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Quality Assurance in Clinical Laboratories: Best Practices and Continuous Improvement Strategies

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ABSTRACT

Introduction: In the last few decades, quality in laboratory medicine has evolved in concert with the transformation and the changes in this sector. Laboratory professionals have faced great challenges, at times being overwhelmed, yet also involved in this progress. Worldwide, laboratory professionals and scientific societies involved in laboratory medicine have raised awareness concerning the need to identify new quality assurance tools that are effective in reducing the error rate and enhancing patient safety.

Aim of work: To explore the best practices and improvement strategies for quality assurance in clinical laboratories.

Methods: We conducted a comprehensive search in the MEDLINE database's electronic literature using the following search terms: Best, practices, improvement, strategies, quality, assurance, clinical, laboratories. The search was restricted to publications from 2018 to 2021 in order to locate relevant content. I performed a search on Google Scholar to locate and examine academic papers that pertain to my subject matter. The selection of articles was impacted by certain criteria for inclusion.

Results: The publications analyzed in this study encompassed from 2018 to 2021. The study was structured into various sections with specific headings in the discussion section.

Conclusion: The significance of laboratory medicine in healthcare has grown, however its full potential remains unacknowledged. The quality of laboratory performances is essential for the accurate diagnosis, effective monitoring, and reliable evaluation of risks. Quality assurance

tools are necessary for evaluating important occurrences in TTP stages. An internet-based software program that ensures security and allows users to report anonymously promotes the comparison of performance and adoption of superior methods. Consistent use of Quality Indicators enhances patient safety, enhances performance improvement, and encourages voluntary reporting.

Keywords: Best, practices, improvement, strategies, quality, assurance, clinical, laboratories.

INTRODUCTION

Laboratories primarily utilize the word "quality" to describe the dependability of their performance. Despite the apparent definition and knowledge of all aspects of this topic, the ongoing advancements in laboratory medicine necessitate a continuous reassessment of the quality characteristics to be considered and the levels of quality to be attained. This is crucial in order to ensure optimal clinical outcomes and patient safety. The importance of quality in laboratory medicine has gained significance due to scientific research that emphasizes its critical role in the process of clinical decision-making and patient care (Braga and Panteghini, 2020).

According to Church and Naugler, the quality of laboratory medicine has developed with the technical, scientific, and organizational advances in the field over the last several decades. Laboratory personnel have encountered significant obstacles, perhaps feeling overwhelmed, but also actively participating in this advancement. In addition, they have become important participants in shaping innovative methods for diagnosis and treatment. In the 1950s, quality assurance tools were primarily concerned with the management of analytical quality in order to get dependable findings. This was accomplished by manual methods or the use of analytical systems that were very accurate. The utilization of quality assurance tools facilitated the evaluation and surveillance of analytical performances, allowing for comparison with previous results within the same laboratory through an Internal Quality Control procedure (IQC), as well as with results obtained by other laboratories through participation in the External Quality Assessment Program (EQAP). The implementation of IQC (Internal Quality Control) and participation in EQAP (External Quality Assessment Program) have significantly enhanced the quality of the intra-analytical phase. This improvement may be attributed, in part, to technical advancements that have led to the continuous automation of diagnostic systems (Schulze et al., 2020).

In 1981, Lundberg proposed the idea of the "brain to brain loop," which expanded and provided a detailed definition of the stages of the total testing process (TTP). It was only after several years that laboratory professionals fully recognized the significance of the "brain to brain loop" and the necessity to create new quality assurance systems to oversee all stages of the TTP (Plebani et al., 2021). The research examining the nature and source of mistakes related to TTP operations emphasized the need of assessing and overseeing both the intra-analytical and extra-analytical phases. It revealed that the extra-analytical stages provide a greater risk of errors. As a result, quality assurance systems have been implemented, along with IQC processes and EQAPs. Globally, laboratory professionals and scientific bodies in the field of laboratory medicine have

emphasized the need of finding new tools that are efficient in decreasing the incidence of errors and improving patient safety (Plebani et al., 2021).

Aim of this paper is to provide an update of the best practices and improvement strategies for quality assurance in clinical laboratories.

AIM OF WORK

To explore the best practices and improvement strategies for quality assurance in clinical laboratories.

METHODS

A comprehensive search was conducted on recognized scientific platforms, including Google Scholar and Pubmed, using specific keywords such as Best, practices, improvement, strategies, quality, assurance, clinical, laboratories.

