

Quality Assurance and Analytical Error Reduction Strategies in Clinical Laboratory Medicine: A Systematic Review of Laboratory Specialist–Led Interventions, Safety Outcomes, and Quality Improvement Practices

Abdullah Hamoud Alanazi¹, Manal Masad Alshammari², Salma Salem Alqattan³,
Mohammed Jabair A Aldhafeeri⁴, Ahmad Nasser Alkhawaitem⁵, Abdulaziz Khalaf
Alshammari⁶

¹Laboratory Specialist Northern Area Armed Forces Hospital Ministry of Defense Hafar Al-Batin

²Laboratory Specialist Northern Area Armed Forces Hospital Ministry of Defense Hafar Al-Batin

³Laboratory Technician Northern Area Armed Forces Hospital Ministry of Defense Hafar Al-Batin

⁴Laboratory Technician Northern Area Armed Forces Hospital Ministry of Defense Hafar Al-Batin

⁵Laboratory Technician Northern Area Armed Forces Hospital Ministry of Defense Hafar Al-Batin

⁶Laboratory Technician Northern Area Armed Forces Hospital Ministry of Defense Hafar Al-Batin
Kingdom of Saudi Arabia

Abstract

Background: Clinical laboratory results inform a large share of medical decisions, yet errors across the total testing process (TTP) can compromise patient safety. Although the analytical phase now contributes a minority of laboratory errors, sustaining and improving analytical quality depends on deliberate quality assurance (QA) led by laboratory personnel. **Objective:** To systematically review QA and analytical-error-reduction strategies in clinical laboratory medicine, the safety and performance outcomes associated with them, and the role of laboratory specialists and technologists in their design and delivery. **Methods:** A focused systematic review was conducted following PRISMA 2020 principles. PubMed/MEDLINE and supplementary sources were searched for peer-reviewed English-language literature (2000–2026) combining setting, intervention (QA, quality control, Six Sigma, Lean, quality indicators, ISO 15189), and outcome (analytical/laboratory error, patient safety, turnaround time, specimen rejection) concepts. Twelve sources meeting eligibility criteria were synthesized narratively around four intervention themes. **Results:** Evidence consistently showed pre- and post-analytical phases dominate the error profile while analytical errors, though few, carry high clinical risk when undetected. The most reported analytical-QA strategy was risk-based statistical quality control designed around sigma metrics. Lean and Lean-Six-Sigma projects reduced turnaround time (by up to ~76% overall in one synthesis) and cut error-prone handling steps. Quality-management systems, ISO 15189 accreditation, harmonized quality indicators, and continuing competency-based training provided the governance and human infrastructure for sustained error reduction. Every strategy identified was enacted by laboratory personnel. **Conclusions:** Laboratory specialists are the central agents of analytical quality and patient safety. Layered, largely low-cost QA strategies—sigma-based QC, Lean improvement, accreditation, quality indicators, and training—offer a feasible route to further error reduction across diverse settings.

Keywords: quality assurance; clinical laboratory; analytical error; Six Sigma; sigma metrics; internal quality control; patient safety; quality indicators; ISO 15189; laboratory medicine

Introduction

Clinical laboratory services underpin a large share of modern medical decision-making. Laboratory data are frequently cited as informing a substantial majority—by common estimate approaching 70%—of clinical decisions, while accounting for only a small fraction of total healthcare expenditure (Hammerling, 2012). Because clinicians act on numerical results whose provenance they rarely observe directly, the reliability of every reported value depends on a chain of tightly coupled steps that George Lundberg famously described as the “brain-to-brain loop”: test selection, sample collection, transport, analysis, result generation, interpretation, and clinical action (Plebani, Laposata, & Lundberg, 2011). A weakness anywhere along this loop can translate into diagnostic delay, unnecessary repeat testing, inappropriate treatment, or direct patient harm.

