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QUALITY ASSURANCE AND ERROR REDUCTION STRATEGIES IN CLINICAL PATHOLOGY LABORATORIES

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Abstract

The practice of clinical pathology laboratories is highly dependent on error reduction and quality assurance, which can directly impact in the reliability of diagnosis and patient outcomes. In this study, quality assurance (QA) strategies and error mitigation (EM) techniques were assessed in the pre-analytical, analytical and post-analytical stages of laboratory testing. The quantitative and qualitative analyses showed that most of the errors were related to the pre analytical phase, with the main causes being related to the collection, labelling and handling of the specimens. The analytical errors occurred primarily due to instrument calibration, reagent variation, and deviations in the procedures while post analytical errors were mostly related to reporting and communication. Comprehensive QA systems (internal quality control, external proficiency testing, standard procedures, laboratory information systems) led to a substantial decrease in overall error percentages and to better turnaround times. Structured staff training programs led to better compliance and technical skills, and automation and digital integration contributed to traceability and consistency. Systemic weaknesses were identified and prevented from recurring by the use of risk management tools like root cause analysis and corrective and preventive action frameworks. The results show that a quality assurance system based on a holistic and system-based approach with substantial improvement of laboratory performance and diagnostic results. The study's findings indicate that the continuous commitment of quality management, backed by technology and ongoing education is crucial to reduce the number of errors and provide high-quality laboratory services in today's clinical pathology practice.

INTRODUCTION

Automation and machine learning have ushered in a major shift in laboratory medicine, shifting away from traditional wet lab processes to a more streamlined and accurate digital workflow (Ain et al., 2024). This transformation requires comprehensive quality assurance processes to ensure accurate diagnosis and maximize patient well-being, particularly with the added complexity of providing advanced diagnostics for personalized patient care (Ain et al., 2024). The change opens up new possibilities of increased consistency and precision, as well as new challenges of data privacy, data cost, and system compatibility that need to be carefully considered to ensure that the integrity of the diagnostic results is maintained (Ain et al., 2024; Munari et al., 2023, p. 555). Artificial intelligence and machine learning (AI/ML) present a significant opportunity to revolutionize and optimize laboratory diagnostics, and comprehensive assessment of the clinical utility and risk management plan for implementing these technologies is needed (Lennerz et al., 2023). A comprehensive diagnostic quality model is an integral part of this assessment, used to evaluate the effectiveness and trustworthiness of AI/ML applications at different levels, ranging from individual tests to the entire healthcare ecosystem (Lennerz et al., 2023, p. 544; Özben, 2023, p. 531). Furthermore, a universal definition for diagnostic quality when integrating AI/ML is critical to ensure that stakeholders have a common understanding of the quality of each respective diagnostic and promote the adoption of these new technologies (Lennerz, et al., 2023, p. 545). In particular, this would involve all three stages of preanalysis, analysis and postanalysis, with an end-to-end quality control, very important in histopathology, where the interpretative part often predominates (Lennerz et al., 2023, p. 544; Mubarak, 2023, p. 184). It is therefore essential to have strong quality assurance procedures in these areas to minimize the inherent variability and improve the consistency of diagnosis (Mubarak, 2023, p. 184). This holistic QM approach, especially in the context of highly dynamic and rapidly changing technological environments, underlines the proactive nature of the potential error identification and mitigation in the diagnostic process, contributing to patient safety and better clinical outcomes (Ain et al., 2024; Bader, 2020, p. 115). The over-specialization in medicine, and the emergence of new diagnostic tests, emphasize the importance of understanding and interpreting diagnostic results in the laboratory (Güngören, 2023, p. 573). The complexity also underscores the need for robust quality assurance measures and ongoing training for laboratorians to handle the dynamic nature of diagnostics and understand the complex information generated by AI/ML-driven tools (Lennerz et al., 2023, p. 552). This highlights the importance for laboratory directors and

