

Quality Improvement in Clinical Laboratories

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Abstract

Clinical laboratories play a critical role in healthcare delivery, providing vital diagnostic information for patient management. Ensuring the quality of laboratory testing is paramount to achieve accurate and reliable results, which directly impact patient care and outcomes. This review article explores the current strategies and advancements in quality improvement within clinical laboratories, highlighting the key areas of focus and future directions.

Key words; Quality improvements, health providers , laboratory

Introduction

The clinical laboratory plays a central role in patient care by providing essential diagnostic information to healthcare providers. Quality improvement (QI) initiatives in the clinical laboratory aim to optimize laboratory processes, ensure the accuracy and reliability of test results, and enhance overall laboratory performance. This review provides an overview of the principles of quality improvement in the clinical laboratory setting, explores different QI methodologies and tools, and discusses the impact of QI initiatives on laboratory performance and patient care. The importance of quality improvement in clinical laboratories is underscored by its impact on patient safety, clinical decision-making, and

healthcare outcomes. This section provides an overview of the significance of quality improvement initiatives and the need for robust systems and processes. Quality improvement (QI) initiatives play a critical role in enhancing the efficiency, accuracy, and reliability of clinical laboratory operations.

Quality Management Systems

Implementation of QMS frameworks, such as ISO 15189:2012, has gained prominence in clinical laboratories(1). This section discusses the key components of QMS, including document control, quality control, proficiency testing, personnel competence, equipment maintenance, and risk management. It emphasizes the role of QMS in standardizing processes, mitigating risks, and facilitating continuous quality improvement.

Automation and Technology

Advancements in laboratory automation and technology have revolutionized laboratory processes. Quality assurance is a fundamental aspect of ensuring the quality of automated systems in healthcare. It involves implementing processes and procedures to monitor and evaluate the performance of automated systems, identify areas for improvement, and take corrective actions when necessary. Quality assurance activities may include system testing, validation, risk assessment, and compliance with regulatory standards. Validation is another critical aspect of ensuring the quality of automated systems in healthcare. It involves verifying that an automated system performs as intended and meets the specified requirements for its intended use. Validation activities may include testing the system's functionality, accuracy, reliability, and safety, as well

as ensuring compliance with regulatory requirements and industry standards(2),(3).

Ongoing Monitoring and Maintenance:

Once an automated system is implemented, ongoing monitoring and maintenance are essential to ensure its continued effectiveness and reliability. This includes monitoring system performance, identifying and addressing any issues or malfunctions, updating software and hardware as needed, and providing regular training and education to users. (4).

Quality management system

Robust QC measures are vital for maintaining the accuracy and reliability of laboratory testing. This section delves into the importance of well-characterized control materials, instrument calibration, and participation in external quality assessment programs. It also explores statistical tools, such as Westgard rules and Levey-Jennings charts, for effective monitoring and management of QC data (5).Continuous:

Education and training

Ongoing education and training programs are crucial for ensuring the competence of laboratory personnel. This section highlights the significance of regular training sessions on new testing methodologies, quality assurance principles, and safety protocols. It discusses the role of competency assessments, professional development programs, and proficiency testing in enhancing laboratory staff's skills and knowledge(6) .

Quality indicators and metrics

Monitoring and measuring key quality indicators (KQIs) enable laboratories to assess their performance and identify

areas for improvement. The quality indicators includes a. process: health care service provided to or on behalf of a patient appropriately based on scientific evidence of efficacy or effectiveness; b. outcome: health state of a patient resulting from health care; c. access: patient's or enrollee's attainment of timely and appropriate health care; d. patient experience: patient's or enrollee's report concerning observations of and participation in health care; e. structure of care: feature of a health care organization or clinician relevant to its capacity to provide health care; g. use of service: provision of a service to, on behalf of, or by a group of persons defined by nonclinical characteristics without determination of the appropriateness of the service; and h. population health: state of health of a group of persons defined by nonclinical characteristics. All quality indicators such as turnaround time, specimen rejection rate, repeat testing rate, and customer satisfaction, it optimize laboratory processes and enhance quality(7)

Trends of quality

The trends of quality includes quality improvements

Conclusion:

Quality improvement in clinical laboratories is a continuous endeavor aimed at ensuring accurate and reliable laboratory testing. This review article summarizes the current strategies, advancements, and future directions in quality improvement. By implementing robust QMS, embracing automation and technology, emphasizing continuous education and training, and monitoring key quality indicators, clinical laboratories can enhance patient care outcomes and contribute to overall healthcare quality.

References

1. ISO. ISO/DIS 15189:2022 Medical laboratories — Requirements for quality and competence. Int Organ Stand. 2022;
2. National Quality Forum (NQF). Safe Practices for Better Healthcare – 2010 Update: A consensus report. National Quality Forum. 2010.
3. Hendee WR. To Err is Human: Building a Safer Health System. J Vasc Interv Radiol. 2001;12(1).
4. Ebubekir B, Nurinnisa O, Nurcan K-B. Automation in the clinical laboratory: integration of several analytical and intralaboratory pre- and post-analytical systems. Turkish J Biochem. 2017;42(1).
5. Westgard JO, Westgard SA. The quality of laboratory testing today: An assessment of σ metrics for analytic quality using performance data from proficiency testing surveys and the CLIA criteria for acceptable performance. Vol. 125, American Journal of Clinical Pathology. 2006.
6. Trenti T. An evidence-based laboratory medicine approach to evaluate new laboratory tests. Electron J Int Fed Clin Chem Lab Med. 2018;29(4).
7. Shahangian S, Snyder SR. Laboratory medicine quality indicators : A review of the literature. Vol. 131, American Journal of Clinical Pathology. 2009.