

Essential standards for safe transfusion in clinical IT systems

SHOT

Serious Hazards
of Transfusion

National
Blood Transfusion
Committee

Northern Ireland
Transfusion
Committee

BHNOG

Scottish National
Blood Transfusion
Committee

These standards have been endorsed
by the four national transfusion
committees across UK.

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Introduction and Purpose of this document

The purpose of this document is to define the essential standards for UK Information Technology (IT) systems that support safety-critical workflows in the clinical transfusion process. These workflows include, but are not limited to:

- Sample labelling
- Storage, collection and distribution of blood components
- Ordering of blood components and transfusion tests
- Authorisation (prescription) and administration of blood components
- Management of transfusion reactions

The standards are intended to ensure that IT systems used in these processes maintain patient safety and operational integrity.

Use of the term “essential standards”

In this document, the term ‘*essential standards*’ is used deliberately to denote requirements that are critical for patient safety. These should be regarded as mandatory (“must”) controls for safety-critical transfusion workflows. The writing group intentionally retained the term *standards* to emphasise their importance and to avoid dilution of their significance through alternative terminology.

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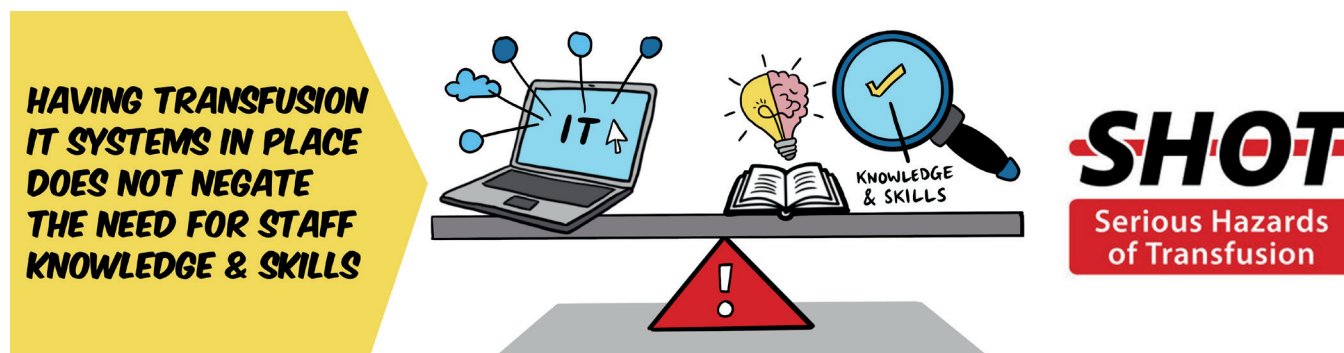
↔ Scope

This document applies to IT systems used in transfusion-related workflows, such as Electronic Patient Record (EPR) systems and Electronic Blood Management Systems (EBMS). The document excludes requirements specific to Laboratory Information Management Systems (LIMS) as these are already covered in other existing guidelines⁵). These standards apply to all healthcare establishments performing transfusion in the UK.

The standards are primarily aimed at:

- Suppliers: To guide the development of systems that meet essential safety requirements for transfusion workflows
- Purchasers: To support inclusion of these standards in User Requirement Specifications (URS) and procurement contracts for new systems
- Hospital Transfusion Teams: To use as a tool for assessing compliance and safety of existing systems

These standards represent a baseline for safety-critical functionality and do not replace national or local procurement guidelines or local SOPs or workflows.