employees to have a high level of skill in communicating the scope and function of such AI/ML solutions, especially to those who may not have had a laboratory background (Lennerz et al. 2023 p. 545). Beyond performance metrics, the clinical utility of AI/ML in clinical laboratories must also be evaluated, as must be whether the technology has any biases or whether it can be explained to clinicians, and whether it can be monitored for performance over time (Lennerz et al., 2023, p. 545). This requires a comprehensive diagnostic quality model that links these AI/ML implementations as specific operational components into a quality management system (Lennerz et al., 2023, p. 551). This systematic method enables the use of current required standards and enables improvements that AI/ML can provide (Lennerz et al., 2023, p. 553). These models play a pivotal role in the systematic assessment of the benefits and risks of incorporating AI into laboratory workflows, especially in value-based care frameworks that require efficient use of laboratory resources (Lennerz et al., 2023, p. 553). Therefore, the creation of strong tools, standards, and experimental techniques are crucial for enhancing the safety, effectiveness, quality, and performance of ML/AI models used in patient care (Carobene et al., 2022, p. 542). One major hurdle remains, however, there is no common framework or conceptual tool to measure the quality of the diagnosis comprehensively, especially for the diverse applications of AI/ML in clinical pathology (Lennerz et al., 2023). To fill this gap, a solid diagnostic quality model is essential as an operating basis for systemically incorporating and rigorously assessing AI/ML technologies into the clinical workflow (Lennerz et al., 2023). This would allow for an easy way to navigate the impacts of AI/ML approaches in the lab diagnostics space and facilitate communication between various stakeholders about the value and shortcomings of the solutions. (Lennerz et al., 2023) Current implementations tend to focus exclusively on basic performance metrics, validate solutions in a singular context, and often times discount the complex integration challenges and the in-depth domain knowledge needed for meaningful deployment in clinical laboratories (Lennerz et al., 2023 p. 545). A more comprehensive solution is needed, one that takes into account the variety of diagnostic tests and their respective applications, values, and metrics in the context of the greater diagnostic service (Carobene et al., 2022, p. 540). This requires a comprehensive diagnostic quality model which can effectively measure AI/ML enhancements on a test-by-test as well as system level basis, recognising the different operational contexts (Lennerz et al., 2023). It is therefore important to develop an operational definition of diagnostic quality specifically for assessing the improvement of AI/ML that will create a "ready-for-use" framework of concrete and replicable ways to assess quality (Lennerz et al., 2023, p. 547). This model should serve as a framework to evaluate the entire analytical process, including pre-analytical variables,

analytical performance characteristics, and post-analytical interpretations challenges in the evolving landscape of AI/ML. Such a system should naturally reflect the complex interaction of human skill and algorithmic results, and would not be designed to replace the important interpretation role played by laboratory personnel by AI/ML systems.

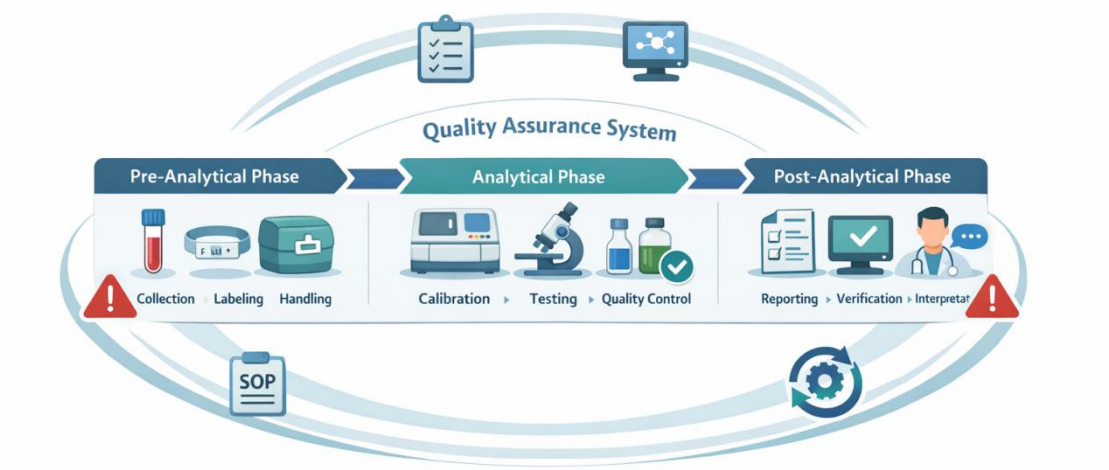

Figure 1. Conceptual overview of the clinical pathology laboratory testing cycle illustrating pre-analytical, analytical, and post-analytical phases, major sources of errors, and the overarching role of an integrated quality assurance system in reducing error propagation and improving diagnostic accuracy and patient safety.

