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ENSURING CONFIDENCE IN LABORATORY DATA: A REVIEW OF QUALITY CONTROL AND ASSURANCE PRACTICES

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Abstract

Ensuring accurate and dependable test findings is of utmost importance in clinical labs, making quality improvement essential. Given the growing recognition of the negative impact that mistakes in laboratory procedures may have on patient results, it is crucial to underline the ongoing need for enhancing laboratory services. A systematic literature review was performed on PubMed and the Web of Science Core Collection from October to February 2021 to assess the scientific rigor of clinical laboratory quality improvement studies. Only peer-reviewed articles written in English that satisfied the criteria for quality improvement were considered. The studies were examined based on the methodologies and treatments used for quality improvement and control, such as training, education, task force, and observation. The findings indicated a consistent enhancement in the quality of improvement papers in the clinical laboratory sector. Specifically, the average score of QI-MQCS increased from 2.5 (1981-2000) to 6.8 (2001-2020). Nevertheless, there is an opportunity to develop a systematic approach for evaluating the quality of clinical laboratory literature and enhancing accrediting processes in the field.

Keywords: performance assessment, comprehensive quality management, analytical quality, QI-MQCS

1. Introduction

The resilience of the healthcare system relies on the clinical laboratory, since clinicians heavily rely on clinical lab findings to make crucial choices about patient treatment.(1,2) Approximately 70-75% of medical diagnoses are derived from clinical laboratory results, indicating that the quality of laboratory services directly affects the quality of healthcare.The laboratory results should strive for maximum precision, while ensuring that all laboratory activities are dependable and punctually reported, ultimately contributing to an advantageous clinical environment.(5) Negligence in laboratory operations, such as the handling, evaluation, and communication of results, may have serious repercussions. These may include problems,

inadequate treatment, and delays in accurate and timely diagnosis. Consequently, needless medical interventions and diagnostic tests may be required.(6–8) A clinical laboratory is an intricate collection of cultures that include several procedural stages, and numerous individuals contribute to its distinctiveness and proficiency. The whole of these intricate procedures that take place throughout a testing process is referred to as the workflow route.(9)

The workflow trajectory in a clinical laboratory starts with the patient and concludes with the generation and understanding of the data. Given the large quantity of samples, limited personnel, and several procedures involved in the testing process, it is expected that errors would occur in any clinical laboratory environment.(10,11) Any errors occurring at any point throughout the whole testing procedure (TTP) might lead to erroneous laboratory results. In order to ensure the accuracy of the outcomes, it is necessary to have a dependable approach for identifying flaws inside the TTP.(12)

2. The importance of quality in the medical laboratory

The Institute of Medicine (IOM) has provided a precise definition of the word "quality" in the healthcare setting. (13) The term "quality of care" is defined as the degree to which healthcare treatments for people and groups improve the likelihood of achieving targeted health outcomes and adhere to current professional knowledge. In modern times, quality has been defined as the act of "performing the appropriate actions for the correct individuals, at the appropriate moment, and executing them flawlessly on the initial attempt." Recently, the concept of quality has expanded to include other aspects. It is increasingly agreed upon that quality includes safety, efficacy, appropriateness, responsiveness or patient-centered care, equality or access, and efficiency.

3. The significance of standardizing

In the field of laboratory medicine, the attainment of accurate diagnostic testing, particularly for ensuring patient safety, is often accomplished by using standardized procedures. Standardization ensures the precision and consistency of test findings, their proper use for the specific patient, and the correctness of the outcomes. The accrediting bodies ensure essential aspects of standardization in laboratory medicine. There are multiple CLIA accreditation agencies, such as the College of American Pathologists (CAP), Joint Commission (JCIA), Accreditation Commission for Health Care, Inc (ACHC), and American Association for Laboratory Accreditation. These agencies have the authority to grant accreditation, which has a substantial impact on quality improvement (QI) in medical laboratories. Nevertheless, the International Organization for Standardization ISO is a non-governmental organization that provides a comprehensive structure for all procedural aspects, including the reporting of outcomes. Over time, the formation and development of each agency have led to substantial advancements in the medical laboratory industry.

ISO 15189 is the most important accreditation compared to others because it focuses primarily on laboratory management systems and processes. This standard includes requirements that cover the entire testing process, including pre-examination, examination, and post-examination stages. The criteria include the development and execution of standard operating procedures, validation procedures, staff training, internal and external quality control methods, laboratory setup, and other related areas. On the other hand, the alternative CLIA-approved laboratory accreditation approach focuses mostly on the technical processes involved in testing. This includes aspects such as policy statements, certification criteria, archive standards, and ensuring proper laboratory testing.

4. Assessment of performance

Evaluating the performance of clinical labs is essential to ensure the accuracy, precision, and repeatability of test findings. This is usually achieved by using quality control materials. These materials, which possess significant values, are used to verify the effectiveness of the laboratory's testing procedures. QC materials may be categorized into internal and external classifications. Internal quality control (IQC) materials are used to ensure consistent monitoring of the laboratory's test systems, while external quality control (EQC) materials are employed for the purpose of comparing the laboratory's results with those of other labs.

Loh et al. (29) conducted a research that examined several techniques used to evaluate the performance of clinical labs, such as quality control materials and inter-laboratory comparisons. The research emphasized the need of ongoing improvement in the quality control of clinical labs.

5. The significance of certification in the clinical laboratory

The accreditation of clinical labs is crucial for enhancing the quality of clinical laboratory activities. The results emphasize the importance of accreditation in clinical labs, which aligns with the findings of Alkhenizan et al.'s study.(30) A significant obstacle to the implementation of certification programs is the doubt expressed by healthcare professionals, especially doctors, about the influence of accreditation on the quality of healthcare services (31, 32). QI activities are often advocated in healthcare as a component of a comprehensive quality management approach, including Kaizen/QI initiatives in nursing care, medical quality, logistics, administrative tasks, and patient services. In clinical labs, the driving factor for quality improvement (QI) is often associated with accreditation. Accreditation provides official recognition and certification from a regulatory organization, indicating that the laboratory is competent and functions efficiently. (33)

The primary role of the clinical laboratory is to provide diagnostic assistance to doctors, facilitating the treatment process and contributing to future advancements. The QI-MQCS was designed to assist stakeholders in identifying high-quality research in their respective sector. Quality improvement (QI) strategies are varied and separate from therapeutic treatments. The

QI-MQCS is a tool that has been scientifically evaluated to assess the unique QI-related qualities of QI publications. This study may be biased due to its exclusion of other important databases such as Embase and EBSCOhost, and its limited inclusion of articles just in English.

6. Conclusion

This research examined the pattern and extent of quality improvement (QI) and quality control (QC) papers in the field of clinical laboratory practice. The results of our research indicate a significant rise in the prevalence of quality improvement (QI) and quality control (QC) measures after the year 2000. This might be attributed to the introduction of standardized QI protocols in laboratories and the certification of clinical laboratory facilities. The focus of our research is on the significance of adhering to high standards of clinical laboratory practice and the possibility of cooperation between accredited and non-accredited firms to strengthen the quality management system and promote continuous improvement in the clinical laboratory sector.

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