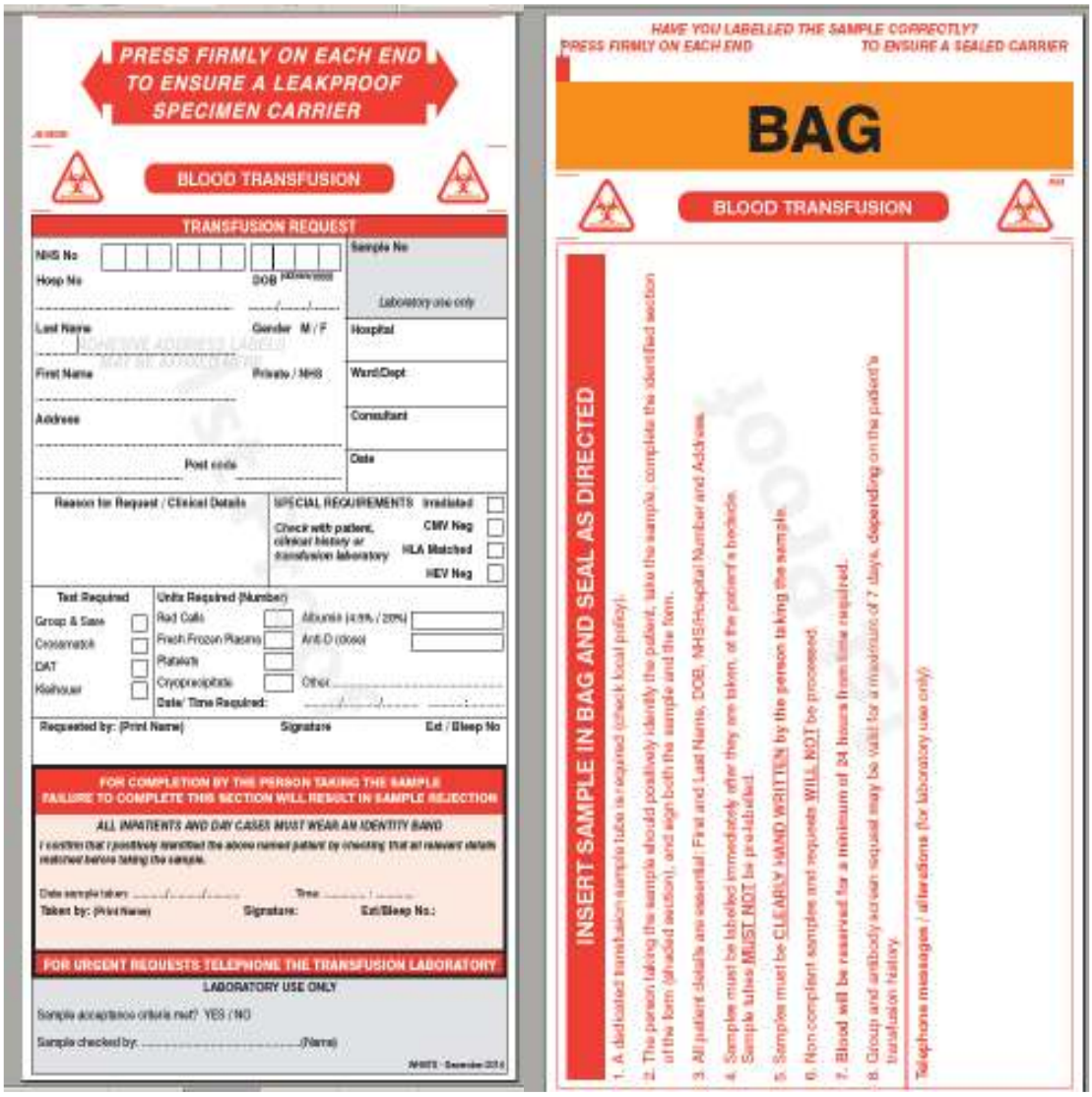
The patient's plasma is screened to identify any atypical red cell antibodies of potential clinical significance. These usually occur after sensitising events and are directed against other blood group antigens (e.g. Kell, Duffy, Kidd) on the surface of red cells. If such antibodies are identified every effort is made to provide blood which is negative for the corresponding antigen to avoid the risk of haemolytic transfusion reactions. This is a time-consuming process and will delay the provision of blood. If a patient should need blood urgently the Consultant Haematologist can advise on the severity of risk if blood is given that is not fully compatible. This risk must be balanced with the risk of delaying transfusion and previously highlighted under complex antibodies complex antibodies

The BTL must be informed of any changes to the patient's clinical condition that may be significant to their transfusion requirements.

Platelets may be issued immediately on a confirmed blood group, but it should be noted that the availability of this resource is limited, and they may need to be ordered from the WBS. If additional Fresh Frozen Plasma (FFP) is required, it should be noted it takes 20 minutes to thaw.

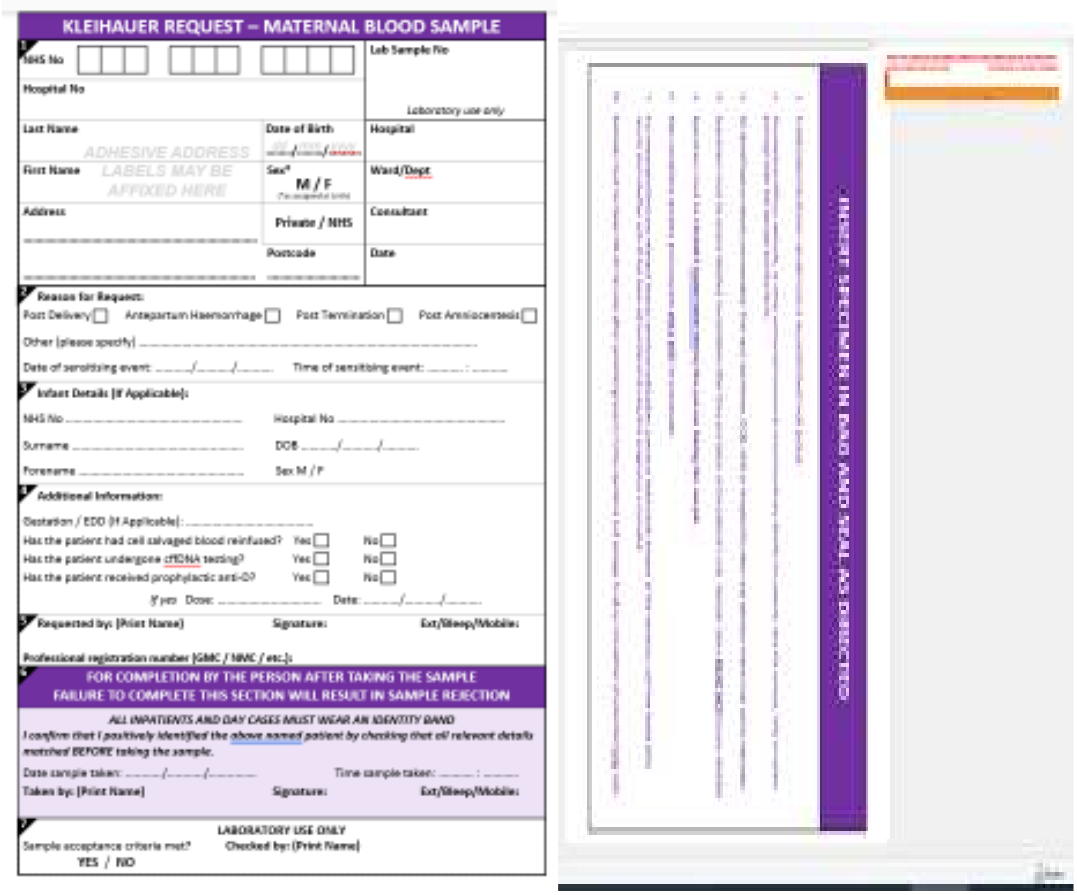
Appendix 8 – Transfusion Documentation

Examples of Transfusion Request/Kleihauer form. All versions available within the UHB




PRESS FIRMLY ON EACH END TO ENSURE A LEAKPROOF SPECIMEN CARRIER
BLOOD TRANSFUSION
TRANSFUSION REQUEST – BLOOD SAMPLE
BLOOD TRANSFUSION
INDICATION CODES FOR TRANSFUSION IN ADULTS (NBTC 2024)

Kleihauer Request form



KLEIHAUER REQUEST – MATERNAL BLOOD SAMPLE

NHS No | Lab Sample No | Laboratory use only

Hospital No

Last Name | Date of Birth | Hospital

ADHESIVE ADDRESS LABELS MAY BE AFFIXED HERE

First Name | Sex* M / F | Ward/Dept

Address | Private / NHS | Consultant

Postcode | Date

Reason for Request:

Post Delivery ☐ Antepartum Haemorrhage ☐ Post Termination ☐ Post Amniocentesis ☐

Other (please specify) .....