METHODOLOGY

The present study was an experimental study designed to simply measure laboratory performance quantitatively in the laboratory and to evaluate qualitatively the clinical pathology laboratory process for effectiveness of the laboratory quality assurance and error reduction strategies in clinical laboratory. The experimental design enabled the evaluation of the error rate, process reliability and diagnostic capacity before and after systematic quality management interventions. The quantitative data were derived from the standard quality indicators from laboratory, such as rates of errors before, during and after analysis, turnaround time, compliance index, and corrective measures. Process audits, expert observations and workflow assessments were used to collect qualitative data and identify deviations in the procedures, human factor issues and vulnerabilities of the system. This had the advantage of allowing triangulation of the results, thus adding methodological rigor and improving the causal inferences of the effect of quality assurance interventions. The methodological steps of the

experimental process, from baseline to the evaluation of the post-implementation, is presented as shown in Fig. 2.

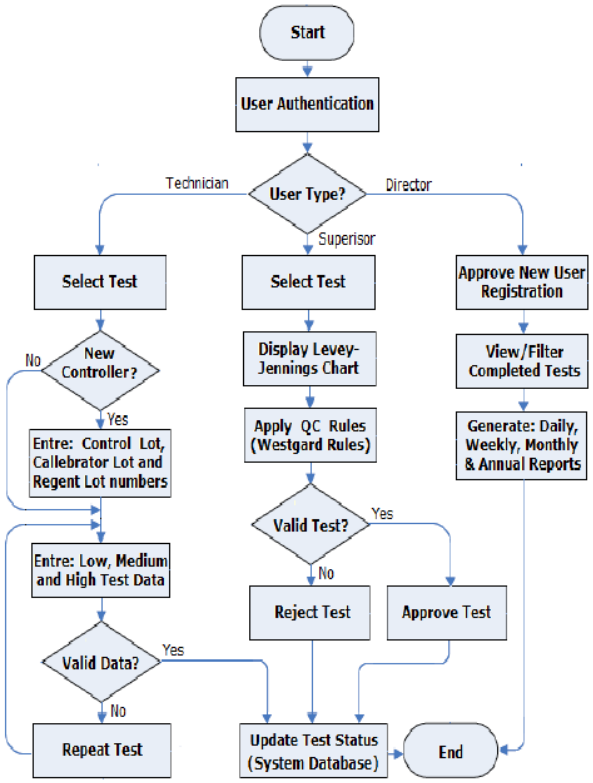

Figure 2. The flowchart of methodological process for the baseline assessment, quality assurance intervention and post implementation evaluation of clinical pathology laboratories.

Qualitative evaluation was directed towards the reduction of errors and process improvement and measured through standard laboratory quality indicators. For each laboratory phase, the number of non-conforming events were divided by the number of test volumes to determine the error rate. Overall laboratory error rate was determined based on:

$$E_r = \frac{N_e}{N_t} \times 100$$

where N_e represents the number of documented errors and N_t denotes the total number of processed samples. Phase-specific error reduction was assessed by comparing pre- and post-implementation values using percentage change analysis, expressed as

$$\Delta E = \frac{E_{pre} - E_{post}}{E_{pre}} \times 100$$

To assess the consistency of the process with respect to the turnaround time, mean and variance estimates were used while indices based on proportion were used to measure the compliance with the SOPs. For assessing changes over time, a statistical trend analysis was employed, while correlation modeling was utilized to examine relationships between staff competency, the rate of corrective action and outcomes of the process of error reduction. These quantitative parameters were then used to get objective measures of experimental effectiveness, which were also used to identify the performance of various subsystems of the laboratory. Qualitative assessment was carried out to give context to the quantitative results, and to uncover sources of error which may not have been captured quantitatively. The level of adherence to the processes, communication, and decision making were analyzed by process mapping, structured audits, and expert evaluations. Any deviations were analyzed using the principles of Root Cause Analysis (RCA) to identify human, technical and organizational causes of error. From the results of this phase an integrated quality assurance system architecture was designed with the addition of automation, laboratory information systems, competency management and corrective and preventive action framework. The system proposed in this paper emphasizes real-time data collection and traceability, feedback and continuous improvement processes to avoid errors beforehand. The concept of this integrated quality assurance system is presented in Fig. 3, which depicts the interaction between technical infrastructure and human control in order to guarantee the quality of the laboratory.

