CONTROLLED DOCUMENT

Blood Transfusion Policy

CATEGORY:	Policy
CLASSIFICATION:	Clinical
PURPOSE:	The policy describes the framework and principles required to deliver best transfusion practice
Controlled Document Number:	014
Version Number:	7.1
Controlled Document Sponsor:	Chief Medical Officer
Controlled Document Lead:	Chair of the Hospital Transfusion Group
Approved By:	Chief Executive
On:	16th December 2020
Review Date:	16th December 2023
Distribution: • **Essential Reading for:** • **Information for:**	All staff involved in the transfusion process

Contents

1 Policy Statement and Objectives

The purpose of this policy and its associated documents is to ensure that University Hospitals Birmingham NHS Foundation Trust (the 'Trust') delivers all aspects of the transfusion process safely. This will be achieved through the following objectives which ensure the Trust complies with The Blood Safety and Quality Regulations 2005 (BSQR 2005).

1.1 **Procurement and Provision:** Materials used in blood transfusion are appropriately procured, stored and are available on a timely basis.

1.2 **Training**: All members of staff who are involved in the transfusion process must be trained and competency assessed according to the Trust's blood transfusion procedures specific to their role.

1.3 **Minimising the use of blood:** Patients who may require transfusion are optimised to minimise the need for allogeneic blood whilst ensuring the best clinical outcome.

1.4 **Ensuring rapid provision of blood when clinically appropriate:** Transfusion of red cells, plasma, platelets and cryoprecipitate must be supplied within pre-determined time frames for transfusion to patients with life-threatening haemorrhage.

1.5 **Minimising the risks associated with transfusion:** Blood transfusion carries significant risks and the clinical team responsible for the patient must adhere to the trust procedures for managing a patient undergoing transfusion to ensure that a risk and benefit assessment has been completed and the right blood is administered to the right patient at the right time for the right reason.

1.6 **Consent:** Informed consent is obtained prior to transfusion.

1.7 **Adverse events:** All incidents occurring during the transfusion process are reported, reviewed, investigated, followed up and lessons learned.

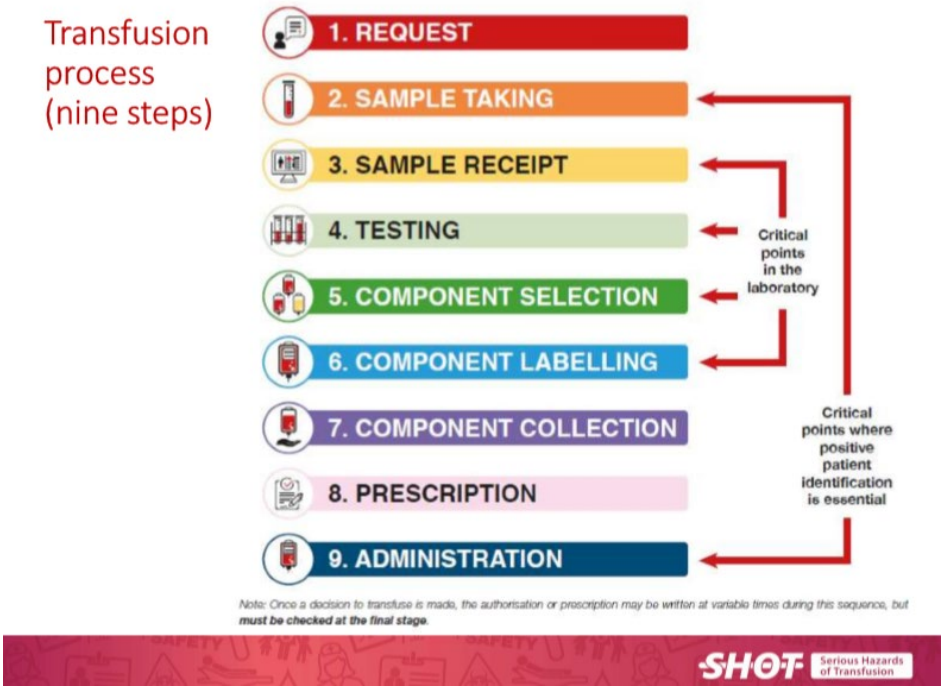
2 Scope

The policy applies to all members of staff including students, locums, bank and agency staff and staff employed on honorary contracts who are involved at any stage of the transfusion process in the Trust, on or off the premises.

