Quality Control Errors in Clinical Laboratories: Sources, Impact, and Preventive Strategies

Aditi Sharma[1], Anshika Dhiman[2], Prachi Rana[3], Tarushi Sharma[4]. Rabi Raj Bhatt[5]
[1,2,3,4,5]*Department of MLT University Institute of Allied Health Sciences Chandigarh University, Mohali, Punjab (India)-140413*

***Abstract*—Quality control (QC) is a cornerstone of reliable laboratory diagnostics, directly influencing patient care, clinical decision-making, and healthcare outcomes. Despite advances in automation and standardization, clinical laboratories continue to face quality control errors that compromise test accuracy and reliability. These errors may arise during pre-analytical, analytical, or post-analytical phases and can result from human factors, instrument malfunction, reagent variability, environmental conditions, or inadequate quality management systems. This review provides a comprehensive analysis of quality control errors in clinical laboratories, including their classification, root causes, and clinical impact. Current quality control practices, statistical tools, and regulatory guidelines are discussed, along with emerging approaches such as risk-based QC, sigma metrics, automation, and digital quality management systems. Strategies for error prevention and continuous quality improvement are highlighted to enhance laboratory performance and patient safety.**

***Index Terms*—Quality control, laboratory errors, analytical errors, sigma metrics, internal quality control, patient safety**

I. INTRODUCTION

Clinical laboratories constitute the backbone of evidence-based medicine, providing objective data that guide diagnosis, prognosis, treatment monitoring, and disease prevention. It is estimated that approximately 60–70% of critical clinical decisions depend on laboratory test results, underscoring the necessity for accuracy and reliability in laboratory services [1]. Even minor analytical deviations can lead to significant clinical misinterpretations, particularly in critical care, oncology, and emergency medicine.

Quality control (QC) serves as a systematic mechanism to ensure analytical consistency and detect deviations before patient results are released. However, the complexity of modern laboratory workflows, coupled with increased automation, high test volumes, workforce shortages, and cost constraints, has made QC management increasingly challenging [2]. Errors persist despite technological advancements, often arising from multifactorial causes spanning human, technical, and organizational domains.

This review aims to provide a comprehensive and structured analysis of quality control errors in clinical laboratories, emphasizing their classification, root causes, clinical implications, and contemporary prevention strategies. By synthesizing evidence from laboratory medicine, quality management, and regulatory frameworks, this article seeks to support laboratory professionals in strengthening quality systems and improving patient safety.

II. OVERVIEW OF QUALITY CONTROL IN CLINICAL LABORATORIES

2.1 Definition and Objectives of Quality Control

Quality control in laboratory medicine refers to a set of operational techniques employed to monitor analytical processes and ensure that test results meet predefined quality standards [3]. QC is not limited to detecting errors but extends to maintaining long-term analytical stability, ensuring compliance with regulatory requirements, and supporting continuous quality improvement.

The core objectives of QC include:

- Ensuring accuracy and precision of laboratory measurements
- Detecting random and systematic errors
- Maintaining consistency across instruments and reagent lots
- Protecting patient safety by preventing erroneous result reporting

- Supporting accreditation and regulatory compliance

Effective QC functions as an early warning system, enabling laboratories to intervene before analytical errors translate into adverse clinical outcomes.

2.2 Internal and External Quality Control

Internal quality control (IQC) involves the routine analysis of control materials alongside patient samples to monitor day-to-day analytical performance. IQC data are evaluated using statistical tools such as Levey–Jennings charts and Westgard rules to detect deviations from expected performance [4].

External quality assessment (EQA), also known as proficiency testing, provides an independent evaluation of laboratory performance by comparing results with peer laboratories or reference values [5]. EQA programs help identify systematic biases, methodological issues, and training gaps that may not be apparent through IQC alone. Together, IQC and EQA form the foundation of a comprehensive laboratory quality assurance system. Laboratory errors can be broadly classified into pre-analytical, analytical, and post-analytical phases, as summarized in Table 1.

Phase of Testing	Type of Errors	Common Causes	Examples	Clinical Impact	References
Pre-analytical	Patient identification errors, hemolysis, improper sample collection	Inadequate training, workload pressure, poor communication	Wrong patient sample, insufficient volume, wrong anticoagulant	Misdiagnosis, repeat sampling, delayed treatment	[7], [8]
Analytical	Calibration drift, reagent instability, instrument malfunction	Poor maintenance, reagent lot variation, SOP non-compliance	Systematic bias, random analytical error	False-positive or false-negative results	[9], [10]
Post-analytical	Transcription errors, delayed reporting, incorrect validation	LIS integration failure, human oversight	Incorrect result entry, missed critical value	Delayed or inappropriate clinical action	[11], [15]

Table 1. Classification of quality control errors in clinical laboratories based on the testing phase, causes, examples, and clinical impact.

III. CLASSIFICATION OF QUALITY CONTROL ERRORS

Laboratory errors are conventionally categorized based on the phase of the testing cycle in which they occur: pre-analytical, analytical, and post-analytical. This framework facilitates targeted interventions and process improvement [6].