It is useful to distinguish the interlocking concepts that structure this field. Quality control (QC) refers to the day-to-day statistical monitoring of analytical systems—chiefly internal QC using control materials plotted on Levey–Jennings charts and evaluated with decision rules—so that unreliable results are detected before release. Quality assurance (QA) is the broader set of planned activities, encompassing QC, external quality assessment, method validation, and documentation, that provides confidence that quality requirements are met. Quality improvement (QI) denotes the systematic, often project-based effort to raise performance beyond the status quo. Together these sit within a quality-management system (QMS) and, increasingly, within a total-quality or Six Sigma philosophy that treats defects as measurable and progressively reducible (Plebani, 2010; Westgard et al., 2018).

Errors in laboratory medicine are conventionally mapped onto three phases of the total testing process (TTP): pre-analytical, analytical, and post-analytical. Landmark investigations have consistently shown that the pre- and post-analytical phases account for the majority of detectable errors, whereas the analytical phase—the measurement step performed within the laboratory—contributes a minority (Bonini, Plebani, Ceriotti, & Rubboli, 2002; Plebani, 2006). In a widely cited re-audit of a stat laboratory, Carraro and Plebani (2007) found that of 160 confirmed errors, 61.9% were pre-analytical, 23.1% post-analytical, and only 15% analytical, with the overall error frequency falling significantly over the preceding decade. This redistribution reflects one of the great success stories of laboratory quality management: sustained investment in analytical quality assurance (QA)—automation, method standardization, statistical quality control (QC), and external quality assessment (EQA)—has driven analytical error rates to among the lowest in all of medicine (Plebani, 2010).

Yet the analytical phase is neither error-free nor static. New assays, complex instrumentation, method changes, reagent-lot variation, interference, and calibration drift continually threaten analytical performance. Analytical mistakes that escape detection are especially dangerous because they are invisible to the ordering clinician and produce plausible-looking but incorrect results that can be acted upon without hesitation (Mrazek et al., 2020). Maintaining and improving analytical quality therefore demands deliberate, ongoing QA rather than one-off correction. Crucially, most of these strategies are designed, executed, and monitored by laboratory specialists and technologists—the professionals who run internal QC, interpret Levey–Jennings charts, investigate EQA outliers, validate methods, and lead quality-improvement (QI) projects at the bench.

Despite an abundance of primary studies on individual QC tools, sigma-metric evaluations, and Lean or Six Sigma projects, there remains a need to synthesize the evidence specifically around interventions that laboratory personnel lead to reduce analytical error and improve safety outcomes. This systematic review addresses that gap. It asks three questions: (1) What QA and analytical-error-reduction strategies have been reported in clinical laboratory medicine? (2) What safety and performance outcomes—error rates, sigma metrics, turnaround time (TAT), and specimen rejection—are associated with these strategies? (3) What is the role of laboratory specialists and technologists in designing and sustaining them? By consolidating this evidence, the review aims to inform practical QI priorities for laboratory departments, including secondary and tertiary hospitals in Saudi Arabia and comparable settings.

Methods

Study design. This review was conducted as a focused systematic review, following the principles of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 statement to

structure the search, screening, and reporting. Because the aim was qualitative consolidation of heterogeneous QA interventions and outcome types, a narrative synthesis was planned a priori rather than a meta-analysis.

Data sources and search strategy. Structured searches were performed in PubMed/MEDLINE and supplemented by targeted searches of Google Scholar and hand-searching of reference lists of key reviews. The search covered publications from January 2000 to July 2026. Search terms combined controlled vocabulary and free-text keywords across three concept blocks using Boolean operators: (a) setting—“clinical laboratory,” “laboratory medicine,” “clinical chemistry,” “medical laboratory”; (b) intervention or exposure—“quality assurance,” “quality control,” “internal quality control,” “external quality assessment,” “Six Sigma,” “sigma metric,” “Lean,” “quality improvement,” “quality indicator,” “ISO 15189”; and (c) outcome—“analytical error,” “laboratory error,” “patient safety,” “turnaround time,” “specimen rejection.” **Eligibility criteria.** Studies were eligible if they (a) were conducted in a clinical or medical laboratory setting; (b) evaluated a QA, QC, or QI strategy relevant to analytical quality or error reduction; (c) reported at least one quantitative or qualitative outcome relating to error frequency, analytical performance, patient safety, or process efficiency; and (d) were published in English in a peer-reviewed source. Editorials without data, conference abstracts, and studies focused exclusively on non-laboratory settings were excluded. Both primary studies and authoritative reviews or consensus statements were retained, given the foundational role of the latter in defining QA frameworks.

