

# **Guidelines for the specification, implementation and management of information technology (IT) systems in hospital transfusion laboratories**

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## **Disclaimer:**

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A full breakdown of each section can be seen in the diagram on page 4

## **Introduction**

### **Background**

Since the BCSH Guidelines for the Use of Information Technology (IT) (BCSH 2007a) in blood transfusion laboratories were published there has been considerable development in IT applications available for use in transfusion medicine. IT has made a major contribution to blood safety throughout the transfusion chain, by facilitating secure electronic data transfer within the laboratory and clinical areas (SHOT 1996 to 2012). There is increasing use of IT solutions to allow laboratories to meet some of the challenges of the Blood Safety and Quality Regulations SI 50/2005 (as amended) (BSQR 2005) legislation, such as traceability. These guidelines update those published in 2007, to reflect these developments.

### **Scope**

These guidelines are intended to support hospital blood transfusion laboratories when changing Laboratory Information Management Systems (LIMS) and provide guidance on the operational use of such systems. The LIMS is the hub of laboratory IT in these settings and whilst many IT systems are in use in transfusion medicine, from vein to vein, these guidelines address applications which interface directly to the LIMS. Supporting blood “tracking” applications are not covered in detail, but the interoperability with the LIMS is referenced where appropriate. Whilst these guidelines are not specifically addressing cells and tissues, organisations should consider the requirements and potential need to manage cells and tissues through the blood transfusion IT system. Wherever possible, other BCSH transfusion guidelines are cross referenced to avoid duplication of information and potential for inconsistency between guidelines.

It is envisaged this document will be used by transfusion laboratories, hospital IT departments and, where applicable, suppliers of IT systems which support hospital transfusion medicine.

Some of the requirements in these guidelines reflect special blood transfusion needs and these may have impact on systems external to the LIMS. Necessary controls must be implemented in these external systems to meet such requirements. It is of particular importance that external systems are not able to update patient demographic data held on the LIMS, and that patient record merging/linking on external systems is verified by the transfusion laboratory where the patient has a transfusion history.

Although these guidelines do not specifically refer to how IT systems should be managed across pathology networks the guidance provided for the LIMS remains as stated in this document.

### **Method**

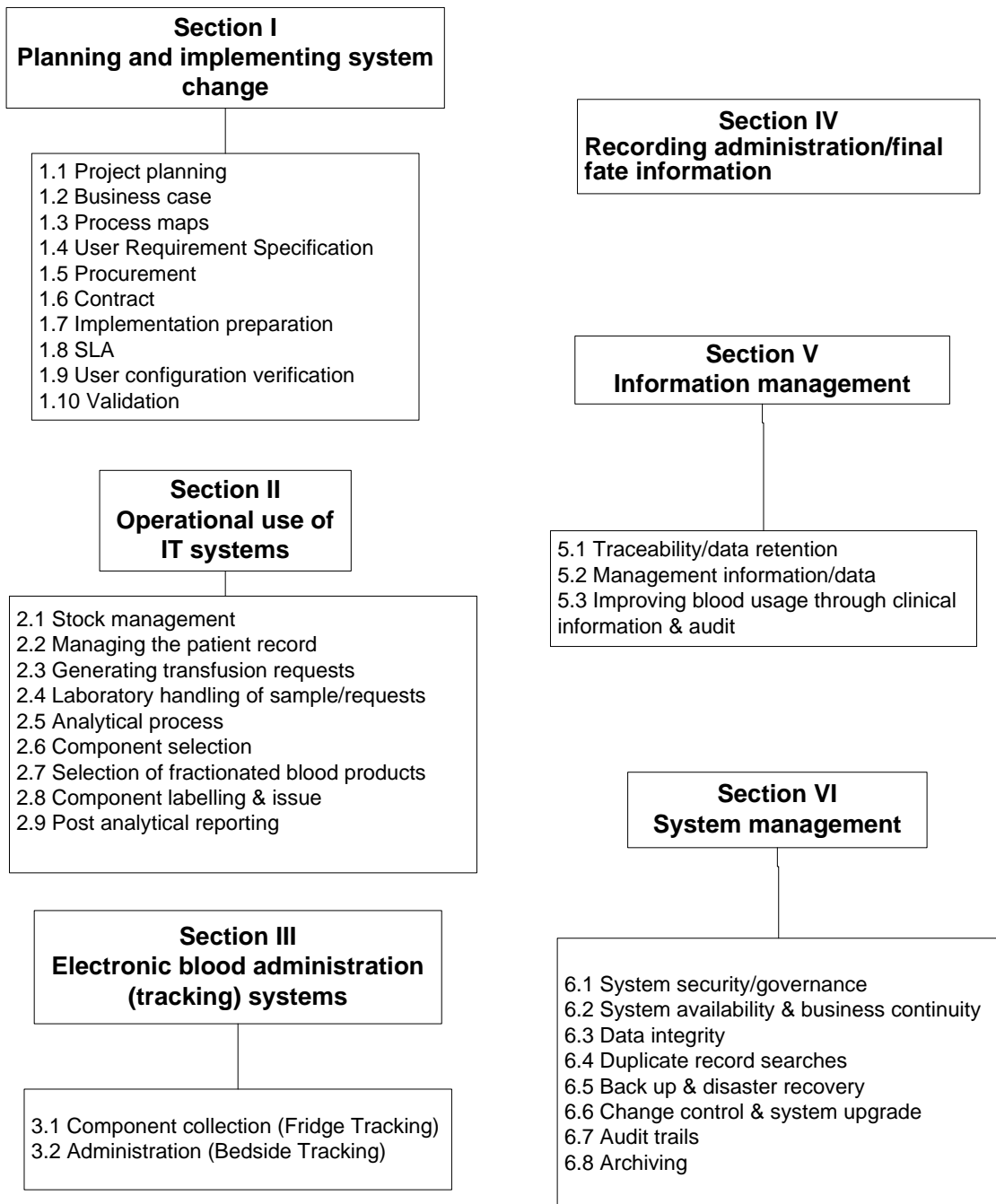
The guideline group was selected to be representative of UK-based scientific, technical and medical experts with practical experience in this field. These guidelines are formulated from expert opinion and based on relevant recommendations from professional groups e.g. the Serious Hazards of Transfusion (SHOT) haemovigilance scheme annual reports (SHOT 1996 to 2012). Where evidence exists to support new and potentially contentious recommendations, this is referenced in the text.

## Structure

The guidelines are presented in six sections:

- I. Planning and implementing system change
- II. Operational use of IT systems
- III. Electronic blood administration (tracking) systems
- IV. Recording administration/final fate information
- V. Information management
- VI. System management

The outline below shows the headings and sections of this guideline:



### **Compliance with these guidelines**

It is recommended that IT systems are audited against these guidelines on a regular basis and are included in the audit schedule of Quality Systems, to ensure ongoing compliance. If appropriate an action plan to address any areas of non-compliance should be instigated.

A sample compliance checklist has been provided to assist transfusion laboratories in the preparation of their audit documentation and is available on the BCSH website.

### **Major Changes from the previous guidelines**

- **A section on implementation of a new or major upgrade to the LIMS**
- **Electronic Issue is not permitted if test results have been manually edited**
- **Label attachment verification**
- **Remote electronic issue**
- **Section on electronic blood administration (tracking) systems**

### **Summary of Recommendations**

There are a large number of recommendations against which compliance should be assessed. This summary shows the important principles underpinning the recommendations.

**Adequate control and resources are required to ensure the IT project complies with regulation, satisfies all quality requirements and ensures safe transfusion practice**

**Necessary controls must be implemented to ensure the integrity, accuracy and consistency of information passing between the LIMS and external IT systems**

**Any changes to IT systems must be managed through a formal change control process, risk assessment and appropriate validation**

**Electronic transfer of data provides greater accuracy than manual transcription and thus helps reduce the risks to patient safety**

**Patient identification is critical across all IT systems and merging of patient data must ensure the traceability requirements of the BSQR 2005 are retained**

## **SECTION I. Planning and Implementing System Change**

This section covers the initial steps for implementing a new system into the transfusion department

### **1.1 Project Planning**

Any IT project requires a multi-disciplinary approach including subject matter experts, IT personnel and a project manager who will develop a project quality plan. This will ensure the necessary controls are in place and managed under the regulatory framework. It should be remembered that the transfusion requirements for and from an IT system may be very different from the requirements of other pathology disciplines and one system may not meet the needs of all. It is essential to ensure that system implementation complies with regulation, satisfies all quality requirements and ensures safe transfusion practice.

Where a new system will bring together information from multiple existing Patient Administration System (PAS) or LIMS systems particular care needs to be taken to ensure that differences in the way information has been structured and entered in these systems is taken into account (e.g. code tables, locally agreed terms and abbreviations etc.). Assumptions about the compatibility of information cannot be made and each system should be fully assessed in its own right at the outset.

Project Management must include:

- **Change Management** - A new Laboratory Information Management System (LIMS) or an upgrade to the current LIMS must be managed under the formal change control system in operation within the organisation.
- **Risk/impact assessment** - In any project a risk assessment must be performed to identify all the factors that impact on the project itself or on continuing service provision and ways must be defined to mitigate the identified risks. Risk assessment must be ongoing throughout the project and should be used to focus the validation effort on the higher risk areas.
- **Responsibilities and authorities** - The project management documentation should define: how the project will be managed; who is responsible and what authority they have; how their responsibility and authority links into business management; and how resources will be allocated.

### **1.2 Business Case**

The business case captures the reasons for initiating the purchase of a new system and identifies the resources, either capital, revenue or staff, that will be required. A well written business case should adequately capture all the requirements of the proposed project. Information in a formal business case should include the background of the project, the expected business benefits, the options considered (with reasons for rejecting or carrying forward each option), the expected costs of the project, a gap analysis against current status and the identified risks.

The business case must also consider what the impact will be on linking to other systems, both within the organisation (e.g. Patient Administration Systems (PAS) and outside (e.g. GP links, Blood Establishments) and define how this will be managed and the degree of interaction permitted between the systems.

The business plan will need to be developed in line with local policies, but the output should clearly identify:

- the scope of the project – what is included and what is excluded with clear boundaries;

- management responsibilities, identifying the project owner and project team members;
- resources available to the project (staff, equipment, accommodation and financial).

### **1.3 Process Maps**

It is important to gain a common understanding of the entire process, the specific roles and contributions of personnel, process inputs and outputs and the interactions of the LIMS system with external IT systems/devices. This can be achieved through a process mapping technique. All processes within the scope of the project should be mapped, together with relevant boundary processes. This type of mapping will help to formulate the detail of the User Requirement Specification (URS). It is also a valuable tool in system configuration to ensure that all necessary process interactions are supported.

Where process changes are planned either as part of the IT project, or to occur in the same timescale as the IT implementation, both existing and new process flows should be mapped to highlight changes.

### **1.4 User Requirement Specification (URS)**

The URS is a structured document which identifies all of the essential and desirable user requirements of the system. Each requirement should be clearly marked as essential or desirable and any weighting that will be used in evaluation should be indicated. The URS is a fundamental part of the contractual agreement, forms the basis of the technical evaluation of bids and provides the requirements against which validation is performed.

Because modern LIMS offer extensive configurability, the database structure and architecture of the LIMS will have an impact on the manner in which processes and functionality will be configured. It is therefore important to specify in the URS **what** is required, but to avoid specifying **how** it is to be achieved unless this is essential to the operational need.

The URS should clearly define all elements required of the LIMS. Its construction will require input from both subject matter experts and IT and validation specialists.

In developing the URS consideration should be given to current and future developments in the field of transfusion medicine information management.

The following will need to be addressed in the URS:

#### **1.4.1 Operational Functionality**

Every functional requirement of the system needs to be detailed within the URS. Requirements should be written in clear numbered paragraphs, with each paragraph identifying a single requirement. Each requirement should be written so that it clearly specifies what is required, giving any specific capabilities and the criteria against which compliance will be measured.

Vague and ambiguous statements must be avoided. This format ensures clarity and provides a good basis for the future validation of the system.

#### **1.4.2 Validation Requirements**

The URS should outline the validation/qualification strategy and clearly define the roles and responsibilities of both the supplier and purchaser.

### **1.4.3 Infrastructure Requirements**

Infrastructure compatibility requirements and constraints should be specified including Wide Area and Local Area Network infrastructure and information security considerations.

### **1.4.4 Interface Specification**

Many instruments and analytical devices provide a means of communicating electronically with LIMS however but there is a lack of standardisation in this area and communication formats vary from device to device. An example of a commonly occurring interface is that between a grouping analyser and the LIMS.

Interface software provides the mechanism to convert the communication from the instrument to a format the receiving system can understand.

Some specialist interface software, known as middleware, may be used to allow multiple analysers and multiple sites to communicate with the LIMS using a common format.

All required interfaces (current and anticipated) should be identified in the URS. Details should include: the data which is to be transferred; batch or real time transfer; error detection and alarms.

There is work on-going at an international level within the transfusion community to develop a further enhanced level of standardisation within existing standards using transfusion-specific coding tables. These tables allow critical data to be transmitted in a tightly defined format thus providing the basis of a generic interface.

