Medicines & Healthcare products Regulatory Agency

MHRA Guidance on Electronic Issue (May 2010)

Introduction:

The UK Blood Safety and Quality Regulations 2005 (as amended) require hospital blood banks to *"establish and maintain a quality system for the hospital blood bank which is based on the principles of good practice, which complies with the Community standards and requirements set out the Annex to Commission Directive 2005/62/EC insofar as these are applicable to hospital blood banks"* (Regulation 9(1) b).

MHRA inspections of hospital blood banks have identified various situations where the practice of electronic issue of blood components has not been conducted in accordance with Good Practice or the relevant technical guidelines stated in the BCSH Guidelines for Blood Bank Computing (2006). This is due to procedural failures, lack of LIMS system functionality, or lack of system validation to verify the effectiveness of the control measures believed to be in place.

In some cases, this has resulted in the potential for incompatible blood components to be supplied to patients. The practice of electronic issue of blood components for transfusion without direct compatibility testing (cross match) between patient plasma and donor red cells is an inherently high risk operation, and therefore the administrative and technical arrangements for the control of this activity must be robust to protect patient safety.

This document aims to clarify the MHRA's expectations relating to the control of electronic issue of blood components and providing further guidance to supplement that in the specific requirements of Good Practice, and the relevant BCSH guidelines. This document is intended to be used in conjunction with:

- BCSH Guidelines for Blood Bank Computing (current version).
- BCSH Guidelines for compatibility procedures in blood transfusion laboratories (current version).
- Blood Safety and Quality Regulations (SI 2005 No. 50, as amended) Regulation 9 (1) b, referencing Commission Directive 2005/62/EC 'standards and specifications relating to a quality system for blood establishments'.

Specific:

Automated pre-transfusion testing[1] should be used wherever possible, due to the security and consistency provided by a validated system. This is strongly recommended to support electronic issue. The use of manual testing systems in general, and specifically for electronic issue, must be robustly designed and controlled to ensure any risks introduced by the use of such a system are identified

[1] Automated testing is considered to include full automation of sample identification, reagent and sample dispensing, result interpretation and transfer to LIMS and fully mitigated. These systems will be subject to increased scrutiny during inspection.

All pre-transfusion testing records must include a contemporaneous record of reaction pattern for ABO/Rh and antibody screen. This record may be retained in either LIMS, Grouping analyser or worksheet. For manual testing methods, the results must be independently reviewed (or re-test of the same sample on an automated testing system interfaced with the LIMS) in a timely manner. It should also be noted that a lack of second operator verification of results prior to issuing blood components is a high risk process, and should be treated in a manner commensurate with the risk.

Robust ABO (D) typing is paramount in all pre-transfusion testing, irrespective of the method for blood component issue (electronic or full cross match). Recipient ABO (D) group must be confirmed (by repeat testing) prior to electronic issue of blood components. This may be achieved by testing replicate samples separated by time, or by verifying the ABO/Rh result using different reagent clones on the same patient sample. It should be noted that replicate testing of a single sample will not detect sample collection errors.

First samples from 'new' patients must be tested for full ABO group (Forward and Reverse), irrespective of the method used. Reagents and test systems must be used in compliance with their CE registration. Particular attention should be paid to confirming that reagents and test systems are CE marked for the purpose required by the transfusion laboratory, and are used fully in accordance with manufacturer's instructions. There should be documented evidence available to demonstrate that this review has taken place.

A procedure should be in place to verify, on receipt of each delivery of reagents, that the instructions have not changed. Test methods should be controlled to detect errors in test performance (e.g. pipetting errors, omission of reagents).

Automated pre-transfusion testing and results transfer to the LIMS system is strongly advised, in order to reduce the risk of transcription error. Where the results from either manual or automated testing require manual input into the LIMS system, entries must be independently verified. This may be achieved by either a second blind entry of results by the original operator, or verification by a second independent operator. One of these verification methods must occur prior to the issue of components.

Where electronic issue is performed, then all aspects of the BCSH electronic issue eligibility criteria must be assessed and controlled within the LIMS system functionality, and cannot be supplemented by manual checks of criteria which are not embedded within the LIMS. The LIMS control of eligibility criteria must be validated.

'Remote' electronic issue:

Remote electronic issue is defined as a situation where the testing laboratory is physically separate from the location of blood component issues. The remote electronic issue process requires two key stages; allocation / reservation (selection of a suitable component for EI), and issue (the removal of the allocated component from 'general stock' storage, to a specific patient, including labelling). The allocation / reservation stage may occur at either the testing laboratory, or the remote storage location. This may involve a link between either a laboratory to laboratory (e.g. 'hub and spoke' models), or laboratory to clinical area.

In all cases, the LIMS systems at the testing and issuing locations must be connected. The generation of component labels must be via the LIMS, or from an interfaced IT system which requires no manual transcription of data between the two systems.

There must be a secure process for the communication of patient 'special requirements' (e.g. irradiated components) to ensure the selection of suitable components, irrespective of the method for blood component issue (electronic or full cross match).

The above provides the opportunity for a robust check of the suitability of supplied components and may assist in protecting against errors in blood component supply seen during previous MHRA inspections.

Proposals for implementation:

The requirements of this guidance note should be implemented by 31st March 2011, and will be verified through the Blood Compliance Report process in 2011.

Implementation plans must be in place by 31st July 2010, which should include an assessment of current risks, and steps taken to mitigate these risks in the interim. There should be evidence of senior management support (at Trust / Board level) for any resource requirements to implement the plan.

Failure to have such an implementation plan will be considered as a deficiency during inspections conducted after 1st August 2010.

If a site is unable to meet the requirements of this guidance note within the implementation dates, then electronic issue of blood components should not be used.