Date of sensitising event: ...../...../..... Time of sensitising event: ..... : .....

Infant Details (If Applicable):

NHS No ..... Hospital No .....

Surname ..... DOB ...../...../.....

Forename ..... Sex M / F

Additional Information:

Gestation / EDD (If Applicable): .....

Has the patient had cell salvaged blood reinfused? Yes ☐ No ☐

Has the patient undergone cffDNA testing? Yes ☐ No ☐

Has the patient received prophylactic anti-D? Yes ☐ No ☐

If yes Dose: ..... Date: ...../...../.....

Requested by: (Print Name) Signature: Ext/Bleep/Mobile:

Professional registration number (GMC / NMC / etc.):

FOR COMPLETION BY THE PERSON AFTER TAKING THE SAMPLE
FAILURE TO COMPLETE THIS SECTION WILL RESULT IN SAMPLE REJECTION

ALL INPATIENTS AND DAY CASES MUST WEAR AN IDENTITY BAND

I confirm that I positively identified the above named patient by checking that all relevant details matched BEFORE taking the sample.

Date sample taken: ...../...../..... Time sample taken: ..... : .....

Taken by: (Print Name) Signature: Ext/Bleep/Mobile:

LABORATORY USE ONLY

Sample acceptance criteria met? YES / NO Checked by: (Print Name)

INSERT SPECIMEN IN BAG AND SEAL AS DIRECTED

Completion of Transfusion Request Form

Transfusion Request Form

To request a blood component for transfusion the hospital transfusion laboratory (HTL) must receive a correctly labelled pre-transfusion venous blood sample and correctly completed transfusion request form.

Even if emergency blood components are being used, a pre-transfusion sample and request form must still be taken and completed, and sent to the HTL.

The transfusion request form fulfils several needs

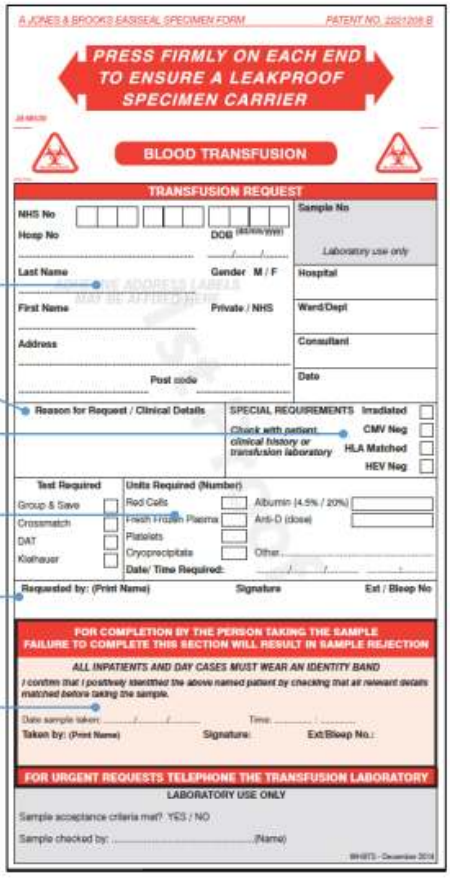
- It acts as a prompt for the person making the request as to the information required
- It provides a written instruction to another person (e.g. phlebotomist) to take the sample
- It provides the HTL with important information about the patient and the reason for the request
- This information may have a bearing on the type of blood component issued
- It constitutes a record of the transfusion request.

Filling out the transfusion request form

- Addressograph label may be used on the form
- 'Reason for Request / Clinical Details' must be completed with all relevant information
- It is the requesters responsibility to identify any special requirements, and indicate on this form
- Only if 'Crossmatch' is required do the number of units required need to be indicated
- Requester contact details are required in case the laboratory need further information.