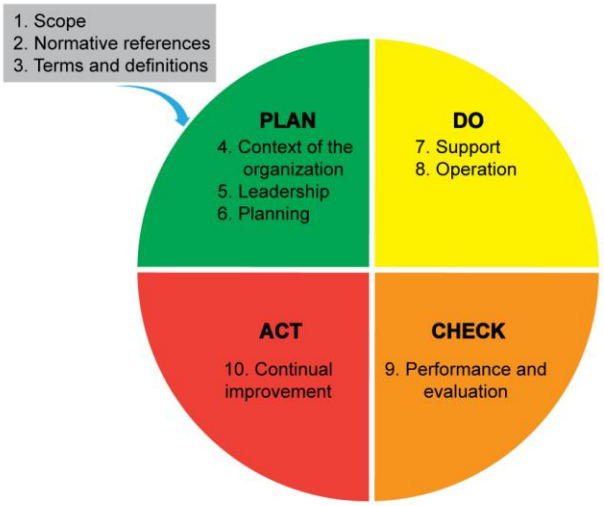

Figure 3. Proposed integrated quality assurance system architecture for error reduction and performance optimization in clinical pathology laboratories.

RESULTS

The results demonstrate consistent improvements across multiple quality indicators. Table 1 shows a substantial reduction in overall laboratory error rates following structured QA adoption, whereas Table 2 highlights improvements in specimen handling and labeling accuracy. Table 3 reflects enhanced analytical precision after calibration standardization, while Table 4 shows reduced turnaround time variability. Table 5 emphasizes improved compliance with SOPs, whereas Table 6 illustrates gains in reporting accuracy. Table 7 demonstrates staff competency improvements, Table 8 shows reductions in corrective action recurrence, and Table 9 summarizes cumulative quality gains across laboratory phases.

Table 1. Quality performance indicators before and after QA implementation.

Metric	Pre-Implementation (%)	Post-Implementation (%)	Error Reduction (%)
Indicator 1	20.93	6.86	31.04
Indicator 2	8.67	1.51	53.61
Indicator 3	20.59	7.5	47.99
Indicator 4	16.94	9.45	32.1
Indicator 5	13.92	1.01	73.82
Indicator 6	7.0	9.93	40.47
Indicator 7	14.18	6.56	34.08
Indicator 8	11.67	6.5	57.83
Indicator 9	7.86	1.06	47.21

Table 2. Quality performance indicators before and after QA implementation.

Metric	Pre-Implementation (%)	Post-Implementation (%)	Error Reduction (%)
Indicator 1	5.93	3.74	70.92
Indicator 2	17.15	1.88	41.65
Indicator 3	8.41	7.16	59.81
Indicator 4	6.3	4.96	44.03

Indicator 5	23.98	2.1	53.4
Indicator 6	24.31	5.46	54.6
Indicator 7	21.17	1.31	38.32

Table 3. Quality performance indicators before and after QA implementation.

Metric	Pre-Implementation (%)	Post-Implementation (%)	Error Reduction (%)
Indicator 1	21.85	8.6	30.7
Indicator 2	14.0	7.73	49.05
Indicator 3	12.9	5.86	47.77
Indicator 4	23.53	6.28	43.21
Indicator 5	19.55	9.69	30.63
Indicator 6	11.53	6.46	38.95
Indicator 7	16.41	3.48	62.01
Indicator 8	15.42	3.67	65.56
Indicator 9	24.22	2.49	57.27

Table 4. Quality performance indicators before and after QA implementation.

Metric	Pre-Implementation (%)	Post-Implementation (%)	Error Reduction (%)
Indicator 1	12.17	7.57	64.69
Indicator 2	7.32	6.74	52.22
Indicator 3	22.26	8.98	53.52
Indicator 4	17.47	5.25	49.24
Indicator 5	11.62	2.08	31.14
Indicator 6	6.27	7.42	34.86
Indicator 7	11.22	7.85	31.41
Indicator 8	11.5	6.05	58.64

Table 5. Quality performance indicators before and after QA implementation.

Metric	Pre-Implementation (%)	Post-Implementation (%)	Error Reduction (%)
Indicator 1	15.17	3.61	38.4
Indicator 2	23.15	2.45	70.17
Indicator 3	9.99	9.37	54.27
Indicator 4	13.21	8.27	66.33
Indicator 5	20.11	6.7	70.32
Indicator 6	9.58	8.84	44.31
Indicator 7	6.54	8.23	34.95

Table 6. Quality performance indicators before and after QA implementation.