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- Rachel Moss, Advanced Transfusion Practitioner, Great Ormond Street Hospital for Children NHS Foundation Trust

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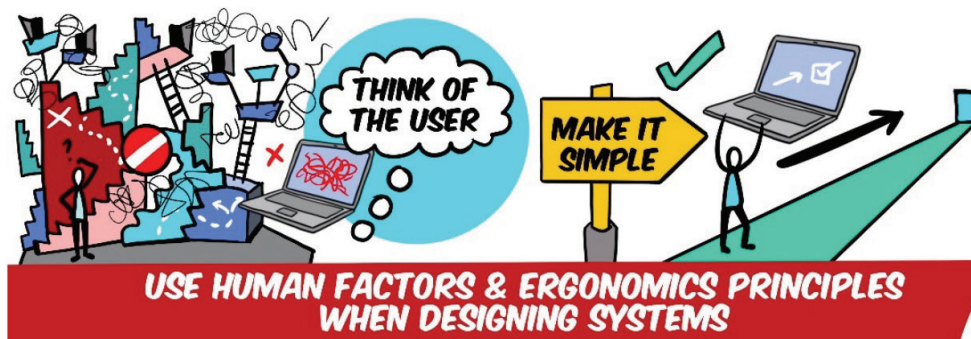
A note of thanks to all key stakeholders from across UK, including members of the Infected Blood Inquiry Recommendations Implementation Group focusing on improving transfusion-related digital systems for their valuable contributions and expert review of this document prior to its release.

The collective insights and rigorous review from all involved have strengthened the quality and applicability of these standards. Input from all key stakeholders have ensured that these standards reflect both clinical best practice and robust safety principles for transfusion-related IT systems.

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Disclaimer


These standards are provided from a safety perspective and are intended to define the essential requirements for transfusion-related IT systems. They do not supersede national or local procurement policies, regulatory requirements, or professional guidelines. Organisations must continue to follow all applicable procurement and governance processes.



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1	 General Requirements	Reference
1.1	System supports safe administration of all blood components and products in accordance with BSH guidelines, SHOT Transfusion Safety Standards, BSQR and any other relevant guideline or regulation.	1, 2, 3, 4, 5, 6
1.2	System functionality operates on all available hardware (e.g., printers, scanners, workstations, handheld devices) used in clinical environments in the UK. Where hardware is supplied or recommended by the Supplier, this must be appropriate for use in the specific clinical environment deployed.	
1.3	System only allows users access privileges to perform parts of the transfusion workflow that are within their remit of job role and/or associated with the user's training and competencies performed. The system must be configurable to alert staff if their training/competency is due to expire and restrict access when expired.	
1.4	Where alerts, flags or warnings are used, these are appropriate, clear, and meaningful to the user. Critical safety alerts cannot be overridden, (e.g., patient ID band mismatch with component label, component expired, ID band not scanned) and must provide a hard stop to the workflow with appropriate notice to the user. Where safety non-critical alerts are able to be overridden, this must only be allowed by an individual with appropriate access level. The system must record justification and include the identification user and is auditable for monitoring. There is ability for the client to customise alerts, e.g., ability turn on/off in the configuration and customise wording (for non-critical alerts only).	6, 7

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	 General Requirements	Reference
1.5	<p>System supports open architecture interoperability with other Trust systems and devices that include information relevant to transfusion, with associated bi-directional data flow (e.g., pharmacy/cell salvage/chemocare/EPR/blood tracking/LIMS). Interface messages must comply with HL7, FHIR and ISBT standards and use recognised codes from the national test catalogue and SNOMED-PaLM.</p> <p>System is configurable to allow critical information received from another system to trigger rules for safe transfusion, (e.g., purine analogue drug prescription message from a pharmacy system trigger irradiated blood requirement in EPR).</p> <p>System is able to share information relevant to transfusion between hospitals and UK Blood Services for the purposes of shared care.</p> <p>Where the system holds data on blood stocks, this is able to be shared with UK Blood Services.</p>	1, 8
1.6	<p>System is configurable to the client's transfusion workflow, access to configuration settings or changes to the transfusion workflows are restricted and auditable.</p> <p>Where a shared single system is accessed by multiple sites or organisations with different requirements the configuration and user visibility of functions is site specific, e.g., site specific MRN input will only return the patient for that site, secure interface messaging where there are patients with overlapping MRNs, test ordering, clinical decision support, sample validity periods.</p>	7