Where enhanced standardisation exists or is being developed it is recommended that the URS makes reference to this work and states compliance as mandatory. Details of the standard and development work can be obtained from the International Society of Blood Transfusion (ISBT) Working Party on Information Technology Interface Task Force. <http://www.isbtweb.org/working-parties/information-technology>

### **1.4.5 Electronic Data Interchange (Interoperability)**

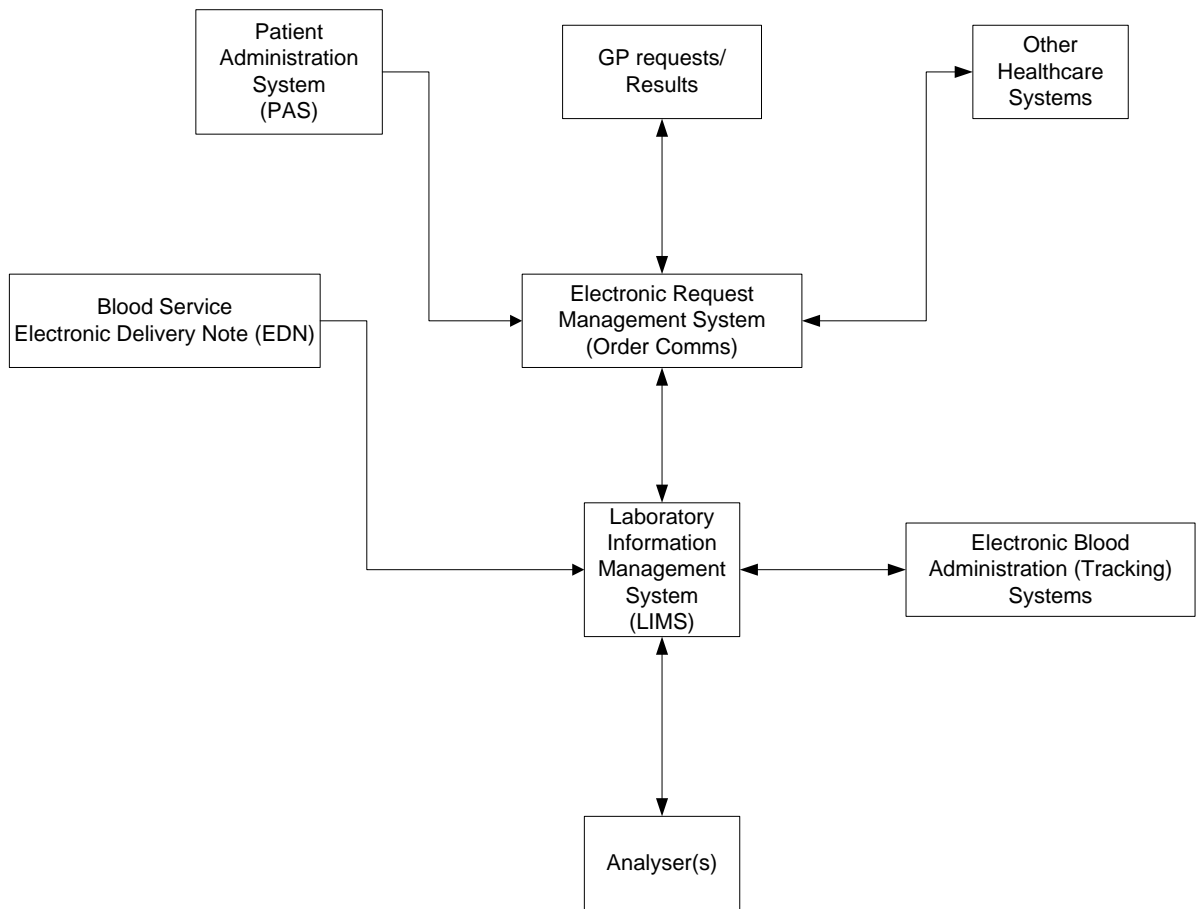
System to system communication is an essential requirement of healthcare computing. The LIMS will need to be able to communicate with the PAS, Electronic Request Systems (Order Comms), Electronic Blood Administration (tracking) Systems () and other hospital systems. Electronic Data Interchange (EDI) is the term used to describe the structured messages and protocols used for such communications in a way that the receiving system can correctly interpret the value, meaning and context of the information sent from the transmitting system. Required EDI functionality should be identified, and EDI standards that are used within the national and local healthcare IT environment should be specified.

Interfaces between computer systems, in particular between the PAS and LIMS must be configured and validated to ensure compatibility between the information formats used by each system. (NCA 2011)

EDI may be uni-directional such as the Electronic Delivery Note (EDN) used to send information from blood centres to hospitals using a fixed format file, or may be bi-directional such as the information interchange that occurs between an electronic request system (Order Comms) and a LIMS during ordering of blood components.



An example of interoperability is shown in the diagram below.



#### **1.4.6 Peripherals and Hardware requirements**

Any items of hardware should be appropriate in terms of specification and numbers to ensure the running, security and performance of the software application. To ensure that the necessary requirements are met the following should be considered when purchasing:

- number of concurrent users;
- maximum transaction rate to be supported;
- anticipated growth rate;
- resilience to single point of failure.

#### **1.4.7 Operational Environments**

An operational environment is a version of the system (software, hardware, users) used for a specified purpose. The 'live' environment is the one in routine use on a day to day basis.

All systems should support multiple environments with a minimum of two environments to allow a separation of live and validation/training environments. Each environment must be completely independent and must be kept fully updated in parallel with the live system. Modern configurable systems may support larger numbers of environments and users should specify the number and type required in the URS.

All environments will need to be able to link to other operational systems (e.g. Order Comms). Consideration must be given to how this can be achieved without impacting on live data and live operational use.

#### **1.4.8 Data Management**

The information held on existing systems forms an essential record, some of which falls within the record retention requirements of the BSQR 2005. In addition, much of this information is critical to the ongoing operation of the department. It is therefore of critical importance to ensure that the management of this information through the system transfer and into the future is well defined and captured within the URS.

Data that needs to be retained may either be migrated to the new system, or may be archived in a manner that makes it accessible for lookback purposes.

The decision on whether this data is migrated or archived will depend on several factors. These will include: the historic data needs of the operational system; the quality of the legacy data; and the cost effectiveness of archiving versus live database retention.

##### **1.4.8.1 Data migration**

Data migration is the transfer of essential information (data) from an existing to a replacement system. It will be necessary to determine what data should be migrated to any new system and this determination should take into account:

- legal requirement (e.g. traceability as defined by the BSQR 2005 (as amended) in terms of the final fate of all components);
- operational requirements e.g. historic group, antibody information, special requirements.

The most direct form of migration is by transferring records directly into the new database. Where this is performed it is important that the quality of data migrated is verified (see 1.7.1) and ideally all patients would be identified with an NHS number (or equivalent).

In more complex situations where information from multiple legacy systems is being transferred into a single new system, variations in the use of key identifiers and the format of data can cause difficulties. One way of overcoming this may be the use of an intermediate database which holds the operational records in a format accessible to the new system in a seamless manner. Where a patient search identifies a record in the intermediate database the system highlights the matching record(s) and allows the user to decide whether to transfer this record to the live database. If this is the preferred option matching to legacy data could be:

- perfect match;
- partial match with defined documented criteria

Secure operational procedures must be in place to minimise the potential for incorrect linking to occur. Each piece of data will need to be evaluated through a number of phases before migration to the new system. A full audit trail for this process is essential.

Retaining operational data on a legacy system that is not electronically linked to the operational system (i.e. interrogating a separate database which is a manual step), is not acceptable for maintaining patient safety within the transfusion laboratory.

##### **1.4.8.2 Archive Data Storage**

Some data may not be required for routine operational purposes but will need to be retained for "lookback"/audit. Where it is decided not to migrate this data consideration will need to be given to ensuring that it remains readily accessible. It is

important that the non-migrated data can be searched using search criteria including: patient identifiers; donation number; and batch/lot number to ensure all “look back” requests can be met. Whichever system is used it is essential to ensure the same data security controls are applied to the archived data as apply to the live system.

There are several possibilities including:

- migrating the data into a data warehouse or equivalent reference database;
- maintaining the legacy system in a non-operational, read only configuration (see below).

In order to effectively maintain the legacy system the following requirements will need to be met:

- adequate backup of the legacy database;
- ongoing system maintenance contract and licensing;
- regular start up and running of system;
- maintenance of staff access to and skills in the use of the system;
- regular “lookback” validation exercises;
- regular review to ensure ongoing hardware and software support;
- planning for ongoing migration or archiving when system can be no longer supported.

The archiving strategy documentation needs to be retained to support “lookback” activity. Whichever approach is adopted the archive system must be fully supported with Standard Operating Procedures (SOPs) and staff training. Included in this documentation will be the requirement to develop new SOPs to ensure “lookback” activity is controlled.

It may be appropriate to categorise the legacy data into that which will be migrated to the new system and that which will be archived. This may be done on the basis of time (e.g. data from the last 5 years is migrated and prior data archived) or may be specific to information types depending on the database structure (e.g. it may be more necessary to transfer patient information, blood group and antibody status than test data and component details).

Where an existing database is to be split into data for migration and data for archiving careful consideration needs to be given to the boundary cases to ensure there is a clean division.

Consideration should also be given to how data is matched/linked when storing data from more than one site. This is especially important where the format of data held on each site prevents an exact match.

#### **1.4.9 Maintenance Requirements**

The URS should address maintenance requirements of the new system including:

- clear definition of services to be provided;
- responsibilities and duties of the hospital transfusion laboratory (customer);
- responsibilities and duties of the hospital IT department;
- responsibilities and duties of the system supplier;
- key Performance Indicators (KPIs);
- problem management procedures;
- change management procedures;
- disaster recovery.
- definition of service period and termination of agreement;
- warranties;
- review periods.

## **1.5 Procurement**

Procurement of a LIMS will require a multi-disciplinary approach and will need to follow the healthcare organisations purchasing procedures. Requirements should be clearly identified as “essential” or “desirable”, recognising that a bid that fails to provide all “essential” requirements would be eliminated from consideration.

### **1.5.1 Bid Evaluation**

Bid evaluation will follow standard procurement procedures. A technical evaluation using a scoring and weighting system should be employed in order to compare the degree of compliance of submitted bids to the URS. Bids will only be technically acceptable if all essential requirements have been addressed. Some bidders may indicate that essential requirements are not currently supported and can be developed and the evaluation scoring system will need to consider how to address this.

### **1.5.2 Gap Analysis**

Once a supplier has been selected, the process maps, URS and technical evaluation should be used to identify all areas of the selected system where there are identified gaps, e.g. desirable requirements that are not met.

These gaps may be addressed by:

- modification of the new system either prior to installation or as an upgrade following installation;
- modification of existing operational processes to address the gap outside of the new system;
- no action required, limitation accepted.

In all cases a risk assessment should be performed to determine the appropriate action and the decisions documented. Where change is required this should be handled through a formal change request process with the supplier.

## **1.6 Contract**

Once the tendering process is complete and a supplier has been selected there will be a phase of contract negotiations to ensure all parties are clear on their responsibilities and commitments. Negotiations may include:

- project management responsibilities of supplier and purchaser;
- communications between parties;
- identification of any changes required as a result of the gap analysis of the bid;
- how training is to be delivered;
- documentation and technical support arrangements;
- implementation planning and support;
- configuration support;
- testing and validation support.

Refer to GAMP5 (GAMP5 2008) category classification for guidance on what the Supplier should deliver for the lifecycle of the system.

## **1.7 Implementation Preparation**

This section addresses tasks which will need to be completed prior to implementation some of which may be undertaken concurrently with earlier stages of the procurement process.

### **1.7.1 Data Cleansing**

Data in an established database is rarely 100% consistent and accurate. Anomalies and corruptions of data can occur for a variety of reasons and whilst these may not

cause problems in their home system, problems can arise when the data is migrated. Data cleansing is a structured approach to examining and analysing an existing database with a view to identifying and correcting anomalies prior to migration. This is an essential process, particularly when migrating data across organisations or across networks and a strategy and methodology should be defined to ensure that it is effectively managed. Data cleansing should be carried out in a quality controlled manner with fully documented procedures in place. Critical areas include patients with antibodies (ensure all codes match across data to be migrated) and patients with special requirements.

The use of the NHS Tracing Services to match NHS numbers to patient records can assist in this data cleansing.

### **1.7.2 Duplicate Records**

A search for duplicate records should be carried out on the legacy system and duplicates resolved prior to data migration.

### **1.7.3 Implementation Strategy**

An implementation strategy is required to define how the new system will be brought into routine operation. The implementation of a new LIMS must be managed in a manner that will meet the regulatory requirements. The strategy to be adopted will depend on several factors including:

- the degree and complexity of data migration;
- whether multiple legacy systems are being combined;
- staff resources, space and infrastructure availability;
- available operational environments.

Consideration must be given to the impact of the implementation on the routine operation of the laboratory. There will necessarily be operational downtime associated with data migration, system configuration and physical connectivity. This will necessitate the transfusion laboratory implementing business continuity planning and engagement with clinical and administrative services to manage interruptions of service and the recovery phase.