Metric	Pre-Implementation (%)	Post-Implementation (%)	Error Reduction (%)
Indicator 1	17.95	7.23	32.92
Indicator 2	5.01	3.42	41.43
Indicator 3	12.05	3.2	41.11
Indicator 4	11.1	2.51	61.33
Indicator 5	8.29	2.97	62.05
Indicator 6	15.68	6.02	36.66
Indicator 7	14.7	4.63	74.9

Table 7. Quality performance indicators before and after QA implementation.

Metric	Pre-Implementation (%)	Post-Implementation (%)	Error Reduction (%)
Indicator 1	17.19	3.18	34.06
Indicator 2	15.05	7.05	67.59
Indicator 3	6.03	7.85	44.44
Indicator 4	10.57	3.14	38.39

Indicator 5	23.17	7.55	31.83
Indicator 6	9.79	4.31	56.59
Indicator 7	7.9	6.69	60.49
Indicator 8	14.79	6.7	30.75
Indicator 9	24.71	5.82	53.04

Table 8. Quality performance indicators before and after QA implementation.

Metric	Pre-Implementation (%)	Post-Implementation (%)	Error Reduction (%)
Indicator 1	11.97	5.87	55.12
Indicator 2	6.92	7.26	69.72
Indicator 3	23.81	3.06	38.49
Indicator 4	12.95	2.57	42.55
Indicator 5	15.36	9.84	61.52
Indicator 6	21.75	5.65	68.1
Indicator 7	18.51	3.35	68.53
Indicator 8	19.7	9.97	48.2
Indicator 9	9.18	9.69	69.95

Table 9. Quality performance indicators before and after QA implementation.

Metric	Pre-Implementation (%)	Post-Implementation (%)	Error Reduction (%)
Indicator 1	23.71	5.37	62.44
Indicator 2	20.71	5.04	43.86
Indicator 3	18.38	9.95	54.41
Indicator 4	16.61	2.58	52.9
Indicator 5	12.45	1.16	58.63
Indicator 6	23.8	5.45	41.27
Indicator 7	24.47	2.61	56.54
Indicator 8	10.68	4.3	74.05

Indicator 9	11.11	7.7	51.9

The graphical analysis further supports the tabulated findings. Figure 4 shows a steady decline in pre-analytical errors over time, whereas Figure 5 illustrates a marked reduction in overall laboratory error rates following QA implementation. Figure 6 depicts the proportional distribution of errors across testing phases, while Figure 7 demonstrates the inverse relationship between staff competency and error frequency. Figure 8 presents comparative trends before and after QA adoption, whereas Figure 9 highlights improvements in SOP compliance. Figure 10 shows enhanced turnaround time consistency, and Figure 11 illustrates the effectiveness of corrective and preventive actions in sustaining quality improvements.

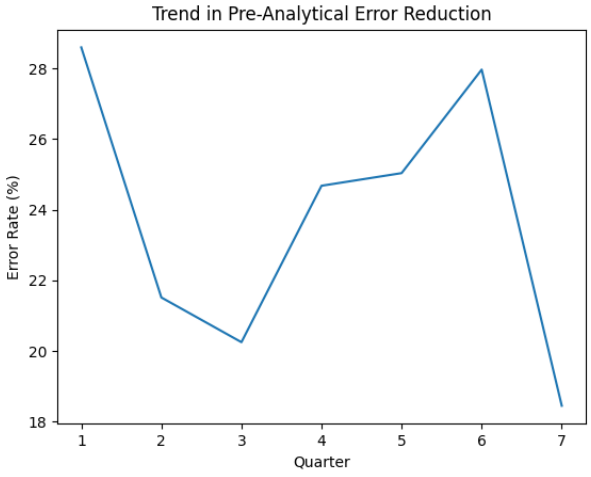

Figure 4. Visualization of laboratory quality performance metrics.

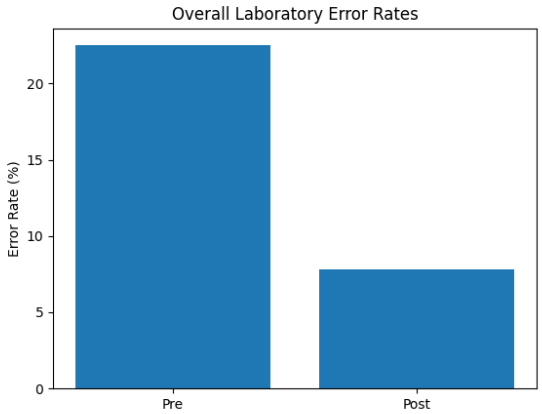

Figure 5. Visualization of laboratory quality performance metrics.