Completing the transfusion request form

- The declaration must be completed after the sample has been taken


A JONES & BROOKS EASISEAL SPECIMEN FORM PATENT NO. 2321208 B

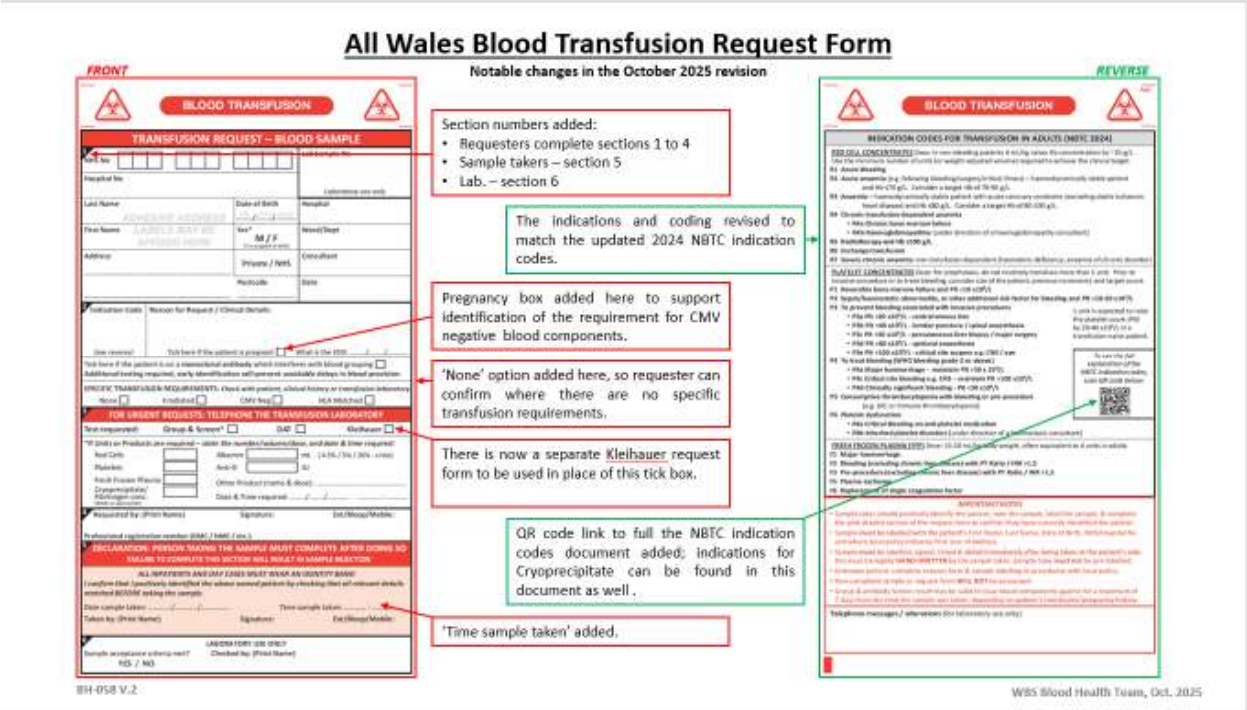
PRESS FIRMLY ON EACH END TO ENSURE A LEAKPROOF SPECIMEN CARRIER

BLOOD TRANSFUSION

TRANSFUSION REQUEST

NHS No
Hosp No
DOB (dd/mm/yyyy)
Sample No
Laboratory use only
Last Name
Gender M / F
Hospital
First Name
Private / NHS
Ward/Dept
Address
Consultant
Post code
Date
Reason for Request / Clinical Details
SPECIAL REQUIREMENTS Irradiated
Check with patient clinical history or transfusion laboratory
CMV Neg
HLA Matched
HEV Neg
Test Required
Units Required (Number)
Group & Save
Red Cells
Albumin (4.5% / 20%)
Crossmatch
Fresh Frozen Plasma
Anti-D (dose)
DAT
Platelets
Kleihauer
Cryoprecipitate
Other
Date/ Time Required:
Requested by: (Print Name)
Signature
Ext / Bleep No
FOR COMPLETION BY THE PERSON TAKING THE SAMPLE
FAILURE TO COMPLETE THIS SECTION WILL RESULT IN SAMPLE REJECTION
ALL INPATIENTS AND DAY CASES MUST WEAR AN IDENTITY BAND
I confirm that I positively identified the above named patient by checking that all relevant details matched before taking the sample.
Date sample taken: Time:
Taken by: (Print Name)
Signature:
Ext/Bleep No.:
FOR URGENT REQUESTS TELEPHONE THE TRANSFUSION LABORATORY
LABORATORY USE ONLY
Sample acceptance criteria met? YES / NO
Sample checked by: (Name)

It is essential that all of the information on the request form is accurate and up to date. The person completing the request form is taking responsibility for this, and in part for the suitability of the blood components supply from the request/sample.


All Wales Blood Transfusion Request Form
Notable changes in the October 2025 revision
FRONT
REVERSE
BLOOD TRANSFUSION
TRANSFUSION REQUEST – BLOOD SAMPLE
Section numbers added:
• Requesters complete sections 1 to 4
• Sample takers – section 5
• Lab. – section 6
The indications and coding revised to match the updated 2024 NBTC indication codes.
Pregnancy box added here to support identification of the requirement for CMV negative blood components.
'None' option added here, so requester can confirm where there are no specific transfusion requirements.
There is now a separate Kleihauer request form to be used in place of this tick box.
QR code link to full the NBTC indication codes document added; indications for Cryoprecipitate can be found in this document as well.
'Time sample taken' added.
BH-058 V.2
WBS Blood Health Team, Oct. 2025

TO ENSURE A LEAKPROOF SPECIMEN CARRIER

BLOOD TRANSFUSION

TRANSFUSION REQUEST

NHS No

Hosp No

DOB (dd/mm/yyyy)

Sample No

Laboratory use only

Last Name

Gender M / F

ADHESIVE ADDRESS LABELS MAY BE AFFIXED HERE

Hospital

First Name

Private / NHS

Ward/Dept

Address

Consultant

Post code

Date

Reason for Request / Clinical Details

SPECIAL REQUIREMENTS

Check with patient, clinical history or transfusion laboratory

Irradiated

CMV Neg

HLA Matched

HEV Neg

Test Required

Group & Save

Crossmatch

DAT

Kleihauer

Units Required (Number)

Red Cells

Fresh Frozen Plasma

Platelets

Cryoprecipitate

Albumin (4.5% / 20%)

Anti-D (dose)

Other.....

Date/ Time Required: ...../...../..... ...../.....

Requested by: (Print Name)

Signature

Ext / Bleep No

FOR COMPLETION BY THE PERSON TAKING THE SAMPLE
FAILURE TO COMPLETE THIS SECTION WILL RESULT IN SAMPLE REJECTION

ALL INPATIENTS AND DAY CASES MUST WEAR AN IDENTITY BAND

I confirm that I positively identified the above named patient by checking that all relevant details matched before taking the sample.

Date sample taken: ...../...../..... Time: ...../.....

Taken by: (Print Name)

Signature:

Ext/Bleep No.:

FOR URGENT REQUESTS TELEPHONE THE TRANSFUSION LABORATORY

LABORATORY USE ONLY

Sample acceptance criteria met? YES / NO

Sample checked by: (Name)

For example it is not sufficient to say 'pre – op' as that gives the laboratory no relevant history.

However 'pre-op, laparotomy AAA repair, Hodgkin's lymphoma' or 'pre-op – renal biopsy pregnant' or 'pregnant 36/52 weeks C-section'.

Key Words:

Pregnant

Hodgkin's lymphoma

On purine analogues (fludarabine, cladribine, deoxycoformicin, bendamustine)

On alemtuzumab

On myeloma drugs (Daratumamab)

Bone Marrow Transplant (BMT)

