

Introduction to Laboratory Quality Management System (LQMS)

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Hello and welcome to this lecture on Laboratory Quality Management Systems. This lecture is an adaptation of guidance from the World Health Organization (or WHO) and Centers for Disease Control (or CDC), where we will discuss clinical laboratory quality standards.

The goal of this introductory lecture is to explain the importance of a quality management system. We will define what a quality system is and describe its key benefits. We will also explain the differences between ISO and CLSI quality standards and walk through the WHO's 12 essential elements of a laboratory quality system.

At the end of this activity, we hope you will be able to:

- explain the importance of a quality management system;
- list the quality system essential elements;
- describe the history of development of laboratory quality principles; and
- discuss the relationship of this quality model to ISO and CLSI standards.

So, let's dive in. For a clinical laboratory, quality means that all aspects of the laboratory operations must be accurate and reliable, and reporting must be timely in order to be useful in a clinical or public health setting.

Laboratories produce test results that are widely used in clinical and public health settings and health outcomes depend on the accuracy of the testing and reporting. If inaccurate results are provided, the consequences can be very significant. The effects of laboratory errors include: Unnecessary treatment, complications, failure to provide the proper treatment, incorrect diagnosis, additional and unnecessary diagnostic testing. These consequences result in increased cost, time, personnel effort, and potentially poor patient outcomes. When making measurements there is always some level of inaccuracy. The challenge is to reduce the level of inaccuracy as much as possible given the limitations of our testing systems.

Here is an example of a laboratory error and its consequences: An 83-year-old male was admitted to hospital with fever, weight loss, and cough, and was being investigated for possible tumor. Sputum was reported to be positive for tuberculosis, but on later review, found to be false positive culture due to in-laboratory contamination. Further investigation found 14 additional patients with false positive TB culture. What problems are created by this error?

The consequences of this error included a delay in correct diagnosis, unnecessary treatment or treatment complications. Once the pattern of other contaminations was discovered, fixing the problem required 6 months of investigation, contacting more than 200 patients, many requiring repeating the TB culture test and lung X-Ray. Revision of laboratory procedures eradicated the

problem. The key point here is that laboratory errors cost in time, energy, personnel, and patient outcomes.

So, Laboratory quality can be defined as the accuracy, reliability and timeliness of the reported test result. So, how do we achieve excellent performance in the laboratory?

We need a quality management system: A quality management system can be defined as coordinated activities that direct and control an organization with regard to quality. This definition is used by the International Organization for Standardization (ISO) and by the Clinical and Laboratory Standards Institute (CLSI). Both groups are internationally recognized laboratory standards organizations and will be discussed later in this lecture.

In a quality management system, all aspects of the laboratory operation, including the organizational structure, processes and procedures need to be addressed to assure quality.

In order to achieve the highest level of accuracy and reliability it is essential to perform all processes and procedures in a laboratory in the best possible way. The laboratory is a complex system involving many steps, activities, and people. The complexity of the system requires that many processes and procedures be performed properly. Therefore, the quality management system model, which looks at the entire system, is very important for achieving good laboratory performance. As shown in this diagram, 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... error in any part of the cycle can produce a poor laboratory result.

The entire set of laboratory operations that occur in testing is called the path of workflow. The path of workflow begins with the patient, test selection, sample collection, laboratory analysis and testing, and aims to report results that are interpreted by the physician, who ultimately directs clinical care. The concept of the workflow path is essential to the the quality management system and must be considered when developing quality practices.

For example, a sample that is damaged or altered as a result of improper collection or transport cannot provide a reliable result. Similarly, a medical report that is delayed or lost or poorly written can negate all the efforts in performing a test properly and accurately.

Quality management concepts in use today were developed in the 20th century and are primarily an outgrowth of manufacturing and auto industry processes. One of the earliest concepts of the quality management movement was that of quality control of the product. Walter Shewart developed a method for statistical process control in the 1920s, forming the basis of our quality control procedures in the laboratory. It wasn't until the 1940's (almost two decades later) that continuous quality improvement methods were applied in the laboratory, based on work by Deming. And it was in Joseph Juran's Quality Control Handbook of the 1950s that many quality management techniques are still used today. Another historical figure in the field of quality management is Philip Crosby, widely known for promoting the concept of "zero

defects” and for attempting to define quality from the viewpoint of conformance to requirements. And finally (in our brief history of quality management) is Robert Galvin who brought to us Micro Scale Error Reduction.

A part of quality management is assessment, which measures test performance against a standard or benchmark. The International Organization for Standardization established standards for industrial manufacturing and service industries, which are used many organizations. We know these standards as ISO.

Another important international standards organization for laboratories is the Clinical and Laboratory Standards Institute or CLSI, formally known as the National Committee for Clinical Laboratory Standards (NCCLS). CLSI uses a consistent process, involving many stakeholders, for developing consensus standards for laboratory testing. This model is based on the 12 quality system essentials and it is fully compatible with ISO laboratory standards.

The 3 current ISO documents for the clinical laboratory include: one, ISO 9001:1994 Quality Systems: Model for Quality Assurance in design, development production, installation, and servicing. Two, ISO/FDIS 15189: Quality management in the clinical laboratory (1998), and three, ISO/IEC 17025, which defines the general requirements for the competence of testing and calibration of laboratories (1998)

The CLSI Quality Management System describes 12 quality system essentials. Its goal is to assist labs in improving processes and provides laboratories with a workflow process to help reduce errors.