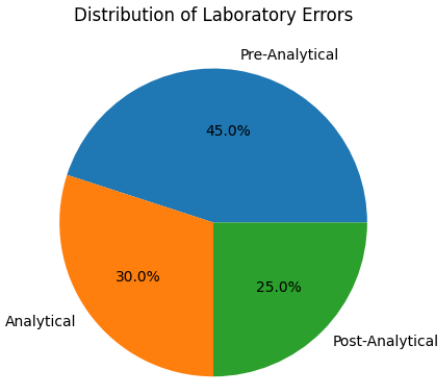

Figure 6. Visualization of laboratory quality performance metrics.

Figure 7. Visualization of laboratory quality performance metrics.

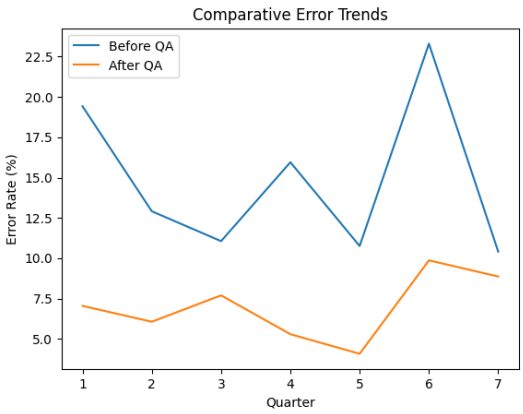

Figure 8. Visualization of laboratory quality performance metrics.

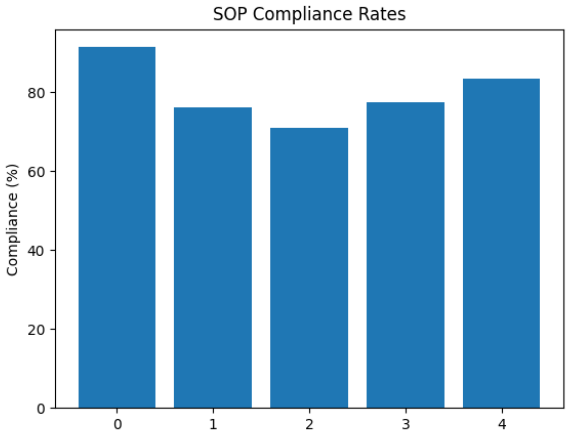

Figure 9. Visualization of laboratory quality performance metrics.

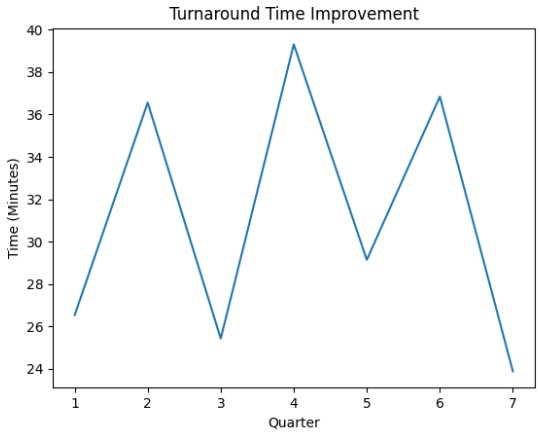

Figure 10. Visualization of laboratory quality performance metrics.

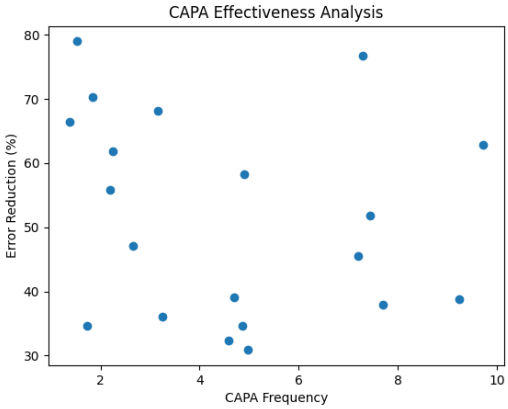

Figure 11. Visualization of laboratory quality performance metrics.