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	 General Requirements	Reference
1.7	<p>System includes, at a minimum, a test environment, a training environment and a production environment.</p> <p>There is an automated, auditable process for transfer of configuration in the test system to the production system.</p> <p>There is ability to export system configuration into user viewable reports, e.g., to support validation evidence.</p> <p>There is ability to retain databases and validation evidence in a retrievable format following system upgrades or decommissioning of the system.</p> <p>The system stores or archives patient data in line with MHRA requirements.</p>	
1.8	System provides full audit trail of user activity in regard to transfusion workflows. Patient demographic changes must also be auditable.	
1.9	The Supplier provides regular system updates, routine maintenance and troubleshooting to enhance operability and resolve defects. Release notes must be provided in advance of system implementation or upgrade. The Supplier must inform the client of any known interoperability issues with other systems already in use by the client. The Supplier must provide known defect lists and provide clinical risk assessments for known defects.	
1.10	<p>There is a business continuity process to maintain essential functions, minimise downtime, and quickly resume normal operations.</p> <p>There is a disaster recovery process that retains the system functionality and settings without the need for rebuild.</p> <p>A downtime report, or equivalent, is available for downtime events. This report is updated regularly over a 24-hour period.</p>	6

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2	 Patient Identification	Reference
2.1	System supports confirmation of positive patient identification at essential points during transfusion workflows including enforced scanning of the patient identity band and client configurable, mandatory safety confirmation prompts for end users. Copies of ID bands/barcodes must not be displayed on the screen.	
2.2	Patient identity bands must be formatted in accordance with NHS standards and ISB0099, DCB1077. The system must be compatible with GS1 barcode standards.	9, 10, 11, 12, 13
2.3	For purposes of transfusion, the patient’s legal name must always be used, not the preferred name or alias (with the exclusion of unidentified patients – see section 2.6). The legal name must be visible to the user at all stages of the transfusion process (i.e., ID band, sample, prescription, administration check) and is electronically transmitted to other interfaced systems. The system must clearly distinguish to the end user the legal and preferred name in all users’ visible views. The patient surname is displayed in capital letters, so it is easily differentiated from the first name in all user visible views and documentation. Where middle name exists in the system, this is clearly differentiated to the user in all user visible views and documentation. The system supports changes to patient name and is auditable.	2
2.4	All patient identifiers (i.e., surname, forename, date of birth, MRN, NHS/CHI number) are included in interface messages with patient matching criteria that prevents transfer of messages where a mismatch is detected. Patient search facility allows use of either or both MRN and NHS/CHI number. NHS number should be the primary identifier where possible.	2

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
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	 Patient Identification	Reference
2.5	If the system supports non-binary genders the genetic gender of the patient, that is the sex, male or female, at birth must be used in algorithms for transfusion activities. Sex assigned at birth is used in interface messages to other IT systems including LIMS. The system allows “unknown” sex in emergency situations where patient identification cannot be performed.	2
2.6	Temporary numbers for unknown or unidentified patients in line with Patient Safety Alert NHS/PSA/RE/2018/008 are supported.	14
2.7	System must recognise characters in the ISO/IEC 8859-1-character set.	
2.8	System supports industry standard barcode formats including (but not limited to) ISBT128, Codabar, Datamatrix, QR. Where barcode readers are supplied by the supplier, these must conform to the industry standard ISO/IEC 15417: 2007 (E): Information technology and be configured to read ISBT128 barcodes.	
2.9	System provides a process for identification of potential duplicate records to the user in real time. System provides a secure process for merging duplicate patient records with audit trails and justification. System provides a process for communication with other interfaced systems when duplicate records have been merged, e.g., automated message to LIMS. System provides a process to unmerge records. Where patient records are merged, there must be a method available to merge/link duplicate records in a way which ensures the integrity of the transfusion record in accordance with BSH IT Guidelines section 5.2.3 .	2

