LABORATORY QUALITY MANAGEMENT

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Abstract: Laboratories in the Republic of North Macedonia are subject to many national requirements. Each laboratory should deliver quality laboratory service for patients in accordance to national regulations and requirements. The International Organization for Standardization (ISO), has developed quality systems to assess specific aspects of health services. A majority of laboratories rely on International Quality Standards known as ISO/IEC/17025 for all types of testing and calibrating laboratories and more specifically ISO 15189 for medical laboratories. These standards are quite comprehensive and often very resource-intensive. Medical laboratories were early leaders in efforts to minimize medical errors and improve patient safety. A quality management system (QMS) is a vehicle to deliver a quality service. The importance of quality in the functioning of health care laboratories is well recognized globally. The poor quality of laboratory results can lead to inappropriate interventions, adversely affect the credibility of the laboratory and may also invite legal action. It is, hence, essential to develop and implement a policy on quality in health laboratories. The QMS defines the organizational structure, responsibilities, policies, procedures, standards and resources required. What is needed is a roadmap for quality that ensures that each laboratory makes its best contribution to patient care and safety.The laboratory quality system essentials are:Organization;Facilities;Personnel; Equipment; Purchasing and inventory. The work quality system essentials are: Process control;Documents and records and Information management. The measurement quality system essentials are:Occurrence management; Assessments: external and internal; Customer service and Process improvement. An important relationship between quality activities that should be designed and supported by laboratory management and the technical activities that produce laboratory results for patient care should exist.Different laboratories are at different levels of quality development and hence a flexible step-wise approach has to been followed.Laboratories not implementing a good quality management system are guaranteed that there will be many errors and problems occurring that may go undetected. Implementing a quality management system may not guarantee an error-free laboratory, but it does yield a high-quality laboratory that detects errors and prevents them from recurring. Identification of a national focal point for laboratories, along with a well-defined national laboratory policy is essential. It is suggested that subsequent to the development of minimum national standards, countries should strive to make these mandatory. Implementation of international standards can be undertaken subsequently through up gradation of national standards.
Keywords: quality management, medical laboratories, ISO standard 15189

INTRODUCTION

Laboratories in the Republic of North Macedonia are subject to many national requirements. Each laboratory should deliver quality laboratory service for patients in accordance to national regulations and requirements. The International Organization for Standardization (ISO) has developed quality systems to assess specific aspects of health services[19]. A majority of laboratories rely on International Quality Standards known as ISO/IEC/17025 for all types of testing and calibrating laboratories and more specifically EN ISO 15189: 2012 for medical laboratories[20]. EN ISO 15189:2012 was developed as a baseline standard for the Quality Management System (QMS) in medical laboratories and is recognized as the connecting standard for all disciplines in laboratory medicine[21,22].

There are many procedures and processes that are performed in the laboratory and each of these must be carried out correctly in order to assure accuracy and reliability of testing[23]. An error in any part of the cycle can produce a poor

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laboratory result[24]. Laboratory system requires that many factors must be addressed to assure quality in the laboratory. Some of these factors include: the laboratory environment, quality control procedures, communications, record keeping, competent and knowledgeable staff, good-quality reagents and equipment[2526]. When all of the laboratory procedures and processes are organized into an understandable and workable structure, the opportunity to ensure that all are appropriately managed is increased. The best model is to organize all of the laboratory activities into 12 quality system essentials. These quality system essentials serve as building blocks for quality management.

1. Organization

The structure and management of the laboratory must be organized so that quality policies can be established and implemented. There must be a strong supporting organizational structure, where management commitment is crucial, and there must be a mechanism for implementation and monitoring.Everyone in the laboratory is responsible for quality performance: Laboratory leaders and managers must commit to meeting quality needs; Laboratory personnel must follow all quality assurance procedures and adhere to requirements and standards.