3 Definitions

Term	Definition
ACP	Advanced Clinical Practitioners
AP	Advanced Practitioner
BHH	Birmingham Heartlands Hospital
BMS	Biomedical Scientist
BSQR	Blood Safety and Quality Regulations (2005)
CCLfT	Consultant clinical lead for transfusion
EBMG	Emergency Blood Management Group
GHH	Good Hope Hospital
HCA	Healthcare Assistant
HCP	Healthcare Practitioner
HTG	Hospital Transfusion Group (Nationally referred to as Hospital Transfusion Committee)
HTT	Hospital Transfusion Teams
IQC	Internal Quality Control
LTP	Lead Transfusion Practitioners
MHRA	Medicines and Healthcare Products Regulatory Agency
MLA	Medical Laboratory Assistant
MSW	Midwifery Support Worker
MW	Midwife
NA	Nurse Associate
NEQAS	National External Quality Assessment Service
NMA	Non-Medical Authoriser
ODA	Operating Department Assistant/Orderly
ODP	Operating Department Practitioner
PA	Physician Associate
QEHB	Queen Elizabeth Hospital
QMM	Quality Management Meeting
SH	Solihull Hospital
TLM	Transfusion Laboratory Manager
TP	Transfusion Practitioners
TSW	Theatre Support Worker
UKAS	United Kingdom Accreditation Service

The Transfusion Process



4 Legal Framework

BSQR (2005) set the standards for quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components. Aspects of the regulations apply to 'blood establishments' (the UK Blood Services) and hospital transfusion laboratories. The Blood Safety and Quality (amendment) Regulations 2006/2013 further amend the BSQR 2005 (SI 2005/50) ("the principal regulations") to make a number of changes to the provisions governing the operation of hospital transfusion laboratories. These changes relate specifically to traceability requirements and notification of adverse reactions and events and introduce community standards and specifications relating to a quality system for blood establishments. The MHRA inspect using the BSQR and issue a license to the Trust transfusion laboratory to issue blood, only if the regulatory requirements are met.

The Trust has specific duties under the following sections of BSQR 2005 and discharges them through the application of this policy:

Section 9:	Hospital blood bank requirements
Section 10:	Requirement for hospital blood banks to provide information to the Secretary of State
Section 11:	Service of notices relating to hospital blood banks
Section 14:	Disclosure of information by blood establishments and hospital blood banks
Section 15:	Inspections, etc.
Part 4:	Storage, transport and distribution conditions for blood and blood components

Part 5: Quality and safety requirements for blood and blood components.

5 Assurance Provision

Assurance regarding compliance with this policy will be provided by the chair of the HTG to the Trust board, as set down in their duties. This takes the form of a biannual report summarising the information set down in the monitoring criteria in Appendix A. The full monitoring requirements, leads, process and timeframes are set down in Appendix A.

6 Policy Framework and Standards

This section describes the broad framework for the Blood Transfusion Policy. Detailed instructions are provided in the associated procedural documents. The HTG shall approve all Trust controlled documents associated with this policy, and any amendments to such documents, and is responsible for ensuring that such documents are compliant with this policy. The chair of the HTG shall provide final written confirmation that the document has been approved.

Documents originating outside of the hospital transfusion team but relating to any part of the transfusion process will be presented to the HTG for approval.

6.1 Procurement and Provision

Standard 1
Materials used in Blood Transfusion must be appropriately procured, stored and be available on a timely basis. **Monitoring 1-5**

The Procurement and Provision is carried out as follows

6.1.1 Procurement of Blood Components

Laboratory Services on behalf of the Trust are responsible for the procurement of blood components. Such materials will only be procured from organisations that comply fully with the United Kingdom BSQR (2005). Blood components will ordinarily only be procured from NHS Blood and Transplant, with the exception of imported pooled solvent detergent frozen plasma (Octaplas).

6.1.2 Procurement and Maintenance of Blood Storage Devices

Procurement
The procurement and validation to BSQR of all blood storage devices is managed by the HTTs. Replacement of existing devices and purchase of new equipment is managed through laboratory change controls. The TLMs are responsible for ensuring all procured equipment complies with BSQR.

Requests for purchasing satellite blood storage devices must be made via the HTT, who will assess the need for this additional equipment to be procured, installed and maintained, and will make a recommendation to the HTG where a final decision will be made. Following successful application, the HTT will assist the requesting department with implementation.

Maintenance
Periodic preventative maintenance, reactive maintenance and associated temperature monitoring and mapping of blood storage devices and compliance with BSQR is managed by the HTTs. This may involve third party companies who are required to hold the relevant UKAS accreditation.