The aim was to gather all relevant research papers. The articles were chosen according to certain criteria. Upon conducting a comprehensive analysis of the abstracts and notable titles of each publication, we eliminated case reports, duplicate articles, and publications without full information. The reviews included in this research were published from 2018 to 2021.

RESULTS

The current investigation concentrated on the best practices and improvement strategies for quality assurance in clinical laboratories between 2018 and 2021. As a result, the review was published under many headlines in the discussion area, including: Significance quality assurance, Approaches For Laboratory quality assurance, Best Practices for Quality Assurance In Laboratory and Continuous Improvement Strategies for Clinical Laboratories

DISCUSSION

1. Significance quality assurance

Quality assurance (QA) is the comprehensive procedure that ensures the utmost accuracy of the final findings provided by a laboratory. This entails examining specimens, evaluating transcriptional measurements, using the most dependable assays, and validating the ultimate results (Fan and Wang, 2021). A QA system guarantees that the testing service conducts the required checks and balances to ensure the accuracy and reliability of HIV testing for surveillance purposes, while also promoting excellent laboratory practices. Implementing nationally standardized testing algorithms, together with standard operating procedures and quality control methods, is crucial for ensuring the accuracy and reliability of testing. The procedure manuals used by laboratory technicians and other laboratory personnel should include components of the QA system. Adhering to these programs will optimize the dependability and precision of test outcomes (Arnold et al., 2019).

Quality control (QC) encompasses the necessary actions that must be implemented throughout each test run to ensure that the test is functioning correctly. This involves establishing accurate temperature conditions, proper kit controls, and so forth. Therefore, QC determines if the test run was legitimate and yielded satisfactory findings. However, it should be noted that QC does not provide an indication of the accuracy of the findings or if they have been reported correctly (Loh et al., 2020).

Quality assessment is a method used to evaluate the quality of outcomes. Proficiency panels are often used to conduct external evaluations of a laboratory's performance. Quality assessment is conducted to examine the efficacy of a quality assurance program. While a strong QA/QC program might reduce the significance of quality assessment in some scenarios, it should be noted that quality assessment can never be replaced by a solid QA/QC program. Failure in assessing the quality of specimens often suggests a flaw in the quality assurance and quality control methods. Moreover, quality evaluation methodologies are far more effective in discerning variations in performance across participating labs rather than among test procedures and techniques (Seery et al., 2019).

Proficiency testing, commonly referred to as an external quality assessment system (EQAS), is a key aspect of QA that involves the external evaluation of a laboratory's performance. The national reference laboratory should provide a proficiency panel consisting of about six to ten specimens to all participating testing agencies for testing. This panel should consist of specimens that are typical of the HIV strains prevalent in a nation, including both HIV-negative and HIV-positive specimens with varying levels of strength. Proficiency testing should be conducted periodically, namely twice per year. An external laboratory, such as a university, or one of WHO's EQA schemes, may offer EQA for the national reference laboratory (Favaloro et al., 2018).

2. Approaches For Laboratory quality assurance

Quality assurance consists of two distinct but complimentary elements: internal quality control and external quality assessment (formerly referred to as external quality control or proficiency testing) (Miller and Nichols, 2020).

2.1 Internal Quality Control (IQC)

IQC, or Internal Quality Control, encompasses the systematic methods used by laboratory personnel to consistently and promptly assess the accuracy and dependability of their test results before releasing them. The process includes a work culture where all potential factors that might impact the outcomes have been examined against established criteria or their suitability has been confirmed (Braga et al., 2021).

2.2 External Quality Assessment (EQA)

EQA serves as an assessment of labs' performance. This technique entails a systematic and retrospective assessment of a laboratory's performance, conducted by an external and independent laboratory via the use of proficiency panels as the evaluation method. The purpose of this initiative is to facilitate interlaboratory comparison, raise awareness among participating labs about their deficiencies, and propose steps for improvement in order to guarantee the reliability of future testing. An effective EQA serves as a means of evaluating the Internal Quality Control (IQC), but it should never be considered a replacement for IQC (Plebani et al., 2021).