2. Personnel

The most important laboratory resource is competent, motivated staff. The quality management system addresses many elements of personnel management and reminds us of the importance of encouragement and motivation. A very important part of the management process is to seek ways to attract qualified personnel, and to provide motivation and appropriate benefits and working conditions so as to retain staff. Personnel are the most important resource in the laboratory. Managers must create an environment that will fully support all laboratory personnel in order to maintain a high quality of laboratory performance. Continuing education is vital to personnel competency, but does not need to be expensive. New testing methodologies and instruments are constantly introduced to the marketplace, and employees need to update their knowledge and skills.

3. Equipment

Many kinds of equipment are used in the laboratory, and each piece of equipment must be functioning properly. Choosing the right equipment, installing it correctly, ensuring that new equipment works properly, and having a system for maintenance are all part of the equipment management programme in a quality management system.All laboratories should have a well-organized equipment management programme. The programme should address equipment selection, preventive maintenance, and procedures for troubleshooting and repair. It is essential that good documents and records be maintained. These will include a complete and accurate inventory of all laboratory equipment, documents provided by the manufacturer on operation, maintenance and troubleshooting, and records of all preventive maintenance and repair activities.A good equipment maintenance programme results in a high level of performance and greater confidence in the reliability of results. A significant benefit to the laboratory will be fewer interruptions in test performance, lower repair costs and elimination of premature replacement of equipment. Increased safety for laboratory workers will result from well-maintained equipment.

4. Purchasing and inventory

The management of reagents and supplies in the laboratory is often a challenging task. However, proper management of purchasing and inventory can produce cost savings in addition to ensuring supplies and reagents are available when needed. The procedures that are a part of management of purchasing and inventory are designed to ensure that all reagents and supplies are of good quality, and that they are used and stored in a manner that preserves integrity and reliability. The system will require planning and monitoring to ensure that appropriate quantities of supplies and reagents are always available, and to prevent wastage. In implementing an inventory management system, the laboratory must assign responsibility for the programme, analyze the needs of the laboratory and establish the minimum stock needed for an appropriate time period. Appropriate forms will be needed, as well as a procedure for receiving, inspecting and storing supplies. The laboratory will need to maintain an inventory system for all reagents and supplies used in the laboratory; this system must include all areas where reagents and supplies are stored. Properly managing inventory will: increase the efficiency and effectiveness of the laboratory, because it will provide an uninterrupted flow of needed materials; ensure products are available when they are needed; ensure that patient and clinical needs are met.

5. Process control

Process control is comprised of several factors that are important in ensuring the quality of the laboratory testing processes. These factors include quality control for testing, appropriate management of the sample, including collection and handling, and method verification and validation.Quality control (QC) was one of the first quality

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practices to be used in the laboratory and continues to play a vital role in ensuring accuracy of testing.A laboratory handbook describing sample collection and providing testing information must be available to everyone who needs this information. It is important to have a system for tracking samples as they move through the laboratory. Each laboratory should establish and implement a policy for sample storage and sample disposal. Maintain sample integrity and assure that all regulations and requirements are met. Sample management directly affects patient care and outcome.QC is part of the quality management system and is used to monitor the examination (analytic) phase of testing. The goal of QC is to detect, evaluate and correct errors due to test system failure, environmental conditions, or operator performance, before patient results are reported.If QC results are not acceptable, laboratory should not report patient results.

6. Information management

The product of the laboratory is information, primarily in the form of test reporting. Information (data) needs to be carefully managed to ensure accuracy and confidentiality, as well as accessibility to the laboratory staff and to the health care providers. Information may be managed and conveyed with Information management is a system that incorporates all the processes needed for effectively managing data—both incoming and outgoing patient information.The system can be entirely paper-based, or it can be partly paper-based with some computer support, or it may be entirely electronic.For either paper-based or computer systems, unique identifiers for patient samples will be needed. Standardized test request forms, logs and worksheets are also important to both systems. In helping to prevent transcription errors, a checking process is beneficial. A good information management system will: ensure that all data—the final product of the laboratory—is well managed; consider all the ways laboratory data will be used when planning a system; ensure the accessibility, accuracy, timeliness and security of data; ensure confidentiality and privacy of patient informationeither paper systems or with computers.

