Key changes in new BCSH Transfusion I.T. Guidelines

Debbie Asher

EPA Network Transfusion Manager

Member, BCSH Guideline Writing Group

Membership

Joan Jones	Head of Quality, Welsh Blood Service
Paul Ashford	Executive Director, ICCBBA
Debbie Asher	TLM, SHOT working expert group
John Barker	Pathology Manager
Linda Lodge	Chair, JPAC Standing Advisory Committee for Information Technology, Scottish Blood Service
Megan Rowley	Consultant Haematologist, NHSBT
Julie Staves	TLM
Tony Coates	TLM
Jenny White	UK NEQAS

Title Change

- **2007** Guidelines for the specification and use of IT systems in blood transfusion practice
- **2014** Guidelines for the specification, implementation and management of IT systems in hospital transfusion laboratories

Scope

- To cover the functionality of the Laboratory Information Management Systems (LIMS) and applications which interface directly to it i.e. Order Comms and Electronic Blood Administration (Tracking) Systems including Remote Blood Issue
- To give clearer guidance on current problems facing transfusion laboratories in regard to IT systems eg database integrity, technical support, meeting regulatory compliance
- To support hospital blood transfusion laboratories when changing the LIMS
- Used by Transfusion Laboratories, Hospital IT departments and, where applicable, Suppliers of IT systems which support hospital transfusion medicine.

Section I Planning and implementing system change

1.1 Project planning
1.2 Business case
1.3 Process maps
1.4 User Requirement Specification (URS)
1.5 Procurement
1.6 Contract
1.7 Implementation preparation
1.8 SLA
1.9 User configuration verification
1.10 Validation

Section II Operational use of IT systems

2.1 Stock Management
2.2 Managing the patient record
2.3 Generating transfusion requests
2.4 Laboratory handling of samples/requests
2.5 Analytical process
2.6 Component selection
2.7 Selection of fractionated blood products
2.8 Component labelling and issue
2.9 Post analytical reporting

Section III Electronic blood administration (tracking) systems

3.1 Component collection (Fridge Tracking)
3.2 Administration (Bedside Tracking)

Section IV Recording administration/ final fate information

Section V Information management

5.1 Traceability/data retention
5.2 Management information/data
5.3 Improving blood usage through clinical information & audit

Section VI System management

6.1 System security/governance
6.2 System availability and business continuity
6.3 Data integrity
6.4 Duplicate record searches
6.5 Back up and disaster recovery
6.6 Change control and system upgrade
6.7 Audit trails
6.8 Archiving

SECTION I. Planning and Implementing System Change

1.1 Project Planning

Any IT project requires a multi disciplinary approach:

- Subject matter experts
- IT personnel
- 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 those requirements of other Pathology disciplines and one system may not meet the needs of all.

Project Planning

- **1.2 Business Case**
  - captures the reasons for initiating the purchase of a new system and identifies whatever resources, either capital, revenue or staff, that should be found in support of a specific business need
- **1.3 Process Maps**
  - important to gain a common understanding of the entire process, the specific roles and contributions of personnel, and the interactions of the LIMS system with external IT systems / devices
- **1.4 User Requirement Specification (URS)**
  - a structured document which identifies all of the essential and desirable user requirements of the system
  - fundamental part of the contractual agreement
  - forms the basis of the technical evaluation of bids
  - provides the requirements against which validation is performed
  - modern LIMS offer extensive configurability, it is 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

URS

- ***1.4.1 Operational Functionality***
- ***1.4.2 Validation Requirements***
- ***1.4.3 Infrastructure Requirements***
- ***1.4.4 Interface Specification***
- ***1.4.5 Electronic Data Interchange (Interoperability)***
- ***1.4.6 Peripherals and Hardware requirements***
- ***1.4.7 Operational Environments***
- ***1.4.8 Data Management***
  - ***Data migration***
  - ***Archive Data Storage***
- ***1.4.9 Maintenance Requirements***

URS

1.4.4 Interface Specification

- 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 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 Working Party on Information Technology Interface Task Force. (Ref ISBT http://www.isbtweb.org/working-parties/information-technology/)

URS

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

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.

2.1 Stock Management

- 2.1.1 Stock ordering
- 2.1.2 Stock Entry - Blood Components
  - Receipt handling with Electronic Delivery Note (EDN)
  - Receipt handling without EDN
- 2.1.3 Stock Entry - Batch Products
- 2.1.4 Stock Tracking
- 2.1.5 Management of Unused Units

2.2 Managing the patient record

- 2.2.1 Unique patient identifiers
- 2.2.2 Patient Information
- 2.2.3 Merging/Linking
  - 2.2.3.1 Merging within the LIMS
  - 2.2.3.2 Merging/linking outside the LIMS
  - 2.2.2.3 Undo linking/merging

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

- 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 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.

2.3 Generating Transfusion Requests

- 2.3.1 Electronic Request Systems (Order Comms)
- 2.3.2 Sample Collection (Order Comms)

2.4 Laboratory Handling of Samples/Requests

- 2.4.1 Manual Receipt and Entry onto LIMS
- 2.4.2 Electronic Receipt and Entry onto the LIMS (Order Comms)

2.5 Analytical Processes

Interfacing between analysers and LIMS wherever possible, otherwise manual entry with robust controls

- **2.5.1 Test Allocation**
- **2.5.2 Worksheets**
- **2.5.3 Laboratory testing**
  - ABO/D Testing
  - Antibody Screening
  - Antibody Identification
  - Crossmatch
  - Pregnancy Related Testing
- **2.5.4 Quality Assurance of analytical processes**
  - Internal QC
  - External Quality Assurance (EQA)
  - Technical authorisation

2.6 Component selection

- LIMS must ensure that components selected meet all necessary requirements to ensure their suitability
- Suggested Logic Rules in Appendix 1:
  - Age related
  - Gender related
  - Clinical/diagnosis related
  - Antigen matching criteria
- Additional Requirements for the Selection of Red Cells
  - Serological Crossmatch (Manual or Automated)
  - Electronic Issue (EI) without serological crossmatch
  - Emergency Issue of red cells

2.8 Component labelling and Issue

- 2.8.1 Compatibility tag
- 2.8.2 Label attachment verification
- 2.8.3 Remote Electronic Issue

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.**

Recommendations:

- **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

3.1 Component collection (Fridge Tracking)
3.2 Administration (Bedside Tracking)

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 V Information management

5.1 Traceability/data retention
5.2 Management information/data
5.3 Improving blood usage through clinical information & audit

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

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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.**

Appendices

- Examples of logic rules to aid component / product selection
- Example SLA with Trust IT department
- Suggested clinical data sets for transfusion and ‘Reason for transfusion’ fields
- Categories of Justification for Transfusion

Summary

- Planning and implementing change
- Emphasised the team approach
- Highlighted problem areas and given advice
- Recommendations

Questions?