The Head BMS is responsible for ensuring maintenance of all laboratory equipment and blood storage devices used in the transfusion process complies with BSQR.

6.1.3 Procurement of articles used in the administration of blood

Ordering of equipment (such as but not limited to pumps or blood warmers) and disposables used for the administration of blood components is the responsibility of the clinical area where the blood is administered. These will be ordered through the Trust's procurement team. The HTT will advise whether particular items are suitable for use and with which blood components.

6.1.4 Provision of appropriate blood components

The transfusion laboratory will provide the most appropriate blood component based on the patient's requirements, current stock availability and urgency.

The Clinician responsible for each patient's care will provide the necessary clinical information in order to inform the transfusion laboratory's choice of component.

Full traceability is a requirement of BSQR. The clinician administering the component is responsible for recording the use of the specific blood component and returning traceability information as detailed in the procedures for administration of blood components.

6.1.5 Supply of blood in times of shortage

When an emergency situation occurs and the supply of blood is likely to be outstripped by demand, the Emergency Blood Management Group will be activated in accordance with the Emergency Blood

Management Plan. The circumstances under which the EBMP is activated, responsibilities of the transfusion team, site and executive teams and functions of the EMBG are set down in the EBMP.

6.1.6 Monitoring of cold chain

Blood is collected and transported correctly from blood storage devices and administered to the patient or placed back into blood storage devices within agreed timeframes, as outlined in the procedures for administration of blood components and procedure for collection of blood components. This is a requirement of the BSQR and components for which appropriate storage cannot be verified will be discarded.

6.1.7 Laboratories

The transfusion Laboratories are run in accordance with BSQR 2005 as enforced by MHRA and are accredited to ISO 15189:2012 by UKAS. Periodic inspections will be carried out by UKAS and short notice non-periodic inspections will be carried out by MHRA; all areas of the Trust will co-operate with these.

6.2 Training

Standard 2

All members of staff who are involved in the transfusion process must be trained and competency assessed to the Trust's blood transfusion procedures specific to their role.

Monitoring 6

The specific training required for clinical staff is set down in the blood transfusion role specific training needs analysis (Appendix B). The training needs analysis for laboratory staff is managed via the laboratory quality management system based on the role and grade of the staff member.

6.3 Minimising the need for Blood

Standard 3

Patients who may need blood transfusion are optimised to minimise the need for allogeneic blood whilst ensuring the best clinical outcome.

Monitoring 7

All patients identified as at risk of needing a blood transfusion must be assessed by medical staff or HCPs working to the expanded practice protocol to authorise blood components.

The HTG oversee the implementation of patient blood management recommendations, including the 2015 Blood Transfusion NICE Guidelines (NG24). Directions from the HTG are actioned by the HTTs and may include the development of Trust guidelines and monitoring of compliance to such guidelines. This will include diagnosis and treatment of anaemia, thrombocytopenia and deranged coagulation so as to avoid transfusion where there are appropriate alternatives.

6.4 Ensuring rapid provision of blood when clinically appropriate

Standard 4

Transfusion of red cells, plasma, platelets and cryoprecipitate must be supplied within pre-determined time frames for transfusion to patients with life-threatening haemorrhage.

Monitoring 8-10

The procedure for provision of blood to patients with life-threatening haemorrhage is laid down in the Major Haemorrhage Procedure.

Blood components for use in an emergency for patients of unknown blood group are in limited supply and the Trust has a responsibility to ensure their judicious use.

The TLMs are responsible for ensuring the laboratory services support appropriate blood use by way of appropriate laboratory procedures for rapid issue of blood, strategic storage of suitable blood at locations around the Trust and rapid processing of samples for patients with life-threatening haemorrhage.

The HTG is responsible for ensuring appropriate procedures are in place to guide appropriate use, training to these procedures is undertaken and for monitoring their use. This may include reporting back to NHS Blood and Transplant.

6.5 **Minimising the risks associated with transfusion**

Standard 5
Blood transfusion carries significant risks and the clinical team responsible for the patient must adhere to the Trust procedures for managing a patient undergoing transfusion to ensure that a risk and benefit assessment has been completed and the right blood is administered to the right patient at the right time for the right reason.

Monitoring 11-14

All patients for whom a blood transfusion is felt to be clinically indicated must be assessed by medical staff or HCPs working to the expanded practice protocol to authorise blood components. They must conduct and document a risk and benefit analysis as part of the decision to transfuse which must be documented in the patient record. All staff involved in the transfusion process must be trained in, and adhere to, the Trust transfusion procedures listed in this document in order to minimise the risks associated with any transfusion given.