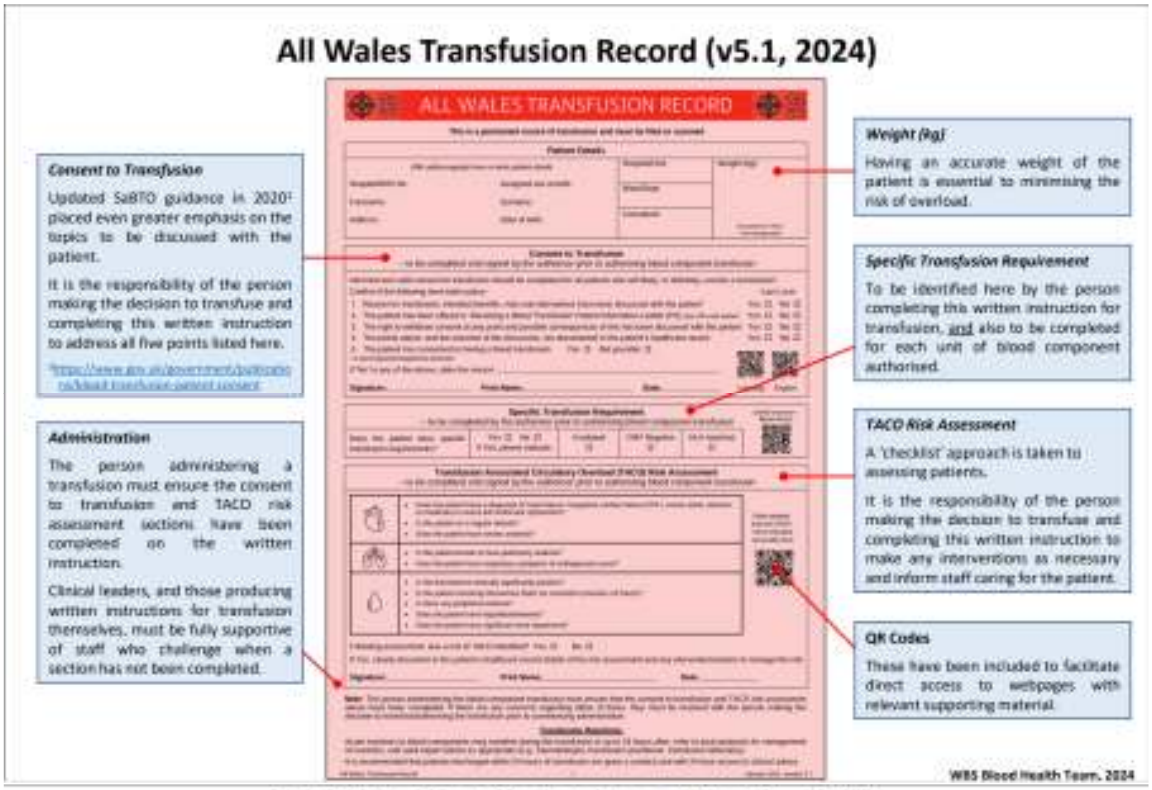
Solid Organ Transplant

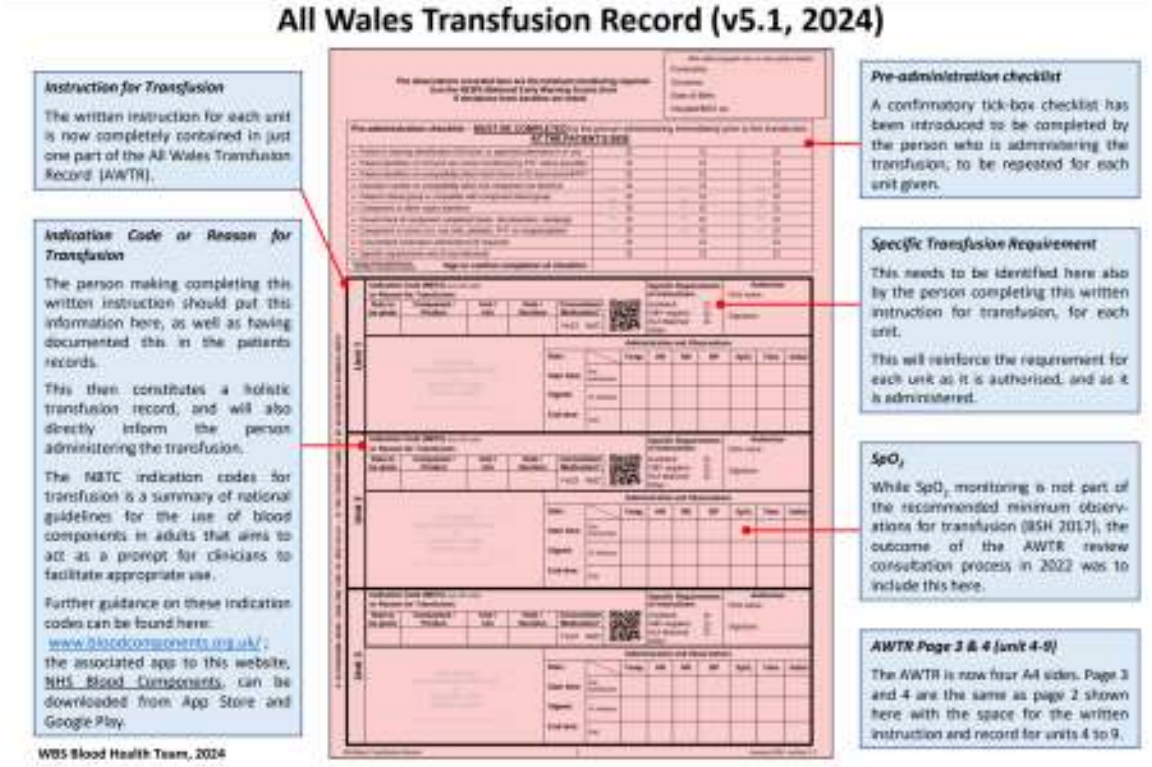
Anti-thymocyte globulin (ATG) treatment

Intrauterine transfusion

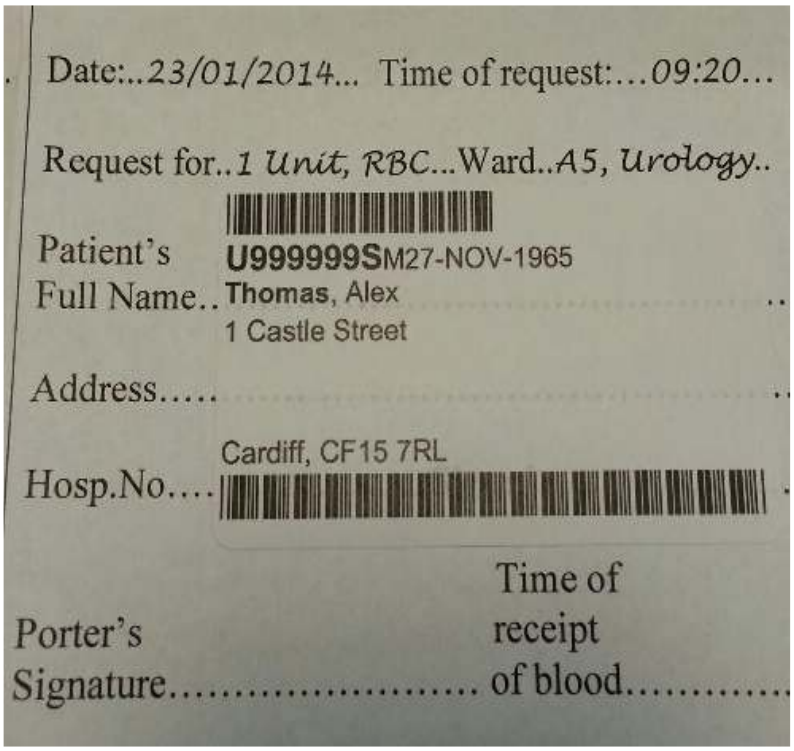
Neonatal transfusion

All Wales Transfusion Record AWTR

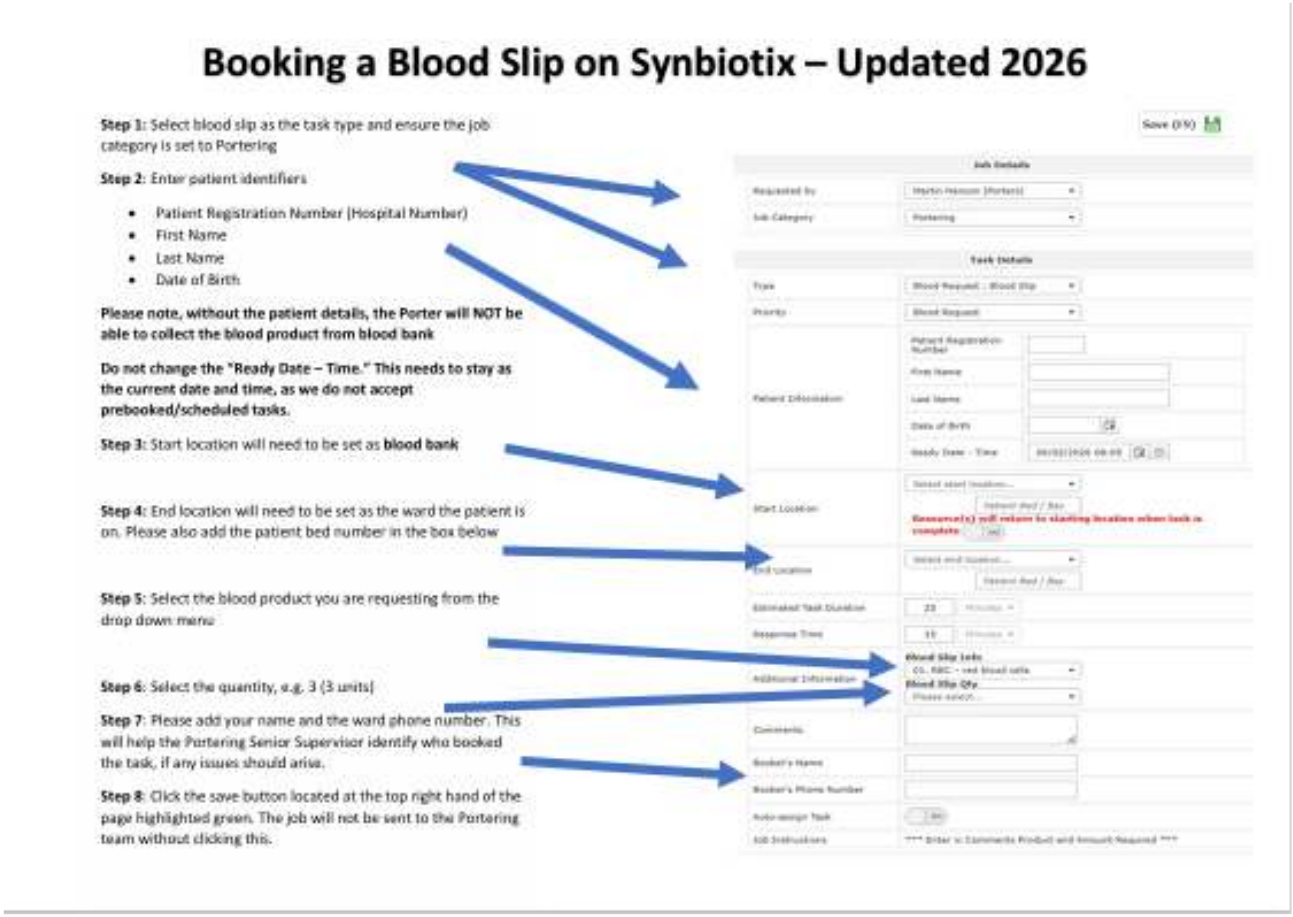




Example of a Porter/Collection Slip (fictious patient for illustrative purposes only)