7. Documents and records

Documents are needed in the laboratory to inform how to do things, and laboratories always have many documents. Records must be meticulously maintained so as to be accurate and accessible.Documents include written policies, processes and procedures, and provide a framework for the quality system. They need to be updated and maintained.Having a good document control programme ensures that the most current version of a document is used, and ensures availability and ease of access when a document is needed.

8. Occurrence management

An "occurrence" is an error or an event that should not have happened. A system is needed to detect these problems or occurrences, to handle them properly, and to learn from mistakes and take action so that they do not happen again.Occurrence management is an integral component of laboratory quality management. It establishes the methods for finding errors and preventing them from occurring again, and also seeks to identify potential errors and prevent them from happening. The laboratory should employ an active process for occurrence management and take a positive approach.

9. Assessment

The process of assessment is a tool for examining laboratory performance and comparing it to standards. Assessment may be internal (performed within the laboratory using its own staff) or it may be external (conducted by a group or agency outside the laboratory). Laboratory quality standards are an important part of the assessment process, serving as benchmarks for the laboratory.Assessment is important in monitoring the effectiveness of the laboratory quality management system. Both external and internal audits yield useful information. Audits are used to identify problems in the laboratory, in order to improve processes and procedures. An outcome of assessment is finding root causes of problems and taking corrective actions. All laboratories should establish an internal audit programme. Conducted on a regular basis, it will provide information for continual improvement.External Quality Assessment(EQA) is important for improvement of the laboratory quality management system, as it is a measure of laboratory performance.

10. Process improvement

The primary goal in a quality management system is continuous improvement of the laboratory processes, and this must be done in a systematic manner. There are a number of tools that are useful for process improvement.The process for continual improvement includes: identification of the problem; analysis of the data and the processes; determination of the root cause of the problem; generation of ideas for solutions.

11. Customer service.

It is important to note that the laboratory is a service organization; therefore, it is essential that clients of the laboratory receive what they need. The laboratory should understand who the customers are, and should assess their needs and use customer feedback for making improvements.Seeking customer satisfaction requires commitment from the laboratory management and staff. It is important to remember that technical competency is not the only goal for the laboratory. Customers or clients of the laboratory include physicians and other health care providers,

hospital and clinic staff, patients and their families, public health officials and the general community. Monitoring customer satisfaction requires some resources, primarily involving staff time. Managers need to ensure that these resources are available. Meeting customer needs is a primary goal of the laboratory. Everyone in the laboratory is responsible for quality and, therefore, for customer service. An active quality management system ensures laboratories meet all client requirements.

12. Facilities and safety

Many factors must be a part of the quality management of facilities and safety. These include:

a. Security: the process of preventing unwanted risks and hazards from entering the laboratory space.
b. Containment: seeks to minimize risks and prevent hazards from leaving the laboratory space and causing harm to the community.
c. Safety: includes policies and procedures to prevent harm to workers, visitors and the community.

CONCLUSIONS

Laboratories not implementing a good quality management system are guaranteed that there will be many errors and problems occurring that may go undetected. Implementing a quality management system may not guarantee an error-free laboratory, but it does yield a high-quality laboratory that detects errors and prevents them from recurring [27,28].

Identification of a national focal point for laboratories, along with a well-defined national laboratory policy is essential[29]. It is suggested that subsequent to the development of minimum national standards, countries should strive to make these mandatory. Implementation of international standards can be undertaken subsequently through upgradation of national standards[30,31,32,33,34,35].Time invested today will help gain quality results, professional and personal satisfaction, and peer recognition. Quality is not a science; it is a way of thinking.

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