



## QUALITY CONTROL IN LABORATORIES: STRATEGIES FOR DETECTING AND MANAGING ERRORS

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### ABSTRACT

This review explores the critical role of Quality Control in laboratories, focusing on strategies for detecting and managing errors within clinical and public health settings. To ensure the reliability, accuracy, and timeliness of laboratory results, the implementation of Quality Management Systems (QMS) is essential. This paper explores the 12 Quality System Essentials (QSEs) defined by the Clinical and Laboratory Standards Institute (CLSI) as a framework for establishing a successful laboratory QMS infrastructure. Additionally, the review highlights the importance of Laboratory Quality Management Systems (LQMS), as emphasized by both the International Organization for Standardization (ISO) and CLSI, in supporting the full laboratory environment across pre-analytic, analytic, and post-analytic phases. The COVID-19 pandemic's impact on laboratory operations underscores the necessity of robust LQMS for managing high test volumes and mitigating risks. The review further discusses tools available for laboratory quality managers, including the World Health Organization's Laboratory Quality Stepwise Implementation (LQSI) tool and third-party LQMS software, which aid in modernizing processes and facilitating accreditation efforts. Challenges such as consolidation of services, outsourcing, and staffing issues are also examined, with a call for systemic changes to ensure quality improvement and patient safety.

**Keywords:** Quality control, laboratory, errors management, patient safety, quality management systems, laboratory quality management systems

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## INTRODUCTION

For medical laboratories to provide accurate, consistent, and timely results to physicians and patients, laboratory directors and supervisors need to implement quality management systems (QMS). By doing so, management teams can reduce reagent and equipment costs, ease the burden on personnel, handle large amounts of documented data and results, and meet patient and client expectations (1). Quality control in the laboratory is a fundamental process aimed at ensuring the accuracy and reliability of patient results and data. This process is critical because it helps identify and correct errors that can arise from various sources, including administrative errors, methodological issues, technical problems with proficiency testing materials, and random errors, as highlighted in a study by Ibrahim and colleagues (2).

To enhance quality control, laboratory leaders employ a range of strategies. These include adopting continuous improvement processes, conducting control sample testing, engaging in monthly peer testing, and undergoing reviews with proficiency testing through accredited organizations such as the College of American Pathologists (CAP) (3). Additionally, quality control can be increased by improving laboratory resources, promptly addressing issues with reagents and equipment, actively training staff, fostering team building, and maintaining effective communication both within the lab team and with external collaborators (4, 5).

A key strategy for advancing quality management in laboratories is the implementation of a Laboratory Quality Management System (LQMS). An LQMS encompasses a comprehensive approach to managing and maintaining quality, focusing on the systematic oversight of all aspects of laboratory operations. This includes standardizing procedures, ensuring the competence of laboratory personnel, validating and calibrating equipment, and continuously monitoring quality control measures to detect and rectify problems promptly. By integrating an LQMS, laboratories can significantly improve their ability to produce accurate and reliable results, thereby enhancing patient care and safety.

Management strategies for preventing errors in the laboratory primarily focus on identifying activities with the highest risk of errors. It is crucial to monitor the system and pinpoint critical areas to ensure that human and economic resources are efficiently used, avoiding the wastage on errors that are less likely to happen. This identification of risk-prone areas is facilitated through the use of error detection systems designed to cover all three phases

of the testing process: preanalytical, analytical, and postanalytical (6).

Areas commonly identified as critical for the prevention of laboratory errors encompass several key aspects. These include ensuring the correct tests are ordered by physicians, accurate identification of patients and specimens, proper collection, transport, and processing of specimens, maintaining the quality of the analytical process, prompt transmission of critical test results, accurate interpretation of laboratory data, and effective communication of these data to physicians. By focusing on these areas, laboratories can significantly reduce the occurrence of errors, enhancing the reliability and safety of laboratory testing outcomes (7).

Risk management is the identification, assessment, and prioritization of risks followed by coordinated and economical application of resources to minimize, monitor, and control the probability and/or impact of unfortunate events or to maximize the realization of opportunities (8, 9). Risk management is essentially the systematic application of management policies, procedures, and practices to the tasks of analyzing, evaluating, controlling, and monitoring risk (10).