Patients must be accurately identified as set down in the Trust Patient Identification Policy to ensure their identity is correctly assigned and this identity is confirmed at every stage of the transfusion process.

Staff performing any part of the transfusion process must adhere to the Trust procedure for the element they are performing.

6.6 **Consent**

Standard 6
Informed consent is obtained prior to transfusion.

Monitoring 15 & 16

Informed patient consent must be obtained and clearly documented in the patient's clinical record before any transfusion takes place. Where the patient is unable to consent the clinician must ensure that no advance decision is in place precluding the use of blood components and enter into the patient's notes the decision to transfuse being made in the patient's best interest.

The patient has the right to consent to or decline a transfusion which should occur following discussion with a healthcare professional competent in consent for blood transfusion.

The Trust's Consent to examination/treatment policy sets out guidance on consent and should be used in conjunction with the risks benefits and alternatives detailed in the procedure for prescribing and requesting blood. Specific guidance for the management of patients who decline blood transfusion for any reason, including on religious grounds, is described in the

procedure for management of the refusal of blood components including the care of Jehovah's Witnesses.

6.7 Adverse events

Standard 7
All incidents occurring during the transfusion process are reported, reviewed, investigated, followed up and lessons learned.

Monitoring 17

All incidents during the blood transfusion process must be reported on the Trust's incident reporting system.

All incidents, including near misses, relating to the blood transfusion process are investigated by TPs and reviewed by LTPs with clinical support from the transfusion consultants as needed. Significant or recurring issues are escalated to the HTTs and reviewed by the HTG (which includes representation from the Clinical Risk and Patient Safety Team) on a quarterly basis. Incidents reported to the HTG must include all NHS England Never Events, any incidents that have triggered a Trust Root Cause Analysis, any Serious Adverse Events and Reactions as defined by the MHRA and any incidents linked by recurrent themes or evolving trends. Inclusion of incidents in the latter categories will be at the discretion of the lead TP and transfusion consultant.

Serious Adverse Events and Reactions as set down by the MHRA are also reported by the LTPs and TLMs (or delegated to sufficiently qualified professionals) to MHRA as part of the Trust's licence conditions and SHOT as a voluntary contribution.

The unintentional transfusion of ABO-incompatible blood components is an NHS England Never Event and must be escalated immediately according to the Trust's incident reporting policy. Members of the HTTs and HTG will co-operate with any investigations undertaken by the Trust relating to transfusion incidents.

The HTTs and HTG will make recommendations based on information presented in the incident reports, in order to reduce the risk of further incidents. These will be enacted by the HTTs.

Transfusion related incidents and any subsequent actions are presented to Clinical Quality Management Group on a 6th monthly basis by the chair of the HTG or a nominated deputy.

7 Duties

7.1 Chair of the HTG

7.1.1 Providing assurance to the Board that blood transfusion is carried out across the Trust according to the policy.

7.1.2 Ensuring that the HTG is conducted according to the Terms of Reference.

7.1.3 Receiving assurance from the Clinical Service Lead for Laboratory Haematology, or the CCLfT, that the actions of HTG/HTT have been implemented.

7.1.4 Approving all procedural documents associated with this policy and introducing and ensuring appropriate changes in practice.

7.1.5 Reporting to and feeding back from the Regional Transfusion Committee as appropriate in relation to the activities of the HTG.

7.2 Site Directors, General Managers, Clinical Service Leads, Site Directors of Nursing, Matrons and Supervisors of Midwives

7.2.1 Incorporating the Blood Transfusion Policy and its associated procedures into Trust working practices.

7.2.2 Ensuring staff implement and adhere to the policy and the associated procedures.

7.2.3 Ensuring protected time is allocated for staff to attend training for transfusion as per the Blood Transfusion Role Specific Training Needs Analysis.

7.2.4 Supporting the implementation of clinical guidelines relating to blood transfusion and in line with this policy.

7.3 Chairs of the Hospital Transfusion Teams (HTTs)

7.3.1 Ensuring the HTT is conducted according to the Terms of Reference.

7.3.2 Oversee the day to day implementation of this policy.

7.3.3 Ensuring the HTT enact the instructions of the HTG.

7.3.4 Report the actions of the HTT to the HTG. This may be delegated to the appropriate HTT members.

7.4 Clinical Service Lead for Laboratory Haematology

Has overall clinical responsibility for implementing the actions of the HTG/HTTs, which may be delegated to the CCLfT.