3.1 Pre-Analytical Errors

Pre-analytical errors are the most frequent and account for up to 70% of total laboratory errors [7]. These errors occur before sample analysis and include patient misidentification, incorrect test requests, improper specimen collection techniques, use of incorrect containers or anticoagulants, insufficient sample volume, hemolysis, clotting, lipemia, and inappropriate storage or transport conditions.

Such errors are often linked to human factors, including inadequate training of phlebotomists, high workload, poor communication between clinical and laboratory staff, and lack of standardized protocols [8]. Pre-analytical variability can significantly alter analyte concentrations, leading to spurious results and diagnostic confusion.

3.2 Analytical Errors

Analytical errors occur during the measurement process and directly compromise test accuracy and precision. These errors may arise from instrument malfunction, calibration drift, reagent instability, environmental fluctuations, or procedural non-compliance [9].

Although laboratory automation has reduced manual handling errors, it has introduced new challenges such as software errors, sensor failures, and dependency on manufacturer-provided calibration protocols [10]. Analytical errors are particularly concerning because they may go undetected if QC systems are inadequately designed or improperly interpreted.

3.3 Post-Analytical Errors

Post-analytical errors occur after result generation and include transcription mistakes, incorrect result validation, delayed reporting, failure to notify critical values, and misinterpretation of laboratory data [11]. While laboratory information systems (LIS) have reduced manual transcription errors, integration failures, alert fatigue, and inadequate result review workflows continue to pose risks.

Post-analytical errors have direct clinical consequences, particularly when critical results are delayed or incorrectly communicated to healthcare providers.

IV. SOURCES AND ROOT CAUSES OF QUALITY CONTROL ERRORS

4.1 Human Factors

Human factors remain a dominant contributor to QC failures across all laboratory phases. Errors may result from insufficient training, lack of competency assessment, fatigue, multitasking, and deviation from standard operating procedures (SOPs) [12]. The increasing reliance on temporary or understaffed personnel further exacerbates this issue.

A strong quality culture that emphasizes accountability, continuous education, and open error reporting is essential to minimize human-related QC errors.

4.2 Instrumentation and Reagent-Related Factors

Modern clinical laboratories depend heavily on automated analyzers and complex reagent systems. Instrument-related errors may arise from inadequate calibration, delayed maintenance, sensor drift, or software malfunctions [13]. Reagent-related issues include lot-to-lot variation, improper storage, expiration, and contamination.

Without robust QC monitoring, these issues can introduce systematic bias that affects large volumes of patient results.

4.3 Environmental and Organizational Factors

Environmental conditions such as temperature, humidity, vibration, and power supply stability can significantly influence analytical performance. Organizational factors, including poor workflow design, inadequate staffing, insufficient management oversight, and lack of investment in quality infrastructure, further increase the risk of QC failures [14].

V. CLINICAL IMPACT OF QUALITY CONTROL ERRORS

Quality control errors can lead to false-positive or false-negative results, resulting in misdiagnosis, inappropriate therapy, delayed treatment, and unnecessary investigations [15]. In critical care settings, erroneous laboratory results can be life-threatening.

Beyond patient harm, QC errors impose substantial economic burdens on healthcare systems due to repeat testing, prolonged hospital stays, medico-legal consequences, and loss of institutional credibility [16]. Ethical considerations also arise, as inaccurate laboratory reporting violates the principle of non-maleficence.

VI. QUALITY CONTROL TOOLS AND STATISTICAL APPROACHES

6.1 Levey–Jennings Charts

Levey–Jennings charts graphically represent QC data over time, allowing laboratories to visualize trends, shifts, and random variation. These charts form the basis for applying decision rules and identifying analytical instability [17].

6.2 Westgard Multirule Procedures

Westgard rules combine multiple statistical criteria to enhance error detection while minimizing false rejection rates. These rules are particularly effective in identifying systematic errors and calibration drift [18].

6.3 Sigma Metrics

Sigma metrics quantify analytical performance by integrating allowable total error, bias, and imprecision. Sigma-based QC enables laboratories to design test-specific QC strategies and allocate resources efficiently [19]. Commonly used statistical and risk-based quality control tools for detecting laboratory errors are summarized in Table 2.

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Table 2. Quality control tools and approaches used in clinical laboratories for detection and prevention of analytical errors.

VII. EMERGING APPROACHES TO REDUCING QUALITY CONTROL ERRORS

7.1 Risk-Based Quality Control

Risk-based QC prioritizes patient safety by tailoring QC procedures based on test criticality, failure modes, and clinical impact. This approach aligns with CLSI EP23-A guidelines and enhances efficiency without compromising quality [20].

7.2 Automation and Digital Quality Management Systems

Advanced middleware, auto-verification systems, and real-time QC dashboards enable proactive error detection and rapid corrective action. Digital QC tools also support trend analysis and predictive maintenance [21].