Whichever implementation strategy is decided upon appropriate risk management plans must be developed. Possible strategies include:

#### **1.7.3.1 Parallel Running**

In parallel running both new and old systems are run together with the routine workload being put through both systems. This involves migrating data from the old to the new system, performing each action in the appropriate areas on both systems. Parallel running allows staff to become fully familiar with full load running of the new system prior to 'go live' and can provide a high level of assurance that the new system is performing as expected post implementation. However such an approach will be resource hungry in terms of staff input. A variation to this approach may involve running only a proportion of the workload in parallel.

The parallel running approach may be facilitated or limited by instrument interfaces, power and IT points availability. It is not always possible to send instrument data to two interfaces or systems simultaneously. Switching an instrument interface between two LIMS systems or environments needs careful control to ensure no changes are made that will require validation. The functionality of the instrument interfaces needs to be understood and carefully managed.

#### **1.7.3.2 Phased Approach**

This will involve staff using both systems whilst transferring specific functions from the existing to the new system over a period of time. The decision will involve identifying when operational areas are to be transferred. This method presents some technical and logistical difficulties such as data transfer, and managing the boundaries between functions running on each system. Each step of a phased approach will need its own risk assessment to address these challenges.

#### **1.7.3.3 Big Bang**

This approach will ensure total transfer to the new system on a defined date. The organisation must ensure that procedures have been written and validated, staff have undergone thorough training, in every area, prior to “go live” and that trial transfer has been run on test and training environments. The risk plan should include a “fall back” plan in the event of a major problem preventing completion of the implementation within the determined time frame.

#### **1.7.4 Validation Strategy**

The validation strategy needs to be determined taking into account the principles of GAMP5 (2008) as set out in the BCSH Guidelines for Validation & Qualification including Change Control, for Hospital Transfusion Laboratories (BCSH 2012a) and the ISBT Guidelines for the Validation of Automated Systems in Blood Establishments (ISBT 2010).

#### **1.7.5 Application Configuration**

The latest designs in LIMS solutions take advantage of modern techniques in software design that are inherently more configurable and adaptable. In order to configure such systems to operate to the requirements of a particular user a set of logic rules and configuration settings has to be established and entered.

These logic rules and configuration settings ensure that, under a defined set of circumstances, the system will consistently take the actions specified at configuration. Criteria can be set which will ensure results and actions support good transfusion practice. This is a powerful tool to ensure reproducibility of actions and it is essential that they are established, managed and monitored closely. Staff who are designated to configure the system, often referred to as “super-users”, should be trained and competent prior to beginning the configuration of the system. The lead “super-user” must be a transfusion expert who is responsible for determining what the rules and settings should be and for ensuring appropriate validation. This individual may be supported by other super-users.

The computer follows the rules specified and is a valuable asset in terms of security. Care must be taken to set up and test rules to ensure they are comprehensive and patient safety is not endangered through an incomplete rule set. The risks/benefits should be assessed before each rule is implemented. Rules may require an “override” function to deal with legitimate exceptions. If incorporated, this must be available only at defined security levels and if used the system should require and document a reason.

Examples of scenarios that may be controlled through configuration include:

- associating user and supervisor alert flags with a specific result profile;
- setting action reminders into the patient record;
- determining whether a patient is suitable for electronic issue of blood;
- helping to prevent issue of incompatible units (e.g. patients with antibodies);
- helping to ensure appropriate blood components/products are issued to a patient (e.g. depending upon their gender/age details prompting selection of appropriate units such as K-, CMV negative etc);

- ensuring appropriate comments are added to reports.

A selection of logic rules, based on BCSH guidelines and good practice is supplied in Appendix 1

### **1.7.6 Data Migration Preparation**

Achieving an accurate data migration will be an iterative process which may be time consuming and will require close co-operation between laboratory staff, IT specialists and the suppliers of the legacy and the new system.

The iterative loop has several distinct steps which may include:

- identify the data to be migrated giving clear reasons for decisions made;
- document the structure and meanings of all fields and values to be migrated and build necessary translation tables;
- extract the required data into a separate file/table/database;
- transformation: manipulate and format the extracted data for upload to the new system ensuring the transformations accurately map data content and meaning;
- upload data into new system;
- create an audit log detailing all steps in the process;
- define the number of records for verification, and the process for selecting a representative sample;
- perform data verification;
- identify migration failures and assess impact;
- revise migration tools as required.

Validation of data migration is a critical process and requires careful planning. The scope of this validation will need to include external systems that interact with the LIMS data. Defining the sampling plans of migrated data can be undertaken using a risk based approach. (for example see Nightingale 2011)

### **1.7.7 Training Strategy and Plan**

The training requirements for implementing a new LIMS should not be underestimated and it is important that a critical mass of staff is fully trained prior to implementation. The URS should identify how training will be provided by the Supplier and how this will be managed (e.g. train the trainer). The training requirements within the organisation should be evaluated to identify:

- who to train - e.g. IT/Pathology/Clinical staff;
- what to include - e.g. Discrete areas/whole system.

Before training can commence SOPs/training manuals should be completed, as a minimum in draft format.

All staff involved in the developing, running and maintaining the LIMS will require training and competence assessment, relevant to the role and these will determine the level of security access required. Assessments should be completed and signed off prior to granting access to the system.

The training and competency assessment programme should be reviewed on a regular basis and following any software upgrades.

## **1.8 Service Level Agreement (SLA)**

In addition to maintenance contracts held directly with system suppliers, there must be a specific Service Level Agreement (SLA) between the transfusion department and any other IT service provider (internal or external) whose activities could impact the LIMS or associated systems. Such SLAs must clearly define the service provision,

controls and authorisations, and performance expectations for any IT support arrangements. An example of an SLA is provided in Appendix 2

### **1.9 User Configuration Verification**

Prior to validation the users should perform informal testing to ensure the system has been configured appropriately to support operational requirements. This is an informal testing process that:

- familiarises staff with the system;
- allows the development of SOPs which are required for validation;
- ensures that the system configuration meets the users needs

Any configuration changes identified should be implemented prior to formal validation. The system must be placed under change control on commencement of formal validation to ensure that any future changes are appropriately controlled (see section 6.6).

### **1.10 Validation**

The Validation strategy will have been determined during implementation preparation (see 1.7.4). Validation is the formal testing and ensures that the system meets the operational requirements of the URS. Both supplier and user will have responsibilities for validation and these should have been defined within the URS (see section 1.4.2)

The content and scope of validation is well documented in the ISBT Guidelines for the Validation of Automated Systems in Blood Establishments (ISBT 2010) which has application for hospital transfusion laboratories and the Guidelines for Validation and Qualification, including Change Control, for Hospital Transfusion Laboratories (BCSH 2012a).

#### **Recommendation**

**A formal process of change control is essential when implementing a new IT system. All of the steps identified in section I are necessary and must be adequately resourced and controlled.**

## **SECTION II - Operational Use of IT Systems**

This section describes essential elements of functionality for a LIMS system in conjunction with identifying areas where the LIMS can support and facilitate safe practice in the hospital transfusion laboratory. This section may not be exhaustive and each organisation should define their requirements and good practice to meet their operational needs.

### **2.1 Stock Management**

It is a requirement of the Blood Safety and Quality Regulations (as amended) (BSQR 2005) and the EU Directive 2001/83/EC (EU 2001) that records are retained allowing tracing of all components and products from source to recipient or final fate and *vice versa*.

The system should hold a local reference table of blood components and batch products in which label barcodes are associated with descriptions and internal codes. There must be the facility to update this table to allow for new components and products to be added by appropriately authorised personnel. Systems must be able to receive blood components labelled from any of the UK Blood Establishments and other products as defined by the users. If organisations require the ability to manage



cells and tissues imported from outside the UK there should be a procedure on entering information into the LIMS to ensure the donor/patient traceability chain is maintained.

### **2.1.1 Stock ordering**

It should be possible to configure the LIMS to take specific actions, based on user defined stock levels, for each blood component and batch product. Actions may include: providing warnings when stock falls below minimum levels; generating advisory reorders; or initiating automatic reordering.

On line blood ordering is available in some areas of the UK but currently is maintained as a stand-alone system. There may be future potential for an automated link between the LIMS and the local Blood Centre.

### **2.1.2 Stock Entry - Blood Components**

A secure method of input is required to ensure the correct information regarding each component is held within the LIMS.

The LIMS must allow for storage of the following minimum information for each unit:

- donation number;
- ABO and D group (where supplied);
- component code, including division numbers, as provided by the supplier;
- expiry date;
- expiry time (where appropriate);
- date and time of receipt into the laboratory and /or time booked into the LIMS;
- source of component (from a Blood Establishment or transferred from another hospital).

The LIMS should also allow for the following component characteristics to be retained against the component:

- antigen typing;
- Cytomegalovirus (CMV) antibody negative;
- gamma/Xray Irradiation;
- Hb S status;
- high titre flags;
- volume;
- comment field.

It may be desirable to record if the above information was received electronically or entered manually.

The LIMS will need to support the current UK combinations of ISBT 128 and codabar labelling systems and be future proofed for potential full implementation of ISBT 128 and the introduction of two-dimensional Data Matrix codes.

#### **2.1.2.1 Receipt handling with Electronic Delivery Note (EDN)**

Electronic dispatch notes (EDN) meeting the standardised specification written by Standing Advisory Committee for Information Technology (SACIT) (MacLennan 2013) are available from UK Blood Services. A LIMS which can upload information on received stock using this method provides a rapid and secure means of data capture.

When the delivery is received at the hospital each component received should be reconciled to the information captured from the EDN. This can be achieved by scanning the relevant pack barcodes, e.g. donation number and component type. Other information may be transferred electronically, including additional information such as red cell typing, which may not be barcoded on the label. The LIMS should be able to store this additional information in a manner that can be searched to support selection of appropriate antigen negative units.

#### **2.1.2.2 Receipt handling without EDN**

If the EDN message is not supported, then entry of stock via individually scanning the relevant barcodes e.g. donation number, group, component type and expiry date barcodes is required. All codes should be entered for each unit and pre-filled fields for this information must not be used, although defaults for supplier and stock storage location are permissible. Manual entry, via keyboard entry, of unit number, component type and blood group should be prevented for routine use and only available for back up purposes (N.B. this must prevent Electronic Issue of red cell units).

It is recommended that additional information should also be recorded in terms of antigen status and special requirements and a robust process (e.g. barcode or double blind entry) should be in place to ensure this information is entered correctly. A risk assessment should be carried out on the amount of data to be entered and the entry mechanism to be used.

#### **2.1.3 Stock Entry - Batch Products**

The system must store the following details of the product:

- date and time of receipt;
- manufacturer;
- name of product;
- batch number;
- expiry date;
- quantity of units received;
- batch comments, including volume and amount of product/bottle (e.g. IU/mL or bottle), where appropriate.

Additional items could include:

- supplier if different to manufacturer;
- type of product;
- ABO group (if applicable).

In general batch products are only identified by the manufacturer down to the level of batch number. Some organisations may wish to allocate local serial numbers to individual items within the batch to allow full traceability of each item. Some special requirements may need to be considered for the handling of SD plasma etc.

There is an international move towards standard bar coding of plasma derivatives/batch products. Information on this is available from the supply chain standards organisation GS1.

[http://www.gs1.org/sites/default/files/docs/barcodes/BD\\_Implementation\\_Guide\\_v1\\_0\\_24\\_aug\\_2010.pdf](http://www.gs1.org/sites/default/files/docs/barcodes/BD_Implementation_Guide_v1_0_24_aug_2010.pdf)

#### **2.1.4 Stock Tracking**

The system must allow the location of stock to be recorded and must support transfer of stock between locations with appropriate audit trails.

Laboratories will have to have procedures to manage the de-reservation of reserved units in accordance with national guidelines and local rules. The LIMS must be able to support compliance with these procedures by electronic de-reservation and the production of a list of units which are beyond their reservation period.

Care should be taken to ensure that the electronic de-reservation on the LIMS is aligned with operational procedures for the physical removal of units from the fridge.

The system must support the recall of units and maintain records of the reason and any incidents related to the component/product.

### **2.1.5 Management of Unused Units**

Not all components issued to patients will be transfused. The system must allow units to be retrieved from being issued/allocated to a patient and returned to the stock of unallocated units. Units which are no longer suitable for use (e.g. past their expiry date or out of temperature control) must be blocked from being returned to stock. There must be the facility to record the fate of discarded and transferred units.

## **2.2 Managing the patient record**

Correct patient demographics are a key feature of any IT system involved in the transfusion process. This applies to the Patient Administration System (PAS), the LIMS, Electronic Blood Administration (tracking) Systems ( ) and any electronic communication system (e.g. Order Comms) used to make requests of the transfusion laboratory. Unless the data is correct and consistent between these systems there is the potential for serious patient harm.

Laboratories should produce and maintain a document which describes the interfaces and flow of information between all systems.

Data integrity is fundamental to safe transfusion practice and must be maintained during sample acceptance, registration, requesting of tests, component (and any subsequent manipulations) and edits on the LIMS system. Processes should be validated to ensure that complete and correct patient and component/product data are entered into the LIMS. Wherever possible information should be entered in a structured manner e.g. coded to ensure data can be easily retrieved and searchable.