7.5 Consultant Clinical Leads for Transfusion

The Trust has two Consultant Clinical Leads for Transfusion; one covering QEHB and one covering BHH, GHH and SH sites.

The appropriate lead provides day to day direction of the service in association with the Head BMS, TLMs and other consultant haematologists and TPs. The CCLfT will usually be the chair of the HTT at the relevant site. CCLfT may provide oversight and supervision cross site when appropriate.

7.6 Individuals involved in the transfusion process

A detailed description of duties and responsibilities of individuals involved in each step of the transfusion process is set down in each specific Trust procedure.

8 Associated Policy and Procedural Documents

For all sites

- Procedure for Prescribing and Requesting Blood
- Procedure for obtaining a pre transfusion sample
- Procedure for the Management of Refusal of Blood Components and Products; including the care of Jehovah's Witnesses.
- Procedures for Administration of Blood Components
- Clinical Guideline for the management of transfusion reactions
- Emergency Blood Management Plan
- Policy for Patient Identification
- Major Haemorrhage Procedure and Urgent Transfusion
- Expanded practice protocol for Non-Medical Authorisation of blood components
- Clinical guideline for indications for transfusion of blood components
- Clinical guideline for the management of severe anaemia

The Queen Elizabeth Hospital site specific documents

- Procedure for Collection of Blood and Blood Components from blood storage devices

Heartlands, Good Hope and Solihull Hospitals site specific documents

- Procedure for Collection of Blood Components from blood bank/satellite fridges and incubators

9 References

Requirements for Training and Assessment in Blood Transfusion. National Blood Transfusion Committee. 2016.

Guidelines for Blood Transfusion. National Institute for Clinical Excellence. 2015

Patient Blood Management. National Blood Transfusion Committee. 2014.

Guidelines for the Blood Transfusion Services in the UK 8th Edition. Joint UKBTS/HPA Professional Advisory Committee. 2013. (BSQR (2005) guidelines)

The Impact of the Blood Safety and Quality Regulations 2005 on Hospital Transfusion Laboratories. NHS Operational Impact Group. 2005.

Never Events List – NHS Improvement 2018

Appendix A – Monitoring Matrix

	Monitoring Of Implementation	Monitoring Lead	Reported To	Monitoring Process	Monitoring Frequency
OVERARCHING ASSURANCE PROVISION					
An annual report to the Board of Directors by the Chair of the Transfusion Committee will summarise the findings below and provide overarching assurance.					
***STANDARD 1* - Procurement and Provision**					
1.	The transfusion laboratories function according to BSQR 2005	HBMSs CSL	Board HTG	Submission of Compliance Report and SABRE annual incidents reports.	Annual
		HBMSs CSL	Board	Monthly report to board meeting of traceability level for previous month.	Monthly
		TLMs	HTG	Datix completed for units failing to meet cold chain requirements and reported as wastage in the HTG incident report.	Quarterly
2.	Emergency blood management arrangements are established	Chair of HTG	HTG	Review following activation or as directed by the HTG.	As per activation
3.	Laboratory tests are quality controlled and assured to ensure consistent accuracy of results	TLMs	Board HTG	Participation in NEQAS quality assessment programs for transfusion laboratory practice.	Quarterly
			QMM	Twice daily IQC results reported to QMM.	Monthly
4.	The transfusion laboratories are practicing within scope for ISO 15189:2007 accreditation	Lead BMSs	Board	External audit conducted by UKAS.	Annually
5.	Appropriate blood is provided in a clinically acceptable timeframe	TLMs	HTG	Review of Datix reports of any avoidable delays to transfusion.	Quarterly
STANDARD 2 - Training					
6.	All members of staff who are involved in the transfusion process	LTPs	HTG	TPs identify clinical staff who need valid transfusion competency. Staff lacking valid competence are identified	Quarterly

