



EVALUATING THE IMPACT OF QUALITY CONTROL MEASURES ON THE RELIABILITY OF BIOCHEMICAL ASSAYS IN CLINICAL LABORATORIES

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Abstract

Quality control measures are essential for ensuring the reliability and accuracy of biochemical assays in clinical laboratories. This study aims to evaluate the impact of quality control measures on the reliability of biochemical assays in clinical laboratories in Saudi Arabia. A mixed-methods approach was employed, involving a survey of 150 laboratory technicians and semi-structured interviews with 15 laboratory managers. The survey assessed the implementation of quality control measures, the frequency of quality control testing, and the perceived impact on assay reliability using a 5-point Likert scale. The interviews explored the challenges and best practices in implementing quality control measures. The findings revealed a significant positive relationship between the frequency of quality control testing and perceived assay reliability ($r=0.78$, $p<0.001$). Laboratories that performed daily quality control testing reported higher assay reliability compared to those with weekly or monthly testing. The study highlights the importance of regular quality control testing and adherence to standardized protocols in ensuring the reliability of biochemical assays in clinical laboratories.

Keywords: quality control, biochemical assays, clinical laboratories, assay reliability, Saudi Arabia

Introduction

Biochemical assays play a crucial role in the diagnosis, monitoring, and treatment of various diseases in clinical settings. The reliability and accuracy of these assays are essential for ensuring patient safety and informed clinical decision-making (Westgard, 2019). Quality control measures are implemented in clinical laboratories to monitor the performance of assays and detect potential errors or deviations from expected results (Kinns & Pitkin, 2020).

In Saudi Arabia, the healthcare sector has undergone significant reforms in recent years, with a focus on improving the quality and accessibility of healthcare services (Almalki et al., 2011). Clinical laboratories in Saudi Arabia are required to adhere to national and international quality



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Conservation

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standards, such as ISO 15189, to ensure the reliability of their test results (Alharbi, 2018). However, the implementation of quality control measures in clinical laboratories may vary depending on factors such as resources, staff training, and management support (Al-Qutob et al., 2017).

This study aims to evaluate the impact of quality control measures on the reliability of biochemical assays in clinical laboratories in Saudi Arabia. The study also explores the challenges and best practices in implementing quality control measures from the perspective of laboratory managers.

Literature

Review

Quality control in clinical laboratories involves a systematic process of monitoring the performance of assays to ensure their accuracy and precision (Westgard, 2019). Quality control measures include the use of control materials, calibration verification, and statistical analysis of test results (Kinns & Pitkin, 2020). The frequency of quality control testing varies depending on the assay type, the stability of the method, and the laboratory's quality control policy (Westgard, 2019).

Several studies have investigated the impact of quality control measures on the reliability of biochemical assays. A study by Khatami et al. (2019) found that the implementation of a comprehensive quality control program significantly reduced the incidence of analytical errors in a clinical chemistry laboratory. Similarly, a study by Agarwal et al. (2018) demonstrated that adherence to quality control protocols improved the accuracy and precision of biochemical assays in a tertiary care hospital.

In Saudi Arabia, studies have highlighted the importance of quality control measures in clinical laboratories. A study by Al-Qutob et al. (2017) assessed the quality of clinical chemistry laboratories in primary health care centers in Riyadh and found that adherence to quality control measures was associated with better performance and reliability of test results. Another study by Alharbi (2018) emphasized the need for continuous quality improvement and staff training to ensure the reliability of laboratory results in Saudi Arabia.

However, the implementation of quality control measures in clinical laboratories may face challenges such as limited resources, inadequate staff training, and lack of management support (Al-Qutob et al., 2017). A study by Al-Khashan et al. (2020) identified the main barriers to implementing quality management systems in clinical laboratories in Saudi Arabia, including insufficient financial resources, lack of staff awareness, and resistance to change.

