Medical Laboratory Scientists Association

Submission to HSE Corporate Employee Relations on Quality Manager Grading in Acute Hospital Laboratories

January 2015

Submission:
A survey undertaken by the MLSA in 2012 of grading for Quality Managers has revealed that currently there exists a large disparity in grades for scientists working as Quality Managers. The MLSA therefore argues that this disparity needs to be addressed.

As part of the 2011 Laboratory Modernisation Agreement, which was concluded in accordance with the terms of the Croke Park Agreement, the HSE committed to engage in discussions on the Quality Manager role.

Role of the Quality Manager:
The Role of Quality Manager is a work stream that developed at a time of considerable change in Medical Laboratories on foot of the EU Directives 2002/98/EC, 2004/33/EC, 2005/61/EC, Government Legislation SI 360 of 2005 and the AML- BB Document on Minimum Requirements for Blood Bank Compliance with Article 14 (Traceability) & Article 15 (Haemovigilance). The key to successful hospital laboratory accreditation is a Quality Management System and key to Quality Management is having a designated Quality Manager in place.

The critical role of the Quality Manager is to act as a hub, co-coordinating with the Laboratory Services Manager for all departments the many and varied accreditation work streams on the path to achieving ISO 15189 Accreditation in laboratory disciplines, or as is the case in larger hospitals where each major discipline may have a Quality Lead, coordinating the work of the sub-specialties within that discipline.

A large measure of responsibility goes with the role of Quality Manager which needs particular recognition in the Medical Laboratory setting. Accreditation places a mandatory governance requirement that places the Laboratory Quality Manager in a unique position reporting directly to the Laboratory Manager/Chief Medical Scientist.

Recognizing the unique role of the Quality Manager can be achieved by promoting the position to at least the grade of Specialist Medical Scientist Level within the promotional grades for Medical Scientists. The MLSA recognises that there can possibly be an argument that Quality Managers responsible for quality in larger hospitals have a greater workload, however, the responsibility and tasks for ensuring that accreditation for ISO: 15189 remains the same regardless of the size of the hospital. Given the higher workload and therefore a more onerous responsibility (more departments or specialties), consideration should be given to promoting these positions to Chief Medical Scientist level.

Current Situation in the HSE and Public Voluntary Hospitals:
There are numerous examples of higher level appointments throughout the HSE and public voluntary hospitals. There is currently a desire amongst members of the MLSA for appropriate grading for all Quality Managers in order to reflect the importance of the Quality Managers in the governance of modern pathology laboratories. Quality Managers normally have all grades within the laboratory, including that of Laboratory Manager, reporting to them on quality matters. Additionally, the Quality Manager often has a direct reporting role to the Hospital CEO.

A number of large teaching hospitals in Ireland have already recognised the importance of the Quality Manager position by grading the position, and making appointments, at

the grade of Chief Medical Scientist i.e. Mater Misericordiae Hospital and the Children's University Hospital.

Discussion:

There is too often little by way of promotional or financial incentive for Medical Scientists to take up quality management roles, given the requisite responsibilities the position entails in a modern medical laboratory.

The Infrastructural deficit (one-off spending from an accreditation perspective) has generally been absorbed into day to day spending and accreditation is continuing to be achieved. Indeed, there are many papers showing that an efficient Quality Management System (QMS) will generate significant savings (e.g. less repeated testing due to better control of pre-analytical, analytical and post-analytical factors). Additionally, if laboratory accreditation were to be withdrawn from any laboratory due to a Major non-conformance then the cost to the relevant hospital service provision could be significant until the major non-conformance is closed out.

There is a requirement for designated named deputies for all key positions in the laboratory. The ISO and INAB accreditation standards both recognise the importance of the deputy to the maintenance of the QMS. While there is great emphasis on deputies for key roles in the whole accreditation process, in small to medium labs most deputies to Quality Managers are already performing routine duties concerned with their primary employment role as a Medical Scientist. Large laboratories would have at least one Senior Medical Scientist full time in a deputy quality manager role.

Laboratories in Ireland, having been early adopters of accreditation, have led the way in healthcare accreditation in the Irish health service. A Laboratory Accreditation programme provides a template that has enabled Laboratory staff to do what they do best, even better than before while facilitating documentation of issues and quality improvements to the service along the way all of which benefits clients and patients.

Quality Indicators are analysed and document the contribution of staff to improved quality, productivity and outputs in the context of our patient care, and their work is accountable to the public through external audit by INAB / IMB.

There is better management of risk, safety and quality within the hospital through adherence to quality management systems, care pathways, disease programmes, protocols, audit, information management systems, etc. Such systems must be developed under the authority of the Quality Manager and Clinical Care team and relevant department heads and activated under the direction and oversight of the relevant clinical leaders at local level e.g. medical, nursing or allied health professional grades, consistent with the recommendations of the Commission on Patient Safety and Quality Assurance; measurable against the Health Information and Quality Authority (HIQA) standards. In relation to this, the Medical Laboratory Quality Manager is a key co-ordinator.

This includes the use of evidence-based performance measurement, to drive continuous improvements in efficiency/effectiveness, measurable by use of Internal Quality Audits, Vertical Haemovigilance and Traceability Audits for Blood Transfusion and External regulatory audits by INAB inspectors.

MLSA Proposal:

In a large teaching hospital the designated or appointed Quality Manager should be at Chief Medical Scientist Grade. In medium and small hospital laboratories the Laboratory Quality Manager pay scale should be revised to that of at least Specialist Medical Scientist grade to reflect the skill sets required and commensurate with the responsibilities that the holder of the position bears in providing a quality management service in the modern medical laboratory in the Hospital care setting.

Appendix 1

Summary of Quality Management & the Role of the Quality Manager in the Laboratory.

- **A Quality Management Programme in a Medical Laboratory has a Quality & Safety Manual which outlines the Management & Technical responsibilities in accordance with the Quality Standard ISO15189 and Irish Law together with the associated AML-BB document "The Minimum Requirements for Blood Bank compliance with Article 14 (Traceability) and Article 15 (Notification of Serious Adverse Reactions and Events) of EU Directive 2002/98/EC".**

- **The ISO 15189 Standard is the document that external assessors / auditors use to test a Quality Manual in the first instance.**

- **All statements in a Quality Manual must be given effect through a master list of approved documents, standard operating procedure (SOP's) quality records & forms.**

- **The role of the Quality Manager is to co-ordinate the activities of the quality management system in conjunction with the Laboratory Manager and Heads of Departments.**

- **The quality management programme will:**

  - **document and control all standard operating procedures, quality records and forms;**
  - **identify, control and analyse non-conformances, complaints and ongoing quality improvements;**
  - **evaluate suppliers;**
  - **document and control critical equipment using an asset register;**
  - **manage equipment maintenance, documenting validation, calibration, service & preventive maintenance and cleaning;**
  - **document corrective action, preventive action and quality checks based on approved quality indicators;**
  - **review of contracts;**
  - **review (clinical) advisory services;**
  - **monitor operational systems through a comprehensive auditing schedule**
  - **document and review through regular (monthly) quality & safety meetings the various activities outlined above;**
  - **document and review through regular hospital blood transfusion committee meetings on-going Haemovigilance activities and the patient consequence / severity of any Serious Adverse Events (SAE's) / Serious Adverse Reactions (SAR's);**
  - **hold an annual management review to assess overall management and technical operations;**