2.3 Total Quality Management (TQM)

The use of comprehensive quality management has lately been adopted to attain ongoing enhancement in laboratory services. It is a comprehensive approach to quality assurance

management that impacts all aspects of quality assurance in the laboratory. The quality policy is formulated by senior management and includes the necessary infrastructure, including both hardware and software, for implementing the quality policy. Furthermore, it guarantees unwavering dedication and active involvement of all laboratory personnel in quality assurance endeavors (Broadhurst et al., 2018). Conducting self-inspection and audits of a laboratory's operations are essential components of Total Quality Management (TQM) with the goal of continuously improving its performance. Total Quality Management (TQM) ensures that all potential factors that might impact the quality of a test have been effectively managed and controlled. While it is not feasible to provide an exact assessment of the benefits of quality control, it is widely accepted that these benefits are many and surely exceed the expenses incurred for the resources used. This statement demonstrates the principle that high quality comes with a price, while low quality ends up being much more costly. The primary objective of responsible management should be to provide a competitive product or service that achieves a harmonious equilibrium between quality and cost. The balance operates on the premise that there is an inverse relationship between quality and cost. As quality decreases, cost increases, and as quality improves, cost decreases (Zaidi and Ahmed, 2020).

3. Best Practices for Quality Assurance In Laboratory

The significance of quality assurance in laboratory automation cannot be overstated. The primary purpose of automation is not only to expedite workflow, but also to enhance the precision of outcomes and the caliber of services provided by contemporary labs (Holland and Davies, 2020). Ensuring the quality of laboratory automation is crucial for maintaining and optimizing the operation of laboratory equipment. It enhances the durability of equipment, the accuracy of analysis, and reduces the probability of interruptions in result delivery. In order to guarantee that the appropriate quality assurance procedures are being used, a concise checklist of recommended methods is compiled (Holland and Davies, 2020).

To achieve efficient time and effort savings in laboratory automation while maintaining accurate findings, it is essential to comprehend and use optimal quality assurance methods. Here are three optimal strategies to give priority to:

3.1 Choosing a LIMS that is Adaptable to Automation

The effectiveness of laboratory automation will heavily rely on the selected Laboratory Management System (LIMS). The effectiveness and compatibility of the LIMS system with your goals and criteria are crucial for quality assurance in laboratory automation. When selecting the appropriate LIMS, it is crucial to prioritize your laboratory operations. It is important to have a clear understanding of the fundamental elements of the laboratory procedure and the many teams responsible for the lab's daily operations. Additionally, it is crucial to take into account the process of data generation and the subsequent route it follows. With a comprehensive understanding of laboratory operations, you will be able to precisely identify the paths that need automation. While automation has significance, it may not be required for every route (Naugler and Church, 2019).

3.2 Preparing and Trusting the Team to carry out Responsibilities

Prior to implementing any new automated routes in the laboratory, it is imperative that laboratory personnel is well prepared for automation. In order for quality assurance to achieve maximum effectiveness, it is essential that all individuals be completely committed and get the necessary training to adequately equip the team. Team members must possess unwavering confidence throughout the whole of the procedure. It is important for them to additionally recognize and fulfill their obligations in maintaining optimal methods and guidelines set by the industry. Thoroughly preparing the team for laboratory automation is crucial, as it boosts team morale and empowers them to independently carry out the necessary activities, while yet receiving overall supervision and direction (Salvagno et al., 2020).

3.3 Tracking Key Performance Indicators

It is crucial to monitor the quality process conducted in any laboratory in order to measure key performance metrics. A reliable Laboratory Information Management System (LIMS) that incorporates robust quality assurance measures will provide precise, accurate, and high-caliber outcomes. By examining the key performance indicators, the specific areas in a laboratory, such as processes, routes, or automation, that need improvement can be identified. It is not possible to address all problems simultaneously, but it is possible to achieve significant advancement by taking one step at a time (Evans et al., 2020).

4. Continuous Improvement Strategies for Clinical Laboratories

4.1 Continuous improvement strategies

Implementing a strong Quality Management System (QMS) is essential for clinical labs. This system includes rules, procedures, and practices that regulate all aspects of laboratory operation (Carey et al., 2018). Standard Operating Procedures (SOPs) provide precise guidance to laboratory personnel on how to collect, handle, analyze, and report samples. It is important to continually evaluate and update these SOPs in order to include the most effective methods and improvements in technology (Freeman et al., 2021).

Regular internal audits are conducted to identify loopholes, instances of non-compliance, and areas that may be improved. Auditors evaluate compliance with SOPs, equipment calibration, proficiency testing, and personnel competence. Subsequent measures are implemented to rectify such shortcomings. Laboratories should aggressively identify and minimize risks in a proactive manner. This task requires evaluating possible risks, such as equipment failure or contamination of substances, and creating backup plans. For example, having backup equipment or redundant procedures guarantees continuous service without interruption (Alrawahi et al., 2021).