## METHODOLOGY

This study is based on a comprehensive literature search conducted on February 2, 2023, in the Medline and Cochrane databases, utilizing the medical topic headings (MeSH) and a combination of all available related terms, according to the database. To prevent missing any possible research, a manual search for publications was conducted through Google Scholar, using the reference lists of the previously listed papers as a starting point. We looked for valuable information in papers that discussed quality control in laboratories: strategies for detecting and managing errors. There were no restrictions on date, language, participant age, or type of publication.

## DISCUSSION

The importance of LQMS is critical, as defined by the International Organization for Standardization (ISO) and Clinical and Laboratory Standards Institute (CLSI), which describe a quality management system as coordinated activities to direct and control an organization with regard to quality. For laboratory accreditation, the presence of a quality management system is often an essential (1).

LQMS is integral in supporting the three phases of the full laboratory environment (11). In the pre-analytic phase, which involves sample preparation and transportation, it is crucial to ensure that

specimens are collected, labeled, and transported correctly to maintain their integrity until analysis. The analytic phase encompasses all activities during the operational testing and research, with a strong emphasis on precision, accuracy, and reliability of test results through rigorous quality control measures. Lastly, the post-analytic phase is dedicated to the reporting of results, ensuring that the data are communicated effectively and efficiently to facilitate timely clinical decisions. The COVID-19 pandemic underscored the necessity of having an LQMS to manage an unusually high volume of test samples effectively, demonstrating that such a system is vital for the long-term success in public health. Additionally, a quality management system helps in mitigating risks and identifying gaps within laboratory

processes. Overall, the implementation of LQMS is pivotal for enhancing the quality and efficiency of laboratory operations, playing a crucial role in improving healthcare delivery (6). By standardizing procedures and implementing consistent quality checks, LQMS reduces errors, optimizes laboratory workflows, and increases productivity. This not only leads to increased customer satisfaction through accurate, reliable, and timely test results but also enhances patient care and trust in laboratory services. Furthermore, LQMS aids in increasing accreditation assessment by demonstrating a commitment to quality and adherence to recognized standards, thereby facilitating the achievement and maintenance of accreditation status.

**Table 1.** ISO standards for laboratories (1)

Standard	Scope and Focus	Key Features and Requirements	Benefits and Impact on Laboratories	References
<b>ISO 9001</b>	Quality management systems applicable to all types of organizations, including laboratories.	-Specifies criteria for quality management systems. Emphasizes the importance of consistent product and service provision. Aims to enhance customer satisfaction through system application and improvement.	- Improves laboratory performance and workflow quality. Significantly reduces errors. Positively impacts healthcare organizations, as demonstrated in Austrian laboratories.	(6, 12)
<b>ISO 15189</b>	Quality and competence in medical laboratories. Covers both management and technical requirements.	Management requirements include quality system, organization responsibility, and audits. Technical requirements focus on operational procedures, environmental conditions, and the quality of examination results.	Facilitates cost reduction and error prevention. Engages personnel for higher quality results, improving patient care. Enhances laboratory credibility and operational efficiency through accreditation.	(13, 14)
<b>ISO 17025</b>	Testing and calibration laboratories, focusing on operational competency and quality of test results.	National and international recognition. Demonstrates operational competency and ability to generate quality results.	Increases laboratory credibility and customer trust. Assures compliance and validated performance. Boosts clientele, reduces costs, and improves efficiency.	(15)

**Tools available for laboratory quality managers**

The primary responsibility of a quality manager in a laboratory is to maintain strict compliance with established standards, guiding the laboratory's operations to ensure efficiency and smooth operation across all components, including reagents, equipment, and personnel. Various tools are available to assist leaders in enhancing quality assurance within their labs.

***The Laboratory Quality Stepwise Implementation (LQSI) Tool by The World Health Organization (WHO)***

The importance of laboratory management for organizations like WHO in developing LQMS to prepare for potential outbreaks and emergencies is well-acknowledged. WHO has contributed to reinforcing global laboratory standards and systems through educational materials and guidance documents (1). In 2014, WHO introduced the Laboratory Quality Stepwise Implementation (LQSI) tool, a complimentary online resource aimed at aiding laboratories in establishing quality management systems towards achieving ISO 15189 accreditation.