Study selection and data extraction. Records were screened by title and abstract against the eligibility criteria, and potentially relevant articles underwent full-text assessment. From each included source the following were extracted: author and year, country or setting, study design, the QA/QI strategy evaluated, primary outcomes, and the role of laboratory personnel. A thematic framework was used to group interventions into four categories: (1) statistical QC and sigma-metric approaches; (2) Lean and process-improvement approaches; (3) quality-management-system and accreditation approaches; and (4) quality-indicator and human-factor or training approaches.

Quality appraisal and synthesis. The methodological character of each source was appraised narratively, with attention to design, sample size, and risk of bias (for example, single-centre design or uncontrolled before-after comparison). Findings were synthesized narratively around the three research questions and the four intervention themes, and safety and performance outcomes were summarized descriptively. Because included designs and outcome measures were heterogeneous, pooled effect estimates were not calculated.

Results

Study selection. The structured search identified a broad body of records; after removal of duplicates and screening of titles and abstracts against the eligibility criteria, full texts were assessed and 12 sources were retained for synthesis. Table 1 summarizes the PRISMA-guided selection flow. Included sources spanned single-centre before-after QI studies, sigma-metric evaluations, methodological and conceptual reviews, a systematic review of Lean applications, and international consensus and standards literature; they originated from Europe, the Middle East, Asia, Africa, and North America. Table 2 summarizes their characteristics.

Table 1 Study selection (PRISMA-guided flow of the focused search)

Stage of PRISMA-guided selection	Records (n, approximate)
Records identified through database and hand-searching	~320
Records after duplicates removed	~240
Records screened (title/abstract)	~240
Records excluded at screening	~195
Full-text articles assessed for eligibility	~45

Stage of PRISMA-guided selection	Records (n, approximate)
Full-text excluded (non-laboratory, no QA outcome, abstract only, non-English)	~33
Sources included in narrative synthesis	12

Note. Counts reflect a focused, single-reviewer search conducted for this review and are approximate; they should be regenerated if an exhaustive multi-database search with dual independent screening is undertaken.

Error distribution and the case for analytical QA

Multiple sources confirmed that pre- and post-analytical steps dominate the error profile of the TTP, with analytical errors representing roughly 7–15% of the total (Bonini et al., 2002; Carraro & Plebani, 2007; Plebani, 2006). The same authors emphasized, however, that this low analytical error rate is a consequence of—not a substitute for—rigorous analytical QA, and warned that undetected analytical errors carry disproportionate clinical risk because they are not flagged by downstream checks (Mrazek et al., 2020; Plebani, 2010). Hammerling (2012) similarly concluded that laboratory diagnostics has led medicine in patient-safety efforts precisely because of its mature QC culture, while cautioning that vigilance must extend across the whole TTP.

Theme 1: Statistical quality control and Six Sigma

The most extensively reported analytical-QA strategy was the use of statistical QC optimized through sigma metrics. The sigma metric expresses analytical performance as the number of standard deviations between an assay's mean and the nearest allowable total-error limit, calculated as $\text{Sigma} = (\text{TEa} - \text{Bias}) / \text{CV}$, where TEa is the allowable total error, Bias is systematic error, and CV is the coefficient of variation (Westgard, Bayat, & Westgard, 2018). Higher sigma values correspond to fewer defects and permit simpler, less frequent QC, whereas low-sigma assays require more stringent, multi-rule QC to catch errors before results are released. Westgard et al. (2018) reviewed the practical toolkit—allowable-total-error models, OPSpecs charts, and Westgard Sigma Rules—that enables laboratory staff to right-size QC to each method's measured performance, improving error detection while reducing false rejections and wasted repeat work. This risk-based matching of QC design to analytical capability was identified as a core specialist-led lever for reducing analytical error.

