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USE OF LAB-GROWN ORGANOIDS IN DISEASE MODELING

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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 possible negative impact of mistakes in laboratory procedures 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 medical laboratory quality enhancement studies. Only peer-reviewed articles published in English that satisfied the criteria for quality improvement were considered. Data extraction was performed using a standardized template, and the publications were evaluated using the Quality Improvement Minimum Quality Criteria Set (QI-MQCS) on a scale ranging from 0 to 16. Of the total 776 papers, 726 were assessed for the examination of quality in clinical laboratory literature. The studies were examined based on quality enhancement and monitoring methodologies and interventions, including education, training, task power, and monitoring. The findings revealed that the average rating of QI-MQCS for quality development articles published between 1981 and 2000 was 2.5. In contrast, for papers published between 2001 and 2020, the mean score was 6.8. This suggests a consistent and significant enhancement in quality within the clinical laboratory field. Nevertheless, there is an opportunity to develop a comprehensive framework for evaluating the quality of medical laboratory research and enhancing accreditation initiatives in the field.

Keywords: performance assessment, laboratory quality, comprehensive quality management, 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 be as accurate as feasible, and all laboratory activities must be dependable and timely in order to provide a positive clinical environment.(5) Carelessness during laboratory procedures, such as handling, evaluating, and communicating, may result in serious outcomes, such as complications, insufficient therapy, and a delay in accurate and timely diagnosis, which can lead to wasteful treatment and diagnostic tests.(6–8)

A clinical laboratory is an intricate collection of cultures that include several stages of activity, 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. It is expected that errors will occur in the testing process in a clinical laboratory owing to the large quantity of samples, the limited workforce, and the several procedures involved.Errors occurring at any level of the total testing process (TTP) may 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 clear and accurate definition of the word "quality" in the context of healthcare.(13) The term "quality of care" is defined as the degree to which healthcare services improve the likelihood of achieving targeted health outcomes for individuals and communities, while also aligning with the latest professional knowledge. In modern times, quality has been defined as the act of "performing the correct actions for the appropriate individuals, at the appropriate moment, and executing them flawlessly on the initial attempt." Recently, there has been a growing agreement that quality encompasses several aspects, including 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 application to the specific patient, and the correctness of the consequences. The accrediting bodies ensure essential aspects of standardization in laboratory medicine. Various 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, have been authorized. These accreditations play a crucial role in enhancing 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 development and maturation 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 specifically 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 creation and execution of standard operating procedures, validation procedures, staff training, internal and external quality control methods, laboratory setup, and other related elements. 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.

Allocation of mistakes between QI and QC papers

In general, mistakes occurring in the preanalytical and postanalytical stages are more common and account for the majority of errors.(24) Errors at the analytical step are often less frequent.The coordinates are (25,26). Our research shows that the occurrence of mistakes during the analytical phase has decreased in recent years. We classified the articles into QI (Quality Improvement) and QC (Quality Control) in order to determine the frequency of mistakes in each context. Our research found that preanalytical mistakes were the most prevalent in quality improvement (QI) studies, accounting for 12 out of the total of 19 publications.

However, it is important to note that the majority of mistakes in quality control (QC) articles were analytical in nature, accounting for 28 out of 33 papers, as shown in Table 1. This discrepancy might be attributed to the specific emphasis of the publications in each category. QI publications often focus on topics like as training, instruction on safety teams, and other treatments that entail direct human engagement, such as phlebotomy. These topics may help explain why there is a greater occurrence of preanalytical mistakes in these papers. QC papers often evaluate techniques or processes for improvement, such as six sigma, accreditation, QC practices, statistical approaches, and other associated methodologies, which include further examination within the given context.

GCLP has the ability to serve as a source for quality improvement (QI). In order to avoid mistakes, the clinical laboratory must exhibit accuracy and precision in its testing procedures. Implementing a quality assurance system that adheres to GCLP criteria may be beneficial, but it requires the dedication of both management and technical personnel. A research conducted by Horace Gumba et al.(27) has shown that enhancing workflow, enhancing patient happiness, assessing performance, and optimizing the test-treatment process are all factors that may lead to quality improvement (QI) in the clinical laboratory. Effective implementation of GCLP principles necessitates proficient management, a strong basis of optimal methodologies, a dedication to quality culture, and comprehensive training and education. A research conducted by Horace Gumba et al. in 2018(28) demonstrated that on-site training and education significantly improve the adoption of quality management systems. The data we previously reported support

and suggest that implementing various interventions, such as writing standard operating procedures, improving documentation practices, following GCLP guidelines, conducting improvement projects, and providing training on quality indicators, can effectively enhance the quality of the clinical laboratory.