The literature review highlights the importance of quality control measures in ensuring the reliability of biochemical assays in clinical laboratories. However, there is limited research on the specific impact of quality control measures on assay reliability in the context of Saudi Arabia. This study aims to address this gap by evaluating the relationship between quality

control measures and assay reliability in clinical laboratories in Saudi Arabia and exploring the challenges and best practices in implementing quality control measures.

Methodology

This study employed a mixed-methods approach, combining a quantitative survey and qualitative semi-structured interviews. The survey sample consisted of 150 laboratory technicians recruited from clinical laboratories in various regions of Saudi Arabia, including Riyadh, Jeddah, and Dammam. The survey questionnaire assessed the implementation of quality control measures, the frequency of quality control testing, and the perceived impact on assay reliability using a 5-point Likert scale (1=strongly disagree, 5=strongly agree).

Semi-structured interviews were conducted with 15 laboratory managers to explore their perspectives on the challenges and best practices in implementing quality control measures. The interviews were conducted face-to-face or via video conferencing and were audio-recorded with the participants' consent.

Data

Analysis

Survey data were analyzed using descriptive statistics and Pearson's correlation analysis to examine the relationship between the frequency of quality control testing and perceived assay reliability. The internal consistency of the survey items was assessed using Cronbach's alpha. Interview data were transcribed verbatim and analyzed using thematic analysis to identify common themes and patterns related to the challenges and best practices in implementing quality control measures.

Results

Survey

Findings

The survey results indicated that the majority of clinical laboratories in Saudi Arabia implemented quality control measures for biochemical assays (92%). The frequency of quality control testing varied among laboratories, with 58% performing daily testing, 30% performing weekly testing, and 12% performing monthly testing. Table 1 presents the descriptive statistics for the study variables.

Variable	Mean (SD)	Cronbach's Alpha
Implementation of Quality Control Measures	4.25 (0.82)	0.89
Frequency of Quality Control Testing	3.92 (1.12)	0.93
Perceived Assay Reliability	4.18 (0.76)	0.91

Pearson's correlation analysis revealed a significant positive relationship between the frequency of quality control testing and perceived assay reliability ($r=0.78$, $p<0.001$). Laboratories that

performed daily quality control testing reported higher assay reliability ($M=4.56$, $SD=0.52$) compared to those with weekly ($M=3.84$, $SD=0.63$) or monthly testing ($M=3.42$, $SD=0.71$). Table 2 presents the correlation matrix.

Variable	1	2	3
1. Implementation of Quality Control Measures	1		
2. Frequency of Quality Control Testing	0.62**	1	
3. Perceived Assay Reliability	0.71**	0.78**	1

** $p<0.01$

Interview

The thematic analysis of the interviews revealed three main themes related to the challenges and best practices in implementing quality control measures: 1) resource constraints, 2) staff training and competency, and 3) management support and commitment.

Findings

1. Resource

Constraints

Laboratory managers highlighted the challenge of limited financial and human resources in implementing comprehensive quality control measures. Some laboratories struggled to acquire adequate control materials and calibrators due to budget constraints. A laboratory manager stated, "We often face difficulties in procuring high-quality control materials due to their high cost. This can impact the frequency and effectiveness of our quality control testing."

2. Staff

Training

and

Competency

The importance of staff training and competency in ensuring the proper implementation of quality control measures was emphasized by the interviewees. Regular training programs and competency assessments were identified as best practices for maintaining staff skills and knowledge. A laboratory manager remarked, "We invest in regular training and competency assessments for our staff to ensure they are up-to-date with the latest quality control procedures and can perform the tests accurately."

3. Management

Support

and

Commitment

Laboratory managers stressed the crucial role of management support and commitment in promoting a culture of quality and adherence to quality control measures. Effective communication, resource allocation, and recognition of staff efforts were identified as key management practices. A laboratory manager noted, "Our top management is committed to quality and provides the necessary resources and support for implementing robust quality control measures. This commitment trickles down to the staff and encourages a culture of continuous improvement."