Example of blood request via Synbiotix

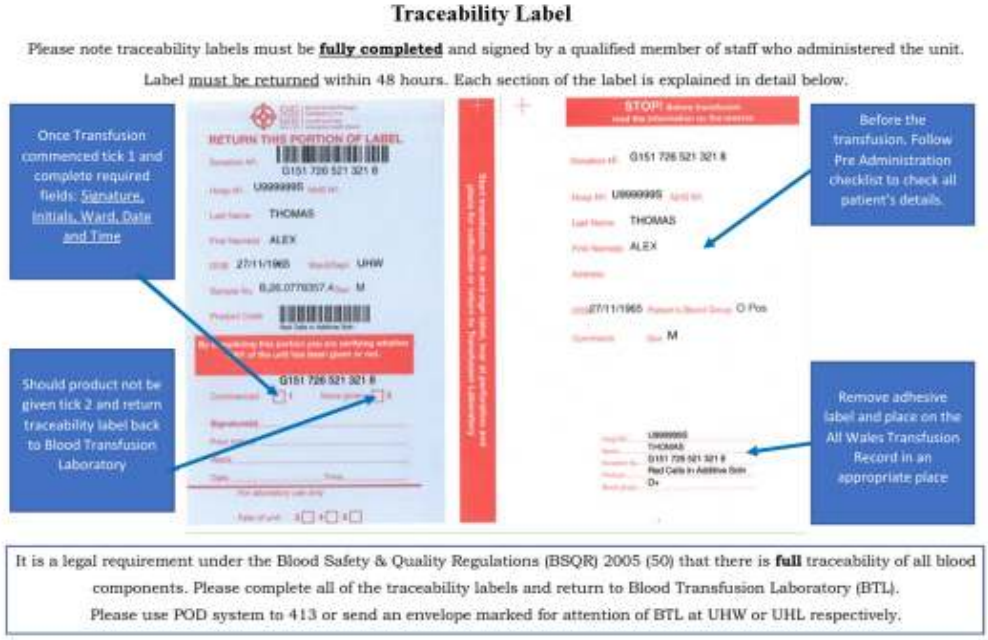


Traceability Labels.

Please be aware that the Blood Safety & Quality Regulations (BSQR) 2005 (50) states that NHS Trusts will –

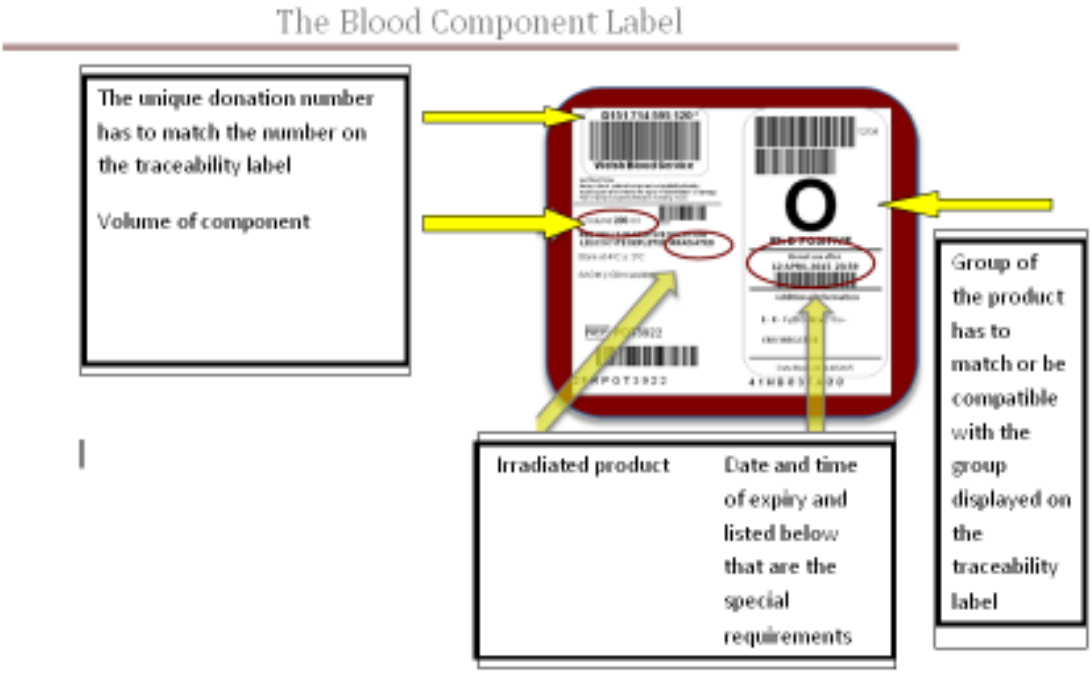
"Maintain, for not less than 30 years, the data needed for full traceability of blood or blood components".

Clinical area (ward staff) responsibilities:



Return all completed traceability labels via internal mail, specimen round or POD system.

Blood Transfusion Bag and What it means



Appendix 9 – Sample Acceptance Criteria

The first part of the request form MUST contain the following details/an addressograph is preferable:

- First name
- Last name
- Date of birth
- Hospital/NHS number
- Name and signature of requesting doctor/nominated deputy

Other fields to be completed on the form in line with best practice, the absence of which would not exclude the sample from being processed:

- Gender
- Location (e.g. ward)
- Consultant
- Date that the blood sample was requested
- Ext/Bleep number of the requester
- Reason for transfusion/relevant transfusion history
- Number and type of blood components required (if any)
- The date and time that blood components are required

Request forms with incomplete or illegible patient details are not suitable for processing and will result in rejection and a new sample requested.

Patient Identification Declaration:

Positive patient identification is essential and the person taking the pre-transfusion sample is responsible for the completion of the second/middle part of the request form. The signature on this part of the form and on the sample confirms that the person signing has followed the correct procedure and they accept responsibility that the sample was taken from the patient identified on the request form.

In accordance with best practice, the person taking the sample must print their name and add their signature. However, if only a legible signature is available (but the identity of the individual who took sample can be determined), and this is comparable to the signature on the sample, then this is deemed acceptable. The date the sample was taken must also be indicated on the form.

Pre Transfusion Sample

The person taking the sample must handwrite the sample label legibly immediately after the sample is taken, beside the patient. Labelling for each patient should be completed before the next patient is bled. Sample labels must

never be filled in before the specimen is drawn, as this is a leading cause of transfusion accidents.

<u>The Sample must contain</u>

First name
Last name
Hospital number
Date of birth
Signature of phlebotomist
Ward
Gender
Date
Time bled

Signature on the sample bottle must match the signature on the declaration on the pre transfusion sampling form.