LQSI tool is accessible to all diagnostic laboratories focused on clinical or public health. It is divided into four phases, each designed to be implemented in a stepwise manner, allowing laboratories to progressively enhance their processes and quality. The first phase focuses on ensuring that all operations are conducted correctly and safely, laying the foundation for accurate and reliable diagnostics. The second phase emphasizes controlling and assuring quality and traceability, which is essential for maintaining the integrity and dependability of laboratory results. The third phase deals with proper management, leadership, and organization, key elements for efficient and effective laboratory operations. The final phase is dedicated to continued improvement, with an aim towards achieving accreditation, signifying a laboratory's commitment to maintaining the highest standards in its practices and services. This structured approach enables laboratories to methodically advance their quality systems and operational efficiency.

An evaluation conducted by Datema et al. in 2018 assessed the LQSI's effectiveness in facilitating quality management system implementation (16). The analysis, reflecting 130,986 unique users with significant user bases in India, the USA, Russia, and the Philippines, indicated enhanced laboratory services, improved clinical care, and boosted disease surveillance capabilities through the tool's utilization.

Beyond the World Health Organization's LQSI tool, laboratory managers have access to various third-party LQMS software-based tools. While not mandated by regulatory agencies, these software tools are highly beneficial for laboratories looking to modernize and automate processes traditionally done manually. Many of these tools are cloud-based, offering significant advantages: they overcome data storage limitations typical of local servers and facilitate the easy and secure sharing of results with other laboratories. This cloud-based approach not only enhances data management and accessibility but also fosters collaboration and data exchange between different labs, thereby improving overall efficiency and accuracy in laboratory operations (1).

***Laboratory Information Management System (LIMS)***

Another pivotal tool for laboratory managers is Laboratory Information Management System (LIMS), a software solution designed for managing samples and associated data. LIMS aids in enhancing the quality and timeliness of laboratory results by streamlining sample management, data tracking, and the integration of reagents, instruments, and other applications. A recent study highlighted the effectiveness of LIMS in managing non-clinical COVID-19 data, showcasing its potential utility in future pandemics for expediting medical research and development through systematic data management (17).

**Limitations and challenges to quality-improvement measures**

The pursuit of quality improvement in laboratory services faces both opportunities and significant challenges. Innovations like the development of near-patient testing and point-of-care testing (POCT) facilities aim to reduce turnaround times for crucial tests, such as those measuring blood gases and serum electrolytes. However, these advancements may compromise the preanalytical phase, including specimen collection and integrity, potentially increasing the risk of errors. Efforts to compare laboratories often focus on reducing the cost per test rather than considering the overall cost of maintaining high quality. This cost-cutting approach may inadvertently elevate the risk of errors in both pre- and postanalytical steps, highlighting a need for a balanced approach that weighs cost efficiency against quality assurance (7).

The drive towards improving the quality of test results through better testing processes, laboratory information technology, automation, and patient safety measures faces several significant

challenges. These challenges include consolidation and outsourcing, where the trend towards larger organizational units and outsourcing of laboratory services can complicate the total testing process. Mega laboratories resulting from consolidation may compromise crucial pre- and post-analytical procedures, such as specimen transportation and communication with healthcare professionals, leading to an increased risk of errors.

Another challenge is staff downsizing, driven by economic pressures, which has significantly increased workloads and affected staff productivity in laboratories. While the effects of staff downsizing may not be immediately apparent, they are likely to emerge over time, resulting in errors and patient safety issues. These challenges underscore the need for careful consideration and proactive measures to ensure the quality and safety of laboratory operations (7).

### **Strategies for managing errors**

To navigate these challenges, systemic changes in laboratory management and operations are required. Emphasizing quality improvement necessitates a comprehensive approach that includes investing in advanced technologies and processes that ensure accuracy and reliability without compromising safety. Additionally, maintaining adequate staffing levels and enhancing communication between laboratories and healthcare providers are critical. Adopting a holistic view that considers the total cost of quality, rather than merely focusing on reducing individual test costs, can help mitigate the risk of errors and improve the overall quality of laboratory services. This approach not only ensures patient safety but also contributes to the long-term sustainability and efficiency of laboratory operations (7).

