



The Pros and Cons of Transfusion IT

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Disclaimer

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ALL RIGHT, BUT APART
FROM THE SANITATION,
MEDICINE, EDUCATION,
WINE, PUBLIC ORDER,
IRRIGATION, ROADS, THE
FRESH WATER SYSTEM
AND PUBLIC HEALTH.....

WHAT HAVE THE
ROMANS
EVER
DONE
FOR US?



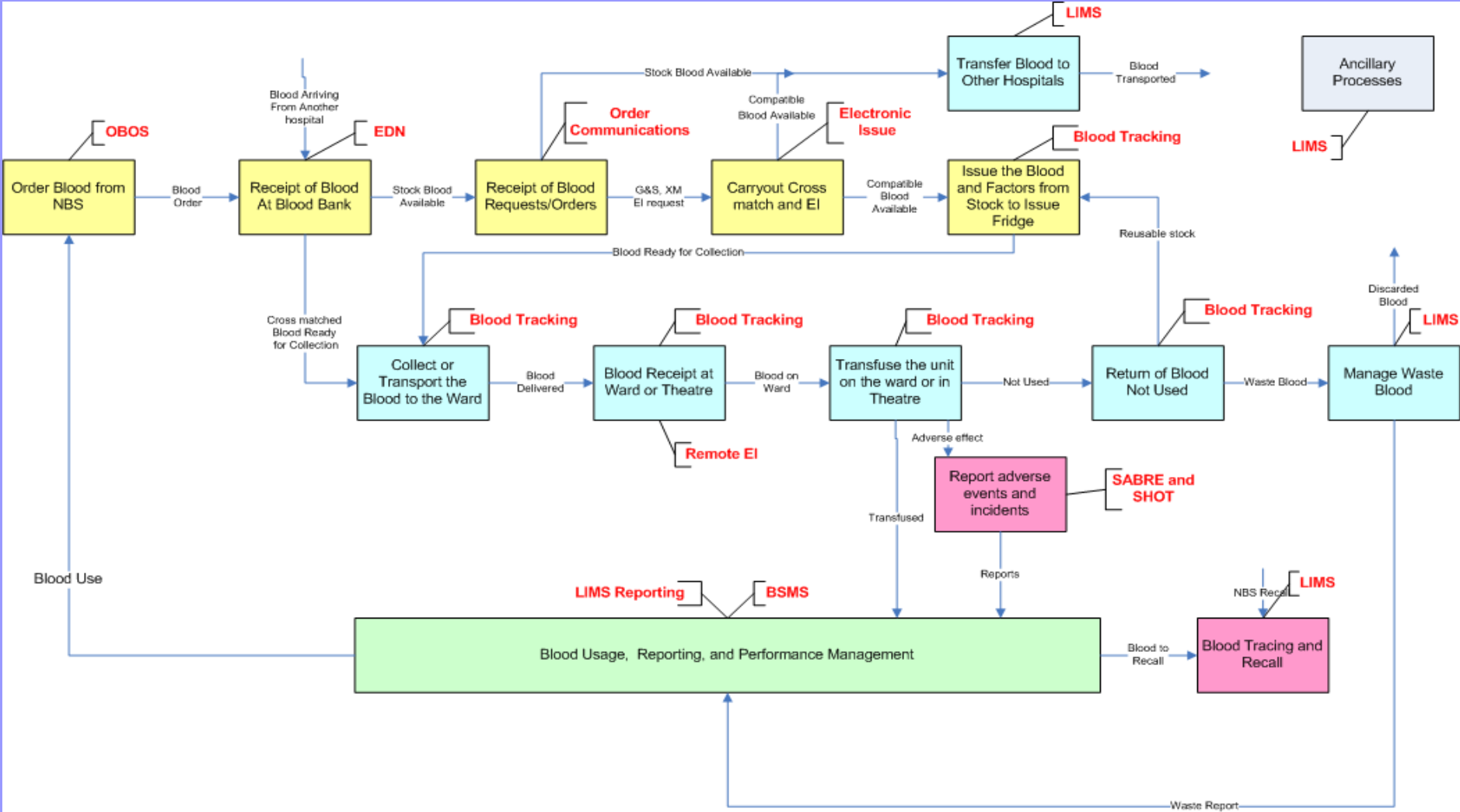
Life before IT

- **Everything hand written**
My personal record one night for a patient was 160 red cells, 40 FFP and 20 platelet units all the tags and issue records written by hand.
- **Paper records in filing cabinets – lots of duplicate patient records, missing records etc.**
- **All results needed to be transcribed by hand and checked – often later when day staff came in.**
- **Traceability – very, very difficult**

Immediate benefits of IT

- No more hand written tags and issue forms
- Reduced transcription errors
- Increased availability and accuracy of patient history
- Traceability made significantly easier
- Enabled electronic issue and remote issue.

The spread of IT



Problems with IT

- Lack of Connectivity
- Too much connectivity
- Being part of one Pathology LIMS
- Resilience/Dependence
- Lack of local expertise
e.g. Failure to understand set up, Failure to control changes
- Meeting regulatory requirements

Lack of Connectivity

- No standardised way of transmitting:
Patient blood groups
Patient antibodies and special requirements
Blood Component details
- No standardisation of anything at all –
translation interfaces needed – extra complexity
- Still entering referred work results manually
- Patients move across health networks but
transfusion histories and special requirements
do not move between trusts.