It is an essential feature of transfusion records that sample information is associated with the patient demographic information relevant at the time of processing. For this reason when the patient demographic details are amended/updated, the previous patient details should be retained against relevant samples.

### **2.2.1 Unique patient identifiers**

The LIMS system must support the use of the NHS number (or equivalent) (NPSA 2007) in addition to other numbering systems as required by the user, e.g. A&E or temporary numbers.

The use of the NHS number (or equivalent) is preferable as use of local numbers may cause problems and potential wrong blood incidents; this is particularly relevant in the modern NHS Healthcare systems with movement of patients, the merging of organisations and the formation of pathology networks.

### **2.2.2 Patient Information**

The system must be capable of holding the following essential information:

- basic patient demographic information including first and last name, DOB, gender, address and postcode;
- all relevant transfusion related patient data;
- all previous transfusion/grouping records relating to a patient;
- historic blood group information;
- special requirements;
- patient antibodies and antigens (should be coded to the international coding structure for antibodies/antigens) (ISBTa)
- previous names and addresses if applicable;
- patient diagnoses/clinical details/reason (justification) for transfusion.

Requests may be received associated with patients who have not yet been fully identified. The system needs to support entry of partial patient records and to allow patient details to be updated as they become available in accordance with local risk management policy.

There will be occasions when records from one individual will need to be associated with another individual's record and the LIMS system must support this. e.g. mother with infant and partner association in pregnancy associated testing.

### **2.2.3 Merging/Linking**

Duplicate patient records within a healthcare database have the potential to create a serious risk to patient safety by increasing the risk of incorrect or inappropriate actions from a lack of recognition of previous results. There must be a method available to merge/link duplicate records in a way which ensures the integrity of the transfusion record.

The MHRA has raised concern about the possibility for traceability records to become lost when merges are undertaken in the LIMS, especially if the LIMS is the primary method of maintaining the traceability record for 30 years (BSQR 2005). It is imperative to have documented policies and procedures to control the merging/linking process.

#### **2.2.3.1 Merging within the LIMS**

Systems must provide a facility for handling duplicate patient records. Duplicate records will be managed either by merging or linking depending on the system being used. Merging is where two or more records are converted into a single merged record usually under one of the original patient identifiers. Record linking is where the independent records are retained but a link is generated such that accessing any one of the records automatically provides access to information from all of the linked records. In general it is usually simpler to undo a linked record than to undo a merged record.

In the remainder of this section the term merging also applies to linking.

Locally defined rules for merging records must be in place and must address the following:

- only nominated staff with appropriate password privileges can use the merge function;
- clear, precise documentation on when a merge can be undertaken (SOP), including the safety criteria and checks applied to ensure that the merge is correct. This should address the retention of all historic grouping and screening information, special requirements (e.g. irradiation) and any specific antibody investigation information plus the identity of the person undertaking the merge;

- training procedures (and records) relating to the SOP;
- Ensure that documentation is maintained to (i) ensure that Traceability requirements as listed in the Blood Safety and Quality Regulations 2005 are met, and (ii) provide an audit trail of the individual records merged to form the single record.

The system must identify and alert the user in the event that the records to be merged have:

- different ABO and/or D blood groups;
- different antibody and/or antigen profiles;
- different special transfusion requirements.

Differences must be resolved or accepted by an appropriately qualified person before the merge can proceed. Password control must be in place in order to override routine control criteria.

Consideration should be given to whether paper or suitably archived electronic records may need to be maintained to ensure that Traceability and other information critical to patient safety are protected.

The audit trail must include

- the full patient details of both records prior to the merge;
- the date/time of the merge;
- the relevant details of the individual who performed the merge.

#### **2.2.3.2 Merging/linking outside the LIMS**

There must be safeguards to prevent changes made to other systems or disciplines from automatically updating the transfusion database. It is not acceptable for any external system to be able to merge LIMS records directly without applying the following specific rules:

- there must be a clear, precise organisational policy on when a merge can be undertaken, and the staff involved must have a clear understanding of the effect of merging on patient healthcare records;
- where transfusion records are present the policy must ensure appropriate notice and authorisation to show the integrity of the transfusion record is not compromised;
- documentation must be sent to the laboratory on what and who has been “merged”;
- traceability records must be maintained.

Where there is a link between the PAS and the LIMS the LIMS should recognise when an external merge has occurred and alert transfusion staff accordingly in order for appropriate update of the LIMS records.

#### **2.2.3.3 Undo linking/merging**

It should be recognised that undoing a merge is a high risk process which has the potential to compromise mandated traceability. A system must be in place to ensure that all information prior to the time of the merge reverts to the original state, and that subsequent information is correctly assigned to the appropriate record. An audit trail must be maintained.

### **2.3 Generating Transfusion Requests**

Transfusion requests for tests and components can be generated electronically or by manual systems. Guidance for manual request management is provided in the

Guideline on the Administration of Blood Components (BCSH 2009) and is not addressed further in this document.

This section addresses the electronic request for transfusion work to be undertaken on a uniquely identified patient and may include the collection and labelling of appropriate samples from the patient. This is a critical control point in the system and both automated and procedural controls must be in place to prevent errors.

Electronic request systems come in a variety of forms from a simple messaging system between the ward and the laboratory through to a comprehensive Order Comms system with full interfacing to the LIMS. In all cases the processes and controls must be clearly specified and interfaces between electronic request system, LIMS and manual actions well defined.

Electronic request management implementation is often a Trust/Hospital wide project with many disciplines involved, often with competing requirements. Management controls must be in place to ensure that the Transfusion Laboratory Manager is informed of all pending changes to systems interfacing with the laboratory. The Transfusion Laboratory Manager must ensure that changes are managed and appropriately version controlled and validated to ensure that the transfusion pathway continues to meet regulatory and quality requirements.

### **2.3.1. Electronic Request Systems (Order Comms)**

When electronic request systems (Order Comms) are used careful consideration must be given to how the transfusion process is managed. Order Comms may improve the management of information but positive patient identification requirements at the bedside must not be compromised.

Essential features of Order Comms must include:

- communication with the LIMS;
- access control ensuring that critical process steps are only available to authorised staff;
- support for the ordering of components including capture of information required by the transfusion laboratory;
- support for the entry of clinical special requirements (e.g. irradiated or CMV negative) and flag these to the laboratory;
- appropriate rules to determine whether a blood sample is required based on information supplied from the LIMS (BCSH 2013);
- alert in situations where a sample is NOT required or is already in the laboratory but action by the laboratory is needed (e.g. issue of components);
- monitoring of the electronic interfaces between the IT systems required to support the electronic request management process (Order Comms/PAS/LIMS) with user alerts in the event of interface failure;
- automatic detection of any discrepancy of demographic data between the LIMS, PAS and Order Comms systems with appropriate user alerts;
- a warning to the requestor if a request is rejected and the reason why;
- a mechanism to monitor work progress and to alert users if predefined sample receipt or process time are not met.

Some of the safety benefits of Order Comms should include:

- prevention of transcription errors by electronic data transfer into the LIMS;
- ensuring a structured requesting process e.g. use of prompts and mandatory fields, which should lead to more complete coded clinical information reaching the laboratory and improved quality of management reports;

- immediate and more convenient access to laboratory results and blood component availability;
- the ability to highlight 'on screen' those patients with antibodies, special requirements etc.

If Order Comms is used manual requests should be kept to a minimum but will have to be used:

- during roll out of a new system;
- during periods of system unavailability.

Mechanisms for manual requesting will therefore need to be in place. It is important to develop robust processes for manual data entry to mitigate risk at each stage of the process (BCSH 2009). Care must be taken to ensure any patient special requirements are captured. Appropriate controls will need to be in place to manage the subsequent update of the relevant IT systems.

### **2.3.2 Sample Collection (Order Comms)**

Acceptance criteria for patient samples is covered in the Guideline for the Administration of Blood Components (BCSH 2009) Order Comms can be used to support sample collection through the generation of phlebotomy lists and by the bedside printing of sample labels provided that appropriate controls are in place.

Use of electronic identification e.g. patient barcoded wristbands can reduce the risk of patient identification errors however, there remain manual steps in the process and the IT system should not be used to replace existing positive patient ID verification steps.

Each sample must be uniquely identified preferably including a unique barcoded sample identification number that can be used throughout the laboratory process thus eliminating the need for any re-labelling. If sample labels are printed by the electronic request management system the following must apply:

- verification of the match between the patient and the computer record and printing of the sample label must be performed at the bedside at the time of phlebotomy;
- date and time of collection of the sample must be recorded on the label.

Where request forms are retained it is essential that patient details on the collected sample match the information on the request form and are sent to the laboratory together.

### **2.4 Laboratory Handling of Samples/Requests**

Receipt of requests into the laboratory may be through either an electronic or a manual system. Receipt of samples and the matching of the request to the appropriate sample is a critical point in the system and correct association of sample and request is essential (BCSH 2013). Processes and controls must be clearly specified and interfaces between Order Comms, LIMS and manual actions well defined.

Care must be taken to ensure that the laboratory staff are appropriately alerted to all requests especially where there are no accompanying samples. Ideally there should be automated request and activity monitoring that will alert management in the event that activity is not performed in a timely manner.

#### **2.4.1 Manual Receipt and Entry onto LIMS**

Manual receipt covers situations where the requesting process is entirely manual or where there may be some electronic requesting support at the bedside that is not directly linked to the LIMS.

When patient demographics are entered onto the LIMS from the request form, the LIMS should be able to identify if the patient is already known and provide options to match to a record in the system. If no match is found a new patient record must be created. If during this process it is identified by the LIMS that a potential duplicate record is being created (i.e. same/similar details but different unique patient identifier entered) the user should be alerted.

Once all patient identification checks are complete the request together with the accompanying samples must be allocated a unique barcoded laboratory number.

When the patient record has been identified or created the unique laboratory number should be scanned and the request details, the collection date and time and any relevant additional information (e.g. special requirements) entered. Any necessary record association (e.g. mother, infant) should be made at this point.

#### **2.4.2 Electronic Receipt and Entry onto the LIMS (Order Comms)**

This covers situations where there is an electronic transfer of information from Order Comms to LIMS. The request must always be identified with a unique request number.

Where samples are required it is strongly recommended that these are labelled with a unique barcoded identification number electronically generated at the bedside. The preferred option is for this barcoded number to be suitable for use in the laboratory thus removing the need for re-numbering.

If samples need to be re-numbered in the laboratory then appropriate procedures, based on local risk assessment, must be followed.

The matching of the request to the appropriate LIMS patient record is a critical point in the system. The degree to which this can be automated will depend on the individual system design. Special rules will need to be in place to cover situations where it has not been possible to fully identify the patient.

Date and time the sample is collected must be entered into the LIMS.

Special patient requirements may be identified in the electronic request or by the LIMS on the basis of patient demographics, clinical diagnosis or previous history. Any necessary record association (e.g. mother, infant) should be made at this point.

Manual systems must be in place to support transfusion activity when Order Comms is unavailable. When the systems are available again appropriate mechanisms must be in place to update them.

### **2.5 Analytical Processes**

Wherever possible, automated links between laboratory equipment and the LIMS should be in place. Where manual entry is necessary robust controls must be in place (e.g. double blind entry) to prevent manual transcription errors.

Ensuring continuity of sample and patient identification is vital throughout the transfusion process. It must be possible to identify testing undertaken against a



specific request at a specified time, as the immunological status of the patient can change.

### **2.5.1 Test Allocation**

The LIMS should have a role in the determination of tests required for a specific request in accordance with predefined test profiles. These tests should be allocated either directly to test equipment through electronic communication or to laboratory staff through worksheets/pick list for manual action.

Testing should follow the guidance provided in the Guidelines for Pre-transfusion compatibility procedures in blood transfusion laboratories (BCSH 2013).

The LIMS should be able to respond to test results that trigger further laboratory investigations by allocating follow up tests (reflex testing) the following are examples of good practice.

<b>Additional Test</b>	<b>Triggered by:</b>
Antiglobulin profile	Positive direct antiglobulin test
FMH estimation	D positive result for a cord associated with a D negative mother
Antibody Identification	Positive antibody screen

There should be a mechanism to prioritise emergency samples.

### **2.5.2 Worksheets**

The system should be able to produce worksheets, configured to user requirements, for recording laboratory results and/or checking specimen identity. It should be possible to view and update worksheets on screen, or print copies for manual completion.

### **2.5.3 Laboratory testing**

Result entry is a critical process and robust control of the process is essential. Wherever possible, laboratory testing should be performed by automated systems with electronic data transfer to the LIMS. Where such systems are in use both the system and the interface used for sending results must be validated. As part of the result information for each test the LIMS should hold the following administrative information:

- whether results have been entered by automatic links or manually;
- whether the result has been edited;
- date (and time) of testing;
- audit trail of activities.

Where interpreted results are sent from the analyser to the LIMS results which have been edited on the analyser must be flagged. This is important for the algorithm for electronic issue (EI). If the analyser cannot flag interpreted results that have been edited then it is preferable that un-interpreted individual test results are sent for interpretation by the LIMS. Any necessary editing would be performed on the LIMS and stored appropriately.