4.2 Continuous Training and Competency Assessment:

Regular training sessions guarantee that laboratory personnel are knowledgeable about the most recent methodologies, safety protocols, and regulatory advancements. The training program should include the cultivation of technical proficiency, proficient communication skills, and strict commitment to ethical values. Laboratories should evaluate the proficiency of their personnel by conducting proficiency tests, practical assessments, and observing their

performance. Proficient personnel enhance the precision of outcomes and ensure the well-being of patients. Training personnel in many departments (such as chemistry, hematology, microbiology) improves adaptability and guarantees smooth workflow in case of staff shortages or crises (Badrick, 2021).

4.3 Utilization of Technology:

Laboratories may enhance productivity by using automation to streamline repetitive processes like as sample handling, pipetting, and data input. Automation minimizes human mistakes and accelerates the time it takes to complete tasks. Laboratory Information Systems (LIS) are designed to optimize data administration, speed result reporting, and enhance inventory control in laboratories. The integration of electronic health records (EHRs) improves communication between labs and doctors. Data analytics is used to analyze data in order to detect patterns, track performance indicators, and forecast resource requirements in labs. Examining turnaround times might reveal areas of congestion (Boyar et al., 2021)

4.4. External Quality Assessment (EQA):

• Participation in External Quality Assessment (EQA) Programs: Laboratories are encouraged to actively engage in external proficiency testing programs. These programs assess and evaluate the performance of a laboratory in comparison to other laboratories, offering important input. Root cause analysis is a method used to uncover the underlying problems that contribute to disparities when they arise. Tackling underlying issues effectively avoids the repetition of a problem (Laudus et al., 2021).

4.5 Customer-Centric approach:

• Effective Communication: Laboratories should engage in clear and concise communication with doctors, patients, and other individuals involved in the process. Promptly notifying healthcare providers of crucial findings and providing insightful explanations enhances the quality of patient care (Karthiyayini and Rajendran, 2021).

• Feedback Mechanisms: Foster input from physicians on the quality of tests, the time it takes to get results, and the level of service provided. Implement constructive comments to improve the delivery of services (Karthiyayini and Rajendran, 2021).

4.6 Lean Principles:

By using lean concepts, labs may identify and reduce inefficient operations, drawing inspiration from the manufacturing industry. Optimizing processes decreases expenses and improves productivity. Fostering a culture that promotes ongoing enhancement and refinement. Cumulative effects occur as a result of small, gradual modifications made over a period of time. Regular sessions of brainstorming have the potential to provide creative ideas (Prakash et al., 2020).

To summarize, clinical labs need to adopt a proactive approach, adjust to technological progress, and emphasize patient safety. Through the implementation of these ongoing enhancement initiatives, labs provide valuable contributions to improved healthcare outcomes and advancements in scientific research. Keep in mind that greatness is not a final goal; it is an ongoing process of continuous improvement.

CONCLUSION

Recently, there has been a growing recognition of the importance of laboratory medicine in healthcare. However, the full extent of its potential has not yet been completely acknowledged. It is important to consistently strengthen the influence of laboratory medicine by implementing the most effective practices that can show how the leadership and participation of laboratory medicine contribute to tangible advantages for patients, clinicians, and the entire healthcare system. Each laboratory professional has the responsibility of ensuring that processes and procedures are conducted with little risk of mistake, while also enhancing the significance of laboratory testing.

The future of laboratory medicine relies heavily on the quality of laboratory performances, since only precise, dependable, and error-free findings have value for diagnosis, monitoring, and risk assessment. The development of methods and practices that provide a systematic feedback on performance to laboratory workers is very important in assessing the risk of mistake and ensuring a high level of performance quality.

QIs, especially tailored for laboratory medicine, are very useful in evaluating and tracking all significant occurrences in the many stages of TTP, particularly in the extra-analytical phases. Furthermore, the presence of a user-friendly, secure, and efficient web-based software application for gathering data on a shared set of Quality Indicators promotes the uniformity of data collection and encourages the monitoring of occurrences that need regulation. Additionally, the ability to produce reports and export data in a secure and private manner offers valuable insights for laboratory experts and promotes the comparison of performance and adoption of optimal methods. One additional benefit of this worldwide initiative is that it enables the independent handling of Quality Indicators (QIs) data processing by participating labs in specific nations via the designation of national leaders. This allows for the fulfillment of any requirements unique to certain settings.

Overall, the consistent utilization of Quality Indicators (QIs) within a well-defined and organized system offers significant benefits. These include fostering a culture of patient safety, enhancing performance through the adoption of policies and practices that encourage open discussion and feedback, and establishing a mechanism for voluntary reporting and learning from unfavorable incidents.

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