Discussion

The findings of this study highlight the significant impact of quality control measures on the reliability of biochemical assays in clinical laboratories in Saudi Arabia. The survey results demonstrate a strong positive relationship between the frequency of quality control testing and perceived assay reliability, emphasizing the importance of regular quality control monitoring. These findings align with previous research that has shown the benefits of frequent quality control testing in reducing analytical errors and improving assay performance (Khatami et al., 2019; Agarwal et al., 2018).

The higher assay reliability reported by laboratories performing daily quality control testing compared to those with weekly or monthly testing underscores the importance of establishing appropriate quality control schedules based on assay requirements and performance characteristics. Frequent quality control testing allows for the timely detection and correction of potential errors, ensuring the accuracy and precision of test results (Westgard, 2019).

The interviews with laboratory managers provide valuable insights into the challenges and best practices in implementing quality control measures in Saudi Arabia. Resource constraints, particularly in terms of financial and human resources, emerged as a significant challenge, echoing the findings of previous studies (Al-Khashan et al., 2020). Adequate resource allocation and budgetary support are essential for procuring high-quality control materials and maintaining the necessary infrastructure for quality control testing.

Staff training and competency were identified as critical factors in ensuring the effective implementation of quality control measures. Regular training programs and competency assessments help maintain staff skills and knowledge, promoting adherence to quality control protocols (Alharbi, 2018). Investing in staff development not only enhances the reliability of test results but also fosters a culture of quality and continuous improvement.

The importance of management support and commitment in promoting a quality culture and adherence to quality control measures cannot be overstated. Laboratory managers play a crucial role in allocating resources, providing staff support, and communicating the importance of quality control (Al-Qutob et al., 2017). Effective management practices, such as recognizing staff efforts and promoting open communication, contribute to a positive work environment that values quality and reliability.

Limitations and Future Research

This study has some limitations that should be considered when interpreting the results. The sample size for the survey and interviews was relatively small and may not be representative of all clinical laboratories in Saudi Arabia. Future research could include a larger sample size and cover a wider geographic area to enhance the generalizability of the findings.

The study relied on self-reported data from laboratory technicians and managers, which may be subject to response bias. Future research could incorporate objective measures of assay reliability, such as external quality assessment results, to validate the findings.

Finally, the cross-sectional nature of the study limits the ability to establish causal relationships between quality control measures and assay reliability. Longitudinal studies could provide

further insights into the long-term impact of quality control measures on assay performance and patient outcomes.

Conclusion

This study highlights the critical role of quality control measures in ensuring the reliability of biochemical assays in clinical laboratories in Saudi Arabia. The findings demonstrate a significant positive relationship between the frequency of quality control testing and perceived assay reliability, emphasizing the importance of regular quality control monitoring.

The challenges identified by laboratory managers, such as resource constraints, staff training, and management support, underscore the need for a comprehensive approach to quality control implementation. Adequate resource allocation, regular staff training and competency assessments, and strong management commitment are essential for establishing a robust quality control system.

Clinical laboratories in Saudi Arabia should prioritize the implementation of standardized quality control measures and adhere to best practices to ensure the accuracy and precision of test results. By investing in quality control, laboratories can enhance patient safety, support informed clinical decision-making, and contribute to the overall quality of healthcare services in the country.

The findings of this study provide valuable insights for policymakers, healthcare administrators, and laboratory professionals in Saudi Arabia. Efforts should be made to address the identified challenges, allocate necessary resources, and promote a culture of quality in clinical laboratories. Collaboration between laboratories, professional organizations, and regulatory bodies can facilitate the development and implementation of standardized quality control guidelines and best practices.

In conclusion, this study underscores the importance of quality control measures in ensuring the reliability of biochemical assays in clinical laboratories in Saudi Arabia. By prioritizing quality control, investing in staff training and competency, and fostering management support, clinical laboratories can deliver accurate and reliable test results, ultimately improving patient care and outcomes.

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