Where manual interpretation and/or entry are required procedures must be in place to reduce the risk of a manual error remaining undetected (e.g. use of double blind interpretation and entry.)

Where results are entered manually into the IT system the historic results should not be displayed on screen and where possible results should be entered into the system as double blind entry or if this is not possible verified by a second operator as soon as possible

#### **2.5.3.1 ABO/D Testing**

Robust ABO and D typing, and storage of results are essential for safe transfusion practice. Any discrepancies between current ABO/D results and historic results must be flagged by the system and appropriate investigation and corrective action must be taken.

#### **2.5.3.2 Antibody Screening**

Antibody screening results can be stored either as individual results against each cell by each technique or as a composite result.

Positive antibody screening results must alert the user and should automatically trigger a request for antibody identification.

The LIMS should display any previously detected antibodies.

#### **2.5.3.3 Antibody Identification**

Antibody identification results can be stored either as individual results against each cell by each technique or as a composite result.

Antibody identification interpretation should be entered as separate specificities, using drop down (coded) lists or equivalent. There should be controls in place to minimise the risk of manual error.

The system should have the ability to categorise antibody specificities according to their clinical significance and use this information to support the generation of reports using standard comments (e.g. possible delay in provision of red cells) (Daniels 2002). The system should allow adjustment of these comments in specific cases.

#### **2.5.3.4 Crossmatch**

Crossmatch results for each unit tested can be stored either as individual results by technique or as a composite conclusion. These results may be transferred electronically from an analyser or entered manually.

Whatever the method of entry the following information must be stored:

- patient identifier;
- donation number;
- test conclusion or results of individual test by technique and reaction grade;
- date, time and identity of personnel/analyser for all actions.

#### **2.5.3.5 Pregnancy- Related Testing**

Testing should be undertaken as outlined in BCSH Guidelines for Blood Grouping and Antibody Testing in Pregnancy. (BCSH 2007b), currently under review.

The IT system should store the following additional information to that identified above:

- number of weeks gestation and EDD (where EDD only has been supplied the LIMS should automatically calculate and display the weeks of gestation);
- partner phenotype (where relevant);
- Free fetal DNA results where relevant
- titre/quantitation results where clinically significant antibodies are present;
- date anti-D prophylaxis administered and dose.

On the basis of patient information and the results entered the LIMS should be able to:

- provide recall testing information against a user defined algorithm with reference to the Guidelines for Blood Grouping and Antibody Testing in Pregnancy (BCSH 2007b);
- indicate requirements for Routine Antenatal anti-D Prophylaxis (RAADP).

### **2.5.4 Quality Assurance of Analytical Processes**

Analytical processes should be subject to quality assurance including both internal quality control (IQC) and External Quality Assessment (EQA). The Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories (BCSH 2013) should be referred to for the content and frequency of IQC.

#### **2.5.4.1 IQC**

The method of recording and storing IQC data might depend on whether the data is generated on automation linked to the LIMS, or in manual systems. However this is handled, it must be possible to associate all tests with valid IQC.

For automated testing, where IQC data is generated but not used by the instrument to control result interpretation and transfer, IQC data should be sent to the LIMS and the LIMS should verify IQC data before accepting the test results.

For automated testing, where the automated system validates IQC data prior to transfer of test results, IQC data should still be retained but can be on the automated system providing there is an approved backup and restore process.

#### **2.5.4.2 External Quality Assessment (EQA)**

The LIMS should facilitate processing of EQA samples, and be able to interpret and store results of EQA samples in the same way as clinical samples.

It should be possible to flag EQA samples so that they are easily identifiable, and can be excluded from laboratory workload statistics if required.

### **2.5.5 Technical authorisation**

The LIMS should be able to support automated authorisation (“auto validation”) when results are transferred from a fully automated analyser; there has been no editing of results; and where there are no discrepancies identified from previous results.

All results which do not fulfil the above criteria, manual and automated, should be reviewed and approved by authorised staff. Staff performing the review must have access to all information associated with the results.

## **2.6 Component selection**

This section applies to the selection of all blood components (red cells, platelets, plasma). The LIMS must ensure that components selected meet all necessary requirements to ensure their suitability (e.g. antigen negative units, neonatal requirements etc.)

In clinical emergencies some requirements may need to be overridden in accordance with pre-agreed protocols and any concessions must be documented.

It is important to take into account the special requirements flagged for the individual patient. Incorrect component selection is a common adverse event identified in the Annual SHOT reports (SHOT 1996-2012). Patient special requirements may be known from previous transfusion history/testing; specified on the sample request; identified through current testing; or determined by the application of predefined demographic/clinical rules see Appendix 1.

Selected components should be reserved for a defined period in accordance with the Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories (BCSH 2013)

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### **2.6.1 Additional Requirements for the Selection of Red Cells**

The selection of red cells will proceed along one of the following paths:

- serological crossmatch (manual or automated);
- electronic Issue (EI) without serological crossmatch;
- emergency issue of red cells.

In all cases the LIMS must ensure that the controls and rules expressed in the Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories (BCSH 2013) are followed. Guidance below addresses the management of some of these requirements by the LIMS.

The following requirements apply:

- the LIMS must not allow selection of ABO incompatible red cell units;
- the LIMS must prevent use of results from an invalid sample;
- the LIMS should not allow issue of units where pre transfusion tests remain outstanding, except in emergency situations, where a controlled override should be possible.

Controls in the LIMS must prevent the following unless appropriate override has been authorised:

- selection of D positive blood for a D negative patient;
- selection of incompatible units for a patient with known antibodies.

#### **2.6.1.1 Serological Crossmatch (Manual or Automated)**

Units for serological crossmatch should be reserved on the LIMS using barcoded entry of selected donations. Some systems can be configured to manage the selection process. This may help stock rotation however this requires staff to locate the selected units from within the available stock.

#### **2.6.1.2 Electronic Issue (EI) without serological crossmatch**

The LIMS must perform checks to ensure that all the requirements for EI have been met including all criteria identified in the Guidelines for Pre-transfusion Compatibility Procedures in Blood Transfusion Laboratories (BCSH 2013). The Medicines and Healthcare products Regulatory Agency (MHRA) have published guidance on EI and this should be referred to (MHRA 2010).

Extensive validation of the EI procedures, protocols and systems must be performed prior to implementing EI and repeated following system maintenance and upgrades.

EI must not be used:

- in the event of LIMS downtime;
- where the patient group or antibody screening results have not been transferred electronically from automation to the LIMS;
- with units that have not been entered into blood bank stock electronically;
- where automated results have been manually edited.

### **2.6.1.3 Emergency Issue of red cells**

There will be occasions where it is necessary to release blood for transfusion without performing/completing pre transfusion testing or crossmatching. In these circumstances the LIMS should allow emergency issue as identified in the Guidelines for Pre Transfusion Compatibility Procedures in Blood Transfusion Laboratories (BCSH 2013).

In all cases entry of retrospective testing e.g. compatibility results, must be possible with full audit trail of entries and amendments available.

If patient information is not available at the time of issue later reconciliation must be possible once the full patient record has been established.

## **2.7 Selection of Fractionated Blood Products**

The LIMS should enable selection of fractionated blood products based on clinical algorithms. These could utilise flags or logic rules (see Appendix 1) to prompt accurate and/or timely selection of the right product (e.g. management of anti-D immunoglobulin).

## **2.8 Component labelling and Issue**

The labelling of blood components is a critical step, and components must be identified with a securely attached compatibility tag before issue.

Units should be authorised and the labels printed and attached, one patient at a time, at a single workstation location. Multiple workstations using a single printer are a potential source of error and should be avoided.

All labels when attached to components should not cover or obscure donation or manufacturer information on the unit base labels.

There must be a way to verify that the correct label has been attached to the correct unit.

### **2.8.1 Compatibility tag**

The compatibility tag should be printed out once the units have been authorised as compatible or suitable for issue. The information required to be printed onto each label is identified in Guidelines for Pre-transfusion Compatibility Procedures in Blood Transfusion Laboratories (BCSH 2013) and this should be reviewed in conjunction with these guidelines. The system must include the following information on the compatibility tag when available:

- i. last name;
- ii. first name;
- iii. date of birth;
- iv. unique patient identification number
- v. 1st line address (mandatory in Wales only)
- vi. patient ABO and D group;
- vii. donation number (ideally in both eye-readable and barcode format);
- viii. component type;

- ix. statement indicating whether the component is compatible or suitable;
- x. date by which the component must be transfused or de-reserved (taking into account the change in expiry date and time when thawing frozen plasma component/products).

It should be possible to print a comment on the compatibility tag, e.g. to highlight where the blood group of the unit and the patient are compatible but not identical.

Where a blood tracking system is to be used in conjunction with the IT system there may be a requirements for additional barcodes.

### **2.8.2 Label attachment verification**

There must be a specific process step to ensure the correct label has been attached to the correct component. Ideally this verification should be by automated means using electronically readable information.

This verification step must include:

- check to ensure donation number on component is identical to the donation number on the compatibility tag;
- check to ensure the component type on the compatibility tag is correct.

Where automated support for verification of the donation number is employed this will require printing of the barcoded donation number on the compatibility tag. The automated system must be designed to ensure that the donation numbers from both the component and the compatibility tag have been compared, (i.e. duplicate entry of one barcode would be detected as an error).

### **2.8.3 Remote Electronic Issue**

In some hospital configurations it may be beneficial to store blood components close to the point of use and this may be at a location that is distant from the hospital transfusion laboratory. In such cases components will be accessed by staff other than laboratory staff. This is referred to as remote issue and should always be supported by electronic systems under the control of the LIMS to ensure correct component release.

Components in remote issue must be managed by the transfusion laboratory and procedures in place to ensure that at all times only suitable components are available. The current location of all blood and components, including thawed FFP, should be available in the laboratory. Records must be kept of all movements of components.

Remote issue of red cells must only be used for patients who have been determined as eligible for EI. Each organisation should define whether patients with special requirements (e.g. irradiated) will be handled through remote issue.

Remote electronic issue must be rigorously controlled through use of standard operating procedures, trained and competent staff and validation of the system in use. The following controls must apply to all remote electronic issue systems:

- the user must be positively identified by the system and verified to ensure they are authorised for the procedure;
- procedures must be in place to ensure all stock is suitable for issue and appropriate stock rotation is in place to ensure units are removed prior to expiry;
- the identification of the patient and the request for components must follow the same rules as identified in section 2.3 and the Guidelines on Administration of Components (BCSH 2009)

- request information must be transferred to the LIMS either through electronic requesting or direct input to the remote issue system. The latter will require secure systems for entry preferably utilising barcoded information;
- the LIMS must verify the patient request and authorise the issue of group compatible components;
- the LIMS must take into account any special requirements that apply to the patient and ensure that these are met;
- selected units must be scanned into the remote issue system and a label produced;
- there must be a system for label verification to ensure that the label attached to the component matches exactly in terms of donation number;
- the system must generate local and remote alarms if a user scans the wrong unit, and give a prompt to return the unit and take out the correct one.

Records stored must include:

- identity of individuals undertaking any step in the process;
- identification of the patient;
- donation numbers of the units placed into stock or issued;
- component type(s);
- date and time of placement and issue.

There should be an alarmed electronic override feature as this is essential for use in emergencies i.e. release of emergency group O blood. All events should be logged and investigated retrospectively.

All blood that has been recalled or removed from the remote issue system for longer than the specified time (depending on the storage conditions) must be quarantined so that it cannot be dispensed.

Remote issue systems must not be used if the interface to the LIMS or any element of the remote issue system fails. Contingency plans must be in place.

## **2.9 Post Analytical Reporting**

The system must support both printed reports and electronic reports available on-line. It should be possible to format reports so that they are clearly presented and contain terminology that is clear and unambiguous. Where possible comments added to reports should conform to those identified in other BCSH guidelines.

Reports must be designed to give all information required for full identification of the patient and essential user information as laid down by Clinical Pathology Accreditation (UK) and ISO15189 standards.

The report must draw the users attention to the date of final authorisation and advise the user to take this into consideration when interpreting the information e.g. report may state that the patient is suitable for electronic issue but this may no longer apply depending on the sample date.

If the compatibility report form (or equivalent) is to be printed it should not be used as part of the administration checking process as recommended in the NPSA Safer Practice Notice 14 (NPSA 2006).

There should be options to have reports by:

- type of test;
- consultant/requestor;
- location;

- blood component/product;
- others as defined by local specification.

Reports can either be:

- final - released following authorisation;
- interim - released prior to authorisation but clearly marked as unauthorised or incomplete.

An audit trail should be in place to show when the electronic report was viewed and by whom.

Increasingly reporting needs will include transfer of information to other IT systems. Such transfer should comply with applicable healthcare communication standards applied within the organisation. Dispatch of the reports must be to a recognised system and must meet the security and information governance recommendations

### **2.9.1 Corrections to reports.**

Correction to issued reports must be treated as a quality incident with appropriate investigation, corrective and preventive actions including:

- withdraw all copies of the report;
- inform the relevant users that the report has been changed
- follow through of actions that other electronic systems have taken on the basis of the original report e.g. Order Comms
- monitor, track and trend the number of incidents where this occurs

The LIMS should support this activity by:

- providing lists of users who have viewed on line reports
- issue of an updated report which clearly indicates its revised status

Where interim reporting is supported consideration should be given to the procedures to be followed when information is changed prior to authorisation.