Cardiff and Vale University Health Board	Revision: 3.0	Filename: EI-BLD-ZeroTolAccept
Laboratory Medicine	Author: L.Parkinson	Authorised by: L. Cross
Haematology Laboratory Service	Date of issue: 29/05/2026	Page: 1 of 1

BLOOD TRANSFUSION LABORATORY

Quality Requirements for Pre-transfusion Samples

Request Form	Sample	Accept	Reject	Reason for acceptance or rejection
123123 Anne Jones 01/01/2001 Meadowbank	*123123* *Ann Jones* *01/01/2001* *Meadowbank*	√		1st name spelling mistake is acceptable as long as it is the same name.
123456 Anne Joyce-Jones 12/12/88 1 High Street	*123456* *Anne Joyce Jones* *12/12/88* *1 High Street*		√	Hyphenated on form not on sample
123123 Anne Elizabeth Jones 01/01/2001 Meadowbank	*123123* *Anne Jones* *01/01/2001* *Meadowbank*	√		The dataset only requires 1st and last name
123123 Anne Elizabeth Jones 01/01/2001 Meadowbank	*123123* *Anne Jones* *01/11/2001* *Meadowbank*		√	Difference in DOB
123123 Anne Jones 01/01/2001 Flat 1 Meadowbank Swansea	*123123* *Anne Jones* *01/01/2001* *Flat 1*	√		1st line of address is **NOT** required on the **sample or form**
123123 Anne Jones 01/01/2001 Meadowbank Swansea	*123123* *Anne Jones* *01/01/2001* *Swansea*	√		1st line of address is **NOT** required on the **sample or form**
G123123S Anne Jones 01/01/2001 Meadowbank	*123123* *Anne Jones* *01/01/2001* *Meadowbank*		√	Hospital number not identical
123123 Anne Jones 01/01/2001 Meadowbank	*123123* *Anne Jones* *01/01/2001* *Meadowbank*	√		Different writings are acceptable – responsibility lies with person signing sample
123123 Margaret Jones 01/01/2001 Meadowbank	*123123* *Mgt Jones* *01/01/2001* *Meadowbank*		√	1st name different. Abbreviations not accepted.

QUALITY REQUIREMENTS FOR PRE-TRANSFUSION SAMPLES

Appendix 10 – Transfusion Reaction

This appendix is an aid to the recognition and immediate management of transfusion reactions [17].

Transfusion reactions tend to occur shortly after the transfusion has commenced. Ensuring that the transfusion observations (i.e. pre-transfusion, 15 minutes into the transfusion and post-transfusion) are accurately monitored, documented and acted upon is crucial.

Acute haemolytic or bacterial transfusion reactions:

Clinical characteristics:
These are reactions with high morbidity which may occur after only a small volume of blood has been transfused. They may result from acute haemolysis (e.g. from ABO mismatch) or, more rarely, bacterial contamination. It can be difficult to tell these apart immediately. In an unconscious patient hypotension, bleeding due to DIC and oliguria may be the only signs. ABO mismatched transfusions are usually due to human error – either at the time the patient is bled for a pre-transfusion sample, in the laboratory or when the blood is given.

Aids to recognition:

- Reaction usually occurs soon after the transfusion is started
- Patient feels unwell, agitated
- Pain at infusion site, and/or back pain
- Shortness of breath
- Fever, rigors
- Hypotension
- Bleeding from wounds or venepuncture sites
- Haemoglobinuria

SHOT further define acute haemolytic transfusion reactions as being a fever and other symptoms/signs of haemolysis within 24 hours of transfusion that is confirmed by a fall in Hb, rise in Lactate Dehydrogenase (LDH), positive Direct Antiglobulin Test (DAT) and positive compatibility test.

Action:

- Discontinue the transfusion immediately
- Perform observations, temperature, pulse, blood pressure and respiratory rate.
- Detach the giving set from the cannula. Leave the intravenous (I.V.) cannula in situ and attach a 500 mL bag of 0.9% saline.

- Recheck the bag traceability label against the information on the bag identifier and patient's wristband (check the patient identification details on the laboratory samples also).
    - Inform the on-call clinical consultant responsible for the patient.
    - Notify the BTL and the on-call clinical haematologist

Take blood for:

- FBC, plasma, haemoglobin (1 x EDTA bottle)
- Repeat blood group, DAT, antibody screen (1 x G&S bottle)
- Coagulation screen (including fibrinogen, thrombin, and Fibrinogen Degradation Products (FDPs), (1 x citrate bottle)
- Urea and Electrolytes (U&Es), Liver Function Tests (LFTs) and creatinine (1 x clotted bottle)
- Blood cultures
- Urinalysis
- A compatibility test using pre- and post-transfusion samples will also be required

Further action to be taken:

- Resuscitate the patient promptly – include broad-spectrum antibiotics. Consider immediate referral to critical care.
- Cap the giving set with a sterile bung to prevent leakage. Take great care not to contaminate the blood pack whilst doing this. Return the blood pack to the BTL for initial investigation via the porters. The BTL will then send the blood pack to Microbiology for continued investigations.
- Monitor urine output and ECG (observe for evidence of hyperkalaemia)
- Repeat FBC, coagulation screen and U&E 2 – 4 hourly until stable
- Observe the patient for evidence of increased red cell destruction; fall in Hb, rise in LDH, Bilirubin (LFTs), haemoglobinuria
- Also observe the patient for evidence of disseminated intravascular coagulation (DIC). A coagulation screen including fibrinogen, thrombin time and FDPs is required

Anaphylaxis:

Clinical characteristics:
Bronchospasm and circulatory collapse due to anaphylaxis may occur soon after transfusion commences. It may also be seen in IgA deficient patients reacting to transfused IgA. SHOT define an anaphylactic reaction as being hypotension with one or more of the following: rash, dyspnoea, stridor, wheezing, angioedema, pruritis, urticaria during or within 24 hours of transfusion.

Action:

- Discontinue the transfusion immediately; detach the giving set from the cannula. Leave the I.V. cannula in situ and attach a bag of 0.9% saline.
- Maintain the airway and give oxygen.
- Inform the on-call clinical consultant responsible for the patient.
- Notify the BTL and contact the on-call clinical haematologist

The treatment of anaphylaxis will need to be urgently implemented and may include general resuscitative measures including administration of oxygen, nebulisers, adrenaline, chlorphenamine and hydrocortisone.

The IgA level and anti-IgA should be measured. If the patient is IgA deficient, any further transfusion must be planned carefully.

Other investigations that should be carried out are a chest x-ray (CXR) if the patient is dyspnoeic to exclude Transfusion Related Acute Lung Injury (TRALI) and mast-cell tryptase. This is a clotted sample to be sent in an SST yellow-top bottle. It must be sent as close to the event as possible; 3 hours post-event and 24 hours post-event to biochemistry.

Non-haemolytic febrile transfusion reactions (NHFTR):

Clinical characteristics:

- Usually occur > 30 minutes after starting the transfusion
- Patient feels fairly well but may be shivering
- Temperature usually < 38.5 ^{o}C; BP normal

Action:

Stop transfusion and assess the possibility that this may be a more serious reaction. If no features of a more serious reaction are present, restart the transfusion at a slower rate. Consider the use of paracetamol.

Minor febrile reactions are less common following leucodepletion which now occurs at source. Haematology advice should be sought if the reactions are recurrent, or if a more severe reaction is suspected. Hydrocortisone should not be given routinely before transfusions.

Allergic Reactions:

Allergic reactions are also common and usually consist of urticaria and itching which may begin shortly after the transfusion starts. They usually resolve if the transfusion is slowed and Chlorphenamine is given in patients who are not thrombocytopenic. The transfusion may be continued if there is no progression of symptoms after 30 minutes. No further action is generally indicated if there are no features of a more serious reaction.

The length of time the transfusion has been paused should be considered to ensure the giving set/I.V. access is patent.

Transfusion Associated Circulatory Overload (TACO):

This may occur particularly in older patients or those with poor cardiac function if too much fluid is given too quickly, or low body weight patients. It usually presents as respiratory distress secondary to pulmonary oedema. Treatment usually includes I.V. Furosemide and oxygen. Oral Furosemide (e.g. 20 mg) can be given with alternate bags of blood to elderly patients as prophylaxis.

Transfusion Related Acute Lung Injury (TRALI):

Clinical characteristics:
Acute lung injury may result following the transfusion of plasma or plasma-containing blood components, due to the interaction of donor antibodies with recipient white cells (reactions between recipient plasma and donor white cells may also occur). This may resemble adult respiratory distress syndrome (ARDS) and is most likely to occur up to 6 hours post transfusion.