	must be trained and competency assessed to the Trust's blood transfusion procedures specific to their role.			to managers. Compliance is reported to HTG.	
STANDARD 3 - Minimising the use of blood					
7.	Patients who may need blood transfusion are optimised to minimise the need for allogeneic blood whilst ensuring the best clinical outcome and authorisation and request of blood is performed according to procedure.	LTPs	HTG	Audit of records, to include a minimum number of non-medical authorisations in keeping with the number of non-medical authorisers practicing.	Annually
STANDARD 4 - MHP					
8.	Blood is issued within locally defined time periods as per SOP for each site.	TLMs	HTG Board	Turnaround times for urgent issue of blood components.	Quarterly
9.	Major haemorrhage protocols are managed according to the procedure	LTPs/TLMs	HTG	Summary of clinical review of Datix reports relating to MHP and activations occurring outside theatres, delivery unit ITU or ED.	Quarterly
10.	O D neg red cells are used appropriately	LTPs/TLMs	HTG	Ongoing audit of use of emergency units.	Quarterly
STANDARD 5 - Minimising the risks associated with transfusion					
11.	Transfusions are carried out safely and risks to the patient are minimised	LTPs	HTG	Review of Datix Incidents.	Quarterly
12.	Samples are obtained in line with the Trust Procedure for Sample Collection	LTPs	HTG	Witness audit – minimum 20 samples across all sites.	Annually

13.	Blood is collected from storage in line with the Trust Procedure for the Collection and Transport of Blood Components	LTPs	HTG	Witness audit – minimum 20 units across all sites.	Annually
14.	Blood is administered in line with the Trust Procedures for the Administration of Blood	LTPs	HTG	Witness audit – minimum 20 units across all sites.	Annually
STANDARD 6 - Consent					
15.	Consent for transfusion is taken and recorded according to procedure	LTPs	HTG	Audit of records – minimum 20 patients across all sites.	Annually
16.	Declaration for refusal of blood is taken and recorded according to procedure	LTPs	HTG	Audit of records – minimum 10 patients across all sites.	Annually
STANDARD 7 - Incidents					
17.	All incidents occurring during the transfusion process are reported, reviewed, investigated, followed up and lessons learned.	LTPs/TLMs	HTG	Summary of incidents and actions presented and discussed.	Quarterly
		CCLfT	CQMG	A six monthly report is presented at CQMG	6 monthly

Appendix B – Training needs Analysis

E-Learning

	Blood transfusion awareness	Obtaining a sample	Administration of blood components	Collecting and returning of blood components **(HGS only)**	Anti-D module
Anaesthetist	✓	✓	✓		
Doctor	✓	✓	✓*		✓*
PA	✓	✓	✓*/***		
AP	✓	✓	✓*	✓*	✓*
Registered Nurse/NA	✓*	✓*	✓*	✓*	✓*
MW	✓	✓	✓*	✓*	✓*
ODP	✓		✓*	✓*	
Perfusionist	✓	✓*	✓*	✓*	
HCA/MSW	✓*	✓*		✓*	
TSW/ODA	✓			✓*	
Phlebotomist	✓	✓			
Porter				✓	
Update Frequency	2 Yearly	2 Yearly	2 Yearly	2 Yearly	2 Yearly

Face to Face (may include virtual) Training Courses

	Transfusion request form Completion/ Special Requirements	Collection of Blood Components **(QE only)**	Preparation and Administration of Blood Components skills session	Cascade Trainer	Non-Medical Authorisation **(NHSBT Course)**
Anaesthetist	Induction (QE)		Induction		
Doctor	Induction				
PA	✓				
AP	✓*	✓*	✓*/***	✓*	✓*
Registered Nurse/NA	✓*	✓*	✓**	✓*	✓*
MW	✓*	✓*	✓**	✓*	✓*
ODP		✓*	✓	✓*	
Perfusionist			✓	✓*	
HCA/MSW		✓*			
TSW/ODA		✓			
Phlebotomist					
Porter		Induction			
Update Frequency		2 Yearly		Yearly	

* Role/Area dependant – Opt-in for training/competency

** Role/Area dependant – Opt-out of training/competency

*** Subject to introduction of statutory registration

Initial Competency Assessments

All sites	Obtaining a Sample	Collection of Blood Components	Preparation and Administration of Blood Components	Non-Medical Authorisation
Anaesthetist	✓		✓	
FY/ST Doctor	✓			
PA	✓			
AP	✓*	✓*	✓*/***	✓*/***
Registered Nurse/NA	✓*	✓*	✓**	✓*
MW	✓	✓*	✓*	✓*
ODP	✓	✓*	✓	
Perfusionist			✓	
HCA/MSW	✓*	✓*		
TSW/ODA		✓		
Phlebotomist	✓			
Porter		✓		
Update Frequency	One off	2 Yearly (QE) 1 off (HGS)	One off	One off

* Role/Area dependant – Opt-in for training/competency

** Role/Area dependant – Opt-out of training/competency

*** Subject to introduction of statutory registration