### **Recommendations**

**Electronic transfer of data, without manual editing, is recommended to ensure patient safety.**

**The use of automated controls for stock management provided by the IT system should be used to the fullest extent possible to minimise the risks due to manual transcription.**

**EI and remote issue must not be used unless all the criteria identified in the relevant EI and Remote Issue sections contained in these guidelines (and other relevant guidelines) are met.**

**The IT system must support component selection and control the issue of components where patients have special requirements.**

**Processes must be in place to ensure that patient identification data are consistent and accurate across all interlinked systems. Special consideration should be given to the interface between transfusion and external systems and the way in which patient record updates on external systems are reflected in the LIMS.**



**There must be a method available to merge/link duplicate records (and to undo merges) within the LIMS in a way which ensures the integrity of the transfusion record and maintains traceability.**

**There must be safeguards to prevent changes made to other systems or disciplines from automatically updating the transfusion database without appropriate validation.**

**The system should be configured employing logic rules to support good transfusion practice (based on BCSH guidance) but with controlled flexibility to ensure that patient safety is not compromised in exceptional circumstances.**

**Wherever possible all information should be entered in a structured manner (i.e. coded) to ensure data can be easily retrieved and is searchable.**

### **Section III Electronic Blood Administration (Tracking) Systems**

Traditional LIMS provide control of activities that take place in the laboratory. Increasingly there is recognition of the need to extend the scope of electronic control through to patient administration. Specialist systems have been developed which interface to the LIMS and control these additional steps.

Electronic systems can be used at the following stages of the transfusion process:

- component collection (fridge tracking)
- remote electronic issues (see 2.8.3)
- administration (bedside tracking)

Electronic control of all steps in the transfusion process using a blood tracking system means that risk of administration errors are reduced and real time data is instantly available with real time warnings/alerts generated (e.g. if expired blood is available for collection).

It is important to define how each system is managed to maintain the necessary control. There should be electronic communication between the LIMS and all electronic blood administration (tracking) systems and all traceability information should be collated onto a single system for lookback and retention. It is recommended that the LIMS should be the ultimate recipient of traceability information and for maintaining this for the legal requirement of 30 years.

The following criteria apply to all these systems:

- access to the system must be controlled and limited to authorised users;
- staff must be given training before access to the system is allowed;
- systems should utilise machine readable information and electronic transfer of critical information wherever possible;
- alerts should be seen/heard at the site where action is required, but the blood transfusion laboratory should also receive these alerts to ensure that appropriate action is taken;
- robust manual procedures must be documented for use during system downtime;
- every transaction on the system must be logged with user ID, date, time and a full audit trail must be maintained;
- the boundaries of responsibility between the LIMS and the electronic tracking systems must be clearly defined.

### 3.1 Component Collection (fridge tracking)

A fridge tracking system is specifically designed to manage and control the movement of components once they have left the transfusion laboratory.

The degree of control imposed by these systems will vary from simple data capture to electronic locking which controls release down to the unit and patient level.

The following requirements apply to fridge tracking systems:

- configuration of the system should be such that there is real time communication between the LIMS and the issue locations;
- the LIMS should electronically notify the fridge tracking system when components are ready for issue to specified patients;
- the LIMS should be able to update the fridge tracking system if units are no longer suitable for use and the system should respond accordingly;
- where multiple storage locations are used each must have a unique identification code;
- systems should require entry of the unique patient identification, in an electronically readable format. Ideally this should be generated from the patient's wristband;
- the system should control access to the fridge/platelet incubator with some form of electronic lock. System design should ensure procedurally controlled access and system alerts in event of network downtime, power failure, clinical emergency etc.;
- the fridge should only unlock if components are available for the specified patient;
- the system must electronically read and recognise unique component IDs including donation number, component code (including split number);
- alert/warnings should be generated if units are no longer suitable for transfusion;
- the transaction history of each component must be stored. This should include, where applicable, the physical transfer of components from stock to issue locations; details of unit movements including transfer between unreserved and reserved stock; transfer to and from satellite refrigerators; issues to wards and departments; and transfers to other hospitals.

### 3.2 Administration (Bedside Tracking)

A bedside tracking system is designed to:

- prevent administration errors by controlling the pre-transfusion checks required between patient and the component to be administered;
- capture administration information in real time at the bedside.

The use of a bedside blood tracking system does **not** replace the role of the well trained and competency assessed clinician who administers blood components.

SHOT has shown that an administration error has the potential to cause significant patient morbidity. The use of bedside tracking systems with electronic capture of information from the patient wristband, component label and compatibility tag significantly reduces the risk of manual transcription errors and omissions (Staves 2008). For this reason bedside tracking systems should be considered for all transfusions.

The bedside tracking system must perform pre-transfusion checks at the patient's side including the following:

- electronic capture of the unique patient identification from the wristband or equivalent;

- electronic capture of the donation number, component code, blood group and expiry date from the unit;
  - a verification process using information from the LIMS (either transmitted by direct communication with the bedside tracking system or by the use of electronically readable information on the compatibility label) which securely links patient and donation information;
  - alert to errors in real time to prevent incorrect blood component transfusions;
- The electronic system may be used to prompt for the manual checks recommended by the Administration of Blood Components (BCSH 2009).

There must be regular monitoring and audit of data download from these bedside devices whether in wireless enabled areas or via docking devices.

Bedside tracking systems may also be able to capture and support the administration information including:

- date and time of transfusion;
- healthcare staff identity;
- transfusion start and end time;
- patient observations.

These may be transferred back to the LIMS together with the patient identification and donation information and support the legal traceability requirements.

If there are emergency overrides these must be risk assessed and have appropriate procedural controls in place.

#### **Recommendation**

**Electronic tracking systems have the potential to provide patient safety benefits but to realise these sufficient resources for training, ongoing support and maintenance should be allocated**

#### **SECTION IV – Recording Administration/Final Fate Information**

Mechanisms must be in place to ensure the final fate of each component is captured. Hospital final fates may include transfusion to the identified patient; discard; transfer to another hospital; recall by the blood service.

Final fate information can be provided to the LIMS in a number of ways including:

- manual entry in the laboratory from the return of paper documents;
- manual entry onto the LIMS from the clinical area;
- electronic transfer from a tracking system.

Where manual entry is used it should be performed as soon as possible after the transfusion. It is essential to assure the accuracy of the data entry. This may be facilitated by the use of a barcoded donation number on the compatibility tag. If electronic entry of donation number is not supported then double blind manual entry is required.

Blood components that are not transfused because they are either not required or are not suitable for transfusion must be returned to the blood transfusion laboratory. Following assessment of the cold chain a decision will be made to return blood/component to stock or discard. If the unit is to be discarded the final fate must be recorded in the LIMS.

## **SECTION V– Information Management**

Effective information management must ensure that information is available when and where it is needed; confidentiality is ensured to prevent access by unauthorised individuals or systems; the integrity of the information “accuracy and consistency” is maintained and the durability of information storage for the required time periods is ensured.

It is essential to ensure traceability throughout the transfusion pathway from donor to recipient (or other fate), and traceability within hospital systems is as an essential element of this system. There are legal requirements for traceability (BSQR 2005).

### **5.1 Traceability and Data Retention**

All records necessary to provide rapid and effective tracking from receipt of the donation into the laboratory until final fate of that donation must be available for 30 years as required by legislation. This will include the final fate traceability captured at the time of use or other disposal. Special care must be taken to ensure the traceability of components is maintained when transferring these between organisations.

The following minimum data set (if applicable) to be retained by hospital blood banks is:

- donation number to include split numbers where applicable;
- component type;
- Blood Establishment/supplier;
- date received;
- identity of the patient who received the blood component or final fate if not transfused.

Traceability of components is a legal requirement for the organisation and requires cooperation between transfusion laboratories and the organisation. This must be documented and identify:

- where traceability information is held;
- how information elements are linked between systems;
- the mechanism and frequency of traceability audits.

This strategy must be updated as part of any IT system upgrade or replacement to ensure historic records are not compromised.

### **5.2 Management information /data collection**

The LIMS must be able to support the reporting requirements of the organisation which should have been identified as part of the URS. This may include pre-defined reports, locally configurable reports or the ability to produce ad hoc reports. If data items can be associated with standard codes this approach to data entry and storage is recommended (e.g. SNOMED-CT).

The LIMS must be able to extract data for statistical analysis such as billing, audit and monitoring of Key Performance Indicators (KPIs).

Examples of KPIs would be:

- turnaround times for various laboratory processes;
- information to support MHRA SABRE reporting;

- information to support MHRA hospital blood compliance reporting.

There will always be requirements to run *ad hoc* enquiries. Staff involved in the production of ad hoc and locally configurable reports should be trained and have appropriate knowledge of how the system works and what needs to be extracted (this should be undertaken in accordance with local policy).

Data stored on the LIMS should be accessible to third party applications to allow further analysis. Access to the database by third parties must always be adequately controlled to ensure data security requirements are not compromised. Third party usage may be by local users (e.g. through spreadsheets or statistical software) or to approved third party organisations such as:

- Blood Stocks Management Scheme (BSMS);
- Anthony Nolan panel;
- Blood Service stock management requirements;

### **5.3 Improving blood usage through clinical information and audit**

The LIMS contains information on blood and blood component usage that can be used by clinicians, managers and hospital transfusion committees when reviewing clinical transfusion practice and service developments that may increase or decrease blood usage.

Blood and blood component usage and wastage can be attributed on the LIMS to patients, clinical locations, clinicians and specialties and extracts of this information can be used to produce regular 'clinical accounts' for blood. The same data can be analysed on an ad hoc basis for clinical audit.

It is desirable to have a standard clinical transfusion data set and to code clinical information such as the *indication* for transfusion and the *reason* for transfusion so that all fields are searchable. This greatly improves the ability to undertake clinical audit and to produce regular data for key clinical performance indicators as well as the previously mentioned clinical accounts.

The demographic and clinical information given at the time of the request for testing or request for blood and blood component issue can either be entered manually or input via order communications systems. Where it is possible to configure the order communications systems to use the same *indication* and *reason* codes for transfusion these can be transmitted to the LIMS with the request.

The LIMS and Order Comms systems can be used to support national and local transfusion policies. This might include getting data from a haematology LIMS such as haemoglobin levels when ordering a red cell transfusion to see if locally agreed transfusion triggers and targets are complied with. It could also be used to record when valid consent for transfusion has been obtained or to record a pre-transfusion platelet count against the issue of a platelet unit.

Although few centres have used this clinical functionality to date, it is important when implementing a LIMS for blood transfusion, to consider the opportunities and specify the fields that will be able to accept these sorts of clinical data. Examples are given in Appendix 3 and Appendix 4

#### **Recommendation**

**Each organisation must have a traceability strategy which is jointly owned by pathology and IT and is part of the quality system.**

**Coded entry of the reason and indication for transfusion as well as supporting laboratory parameters should be stored and retrievable from the LIMS in order to support safe and rational component use.**

## **Section VI System Management**

The Laboratory will need to ensure effective information security (confidentiality, integrity and availability) in line with regulations and best practice and effective control of system changes and upgrades.

### **6.1 System Security and Governance**

Information held on laboratory systems must be appropriately managed to ensure confidentiality, integrity and availability are maintained in compliance with regulation and NHS guidance. The NHS Information Governance toolkit is available at: <http://systems.hscic.gov.uk/infogov>

Governance applies to all databases including legacy systems and data archives.

Access levels must be controlled to ensure that staff can only access areas of the system for which they have been appropriately trained and assessed as competent. Procedures must ensure a prompt removal of access once an individual's authorisation terminates.

### **6.2 System Availability and Business Continuity**

Systems will normally need to be available 24 hours a day, seven days a week, but this may vary according to local situations. Appropriate fallback and support arrangements need to be in place that can ensure continued service delivery in the absence of the IT system. Availability requirements must be reflected in system and network design and maintenance/ support arrangements.

When determining acceptable down time the following must be considered:

- throughput;
- staff resources;
- manual data recovery.

Even in the most robust systems there will be inevitable downtime. Risk assessments must be performed to identify those risks associated with system failure and be used to inform system design, implementation and backup and recovery procedures.

The system architecture should be designed to have no "single point of failure" e.g. where possible there should always be an alternative server or connection that can be brought into play manually or automatically if possible. For multi-site organisations the wide area network configuration must support the necessary degree of resilience and recovery.

Business continuity plans must be regularly stress tested to demonstrate their effectiveness and identify their limitations. This must include the recovery phase where the IT system is brought up to date with all the transactions.

### **6.3 Data Integrity**

Transfusion related information will be stored in the LIMS and in other associated systems. It is essential that this is retained in a consistent state across all systems e.g. it would be unacceptable for the status of a donation to be in stock in the LIMS but issued on the blood administration (tracking) system.