Aids to recognition are:

- Respiratory compromise occurring post-transfusion without other obvious cause
- Fever, cough and shortness of breath
- Hypoxaemia
- CXR showing bilateral lung field shadows

SHOT define TRALI as acute dyspnoea with hypoxia and bilateral pulmonary infiltrates during or within 6 hours of transfusion, not due to circulatory overload or other likely cause.

Action:

- Treat as for respiratory distress syndrome with respiratory support as appropriate
- Inform the on-call clinical consultant responsible for the patient

- Notify the BTL and contact the on-call clinical haematologist to plan investigation and management
- Laboratory investigations will need to include investigation of donor HLA and HNA antibody status; finding of cognate antigen in the patient and lymphocytotoxic compatibility testing and granulocyte compatibility testing if a patient sample is available

Delayed Haemolytic Transfusion Reactions (DHTR):

SHOT defines DHTR as fever and other symptoms/signs of haemolysis more than 24 hours after transfusion. This will be confirmed by a fall in Hb, rise in Bilirubin, positive DAT and positive compatibility testing not detectable pre-transfusion. Simple serological reactions (development of antibody without positive DAT or evidence of haemolysis) are excluded.

Clinical characteristics:

- Usually occurs 5 – 10 days after transfusion
- Patient may be febrile
- There may be an unexplained drop in haemoglobin, jaundice and urobilinogenuria

Action:

- Request FBC, reticulocyte count, U&E, LFTs, DAT, red cell antibody screen
- Compatibility testing using pre- and post-transfusion samples if available
- Inform the on-call clinical consultant responsible for the patient
- Notify the BTL and contact the on-call clinical haematologist to plan management
- Observe the patient for evidence of increased red cell destruction; fall in Hb, rise in LDH, Bilirubin

Transfusion Associated Graft-versus-Host Disease (TA-GvHD)

Clinical characteristics:

Transfusion of non-irradiated blood or platelets to patients who are either immuno-compromised or have a similar HLA type to the donor can cause a severe form of graft-versus-host disease with high mortality. This usually occurs 1 – 6 weeks after transfusion.

- Unexplained fever
- Rash
- Abnormal liver function
- Diarrhoea
- Pancytopenia

Action:

- Notify the BTL and the on-call clinical haematologist to plan management

Post Transfusion Purpura:

SHOT define this as thrombocytopenia within 12 days after transfusion of red cells, associated with presence in the patient of antibodies directed against the HPA systems.

Action:

- Notify the BTL and contact the on-call clinical haematologist to plan management
- Investigations will need to include a platelet count, coagulation screen to exclude DIC as a cause of thrombocytopenia and HPA typing and HPA antibodies

Transfusion transmitted virus infections

Clinical characteristics
These are now rare, but notification to the BTL and onward to the supplying blood service is important to trace the donor if this occurs. Symptoms depend on the virus and may include jaundice, malaise and rash. Such transfusion transmitted infections usually occur weeks or months post-transfusion.

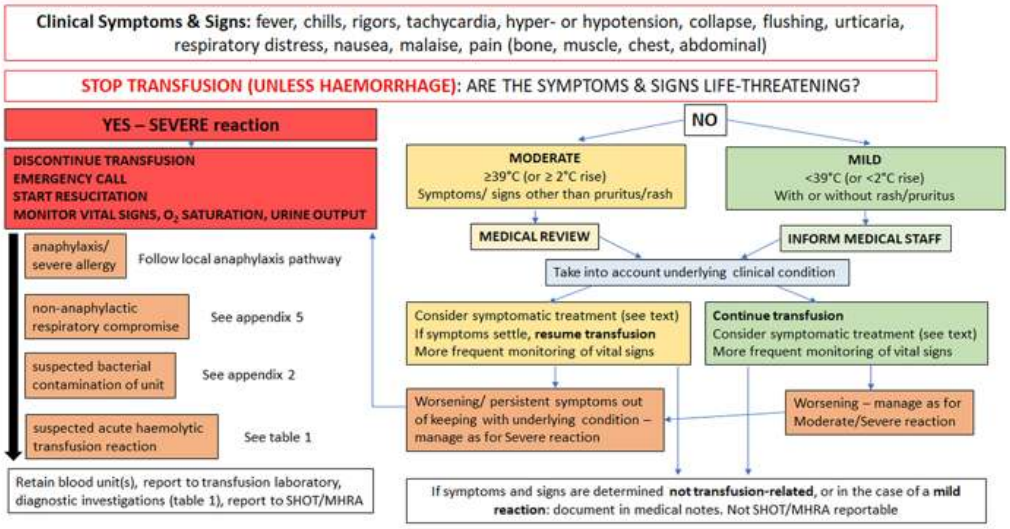
Action:

- Notify the BTL immediately
- Refer as appropriate for management of viral infection

Further advice can be obtained here

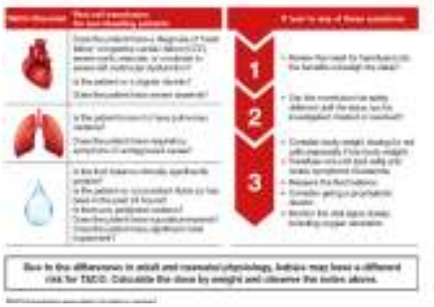
Guidance from BSH Guidelines for transfusion reaction[17]

Guideline on the investigation and management of acute transfusion reactions



Br J Haematol, Volume: 201, Issue: 5, Pages: 832-844, First published: 26 April 2023, DOI: (10.1111/bjh.18789)

SHOT TACO checklist – this is included in the AWTR



SHOT (2023) [18]

Appendix 11 Satellite Fridge

When blood is transported from the main BTL fridge to the satellite fridge it must be accompanied by the Blood Transfusion Issue Record.

The blood must be 'received' at the satellite fridge to confirm the 'cold chain' audit trail. This is done by completing the appropriate section on the Blood Transfusion Issue Record.

Only staff that have been annually trained and competency assessed, in line with NPSA SPN 14, may receive or remove blood from a satellite fridge. All staff trained and assessed as competent to access the satellite fridge will be clearly identified on the authorised user list placed on the front of the fridge door. Currently, this list is controlled by the Transfusion Practitioner Team using document control.

Patient identity must be properly confirmed when blood is withdrawn from the satellite fridge. This can be done with a correctly completed patient's All Wales Transfusion Record or with a collection slip with the following information: (Addressograph labels are acceptable and recommended on collection slips)

- First name
- Last name
- Gender
- Date of Birth
- Hospital number (NHS Number)
- Location (e.g. Ward)

The details on the collection slip (or patient's notes), the traceability label and the bag identifier must be checked against the Blood Transfusion Issue Record when the blood is collected. The Blood Transfusion Issue Record must be signed and the time and date the blood was taken recorded. Units of blood should be taken one at a time from the satellite fridge, as they are required. The team member collecting the blood must ensure the 'cold chain' audit trail is complete before use, if in doubt the BTL must be informed. Care should be taken to ensure that the fridge door is properly shut after blood has been removed.

In the event of the fridge alarm sounding or other fridge failure, the appropriate local protocol should be followed immediately. In case of any doubt, or if the reason for the fridge failure is not clear, the BTL must be contacted immediately.

Any clinical area with a satellite fridge is expected to comply with the relevant SLA, Standard Operating Procedures and Blood and Component Transfusion

Policy. Compliance to the relevant agreements and procedure/policy documents will be audited. It is imperative that clinical areas responsible for a satellite fridge understand the importance of compliance to the BSQR (SI 2005 No. 50 as amended) [4] and appreciate the impact of non-compliance to the Regulations.

Appendix 12 – Refusal of Blood/Components and Products

Some patients may prefer to be treated without the use of blood components and products. This may either be due to personal preference relating to public health concerns or religious convictions, i.e. Jehovah's Witnesses.

A competent adult (i.e. a person aged 16 years and over) with capacity has the right to refuse medical treatment. If the decision to refuse treatment appears to have been made with undue influence or if the patient is a child ('Gillick competent' or not) advice should be sought. Refer to the Consent Policy.