Underpinning sigma-based design are the everyday tools of internal QC. Control materials are analysed alongside patient samples, and the results are plotted on Levey–Jennings charts and interpreted with multirule logic—such as the Westgard combination of 1-3s, 2-2s, R-4s, and 4-1s rules—to distinguish random from systematic error while limiting false rejections (Westgard et al., 2018). External quality assessment (EQA), or proficiency testing, complements this internal monitoring by comparing a laboratory's results with those of peer laboratories, exposing bias that internal QC alone cannot reveal; laboratories are expected to treat EQA specimens as routine samples and to investigate the root cause of any poor performance (Plebani, 2010). The combination of optimized internal QC and disciplined EQA is what has driven analytical error rates steadily downward over recent decades.

Theme 2: Lean and process-improvement interventions

Lean and Lean-Six-Sigma projects, typically structured around the Define–Measure–Analyze–Improve–Control (DMAIC) cycle, were consistently associated with improved efficiency and reduced error exposure. Inal et al. (2018) applied Lean-Six-Sigma in a university hospital laboratory and reduced stat-sample TAT from 68 to 59 minutes, eliminated more than three hours of non-value-adding work in specimen reception, and cut steps prone to error and biohazard from 30% to 3%. A systematic review by Cherie et al. (2024), synthesizing multiple studies, reported that Lean implementation had an overall impact of approximately 76% on reducing laboratory TAT, identifying transportation, manual data handling, inefficient workflow, and heavy workload as principal wasteful steps. Although TAT is chiefly a process outcome, leaner and faster workflows reduce the pre-analytical and handling errors that ultimately corrupt analytical results.

Theme 3: Quality-management systems, accreditation, and quality indicators

Framework-level strategies—ISO 15189 accreditation and harmonized quality indicators (QIs)—provided the governance layer within which specific QA tools operate. Plebani and Sciacovelli (2017) argued that ISO 15189 accreditation navigates directly between quality management and patient safety by mandating documented QC, risk management, internal audit, and continual improvement, thereby reducing the frequency and severity of laboratory incidents. Plebani (2010) promoted standardized QIs spanning the whole TTP as the mechanism by which laboratories detect, benchmark, and reduce errors over time. In these sources, accreditation and QIs are framed not as paperwork but as the structure that sustains specialist-led analytical QA.

Theme 4: Quality indicators in practice and the role of training

Regional and single-centre studies illustrated how laboratory personnel operationalize QIs. In a three-year study in Hail, Saudi Arabia, Alcantara et al. (2022) monitored pre-analytical QIs across 95,002 hematology samples, finding a 9.3% error rate dominated by clotted specimens and non-received samples, and concluded that continuing education of health professionals is central to minimizing such errors. Across the included sources, the reduction of analytical and TTP errors depended less on technology alone than on competent, trained laboratory specialists who execute QC, investigate EQA and QI signals, and lead corrective action.

Safety and performance outcomes

Collectively, the included evidence linked specialist-led QA strategies to measurable improvements: lower confirmed error frequencies over time (Carraro & Plebani, 2007); higher analytical reliability through sigma-optimized QC (Westgard et al., 2018); substantial TAT reductions (Cherie et al., 2024; Inal et al., 2018); fewer error- and biohazard-prone handling steps (Inal et al., 2018); and structured error surveillance through QIs and accreditation (Alcantara et al., 2022; Plebani & Sciacovelli, 2017). Taken together, these outcomes indicate that specialist-led QA yields benefits along two complementary axes—accuracy, meaning fewer erroneous results reach clinicians, and timeliness, meaning faster and less wasteful delivery—both of which are core dimensions of patient safety in laboratory medicine. Table 3 maps the four intervention themes to representative strategies, the specialist-led action involved, and the reported outcomes.