4. Performance Assessment

Performance assessment in 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 test methods. QC materials may be categorized into internal and external classifications. Internal quality control (IQC) materials are used to consistently monitor the laboratory's test systems, whilst EQC materials are employed for the purpose of comparing them to those of other labs. Loh et al. conducted a research (29) that examined several techniques for evaluating the performance of clinical labs, such as quality control materials and inter-laboratory comparisons. The research emphasized the need of continuous improvement in the quality control of clinical labs.

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 major 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.The coordinates are (31, 32). QI activities are often advocated in healthcare as a component of a comprehensive quality management approach known as total quality management (TQM). These activities include Kaizen/QI initiatives in several areas such as nursing care, medical quality, logistics, administrative work, and patient services. Accreditation is a significant factor in clinical labs, since it provides official recognition and certification from a regulatory organization, indicating that the laboratory is competent and functions efficiently.33

5. The impact of certification on quality improvement (QI) and quality control (QC) research

In order to evaluate the trajectory of Quality Improvement (QI) in clinical labs, we conducted an analysis of publications published between 1981 and 2021, leading to some fascinating discoveries. During the period from the 1980s to the 2000s, there was a lack of extensive study on QI (Quality Infrastructure) or control. This might be attributed to inadequate quality infrastructure, obstacles to globalization, and restricted availability of contemporary information. Analysis of data categorization indicated a substantial rise in QI (Quality Improvement) and QC (Quality Control) trends after the year 2000, indicating a noteworthy improvement in the laboratory sector. There are other potential reasons for this pattern, such as a growing recognition of the significance of high-quality healthcare and the establishment of effective quality management systems. The

primary determinant is the emergence of accrediting authorities such as ISO 15189 and CAP. The clinical laboratory industry has been significantly influenced by CAP and ISO 15189 via many programs and recommendations.34

From 1994 to 2020, CAP underwent many modifications, such as the introduction of training and unannounced inspection programs for pathology labs, the establishment of a multiyear plan to develop the pathology specialty, and the optional implementation of CAP 15189. ISO 15189 was first released in 2003 to provide information on the medical laboratory industry and provide rules for many aspects such as sample methods, interpretation of findings, acceptable timeframes for completing tasks, collecting of patient samples, and the laboratory's involvement in training and teaching healthcare personnel. The revision in 2007 was made to comply with ISO/IEC 17205. In 2012, a third version was produced, as shown in Table 4. This edition made changes to the previous structure and included a new section on laboratory information management.35 The impact of these modifications on Quality Improvement (QI) in clinical labs is evident in findings shown in Figure 1, starting from the year 2000. This graph clearly demonstrates a discernible trend of QI in medical laboratories.

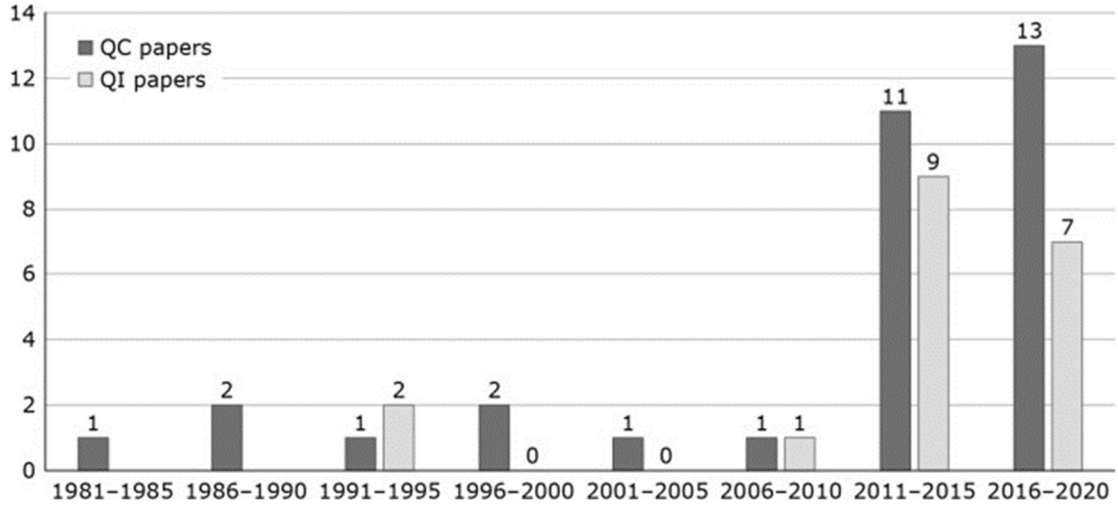

Figure 1. The impact of these modifications on Quality Improvement (QI) in clinical labs starting from the year 2000.

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. Our research uncovered a significant rise in the prevalence of quality improvement (QI) and quality control (QC) 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 research highlights the need of adhering to high standards of clinical laboratory practice and the possibility of cooperation between certified and

non-accredited firms to strengthen the quality management system and promote steady advancement in the clinical laboratory sector.

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