To enhance quality improvement in laboratory medicine and ensure patient safety, significant changes are required in several key areas. Achieving substantial improvement in laboratory services necessitates the following shifts. Firstly, a cultural change in healthcare provision is essential. There must be a fundamental shift towards instilling a culture of safety among laboratory staff. This entails convincing every member of the importance of adhering to safety practices as an integral part of their job, including proper handwashing and accurate patient identification before specimen collection. Additionally, new healthcare professionals entering the laboratory should receive comprehensive education on safe care practices from the beginning (18). Secondly, system-wide transparency is crucial. Enhancing the

accuracy of the entire testing process requires transparency throughout the laboratory system. Adopting a system-based approach recognizes that errors often result from systemic flaws rather than individual shortcomings. This perspective creates a more constructive environment where staff can identify and address procedural weaknesses, encouraging open reporting of errors and hazards (19). Thirdly, the development of multidisciplinary teams is essential due to the complexity of medical tests and the need for high-quality results. Collaborative efforts involving a range of healthcare and laboratory professionals, including pathologists, medical technologists, nurses, and physicians, are necessary to deliver optimal patient care (19).

Furthermore, the integration of information technology can significantly advance patient safety. Leveraging current information systems facilitates real-time care delivery and retrospective analysis. Integrating laboratory information systems with other clinical systems enables healthcare and laboratory professionals to identify and mitigate risks more effectively. Laboratories should actively support national and international patient safety programs. This includes disseminating safety guidelines and seeking accreditation from relevant agencies, demonstrating a commitment to maintaining the highest safety standards.

Lastly, adopting a "patients first" approach is essential. Laboratory personnel should prioritize patient perspectives and consider them as partners in safety. Encouraging feedback on laboratory services, infection control, and patient safety can enhance the quality of care and increase patient satisfaction.

By focusing on these areas, laboratories can significantly improve their services, align with best practices for patient safety, and foster a culture of continuous quality improvement.

### **The 12 essentials in quality management**

Implementing a Quality Management System (QMS) within laboratory environments is essential for ensuring the accuracy, reliability, and timeliness of laboratory results, which are crucial for patient care and medical research. CLSI has identified 12 Quality System Essentials (QSEs) as the cornerstone for building a successful QMS infrastructure in laboratories. These QSEs cover comprehensive aspects of laboratory management and operations, ensuring a holistic approach to quality (1).

**Table 2.** Summary of the 12 essentials in quality management as outlined by CLSI (1)

Quality System Essential	Description
Organization and Leadership	Activities of key leadership responsibilities to meet regulatory requirements.
Customer Focus	Meeting the expectations of clients and customers.
Facilities and Safety Management	Maintenance of programs and facilities for safety.
Personnel Management	Recruiting and maintaining skilled laboratory staff.
Supplier and Inventory Management	Establishing partnerships with suppliers and vendors.
Equipment Management	Upkeep and maintenance of laboratory equipment.
Process Management	Managing workflow requirements efficiently.
Documents and Records Management	Managing procedural documents and records for workflow.
Information Management	Effective recordkeeping and data management.
Nonconforming Event Management	Identifying and correcting nonconformances or problems.
Assessments	Monitoring laboratory processes for functionality.
Continual Improvement	Actively finding and implementing opportunities for improvement.

Each of these essentials plays a critical role in ensuring a laboratory's quality management system is effective, contributing to the reliability, accuracy, and timeliness of laboratory results.

By adhering to these QSEs, laboratories can enhance operational efficiency, maintain compliance with regulatory standards, and continuously improve, ensuring the delivery of high-quality results. This comprehensive approach to quality management not only meets the expectations of healthcare providers and patients but also contributes significantly to the advancement of healthcare outcomes.

## CONCLUSION

Implementing effective QMS in laboratories is crucial for ensuring the accuracy and reliability of medical tests, vital for patient care and research. Despite challenges like service consolidation and workforce reductions, adopting systemic changes, investing in technology, and fostering continuous improvement are essential for maintaining quality and enhancing healthcare outcomes.

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