

Purpose of Paper:	Business Case
Subject:	Medical Laboratory Assistant
Date of Paper:	
Paper Prepared by:	

Executive Summary

New Regulations

Statutory Instrument 2005 No. 50 - The Blood Safety and Quality Regulations 2005

The Medicines and Healthcare products Regulatory Agency (MHRA), has agreed to be the Competent Authority and has undertaken the responsibility of discharging the new Regulation, formerly a European Directive, which is now incorporated into UK law. This has a direct impact on hospital transfusion laboratories and *i) will result in an inspection by the MHRA or ii) with the complex service that we provide, it has necessitated ours to register as a Blood Establishment and undergo an inspection by the MHRA.*

In accordance with the recommendation from the Operational Impact Group (OIG) to MHRA we should like to establish a post to enable the Trust to fulfil the obligatory requirements of a large teaching hospital. In particular, by November 2005 we are required to comply with the vein-to-vein traceability of blood from donor to recipient and holding this record for 30 years.

Background

In accordance with the Government Directive HSC 1998/224 'Better Blood Transfusion' the responsibility of Clinical Governance ensures that trained staff carries out Blood Transfusion and that practice accords to national standards. At present the Clinical Pathology of Accreditation (CPA) has set standards which cover only pursuits within the laboratory and activity outside which is directly under laboratory supervision. The Serious Hazards of Transfusion report (SHOT) makes specific recommendations for the safety of administration of blood and blood products, and has recommended that a CPA laboratory should extend to include the whole process of blood transfusion practice, ultimately to the wards and theatres. This has been taken further by the Operational Impact Group and is now perceived as a necessity by the MHRA and ultimately the Secretary of State and must be implemented by November 2005. The MHRA is to introduce a new serious adverse event reporting system (SABRE) in the immediate future. A Quality Management System has been developed which contains the specific requirement that the record of transfusion must be held within the Blood Transfusion Laboratory.

Scope and responsibility

Insert your reconciliation procedure, e.g.: -

In order to evolve with the new regulations, we have already produced but are yet to instigate, a novel blood label and accompanying software. Moreover, we have installed an electronic blood tracking system that will enable us to record the transport of blood throughout the island site. Eventually, when fully implemented with its sister system (bedside bar-coded wristband production), all blood transfusion events will be recorded by tracing the whole of the cold chain. Within this combination of systems lies a trust-wide area of training and trouble-shooting that we perceive as an immense undertaking, the policing of which could prove to be a full-time commitment. In accordance with the recommendations made by OIG and accepted by the Secretary

of State, a large hospital such as the Central Site should have at least two Specialist Practitioners of Transfusion (SPoT). The Directorate Quality Manager has listed the problem as number 1 on our local risk register (attached) with an initial risk rating of the maximum.

Procedures that are novel to the laboratory but essential within the new regulation include: -

- Change control procedures
- Self audit
- Management of corrective actions
- Preventative actions
- Unremitting documentation of the QMS.

Add to MLA core job description: -

HAEMOVIGILANCE DUTIES

- *Police the cold chain:* -
 1. Access wards/patients' notes.
 2. Assist in the training and education of those involved in the cold chain.
 3. Assist in the management of corrective actions.
 4. Monitor and report on the satellite blood bank system
- *Observe the traceability system:* -
 1. Audit non-return of collection slips.
 2. Pursue the receipt of unsigned labels.
 3. Assist in the management of corrective actions.
 4. Daily update electronic details.

Proposed solution

The Hospital Transfusion Team (HTT) has agreed that extra staffing will enable the Trust to comply with existing and the future regulatory requirements and comply with the requirements of the MHRA report. However, although a second SPoT is considered ideal, the HTT has accepted that time is pressing and that the employing of a lesser position should prove to be a suitable interim measure.

Financial implications/other major implications

MLA salary from £ 10,249 to £ 12,741 plus on-costs.

Failure to comply with the regulation places the CEO in breach of criminal law.

Benefits

We expect that dedicated personnel will: -

- alleviate the burden from current employees
- increase the standards enabling compliance with the Regulation
- satisfy the conditions demanded by the MHRA report
- improve safety
- reduce the irrational use of blood and blood products (and thereby should prove self-financing).

The main aim is to roll out the programme of blood traceability in compliance with the UK Regulation, Statutory Instrument 2005 No. 50.

Recommendations

The HTC should pursue the employing of a second SPoT but concedes that in the interim and whilst awaiting the full electronic system, the employing of a dedicated Medical Laboratory Assistant (MLA) will prove a necessity. This should lower the risk rating to an acceptable level.

Current Service Profile

None.

Case for Change

The risk consequence will stay at 5 but the likelihood of failure will drop to 1. Thus the risk level changes from 25 to 5 representing an 80% reduction in risk.

Options and Preferred Option

- 1) Do nothing – failure to meet legal requirements.
- 2) Long-term employment of a second SPoT.
- 3) Short-term employment of an MLA is the preferred option at this juncture.

Option 1

This would result in a reduction in the blood transfusion service available to the trust using in-house resources. There would be increased costs brought about by buying-in suitable products.

Option 2

This option is the favoured long term option. At present the central site employs a single SPoT and the time required for ongoing training of trust staff, following up on adverse reactions and clinical audit could seriously compromise the quality of service.

Option 3

This is a quick-fix solution and would comply with the regulations in the short term. This is also the lowest cost option and is preferred as the time limit on the law being enacted is less than three months. This option also allows for assistance in the quality management system required.

Income and Cost analysis

There will be a number of benefits to the Trust which might have a positive financial effect. The granting of the licence and the operation of the blood transfusion system in line with statutory requirements will assist the trust in gaining the next banding on CNST and RPST. However failure to achieve and maintain licensing will result in the trust having to buy-in products such as irradiated blood and this will have cost implications. This could have an adverse effect on some specialties and result in a potential reduction in trust income.

Discussions with commissioner

Names of Consultants/QM and members of the HTC who have agreed that the position should be made available at the earliest convenience.

Timetable and Next Steps

Distribute to the involved personnel for comment etc.

Ownership and signoff