7.3 Accreditation and Regulatory Frameworks

Accreditation standards such as ISO 15189 and NABL requirements mandate structured QC programs, documentation, internal audits, and continual improvement processes. Compliance with these standards strengthens laboratory quality governance [22].

VIII. STRATEGIES FOR ERROR PREVENTION AND CONTINUOUS QUALITY IMPROVEMENT

Preventing quality control errors in clinical laboratories requires a systematic, proactive, and multidisciplinary approach that extends beyond routine QC checks. Continuous quality improvement (CQI) emphasizes prevention rather than correction and integrates technical, human, and organizational dimensions.

8.1 Standardization of Laboratory Processes

Standard operating procedures (SOPs) must be clearly written, regularly updated, and uniformly implemented across all laboratory sections. SOP standardization minimizes procedural variability, particularly in high-risk processes such as specimen handling, reagent preparation, calibration, and result validation. Harmonization of procedures across laboratory shifts and sites is especially important in large diagnostic networks.

8.2 Training, Competency Assessment, and Workforce Engagement

Regular training and competency assessments are essential to reduce human-related QC errors. Competency evaluation should include direct observation, proficiency testing, blind sample analysis, and assessment of problem-solving skills. Continuous professional development ensures that laboratory personnel remain updated on evolving technologies, guidelines, and quality practices.

Equally important is fostering staff engagement and accountability. Encouraging a non-punitive error-reporting culture allows laboratories to identify near-misses and latent system flaws before they result in patient harm.

8.3 Root Cause Analysis and Corrective Action

When QC failures occur, root cause analysis (RCA) should be systematically performed to identify underlying causes rather than superficial symptoms. Tools such as fishbone (Ishikawa) diagrams, the “5

Whys" technique, and failure mode and effects analysis (FMEA) help laboratories implement targeted corrective and preventive actions (CAPA).

8.4 Quality Indicators and Performance Monitoring

Quality indicators (QIs) provide measurable metrics to monitor laboratory performance across pre-analytical, analytical, and post-analytical phases. Common indicators include sample rejection rates, turnaround time compliance, QC failure frequency, and critical value reporting times. Continuous monitoring of QIs enables benchmarking, trend analysis, and informed managerial decision-making.

8.5 Leadership and Quality Culture

Sustainable quality improvement requires strong leadership commitment. Laboratory management must allocate adequate resources, support quality initiatives, and integrate quality objectives into organizational strategy. A strong quality culture where accuracy, transparency, and patient safety are prioritized serves as the foundation for effective QC systems.

IX. FUTURE PERSPECTIVES IN QUALITY CONTROL MANAGEMENT

The future of quality control in clinical laboratories is shifting toward predictive, data-driven, and patient-centered models, supported by technological innovation and advanced analytics.

9.1 Artificial Intelligence and Predictive Quality Control

Artificial intelligence (AI) and machine learning algorithms are increasingly being explored for QC data analysis. These tools can identify subtle patterns, trends, and anomalies in large QC datasets that may not be apparent through traditional statistical methods. Predictive QC systems have the potential to anticipate analytical failures before they occur, enabling proactive intervention.

9.2 Personalized and Test-Specific QC Strategies

Future QC approaches are expected to move away from uniform QC protocols toward test-specific and risk-based strategies. High-risk analytes with narrow clinical decision limits may require more stringent QC, whereas stable, low-risk tests may be monitored less frequently. Such personalized QC improves efficiency while maintaining patient safety.

9.3 Integration of QC with Digital Laboratory Ecosystems

Fully integrated laboratory ecosystems that connect analyzers, middleware, LIS, and hospital information systems will enhance real-time QC monitoring and automated decision-making. Cloud-based QC platforms allow centralized oversight across multiple laboratory sites, supporting standardization and remote quality audits.

9.4 Regulatory Evolution and Global Harmonization

Regulatory frameworks are expected to evolve in response to technological advances. Future accreditation standards may increasingly emphasize risk management, digital traceability, and outcome-based quality indicators. Global harmonization of QC guidelines will facilitate consistency in laboratory quality across regions and healthcare systems.

X. CONCLUSION

Quality control errors in clinical laboratories represent a persistent and multifaceted challenge with direct implications for patient safety, clinical decision-making, and healthcare efficiency. Despite advancements in automation and analytical technologies, errors continue to arise due to human factors, system complexity, and organizational constraints.

This review highlights that effective quality control extends beyond routine statistical checks, requiring a comprehensive quality management framework that integrates robust QC tools, risk-based strategies, continuous training, and strong leadership commitment. Emerging technologies such as artificial intelligence, digital quality management systems, and predictive analytics offer promising opportunities to transform QC from a reactive to a proactive discipline. Ultimately, the goal of quality control in laboratory medicine is not merely regulatory compliance, but the delivery of accurate, timely, and clinically meaningful results that support optimal patient care. Sustained investment in quality systems, workforce development, and innovation will be essential to meet the growing demands of modern healthcare and to ensure trust in laboratory diagnostics.

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