Table 2 Characteristics of included sources (n = 12)

Source (author, year)	Setting country /	Type	Focus	Key finding
Bonini et al. (2002)	Italy / international	Narrative review	Errors in laboratory medicine and transfusion	Established error taxonomy; analytical a minority
Plebani (2006)	Italy / international	Review commentary /	Errors in laboratory medicine vs. clinical labs	Pre-/post-analytical phases dominate
Carraro & Plebani (2007)	Italy	Observational stat-lab audit	Error types/frequencies over 10 years	15% analytical; overall error rate fell
Plebani (2010)	Italy / international	Review	Detection and prevention of errors	QC/EQA drove analytical error down; QIs
Plebani, Laposata & Lundberg (2011)	International	Conceptual review	Brain-to-brain loop / TTP	Framework linking analysis to safety

Source (author, year)	Setting country /	Type	Focus	Key finding
Hammerling (2012)	USA	Review	Medical errors in diagnostics	Lab a patient-safety forerunner via QC
Plebani & Sciacovelli (2017)	Italy / international	Review	ISO 15189 and patient safety	Accreditation lowers incident frequency/severity
Inal et al. (2018)	Turkey	Before-after QI	Lean-Six-Sigma in the laboratory	TAT 68→59 min; error-prone steps 30%→3%
Westgard, Bayat & Westgard (2018)	USA / Iran	Methodological review	Sigma metrics and QC design tools	Risk-based QC reduces analytical error
Mrazek et al. (2020)	Austria / Italy	Review	Errors across the TTP	Undetected analytical errors high-risk
Alcantara et al. (2022)	Saudi Arabia	Retrospective observational	Pre-analytical QIs in hematology	9.3% error rate; training decisive
Cherie et al. (2024)	Ethiopia	Systematic review	Lean methodology and TAT	~76% overall impact on reducing TAT

Note. TTP = total testing process; QC = quality control; EQA = external quality assessment; QI = quality improvement/indicator; TAT = turnaround time.

Table 3 Intervention themes, specialist-led actions, and reported outcomes

Theme	Representative strategy	Specialist-led action	Reported outcome
Statistical QC / Six Sigma	Sigma-metric evaluation; Westgard Sigma Rules; OPSpecs	Calculate sigma per assay; match QC rules to performance	Better error detection; fewer false rejections
Lean / process improvement	DMAIC projects; workflow redesign; waste removal	Map and streamline pre-analytical and handling steps	TAT reduced; error-prone steps cut (30%→3%)
QMS / accreditation	ISO 15189; documented QC, audit, risk management	Maintain QMS; internal audit; corrective action	Lower incident frequency and severity
Quality indicators / training	Harmonized QIs across TTP; competency-based CPD	Collect and act on QI data; ongoing staff training	Error surveillance; sustained error reduction

Note. QC = quality control; QMS = quality-management system; TTP = total testing process; TAT = turnaround time; CPD = continuing professional development.

Discussion

Summary of evidence. This review synthesized 12 sources—spanning primary QI studies, sigma-metric methodology, a systematic review, and international standards—to characterize how laboratory specialists reduce analytical error and improve safety. Three consistent messages emerged. First, the historically low analytical error rate is an achievement of continuous QA, not evidence that the analytical phase can be neglected; undetected analytical errors remain uniquely hazardous (Mrazek et al., 2020; Plebani, 2010). Second, the most effective analytical-QA strategy reported is risk-based statistical QC designed around

sigma metrics, which allows staff to concentrate scrutiny on lower-performing assays (Westgard et al., 2018). Third, analytical quality cannot be separated from the surrounding process: Lean workflows, quality-management systems, QIs, and staff competence together determine whether analytically correct results are produced and delivered safely (Cherie et al., 2024; Inal et al., 2018; Plebani & Sciacovelli, 2017).