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3	 Sample Labelling	Reference
3.1	The sample labelling process must conform with the BSH Guideline for the Administration of Blood Components and pre-transfusion compatibility testing.	13, 15
3.2	System enforces the scanning of patient identification band at the start of the process.	16
3.3	System supports an end-to-end uninterrupted process for sample collection. If the process takes too long, an interruption must be assumed so the user will need to start the workflow again, rescanning patient ID band. The interval must be configurable by the client. System alerts the end user if there is an ID band mismatch during this process and terminates the process.	16
3.4	System displays the patient information, samples/tests that need to be collected at the phlebotomy event. System provides prompts for the end user for sample collection, e.g., sample type, volume required, patient preparation.	
3.5	System supports a process for ensuring that the sample label is printed from the printer associated to the device (handheld device or PC/workstation) and that labels cannot be printed to remote printers. System supports a process for ensuring that the sample labelling process is performed at the bedside. Ability to generate sample labels is configurable/restricted to individual or specific types of devices/workstations, e.g., labels cannot be printed from a static PC on a ward desk but can be printed from a workstation on wheels. System includes a record of confirmation that the individual taking the sample has positively identified the patient and generated the label at the time of the phlebotomy event and printed the label at a device at the patient side (not a centralised or remote printer).	1, 3, 16

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	Sample Labelling	Reference
3.6	<p>System generates a unique barcoded sample number that can be utilised as pass through in the laboratory (readable by LIMS and analyser systems).</p> <p>System must include a process to prevent the production of more than one label per sample, unless two samples are required (e.g. for group and save plus genotyping requests).</p> <p>System supports combining of samples where multiple tests can be performed on a single sample.</p>	2
3.7	<p>System supports a two-sample policy to include an alert to the requestor if a second sample is required prior to release of red cells.</p> <p>System supports process for identification of patients where 2 samples are required for referral purposes.</p>	
3.8	<p>The label displays patient identifiers in a clear, eye-readable format.</p> <ul style="list-style-type: none"> • Surname and forename • DoB • NHS number (CHI or H+C number) • MRN • Date and time sample taken • Identification of staff taking sample (could be on system rather than label) 	
3.9	<p>System provides information for the end user of the status of the sample, e.g., collected, receipted in lab, testing in progress.</p> <p>System supports a process for communication to the requestor of samples that have been rejected, including the reason for rejection.</p>	1, 3

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4	 Patient Blood Management	Reference
4.1	<p>Transfusion special requirements (such as irradiated, CMV-, HbS neg, HLA matched) and red cell antibody status (including historical) are visible to the clinician on the patient record.</p> <p>System supports automated addition of specific requirements to the patient record based on other data as appropriate, (for e.g., medications, patient diagnosis, transfusion reaction information, test results).</p> <p>System supports an electronic process for notification of specific requirements, or cessation of requirements, from the clinician to the laboratory and vice versa.</p>	1, 3
4.2	<p>System provides a process for electronic clinical decision support for appropriate transfusion in accordance with BSH guidelines, NBTC Indication Codes, national transfusion triggers and NICE guidance.</p> <p>System includes an alert to the end user where components are ordered outside the indications codes. Alert override with justification mandated and auditable.</p>	13, 18, 23
4.3	System supports compliance with NICE QS138 recommendations.	1
4.4	System supports integration with cell salvage platforms, allowing clinicians visibility of when such systems were used, how much blood was collected and re-infused and relevant associated metadata.	1
4.5	System supports integration with viscoelastic testing platforms such as TEG/ROTEM, allowing clinicians to view results and support decision making algorithms on appropriate blood component use based on these results and other POCT devices.	1

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	 Patient Blood Management	Reference
4.6	System provides functionality to support individualised care pathways for chronically transfused patients based on Hb or other parameters for that patient. System supports monitoring and auditing of transfusion practices, including but not limited to NICE QS138. System provides alert for patients with severe anaemia (e.g., Hb<60g/L) with decision support for transfusion.	1
4.7	System supports safe and appropriate practice in major haemorrhage situations.	1
4.8	The system supports clinical decision making for the identification and management of iron deficiency and vitamin B12/folate deficiency, based on laboratory results such as Hb, MCV, and iron studies.	