If the patient (aged 18 years and over) has made a valid and applicable advance decision to refuse blood products, and then loses capacity, the advance decision will be legally binding on staff

Communication

It must be communicated widely to appropriate members of the healthcare once it is known that a patient prefers not to, or refuses to, be treated with blood components and products, or if the patient has made an advance decision. Good communication and planning are essential in the management of such patients. Appropriate staff would include
Surgical, Obstetric or Medical consultant
Anaesthetists
Haematologist

Member of the Hospital liaison committee for Jehovah's Witnesses (contact details are available from the Transfusion Practitioner or BTL or switchboard)

Obstetric patients must be referred to specialist Obstetric/Haematology joint clinic after the 12-week booking clinic

Documentation

A comprehensive discussion about the patient's wishes must take place and be documented fully in the medical records. This must include information specifically as to what the patient will accept and refuse as there is some individual variation around specific products (ie. fibrinogen concentrate, cell salvage).

The UHB 'Jehovah's Witnesses checklist for Adults' available at should be used and be communicated to all relevant staff

There should be clear documentation of discussion with the patient/family regarding the risks (short and long-term), benefits and alternatives to proposed interventions.

Investigation

A careful personal and family history of bleeding is essential

Consider carefully the use of anti-platelets agents such as aspirin or anticoagulants such as the apixaban which increase the risk of bleeding

The use if prophylactic anticoagulation may need to be reviewed

While unnecessary blood sampling should be avoided and the use paediatric tubes used if ongoing sampling is required, the initial base line blood tests should be taken

FBC and reticulocyte count
Iron studies
B12 and folate
Coagulation screen
U+Es, LFTs and a Bone Profile
Group and Screen

Elective Surgery

Pre-admission assessment should occur at least 6 weeks prior to the operation (may not be possible in elective cancer surgery) in order to optimise.

Cardio-respiratory function
Optimise Haemoglobin
Plan optimal intraoperative management

A comprehensive care plan should be drawn up taking into consideration the risk factors, including a completed check list and then employing an optimal combination of alternative strategies. The care plan should be discussed before admission with the patient, who may wish to be accompanied by a relative or a representative of the Hospital Liaison Committee for Jehovah's Witnesses.

Optimisation of Haemoglobin

The decision to use EPO must be made by a consultant Haematologist and the team responsible for the patient following an assessment of benefits vs risks of side effects

- The use of EPO pre-operatively can be considered for patients with Hb <130g/l who are at risk of significant blood loss during their procedure
- The first dose should be given 3 weeks before surgery and the last dose on the day of surgery. If sufficient response is seen after the 2nd or 3rd dose, then subsequent doses should be omitted. EPO should not be initiated in patients with a baseline Hb>130g/l as there may be an increased risk of post-op thrombotic events. EPO must be stopped if Hb>150g/l. Caution is advised using EPO in older patients >70 years.
- EPO is relatively contra-indicated in patients who have any of the following: Uncontrolled hypertension, severe coronary, peripheral arterial, carotid or cerebrovascular disease (increased thrombotic risk as PCV increased). Recent MI or CVA within one month; unstable angina; previous history of thrombosis.

- EPO should be used with caution in patients who have any of the following: Raised platelets, hypertension, epilepsy, chronic liver failure, pregnancy and lactation, malignancy.
- Examples of dosage regimes include: Epoetin alfa or epoetin zeta given subcutaneously: 600 units/kg once a week for 3 weeks before surgery (and on day of surgery) or 300 units/kg daily for 15 days starting 10 days before surgery
- EPO is ineffective if the patient is deficient in iron, vitamin B12 or folate. If baseline ferritin is <100, IV iron should be administered. Ferritin levels inevitably fall in all patients receiving EPO therapy. Patients with baseline ferritin >100 should be prescribed oral iron (ferrous sulphate 200mg tds). If oral iron is not tolerated or ferritin falls<100 despite oral iron, IV iron should be prescribed.
- Patients must have the standard screening blood tests and during EPO treatment the FBC must be checked at least weekly
- Potential EPO side effects include hypertension, flu-like symptoms, mild pain on injection site, pure red cell aplasia, stroke and thrombosis.

Optimal Intraoperative management

It is essential that all available and reasonable steps are taken to reduce blood loss. Where appropriate these may include

- Operative approaches or techniques that can minimise the loss of blood, such as laparoscopic rather than open surgery, interventional radiology, staged procedures and the use of vasoconstrictors, tourniquet and clamps to stem blood flow
- The appropriate the use of controlled hypotension and/or deliberative controlled hypothermia
- The use of intraoperative cell salvage and cell salvage via wound drainage
- The use of normovolaemic haemodilution.
- The use of coagulation stimulants such as tranexamic acid, recombinant clotting factors (such as fibrinogen concentrate), topical haemostatic agents (tissue sealants/adhesives) and desmopressin
- The use of haemostatic aids, diathermy, harmonic scalpels and radiofrequency ablation
- Use of minimum intraoperative blood samples

Emergency Surgery

The same principles apply as above, though preoperative optimisation will not be possible. It is essential that there is early clarification of the products that the patient will accept (using the UHB ‘Jehovah’s Witnesses checklist for Adults’), initial investigations are undertaken including the rationale of any antiplatelet/anticoagulant medication and early discussion with all relevant clinical teams. The consent process must be clearly documented. A proactive approach is essential.

Post-operative management
Once haemostasis is controlled recheck FBC and iron status

- Hb >100g/l Consider oral iron replacement for 6 weeks
- Hb 70 – 100g/l Consider IV or oral depending on symptoms and comorbidities
- Hb <70g/l Consider IV iron and EPO therapy

If IV iron and/or EPO are considered discussion with haematology is recommended

Jehovah's Witness checklist for Adults (pre-op)
Jehovah's Witness Antenatal checklist

Refusal of Blood Documentation for completion here

PATIENTS WHO LACK CAPACITY TO CONSENT TO TREATMENT

Where patients aged 16 years and over lack capacity to consent to or refuse treatment, the Mental Capacity Act 2005 and its accompanying Code of Practice must be followed.

Staff need to be aware that any patient (aged 18 years and over) may have

- Made an advance decision to refuse blood or blood products
- made a Lasting Power of Attorney, giving another person (or persons) the power to take decisions about treatment
- a Court appointed Deputy (although this is rare) with the power to take decisions about treatment

For further information about the Mental Capacity Act, please see the Mental Capacity page on the intranet.

Appendix 13
Blood Components Apps Available for download

Blood Components App

The Blood Component Indication App summarises relevant national transfusion guidelines for adults, children and neonates.

Developed by the NHS Blood and Transplant, to act as a prompt to facilitate appropriate use of blood components and assist with the use of indication codes.

The App is available to download free on Apple and Android devices by searching 'blood components' on App store or Google Play.

Special Requirements for Transfusion App

The Special Requirments for Transfusion decision support tool provides information on patients groups that have special transfusion requirements (irradiated, CMV-), in line with current published recommendations.

Developed by learnPro Ltd., you will need you a learnbloodtransfusion (learnPro) login username and password to open this App.

The App is available to download free on Apple and Android devices by searching 'learn blood' on App store or Google Play.

Additional advice can be obtained on our sharepoint page here

LIST OF ABBREVIATIONS

APTT – Activated partial thromboplastin time

AWTR – All Wales Transfusion Record

BSH – British Society for Haematology

BSQR – Blood Safety and Quality Regulations

BTL – Blood Transfusion Laboratory

CMV neg – Cytomegalovirus negative

FBC – Full Blood Count

FFP – Fresh Frozen Plasma

GMP – Good Manufacturing Practice

HLA – Human Leucocyte Antigen

HTT – Hospital Transfusion Team

MHRA – Medicines and Healthcare products Regulatory Agency

NHS – National Health Service

NPSA – National Patient Safety Agency

PT – Prothrombin Time

QMS – Quality Management System

D – Rh D antigen

SPN – Safer Practice Notice

UHB – University Health Board

WBS – Welsh Blood Service

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