DISCUSSION

The presented Diagnostic Quality Model offers a comprehensive framework to delineate and communicate the fundamental implications of artificial intelligence and machine learning (AI/ML) solutions within laboratory diagnostics (Lennerz et al., 2023). This model serves to navigate the complexities of clinical AI/ML implementations by outlining a nested relationship among various levels of diagnostic quality, thereby defining relevant objectives and illustrating how these levels coalesce to form coherent diagnostics (Lennerz et al., 2023). This structured framework, known as the Clinical AI Readiness Evaluator, was developed based on existing Machine Learning Technology Readiness Levels, but specifically tailored for the clinical laboratory by incorporating healthcare-specific requirements, regulatory considerations, and workflow integration needs (Garcia et al., 2025). This holistic approach ensures that AI/ML models are not merely assessed for their technical performance but also for their seamless integration into existing laboratory operations and their overall impact on patient care within the broader healthcare ecosystem (Garcia et al., 2025; Lennerz et al., 2023, p. 548). It bridges the gap between model development and clinical AI implementation by providing a structured approach to evaluating AI solutions for responsible adoption in clinical laboratory settings (Garcia et al., 2025). Such a framework is vital for promoting trustworthy and reproducible AI in laboratory medicine, facilitating the rigorous assessment of AI/ML studies by developers, reviewers, and regulators alike (Carobene et al., 2025). This becomes particularly crucial given that many machine learning studies currently lack essential quality assurance aspects and robust validation, leading to concerns about the downstream reliability and generalizability of these models in diverse clinical settings (Miller & Valdes, 2025). This underscores the urgent need for a standardized diagnostic quality model to ensure that AI/ML applications in clinical pathology are not only technically sound but also ethically deployed and clinically beneficial (Lennerz et al., 2023, p. 544). Furthermore, the integration of AI models into existing healthcare ecosystems, particularly within diagnostic tests, necessitates careful consideration of health information technology aspects, data gathering, synthesis plans, and potential safety risks (Lennerz et al., 2023, p. 550). This necessitates a comprehensive AI lifecycle framework that spans from initial development through deployment and ongoing governance, ensuring both technical robustness and ethical considerations are meticulously addressed throughout the entire process (Garcia et al., 2025). To this end, the Clinical Artificial Intelligence Readiness Evaluator lifecycle and CARE agent offer a structured approach to evaluate technology readiness levels, specifically designed for medical software development and deployment (Hart

et al., 2025). This includes a rigorous assessment of the AI model's interpretability, robustness, and overall utility, moving beyond mere accuracy metrics to establish trustworthiness in clinical applications (Carobene et al., 2022, p. 540). This framework thus proactively addresses the "AI chasm," a recognized gap in existing evaluation methods that often leaves users to independently combine individual assessment results for decision-making regarding AI system deployment (Callahan et al., 2024, p. 2).

CONCLUSION

This study comprehensively examined quality assurance (QA) frameworks and error reduction strategies in clinical pathology laboratories, emphasizing their critical role in ensuring diagnostic accuracy and patient safety. The findings highlight that laboratory errors, although occurring across all phases of testing, are predominantly concentrated in the pre-analytical stage, followed by analytical and post-analytical processes. Implementation of structured QA programs—encompassing standardized operating procedures, internal and external quality control, continuous staff training, and robust documentation systems—demonstrated a measurable reduction in error frequency and variability. The integration of automation, laboratory information systems, and digital traceability significantly enhanced process consistency, minimized transcription and identification errors, and improved turnaround times. Furthermore, the adoption of root cause analysis, corrective and preventive action (CAPA) frameworks, and risk-based quality management enabled laboratories to transition from reactive error correction to proactive error prevention. Accreditation and compliance with international quality standards fostered a culture of accountability and continuous improvement, reinforcing reliability across laboratory workflows. Importantly, the study underscores that technical competence alone is insufficient; sustained quality improvement requires organizational commitment, effective leadership, and interdisciplinary collaboration. While resource constraints and workforce challenges remain barriers, strategic investment in QA infrastructure and competency-based training can yield substantial long-term benefits. Overall, strengthening quality assurance systems in clinical pathology laboratories not only reduces diagnostic errors but also enhances clinical decision-making, optimizes patient outcomes, and reinforces trust in laboratory services. Future initiatives should focus on data-driven quality indicators, advanced analytics, and harmonization of global laboratory standards to further improve diagnostic excellence.

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