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5	 Ordering Blood Components, Blood Products and Tests	Reference
5.1	Where blood component orders are sent electronically to the LIMS (Order comms), these must comply with the specifications stated in the BSH guidelines.	2, 13
5.2	System provides electronic clinical decision support for appropriate transfusion in accordance with BSH guidelines, NBTC Indication codes PBM including: <ul style="list-style-type: none"> • Use of national transfusion triggers • Alerts if the patient blood results do not support ordering of a particular component type • Single unit transfusions in non-bleeding adults • Single unit platelet transfusions • Prompt for Hb check between transfusion for non-bleeding patients • Component volume calculation for paediatric and neonatal patients and also for adult patients (weight adjusted red cell dosing) • Easy access to patient information leaflets (PIL) and other information supporting safe and appropriate transfusion. For example, hyperlinks to UK Blood Services PILS, Blood Assist and Blood Components apps, internal transfusion policies, patient information pages on the Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (JPAC) and SHOT websites as well as the My transfusion app from SHOT • A process to identify anaemia in patients as part of the pre-operative screening and prompts for appropriate treatment • A process for recording the outcome of the transfusion • Consent at component ordering, prescription and administration (see section 6) • Recording patient refusal of components and products, with alert if order attempted • Access to information relating to risks of transfusion to support consent process 	1, 2, 17, 18, 21, 23

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	 Ordering Blood Components, Blood Products and Tests	Reference
5.3	<p>System supports appropriate management of anti-D Ig in pregnancy in accordance with BSH guidelines.</p> <p>System supports appropriate management of women with red cell antibodies in pregnancy in accordance with BSH guidelines.</p> <p>System supports appropriate management of D-negative women post-birth of D-positive infant, including requirement for repeat FMH testing where relevant.</p> <p>System supports safe process for ordering cord blood tests and labelling samples (e.g., infant name is not changing pre- and post-birth).</p>	19
5.4	<p>System must be able to receive data from the LIMS in regard to the progress of the order and display this to the end user.</p> <p>The order for blood components/products must remain visible on the system and discontinued or refused orders must be clearly delineated.</p> <p>Blood components that are issued to patients must be visible to the clinician and the status of these units should be updated in real time when they are moved out of storage/transfused/no longer available.</p> <p>Order cancellations send electronic message to interfaced systems to cancel orders and alert users.</p>	1
5.5	<p>System supports a process for appropriate automatic ordering of red cell phenotyping and/or genotyping linked to clinical condition/diagnosis (e.g., sickle cell disease, thalassaemia, chronic transfusion).</p>	
5.6	<p>The clinician must be alerted if a similar or duplicate order already exists in the system</p> <p>There should be a process for vetting or review of component orders by selected staff with a feedback mechanism to the requesting clinicians if the request is refused as inappropriate.</p> <p>System supports an alert where requests are out-with local policies, e.g. MSBOS.</p>	

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	 Ordering Blood Components, Blood Products and Tests	Reference
5.7	<p>Creation of the authorisation (prescription) for blood components must be restricted to staff with appropriate prescribing permissions (e.g. doctors, NMA).</p> <p>The authorisation (prescription) displays and highlights specific patient transfusion history including special requirements, patient blood group, antibodies (including historical) and known clinical conditions.</p> <p>The authorisation (prescription) must include instructions of the time-period for administration, volume of component and pump settings where appropriate. Prescribing process must document completion of a TACO risk assessment in accordance with National Patient Safety Alert CAS alert 2024.</p> <p>There must be a process for the real time or retrospective authorisation (prescription) of blood components in an emergency situation or major haemorrhage. This process must reduce the risk of delays in transfusion.</p> <p>Process for ensuring that blood component authorisation (prescriptions) is completed or cancelled, as appropriate within the prescribed time frame.</p> <p>The authorisation (prescription) must be clearly delineated from the order for the blood component.</p>	1, 13, 20
5.8	System records prescription and administration of blood products and medications such as Anti-D Ig, PCC, TxA, Epo. These must be visible to clinicians and electronically transferred to other systems where needed (e.g., Anti-D Ig).	
5.9	System displays clear transfusion history including component type, specific requirement, previous reactions, date/time of transfusion, volume transfused.	