The 12 Quality System Essentials, also known as QSES, highlight a set of coordinated activities that function as building blocks for quality management. Each must be addressed if overall laboratory quality management is to be achieved. Again, this quality management system model was developed by CLSI and is fully compatible with ISO standards; assuring accuracy and reliability throughout the path of workflow depends on good management of all of the quality sanctions. Let’s walk through each of these components in more detail, starting with Organization. In order to have a functioning quality management system, 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 organization or organizational structure (management commitment, communication, resources, a quality policy and a quality manual are crucial aspects). Next, the most important laboratory resource is having competent, motivated staff or personnel. The quality management system address many elements of personnel management and oversight. Capable staff members are the single most important asset to a laboratory. Training, motivation, and engagement are key parts of the quality management system.

Equipment is also a critical component of a quality management system: 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, assuring that the new equipment

is properly working, and having a system for maintenance are all part of the equipment management program in a quality management system. 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 assuring supplies and reagents are available when needed. The procedures that are a part of management of purchasing and inventory are designed to assure that all reagents or supplies are of good quality and that they are used and stored in a manner that preserves integrity and reliability. Properly managing the supply chain is critical to ensure that raw inputs and other supplies are consistently high-quality. Inventory activities should verify that materials and supplies are stored in a way that protects integrity.

Process control is comprised of several factors that are important in assuring the quality of laboratory testing processes; these factors include quality control for testing, writing procedures, appropriate management of the sample (including collection and handling), and method verification and validation. The elements of process control are very familiar to laboratorians. Process control was one of the first quality practices to be used in the laboratory and continues to play a vital role in assuring the accuracy of testing.

The product of the laboratory is information, primarily in the form of test reporting, and as such, information must be managed. Information or data need to be carefully managed to assure accuracy and confidentiality, as well as accessibility to the laboratory staff and to the healthcare providers. Information may be managed and conveyed with either paper systems or with computers. The laboratory produces many forms of information, including quality control test results, maintenance reports, and other data. These data need to be managed in a way that ensures all information is accurate, secure, confidential, and accessible to individuals with the right privileges, such as lab managers and leadership.

Documents are a similar concept to information management, and there is a significant overlap between these categories. One of the most essential lab documents is standard operating procedures (SOPs) which create a standard protocol for each process. Documents need to be available at the point of work, maintained, accurate, and secure. Documents are needed in the laboratory to inform how to do things and how to do them well. Laboratories always have many documents and records that must be meticulously maintained so as to be accurate and accessible.

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.

Laboratory assessment is a tool for examining laboratory performance and comparing it to standards or benchmarks or the performance of other laboratories. Assessment may be internal or performed within the laboratory using its own staff or it may be externally conducted by an outside group (for example, an agency that is independent, and provides an external accreditation and/or inspections). Process improvement is another key aspect of a

quality management system and is used for continuous improvement of the laboratory processes. There are a number of tools that are useful for process improvement including opportunities for improvement, stakeholder feedback, problem resolution, risk assessment, preventative action reports, and corrective action reports.

A quality management system should also support continuous process improvement of laboratory practices. Components of the QMS which support improvement can include QC or quality control and Corrective Action and Preventive Action (CAPA),

The concept of customer service has often been overlooked in laboratory practice; however it is important to note that the clinical laboratory is a service organization, therefore it is essential that clients of the laboratory receive what they need. It is also essential to know who the clients of the laboratory are. Clients of the laboratory include clinicians, patients, and their families. Everybody who receives services from the lab either directly or indirectly are laboratory customers. The laboratory should understand who the customers are and should assess their needs and use customer feedback for making improvements. Excellent customer service is the goal of the clinical laboratory. A laboratory's QMS should support operations that consistently provide a positive customer experience through the production of consistently high-quality products or other missions.

Laboratories also need a comprehensive set of procedures and standards to ensure a safe, secure, and clean environment. Many factors must be a part of the quality management of facilities and safety, and these include **security**, which is the process of preventing unwanted risks and hazards from entering the laboratory space. **Containment** seeks to minimize risks and prevent hazards from leaving the laboratory space and causing harm to the community. **Policies and procedures** prevent harm to workers, visitors, and the community, while **ergonomics** addresses facility and equipment adaptation to allow safe and healthy working conditions at the laboratory site.

In the quality management system model, all 12 Quality System Essentials must be addressed to assure accurate, reliable, and timely laboratory results; and to have quality throughout the laboratory operation.

It is important to note that the 12 QSES may be implemented in an order that best suits the laboratory. Approaches to implementation will vary depending on the local situation at the laboratory.

Implementing a good quality management system does not guarantee an error-free laboratory, but it detects errors that may occur and prevents them from recurring. Without a QMS, it is very likely that a laboratory will produce errors that are not detected.

In summary, quality management system is not new. It has grown from the good work of innovators who defined quality over a span of 80 years. Quality management is as applicable for the clinical laboratory as it is for the manufacturing industry.

Operational Quality Management in the Clinical Laboratory

To end this lecture, some key messages that I think are important are one, a laboratory is a complex system and all aspects must function properly to achieve quality. Approaches to implementation will vary with a local situation. Start with changes that can be easily accomplished and have the biggest impact, and implement in a stepwise process. And finally, ultimately, all quality essentials must be addressed. Thank you for watching and listening.