Too much Connectivity

- Poor quality data creates unacceptable risk with respect to patient safety and organisations have a responsibility to ensure the quality of data is not compromised. Where the quality of data with respect to patient ID is poor those data sets should be discarded rather than accepted in cases of partial patient identity.
- The implementation of a new LIMS, especially where this involves a change in system, represents significant risk of perpetuating poor historical data as any data taken on from a legacy systems requires substantial control and validation of the quality of the data from transfusion departments and this is not often fully understood by management groups from other areas.
- **Particular concern has been raised about control of data transferred from outside of transfusion IT systems, these interfaced systems are subject to the same regulatory requirements as the transfusion specific IT. Implementation of new interfaced systems represent a similar risk to transfusion data as a new LIMS and must be subject to the same considerations of control and validation as when implementing a new LIMS.**
- Therefore Pathology, and in particular transfusion departments, need to be party to organisational decision making in regard to relevant IT systems (PAS, Order Comms etc.). Organisational decisions taken regarding these systems should be taken and agreed at the Pathology Executive Board meetings and any planned changes to systems signed off by this Board. The departments responsible for these systems external to transfusion IT should work with transfusion departments to ensure their processes and documentation meet GMP requirements

Being part of one Pathology LIMS

- Many hospital transfusion labs IT are part of overarching Pathology system. We may have a system that is not best for us because it is good for another area e.g. Biochemistry.
- Updates can be too slow.
 - transfusion not a big priority of supplier (only a small part of Pathology)
 - companies do not like patches any more and prefer updates so all disciplines need to update at same time – can be like herding cats
- Changes in other disciplines may affect transfusion – MHRA expect us to be confident that other interfaces have no impact – may need to validate our system when others implement interface changes.

Resilience

- Our processes and staffing levels are predicated on our IT systems working
- IT (like automation) does occasionally fail.
- Capacity planning needs to ensure:
 - sufficient resource available to cope with failure or planned downtime
 - sufficient resource available to develop, maintain and test resilience systems
 - ensure clinical work load responds to laboratory IT failure
- What is major IT failure like – Leeds experience

Lack of local expertise

- IT needs continual care and development
- Network usually responsibility of Trust IT depts (how well are these resourced?)
- Discipline specific IT functionality often the responsibility of laboratories
 - how much expertise is available in the lab?
 - how much time is available in the lab?
- Systems that have been in place for a long time often have rules and architectures set up by staff no longer employed – knowledge gaps.
- Need better support from suppliers.

MHRA and transfusion IT

- It is the responsibility of the user to ensure that equipment (including IT systems) is fit for purpose. If a laboratory identifies that their LIMS system (or proposed future upgrade) is unable to meet specific user requirements, action should be taken to mitigate the identified risks by other means.
- If the risks identified in the new version of LIMS are considered to be greater than those in the current version, it may be necessary to mitigate the risks in the current system and defer the upgrade until the problems have been corrected.
- LIMS systems should be considered as a component part of a process, which consists of various steps, such as:
 - inputs (e.g. sample receipt, reagents, information)
 - operations (e.g. sample preparation, reagent preparation, equipment functionality)
 - data assessment (e.g. interpretation of test results)
 - outputs (e.g. blood group determination, selection of compatible blood components).

MHRA and transfusion IT

- When assessing the risks associated with LIMS system functionality, attention should also be applied to assessing the inherent additional hazards elsewhere in the process such as those involved in short term manual workarounds and lone working arrangements.
- There should be clear evidence of managerial (Executive Board Level) support to addressing the remaining LIMS / electronic issue deficiencies in a timely manner. The risk mitigation activities should only be considered a short term approach to ensuring continuity of patient care in situations where lack of timely provision of the required blood components (e.g. by manual cross matching methods) places patients at greater risk.
- MHRA Data Integrity guide
<https://mhrainspectorate.blog.gov.uk/2018/03/09/mhras-gxp-data-integrity-guide-published/>

MHRA and merging

When merging patients the following should be followed:

- Ensure there is a full and complete patient identification record
- If there is a transfusion history that is discrepant ensure a root cause can be identified and documented (e.g. Transplant) before proceeding
- Identify requirements for the system involved in merging
 - Manual – knowledge, training and a strict protocol to follow
 - Electronic:
 - Rule based when there is a discrepant transfusion history
 - Discrepancy in patient identification = no merge
- **Ensure there is a robust and validated interface between the LIMS and any other system involved and that any such interfaced system is not able to overwrite patient demographic or transfusion data on the transfusion module of a LIMS without being subject to the same merge controls as the LIMS.**

BSH guidance

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Future developments of IT in Transfusion

- Networked laboratories and more Multidisciplinary 24/7 departments
- Integrated Automation
- Integrated Transfusion Service
- Computer Intelligence
 - Best Match” for blood by the LIMS
 - Remote EI for patients with antibodies
 - Warnings about the wrong process being followed (not able to easily circumnavigate)
- SMART technology (self monitoring analysis and reporting technology)
- RFID of components, products and reagents
- New infrastructures
 - Wi-Fi (no leads)
 - Mobile Technology
 - Cloud
- “Tied down processes (e.g. checkout at a supermarket)
- Using ‘big data’ for better patient blood management

- Computing's central challenge, “How not to make a mess of it,” has not been met. On the contrary, most of our systems are much more complicated than can be considered healthy, and are too messy and chaotic to be used in comfort and confidence.” — *Edgser Dijkstra*