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6	 Consent	Reference
6.1	<p>System supports a mechanism for recording patient consent to transfusion in accordance with SaBTO guidelines. This includes a mechanism for recording consent across more than one blood transfusion episode, or across the duration of a patient admission period.</p> <p>System supports a mechanism to enable a retrospective recording of consent. The digital documentation of informed and valid patient consent must be easily accessible to clinicians and patients.</p>	21
6.2	<p>System provides access/prompts to information about transfusion suitable for medical staff (e.g., risks of transfusion, alternatives to transfusion, specific requirements) to assist them with the consent process.</p> <p>System supports a mechanism for recording provision of patient information.</p>	1
6.3	<p>System supports a mechanism for recording if patient has refused to receive blood components/products. The documentation of blood refusal must be easily accessible to treating teams. Alerts should be given to the user if an order is attempted for a patient who has previously refused blood.</p>	1

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7	 Blood Component and Blood Product Collection	Reference
7.1	System allows rapid access to emergency blood components/products in a manner that preserves traceability and access audit trails.	
7.2	System allows clinical users to view real-time availability and location of components/products for specific patients and availability and group of emergency units. This availability is updated when units are in transit or no longer available.	
7.3	System generates electronic and/or paper pickup slip that contains: <ul style="list-style-type: none"> • Core patient identification in GS1 compliant barcode format and eye readable • Type and number of component/product for collection • Location of components/products for collection • Location for delivery Pickup slips are single use only. Electronic pickup slips are cancelled from the device after use.	12
7.4	System includes a process for ensuring: <ul style="list-style-type: none"> • The component/product removed from storage is labelled for the patient on the pickup slip • The component/product type removed from storage is the same as that on the pickup slip • The component/product with shortest shelf life is collected first • The component/product is scanned for traceability at the time of collection • Expired, quarantined and unsuitable components/products cannot be removed from storage (if not physically prevented then alerts to end user and central transfusion system/laboratory team) • Alerts are generated to the end user if there are patient ID mismatches on the pickup slip and component label 	2

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	 Blood Component and Blood Product Collection	Reference
7.5	System supports a process for handover of components/products in the clinical area for chain of custody audit trails.	
7.6	System is configurable to set out of storage control time periods for each type of component/product. System does not allow return and re-collection of components/products that have been out of temperature control. System supports process for remote changes to component/product status to make them unavailable for collection (e.g., quarantining for recall).	
7.7	System includes information to end users relating to time of collection and when transfusion must be completed. System generates visible and audible alerts to end users relating to errors within any part of the system, including: <ul style="list-style-type: none"> • Failure to scan component/product at collection • Patient ID mismatch between pickup slip and component/product label at collection • Emergency component/product collected • Stock level below configured value • Label level below configured value • Connectivity loss • Component/product past dereservation date/time • Expired component/product in storage The alerts are transmitted contemporaneously to a central laboratory-based system generating audible and visual alerts.	

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8	 Administration of Blood Components	Reference
8.1	System enforces safety scan of patient ID band (2D barcode) against component and compatibility label information, with safety features (e.g., include enforced scanning of patient ID band, time-out function for re-scanning ID band if process takes too long, checklist or confirmation of initial positive patient identification). Safety scans of ID bands are not overridable.	
8.2	System includes a step-by-step process, with prompts for safe practice that is easy to follow and ensures that no steps/checks are missed.	
8.3	The component authorisation (prescription) with component type and special requirements is visible on the screen at administration. The authorisation (prescription) is visible at the start of each transfusion, not requiring staff to open separately, to ensure this has been viewed with a function to record acknowledgment prior to transfusion. Includes confirmation that the prescription, consent and TACO risk assessment has been completed and reviewed before transfusion can be started.	
8.4	System must record and display transfusion start time, end time and volume transfused. System prompts users to take and record transfusion observations (e.g., temperature, blood pressure, pulse, respiratory rate at intervals specified by the transfusion policy).	13
8.5	Where multiple units are being transfused in one transaction each unit must be scanned and the data transmitted after each unit, not at the end of the overall transaction.	
8.6	Confirmation of transfusion with date and time component/product transfused must appear in the patient record and be visible to clinicians.	