Data integrity checks are performed to identify any areas of inconsistency that have developed. There must be policies in place to ensure adequate and comprehensive data integrity scans are performed at regular intervals to achieve this objective. Where integrity errors are identified corrective and preventive actions must be implemented.

### **6.4 Duplicate Record Searches**

A system should be in place for searching the LIMS for potential duplicate patient records. SHOT annual reports have highlighted the clinical problems which can arise when more than one patient record is in existence. Amalgamation of organisations, and hence LIMS records, has increased this problem. Where patient records are being merged/linked across networks it is important the local hospital transfusion laboratory is involved.

The following functionality should be supported:

- searches should run automatically at pre-determined time periods with the ability to activate manually if required;
- user definable search criteria;
- use of a limited dataset search to allow for misspellings of patient names or amended date of birth entries;
- “soundex” or similar intelligent style searches.

Local procedures should be in place to define the corrective and preventive actions to be taken if a duplicate is found. Merging of any duplicate records should be handled as outlined in Section 2.2.3 above.

### **6.5 Backup and Disaster Recovery**

Backup should comprise a regular copying of the database to secure media which are stored separately from the main database and a journal system which allows recovery of data from the period of last backup to the time of failure.

The storage location for backup media must be based on an appropriate risk assessment of the likely disaster scenarios.

The backup process must be documented and validated and regularly tested to demonstrate its ongoing effectiveness. Recovery procedures must be in places that cover all steps from the moment of system failure through to the resumption of routine operations. This must include verification that: the data has been fully retrieved; the system has been returned to the same state as the time of failure; operational processes resume from the point of failure.

### **6.6 Change Control and System Upgrade**

Systems are being continually updated by vendors and new versions of software being released. System upgrades should be evaluated both in terms of their immediate impact and the long term consequence of not installing when available. Care must be taken to ensure that software is updated in line with the vendor support strategy to prevent loss of vendor maintenance.

The change control process must apply to all individuals involved in the management and use of the LIMS and associated transfusion systems. This may include other

pathology disciplines and hospital IT departments where transfusion is part of a larger pathology discipline. Any change to the system, however minor it may seem at the outset, will need to be critically evaluated, a change control raised and appropriate risk assessments performed to identify the level of validation required.

Supplier access to systems must be controlled to prevent un-validated system changes.

### **6.7 Audit Trails**

It is essential that audit trails are available on the system to provide accountability and to assist in investigation. The system must:

- maintain an audit trail of critical actions associated both with patient records and transfusion activity;
- record all significant process actions e.g. inputs, amendments, overrides and actions associated with a date/time of action, and identification of the individual performing the action;
- provide access to records for review and retrospective search, as necessary.

Each organisation should risk assess and document which actions and processes need to be maintained in the audit trail and should validate and carry out periodic audits to ensure system conformance.

### **6.8 Archiving**

Archiving of all data and documentation must conform to BSQR 2005 and the guidelines from The Report of the Working Party of Royal College of Pathologists and the Institute of Biomedical Science "The Retention and Storage of Pathological Records and Archives" 4<sup>th</sup> edition 2009. (RC Path 2009),

#### **Recommendations**

**All systems must have an appropriate backup strategy that will ensure data recovery within a time frame during which business continuity plans are effective.**

**Any updates or amendments to the system must be controlled through the Quality System using a formal change control process.**

**Access and security of the LIMS must be controlled in line with Trust and National IT policies.**



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**Examples of Logic Rules:**

Regulation and guidelines require that many rules are applied when determining the suitability of components for transfusion. Wherever possible it is advisable to embed these rules into the operating logic of the LIMS. However the LIMS can only apply rules on the basis of information known to the system. In practice the correct application of rules will rely on a combination of logic rules applied by the LIMS and procedural rules applied by laboratory staff. These may be combined in a situation where a member of laboratory staff follows procedural rules to apply a 'flag' to a patient record, and the LIMS then applies logic rules specific to the flag to control issue of components. This applies in particular to the clinical/diagnosis section below. This appendix provides a reference list of rules that must be taken into account when configuring the logic rules of the LIMS and developing the supporting standard operating procedures. The rules identified are correct at the time of writing but are subject to change as referenced documents are updated. The list may not be comprehensive and it is the responsibility of the laboratory manager to ensure that all necessary controls are in place.

Logic rules specify the way in which the LIMS operates and should be configured to ensure the system meets all necessary legislation and guidelines. LIMS logic rules are established to control component release under normal circumstances, however there will sometimes be occasions when there is a need to override a specific logic rule (e.g. in a clinical emergency) and the system must allow this in a controlled manner and by appropriately authorised staff. Override actions must be defined and controlled through standard operating procedures. There must be an audit trail of all overrides capturing the reason and the operator.

The following rules that have been split into age, gender, clinical/diagnosis and antigen matching related sections.

<b>Logic rule</b>	<b>Reference</b>
<b>Age-related</b>	
Imported (non-UK) MB FFP (or SD FFP) for patients born after 1 <sup>st</sup> Jan 1996	SaBTO Updated Risk Assessment and reissued guidance 2012 (SaBTO 2012a)
Irradiated blood and platelets for intrauterine transfusion	BCSH Transfusion Guidelines for Neonates and Older Children 2004 (BCSH 2004) Guidelines on the Use of Irradiated Blood Components 2011 (BCSH 2011)
CMV seronegative red cell and platelet components for intrauterine transfusions and for neonates (i.e. up to 28 days post expected date of delivery).	BCSH Transfusion Guidelines for Neonates and Older Children 2004 (BCSH 2004)  SaBTO cytomegalovirus tested blood components Position Statement March 2012 (SaBTO 2012b)

<b>Gender-related</b>	
K- red cells for females under 50 years of age	BCSH Guidelines for Pre-transfusion Compatibility Procedures in Blood Transfusion Laboratories (BCSH 2013)
CMV seronegative red cell and platelet components for transfusions during pregnancy The guideline indicates this is not required for transfusion during delivery however, the LIMS may not have the necessary information to include this in the logic rule.	RCOG Green-top guideline (47) Blood Transfusion in Obstetrics (RCOG 2007) SaBTO cytomegalovirus tested blood components Position Statement March (SaBTO 2012b)
Red cells negative for Rhc to Rhc negative females of child-bearing potential	Good practice agreed across Wales
Prophylactic anti-D immunoglobulin to non-sensitised pregnant RhD negative women	RCOG Green-top guideline (22): The Use of Anti-D Immunoglobulin for Rhesus D Prophylaxis (RCOG 2011) BCSH Guidelines for the use of Prophylactic anti-D Immunoglobulin (BCSH 2006)
<b>Clinical/Diagnosis-related</b>	
Irradiated products required for: <ul style="list-style-type: none"> <li>• Patients with Hodgkin's Disease</li> <li>• Patients within 7 days of autologous haemopoietic stem cell collection</li> <li>• Patients undergoing haemopoietic stem cell transplantation</li> <li>• Patients receiving purine analogue drugs</li> <li>• Patients post intrauterine transfusion whilst in the neonatal period</li> </ul> Consideration to length of time irradiated products are required for must be considered	Guidelines on the Use of Irradiated Blood Components (BCSH 2011) BCSH Transfusion Guidelines for Neonates and Older Children 2004 (BCSH 2004)
Rh and K-matched and HbS negative red cells for patients with Sickle Cell Disease	Standards for the care of adults with sickle cell disease in the UK (NHS 2008) Sickle cell disease in childhood: standards and guidelines for clinical care (NHS 2010) BCSH Transfusion Guidelines for Neonates and Older Children 2004 (BCSH 2004)
Rh and K-matched red cells for patients with $\beta$ -Thalassaemia major	Standards for the Clinical Care of Children and Adults with Thalassaemia in the UK (NHS 2008)

	Thalassaemia International Federation Guidelines 2 <sup>nd</sup> edition (Thal 2008)
Red cell units within 14 days of collection for red cell exchange in sickle cell disease or other haemoglobinopathy	Standards for the clinical care of adults with sickle cell disease in the UK (NHS 2008) Sickle cell disease in childhood: standards and guidelines for clinical care (NHS 2010)
CMV seronegative red cell and platelet components <i>according to local policy and if flagged</i> e.g. haemopoietic stem cell transplantation, solid organ transplantation	European Bone Marrow Transplant handbook (EBMT 2012)
SD FFP for patients with TTP and HUS	BCSH Guidelines on the diagnosis and management of thrombotic thrombocytopenic purpura and other thrombotic microangiopathies (BCSH 2012)
Platelets in PAS for those flagged	
Washed red cells for those flagged	
<b>Antigen Matching Criteria</b>	
Antigen negative for red cell antibodies of potentially clinically significant antibodies	BCSH Guidelines for Pre-transfusion Compatibility Procedures in Blood Transfusion Laboratories (BCSH 2013)
HLA or platelet specific antigen-negative selected platelets for patients with HLA or HPA antibodies	BCSH Guidelines for the use of Platelet Transfusions (BCSH 2003) BCSH Transfusion Guidelines for Neonates and Older Children 2004 (BCSH 2004)
IgA deficient products (or equivalent) for those with anti-IgA antibodies	

**Example**

**Blood Transfusion**

**Service Level Agreement**

**with**

**Information Technology Department**

## 1 PARTIES TO AGREEMENT

### PROVIDER (CONTRACT GIVER)

Information Technology Department,  
*Add address*

Head of IT *(add name)*

Signature: .....

Date: .....

### PURCHASER (CONTRACT ACCEPTOR)

Blood Transfusion,  
*Add address*

Head of Laboratory Medicine *(add name)*

Signature: .....

Date: .....



## 2 SERVICE OBJECTIVES

The purpose of this document is to define the details of the service provided by the IT Department to Blood Transfusion in order to comply with regulatory requirements.

These Regulations require consideration of and agreement on:

- Clears lines of responsibility and accountability between IT and Blood Transfusion Department;
- Procurement and on-going maintenance and support of IT equipment (hardware and software) and associated data;
- The mechanism by which hardware and software updates are controlled;
- Provision of a robust mechanism(s) for the security of data held for Blood Transfusion. This will need to include the means by which data is restricted only to those with a legitimate right to access it and evidence of a regularly tested mechanism for disaster recovery of the data;
- The approved mechanism by which data may be archived;
- Data retention and traceability strategy.

## 3 LEGISLATION AND GUIDANCE

- a. All blood transfusion equipment and data must be supported in accordance with the Blood Safety and Quality Regulations, SI 50/2005 (as amended). As part of these Regulations the Trust is required to submit an annual compliance report to MHRA who may carry out risk based inspections of the premises and equipment. MHRA also have the power under the Regulations to make unannounced visits and to require immediate cessation of activity in the event of identifying a critical failure.
- b. UK Pathology Laboratories are required to be registered with and undergo peer assessment by Clinical Pathology (UK) Ltd – a subsidiary of the United Kingdom Accreditation Service (UKAS). Although CPA do not have legislative powers to shut down facilities the withholding or withdrawal of accredited status can affect the laboratory's ability to retain existing contracts and may hamper its ability to attract further contracts.

## 4 SERVICE DESCRIPTION

### 4.1 System Descriptions

This service level agreement covers the following facilities and systems:

- All desktop computing, data storage, data backup, printing and network infrastructure hardware and software that may have access to transfusion related systems.
- The application server hardware and operating systems for the following services:
  - *Enter LIMS system here*
  - *Enter any electronic blood administration (tracking)systems*
  - *Enter compliance management software, (e.g. QPulse)*
  - *Any cold chain monitoring equipment with network links*
  - *Trust shared network drives which are used for the storage of data which is regulated through the Blood Safety & Quality Regulations 2005 (as amended)*
  - *Any other relevant GMP applications*
- The interfaces between external systems (e.g. PAS, Order Comms) and the LIMS
  - *Insert a system map showing all relevant systems and interfaces*

## 5.0 Service Provided by the IT Department

### 5.1 Services provided

The IT Department will provide the following services to Blood Transfusion department:

- a. Maintenance of the IT infrastructure supporting the hardware and software systems covered by this agreement. This maintenance may be undertaken by the third party supplier of the hardware/software, Trust IT staff or sub-contracted out to third-party providers in agreement with Blood Transfusion.
- b. Planned regular data backups to secure location(s) as per Attachment A,
- c. Support Services in accordance with target response/fix times as per Attachment B. These targets must be carried through to any 3<sup>rd</sup> party maintenance contracts entered into by the IT department
- d. Regular documented tests to demonstrate that backed up data can be successfully restored to the live environment in a timely manner as required.
- e. Ensure that data servers and network infrastructure are secure and that access is restricted only to authorised staff Regularly monitored and updated system access controls to

ensure sensitive or confidential data is only available to authorised users; Ensure that maintenance access to transfusion related systems is controlled

- f. Participation in the development of specifications for and validation of new and / or upgraded laboratory equipment, including associated instrument interfaces
- g. An effective documented change control mechanism to ensure that the implementation of new or upgraded IT equipment or software which may impact on transfusion systems is controlled..
- h. Ensure that all transfusion related data can be accessed in a timely manner for the required retention periods. This must apply to both active and archived data;
- i. Ensure compliance with the IT requirements specified in the BCSH guidelines

## 5.2 Authorisation to work

There is a requirement by the MHRA that all maintenance and calibration of equipment is supervised to ensure compliance and the responsible and knowledgeable persons should be aware and assess the compliance of such.