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	 Administration of Blood Components	Reference
8.7	<p>There must be a process for the administration and recording of blood components/products given during emergency situations.</p> <p>System must recognise emergency components/products released by the laboratory providing an alert to the end user that the component has not been labelled for the patient.</p> <p>System links emergency components/products to the patient ID and transmits contemporaneous message to laboratory system/users for traceability purposes.</p>	
8.8	<p>System alerts the user where the component is due to expire before the transfusion is due to complete.</p> <p>System clearly displays the expiry date/time of the component/product, including where the expiry date/time has been amended from manufacturers (e.g., thawed plasma components).</p>	
8.9	<p>System provides an alert to the user (by use of visual and audible alarms) and contemporaneously to the laboratory where:</p> <ul style="list-style-type: none"> • there is a blood group (ABO/D) mismatch between the patient and the blood component • component/product type does not match that in the authorisation (prescription) • specific requirements do not match on authorisation (prescription) and component • there is a mismatch between patient details on the blood component and patient wristband • There is a mismatch between unit details on the blood component and compatibility label 	

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	 Administration of Blood Components	Reference
8.10	System includes a process for recording and managing transfusion reactions in accordance with the BSH guidelines. System provides visible flag in the patient record if a patient has had previous transfusion reactions, including requirements for pre-transfusion medications and specific requirements.	3, 22
8.11	Discharge summary includes record of components transfused during the patient's admission including information relating to patient outcomes in accordance with the SHOT Transfusion Safety Standards.	6
8.12	System supports a process to identify where components/products have been removed from storage but not transfused or returned (i.e. "in transit"). Components/products implicated are visible to the laboratory team for traceability review and stock management.	
8.13	System supports a process for alerting users where transfusions have not been ended after 4 hours.	

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Glossary of Abbreviations

Abbreviation	Definition
Anti-D Ig	Anti-D immunoglobulin injection
BSH	British Society for Haematology
BSQR	Blood Safety and Quality Regulations 2005
CAS	Central Alerting System
CMV	Cytomegalovirus
Epo	Erythropoietin
EPR	Electronic patient record
FHIR	Fast Healthcare Interoperability Resources – next generation HL7 standards framework
FMH	Fetomaternal haemorrhage
GS1	barcode format
HbS	Haemoglobin S
HL7	Health Level Seven standard of healthcare interoperability
HLA	Human Leucocyte Antigen
ISBT	International Society of Blood Transfusion
ISO/IEC	International Organisation for Standardization/International Electrotechnical Commission
LIMS	Laboratory Information Management System
MRN	Medical records number
MSBOS	Maximum surgical blood ordering schedule (also SBOS)

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Abbreviation	Definition
NBTC	National Blood Transfusion Committee
NHS/CHI/H+C	NHS number (England, Wales)/Community Health Index number (Scotland, Health & Care number (NI))
NICE	National Institute for Health and Care Excellence
NMA	Non-medical authorisation
PIL	Patient information leaflet
POCT	Point of care testing
ROTEM	Trade name for analyser that does Thromboelastography (Werfen)
SABRE	Serious Adverse Blood Reactions and Events
SaBTO	Advisory Committee on the Safety of Blood, Tissues and Organs
SCD	Sickle Cell Disease
SCRIPT	SHOT UK Collaborative Reviewing and reforming IT Processes in Transfusion
SHOT	Serious Hazards of Transfusion
SNOMED CT-PaLM	Systematized Nomenclature of Medicine – Clinical Terms for Pathology and Laboratory Medicine
TACO	Transfusion Associated Circulatory Overload
TEG	Thromboelastography – also a trade name for an analyser that does this test (Haemonetics)
THAL	Thalassemia
TxA	Tranexamic Acid
URS	User requirement specification

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