To enable compliance with this requirement, with the exception of regular data backups, no work must not be carried out on the *LIMS* or *EBTS* system without initially notifying and obtaining approval from the Blood Transfusion Manager or nominated deputy. Where 3<sup>rd</sup> party contracts are in place the contract conditions must ensure this requirement is recognised.

IT will use a Change Management process based on the ITIL® (Information Technology Infrastructure Library) **Ref** Best Practice guidelines.

If any of this work is outsourced this must comply with the requirements of Chapter 7 Outsourced Activities in Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use Vol 4

## 5.3 Periods of Systems Unavailability

Under normal condition the LIMS and other transfusion related systems should be available 24/7.

The IT Department must contact the Blood Transfusion Manager or nominated deputy within xx minutes of an unplanned network or server issue which would impact on these systems. This contact will be expected to provide:

- An indication of the nature of the problem, its extent and the cause if known;
- The action being taken to resolve the problem;
- An indication of the likely period of down time;
- Agreement to provide regular updates on progress with resolving the problem.

Upon restoration of the system and return to a steady state but prior to general user access the following steps must be carried out:

- IT to provide update on nature and cause of the problem and corrective actions taken;
- The system manager, or nominated deputy, must review the report and risk assess to determine what ,if any, system revalidation is required;
- Any necessary validation to be performed;
- Once satisfied the system can be signed off for routine use.

There should be a follow up to review the handling of the event and determine any preventative actions required.

## **5.4 System Modification**

System modifications or alterations to any Blood Transfusion systems must not be made without notifying and obtaining approval from the Blood Transfusion Manager or nominated deputy.

## **5.5 System Information**

The IT department will monitor and report to the Blood Transfusion Department the following information:

- System performance
- System errors
- Unauthorised access attempts

## **6. BLOOD TRANSFUSION DEPARTMENT - OBLIGATIONS**

The Blood Transfusion Department will:

- i) Use standard Trust procedures to log incidents and service requests (add organisation specific details as required)
- ii) Ensure that any modifications or alterations that will have an impact on the operating system, network or other component under the control of the IT Department. are appropriately approved by IT Management prior to implementation. Carry out any testing/validation following an application upgrade or change to ensure that the whole system operates as expected
- iii) Ensure that procurement of new or replacement equipment with an IT element follows Trust processes (including consideration of Information Governance requirements, contract requirements, etc) and is managed under the transfusion laboratory change control and qualification procedures.
- iv) Manage access to the supported applications in line with Trust policies and any layered access within the application and authorise users appropriately<sup>1</sup>.
- v) Be the first line for user support for application errors.
- vi) Provide application training for Blood Transfusion users
- vii) Be responsible for monitoring and data quality within the application data bases pertinent to Blood Transfusion.
- viii) Responsible for application performance monitoring

## **7. QUALITY STANDARDS & TECHNICAL AGREEMENT**

The IT Department must only use suitably trained staff or approved sub-contractors to provide this service. Staff working on GMP critical systems and infrastructure must attend annual GMP training

## **8. METHOD OF MONITORING**

This agreement will be periodically audited for compliance by Blood Transfusion staff as a requirement to provide assurance to the MHRA as part of the annual submission of the blood compliance report. This SLA may also be requested for review by the MHRA and CPA during inspection visits.

The following measurements will be established and maintained by the IT department to ensure optimal service provision:

Measurement	Definition	Performance Target
Uptime	Percentage of system availability	99%
Response Times in Attachment B	No of calls within SLA	90%

## 9. COMMUNICATION AND CONSULTATION ARRANGEMENTS

### 9.1 Management

**I.T. Department** - IT Service Manager

**Blood Transfusion Services-  
Manager  
Transfusion Manager** - Laboratory Medicine Services  
Blood  
Blood Transfusion IT Lead

### 9.2 Operational

Access to support services is via the IT Service Desk (*enter phone number and email address*).

Number for manager or deputy -  
Out off hours number -

## 10.0 DOCUMENT MANAGEMENT INFORMATION

Version	Drafted by	Updates	Issue Date	Next Review Date
Draft A	xxx	Initial Draft	November 2012	n/a (Draft)

## Attachment A – Data Backup (Example only)

Section 6.5 of the guidelines must be complied with. Backups of the systems supported will be carried out as follows:

*Indicate for your organisation how each system will be managed as this is an example only. Define also the backup media.*

<b>Name of system</b>	<b>Database backup frequency</b> (backup of all user data e.g. patient names, test results)	<b>Configuration &amp; system backup frequency</b> (Backup of logic rules and system programmes)	<b>Frequency of backup &amp; restore testing</b> (How often the organisation will verify the backup and restore returns the database to the original position)	<b>Specified recovery window</b> (agreed time interval within which a database restore will be performed)	<b>Backup cycle</b> (Number of previous database backups available to restore)	<b>Backup/Archive</b> (Long term storage of backup)
<i>LIMS</i>	<i>Daily</i>	<i>Monthly</i>	<i>Annual</i>	<i>4 hours</i>	<i>28</i>	<i>7 years</i>

## Attachment B – Support Response/Fix Targets/Estimated Recovery Times (Example Only)

When an IT failure occurs the blood transfusion manager and IT services manager, or their nominated deputies, must agree on the severity of the failure and the response times will be in accordance with the following agreement.

Level of criticality	Response time core hours	Response time non core hours	Target fix time
<b>Critical</b> - A major function of a service is unavailable for multiple users	<i>15 minutes</i>	<i>60 minutes</i>	<i>4 hours</i>
<b>High</b> – A major function is not operational for a single user	<i>4 hours</i>	<i>4 hours</i>	<i>24 hours</i>
<b>Medium</b> – Limited or reduced functionality available for single or multiple users	<i>8 hours</i>	<i>N/A</i>	<i>32 hours</i>
<b>Low</b> – Moves, requests, queries and/or quotations	<i>72 hours</i>		
<b>Other</b> - Non urgent requests for change	<i>1 week</i>		



## Clinical data sets for transfusion

The following tables give suggested coded reason and indications for transfusion as well as a clinical data set that should be considered when specifying a new LIMS so that clinical transfusion reports, clinical transfusion audit and key performance indicators can be produced with ease, accuracy and reproducibility

### Reason for transfusion fields by speciality

#### Gastrointestinal

GI-Oesophageal  
 GI-Gastric  
 GI-Pancreatic  
 GI-Liver surgery  
 GI-Colorectal  
 GI-Other surgery  
 GI-Upper GI bleed (non-variceal)  
 GI-Upper GI bleed (variceal)  
 GI-Lower GI bleed  
 GI-Liver failure  
 GI-Pancreatitis

#### Genitourinary

GU-Cystectomy  
 GU-Nephrectomy  
 GU-Prostatectomy  
 GU-Other surgery

#### Gynaecology

Gyn-Surgical malignancy  
 Gyn-Surgical non-malignant  
 Gyn-Non surgical

#### Maxillo-facial Surgery Plastic Surgery

#### Neurosurgery

Neuro-Intracranial bleeding  
 Neuro -Malignancy  
 Neuro -Spinal  
 Neuro -Other surgery

#### Obstetrics

Obs-APH  
 Obs-PPH  
 Obs-Placenta praevia  
 Obs-DIC

Obs-Caesarean section  
 Obs-Other surgery

#### Orthopaedics

Ortho-Primary Hip  
 Ortho-Redo Hip  
 Ortho-Primary Knee  
 Ortho- redo Knee  
 Ortho-Spinal  
 Ortho-Other surgery  
 Ortho-RTA  
 Ortho-# femur  
 Trauma-  
 Burns

#### Transplant

Trans-Heart  
 Trans-renal  
 Trans-renal/pancreas  
 Trans-Liver  
 Trans-Lung  
 Trans-Pancreas  
 Trans-Small Bowel

#### Renal

Renal-CRF  
 Renal-ARF

#### Vascular

Vasc-Elective AAA  
 Vasc-Emergency AAA  
 Vasc-Leg artery grafts

#### Haematology

Haem-Aplastic anaemia  
 Haem-AML  
 Haem-ALL  
 Haem-MDS  
 Haem-MPD  
 Haem-Chronic leukaemia  
 Haem-Lymphoma  
 Haem-Myeloma

Haem-Iron deficiency  
Haem-B12/folate deficiency  
Haem-Anaemia of chronic disorders

Haem-Haemolysis acquired  
Haem-Haemolysis congenital  
Haem-Sickle cell disease  
Haem-Thalassaemia  
Haem-ITP  
Haem-Congenital platelet disorder  
Haem-DIC  
Haem-TTP  
Haem-Reversal of warfarin  
Haem- single factor deficiency

**Infection**-Malaria

**Oncology**

Onc-Chemo  
Onco-Anaemia of malignancy

Onco-Radiotherapy

**Paediatrics**

Paed- exchange transfusion  
Paed- top up transfusion  
Paed-Neonatal alloimmune  
thrombocytopenia  
Paed-Sepsis

**Procedure**

Pro-Ascitic tap  
Pro-Chest drain  
Pro-Endoscopy  
Pro-ERCP  
Pro-Laparoscopy  
Pro-Line Insertion  
Pro-Liver biopsy  
Pro-Lumbar puncture

**Other**

## Clinical Transfusion Dataset

Data item	Source of data	Mandatory (M) or desirable (D)?
<b>Group and screen</b>		
Patient identifier	Transfusion request into LIMS	M
Consultant responsible for care	Transfusion request into LIMS	D
Clinical Speciality	Transfusion request into LIMS	M
Year of birth	Transfusion request into LIMS	M
Gender	Transfusion request into LIMS	M
Previous transfusion history	Transfusion request into LIMS	D
Previous obstetric history	Transfusion request into LIMS	D
<b>Blood component order</b>		
Patient identifier	Transfusion request into LIMS	M
Consultant responsible for care	Transfusion request into LIMS	D
Clinical Speciality	Transfusion request into LIMS	M
Year of birth	Transfusion request into LIMS	M
Gender	Transfusion request into LIMS	M
Previous transfusion history	Transfusion request into LIMS	D
Previous obstetric history	Transfusion request into LIMS	D
Number of units (mL) required	Transfusion request into LIMS	M
Coded clinical reason for use	Transfusion request (selected by the requester)	M
Truncated National Indication Code	Transfusion request (selected by the requester)	M
Has consent been documented?	Transfusion request into LIMS	M
Was the patient transfused? Yes / No	LIMS	M

Date of transfusion	LIMS	M
Time of transfusion	LIMS	M
Transfused component (ISBT)	LIMS	M
Blood group of transfused component	LIMS	M
Blood group of patient	LIMS	M
Expiry date of component	LIMS	M
Pre transfusion lab test result (coag, Hb, plts)	LIMS - Haematology	M
Post transfusion lab test result (coag,Hb, Plts)	LIMS - Haematology	M
Hb 14-42 days pre op (if date of procedure known)	LIMS - Haematology	M
Immediate Pre op Hb (if date / time of procedure known)	LIMS - Haematology	M
Discharge Hb (if date of discharge known)	LIMS - Haematology	M
Date of admission	PAS	M
Date of discharge / death	PAS	M
Did patient die in this admission?	PAS	M
ICD10 code (diagnostic code code)	PAS	M
OPCS4 code (procedure code)	PAS	M
HRG code	PAS	M
Date and time of procedure	PAS	M
Adverse event?	Not currently collected	D
Near patient test result: Hb, coag, TEG/ROTEM, plt function test	LIMS - Haematology	D
Was cell salvage used?	Theatre record	D
Volume of salvaged red cells returned	Theatre record	D
Was tranexamic acid prescribed?	Paper prescription / electronic prescription	D
Was the prescriber trained in blood ordering?	Collected as part of transfusion request	D

### Categories of Justification for Transfusion to Support Appropriate Use

#### Red cell concentrates

R 1	Acute bleeding with BP instability
R 2	Hb $\leq$ 70 g/L in stable ICU patient
R 3	Hb $\leq$ 80 g/L non-ICU patient with signs/symptoms of anaemia
R 4	Hb $\leq$ 100 g/L with acute cardiac ischaemia
R 5	Surgical blood loss anticipated
R 6	Other (free text)

#### Fresh frozen plasma

F 1	Massive bleeding
F 2	INR $\geq$ 1.6 with bleeding
F 3	INR $\geq$ 1.6 and pre-procedure
F 4	Therapeutic exchange
F 5	Other (free text)

#### Cryoprecipitate

C 1	Active bleeding
C 2	Fibrinogen $\leq$ 1.0g/l & pre-procedure
C 3	Other (free text)

#### Platelets

P 1	PLT count $\leq$ 10 x 10 <sup>9</sup> /l stable patient
P 2	PLT count $\leq$ 20 x 10 <sup>9</sup> /l with platelet consumption
P 3	PLT count $\leq$ 50 x 10 <sup>9</sup> /l pre-procedure
P 4	Bleeding on anti-PLT medication
P 5	Massive bleeding
P 6	Other (free text)