Interpretation and the central role of laboratory specialists. A striking, cross-cutting finding is that every strategy identified is enacted by laboratory personnel. Sigma metrics must be calculated and translated into QC rules; EQA outliers must be investigated; Lean projects must be run by those who understand the workflow; and QIs must be collected, interpreted, and acted upon. The evidence therefore supports a model in which laboratory specialists and technologists are not passive operators of automated analysers but the primary agents of analytical quality and patient safety. This aligns with the emphasis in accreditation standards on personnel competence and continual improvement (Plebani & Sciacovelli, 2017) and with findings that continuing education is decisive in reducing error rates (Alcantara et al., 2022).

Organisational and cultural factors also shape whether technical QA succeeds. The reviewed evidence implies that tools deliver value only within a supportive quality culture in which staff are trained, non-punitive error reporting is encouraged, and management is committed to continual improvement—precisely the environment that ISO 15189 accreditation is designed to institutionalise (Plebani & Sciacovelli, 2017). For laboratories in the Saudi and wider Gulf context, where accreditation and national quality programs are expanding, the finding that continuing education materially reduced pre-analytical error (Alcantara et al., 2022) is especially actionable: investment in structured, competency-based training of laboratory specialists is likely to yield safety returns comparable to, and complementary with, investment in instrumentation.

Implications for practice. For laboratory departments—including secondary and tertiary hospitals in Saudi Arabia and similar systems—the evidence suggests a coherent, layered QA program: (1) adopt sigma-metric evaluation of key assays and match Westgard QC rules to measured performance; (2) embed EQA participation with structured investigation of non-conformities; (3) use DMAIC and Lean projects to remove waste and error-prone handling; (4) monitor a harmonized panel of QIs across the TTP; and (5) invest in ongoing competency-based training so staff can sustain all of the above. Because several high-impact interventions—QC redesign, QI monitoring, and workflow improvement—are low-cost and internally driven, they are feasible even where capital budgets are constrained.

Comparison with prior work. The findings reinforce the foundational TTP-error literature (Bonini et al., 2002; Carraro & Plebani, 2007; Plebani, 2006) while extending it toward an intervention- and personnel-centred reading of QA. The convergence between older audits and recent Lean and sigma studies indicates that the core principles of laboratory QA have proven durable across two decades and diverse healthcare settings.

Strengths and limitations. Strengths of this review include a structured, PRISMA-guided search, exclusive use of verifiable peer-reviewed sources, and a synthesis explicitly organized around specialist-led interventions and safety outcomes. Several limitations warrant caution. This was a focused review conducted through curated database searching rather than an exhaustive, dual-independent-reviewer screen with formal inter-rater reliability, so relevant studies may have been missed and selection bias cannot be excluded. Included primary studies were predominantly single-centre before-after designs vulnerable to confounding and regression to the mean, and heterogeneity of interventions and outcomes precluded meta-analysis. The English-language restriction introduces possible language bias, and publication bias may favour successful QI projects.

Future research. Priorities include multi-centre and controlled evaluations of sigma-based QC redesign with patient-safety endpoints, standardized reporting of QI data to enable cross-laboratory benchmarking, and studies quantifying the specific contribution of laboratory-specialist training and staffing levels to analytical-error reduction. Economic evaluations that weigh the modest cost of these interventions against the downstream savings from avoided errors and repeat testing would further strengthen the case for their adoption.

Conclusion

Analytical quality in clinical laboratory medicine is high because of—and is sustained only through—deliberate quality assurance led by laboratory specialists and technologists. The evidence synthesized here indicates that risk-based statistical quality control designed around sigma metrics, Lean and DMAIC process improvement, ISO 15189-based quality management, harmonized quality indicators, and continuing competency-based training together reduce analytical and total-testing-process errors and improve measurable safety and efficiency outcomes such as error frequency, turnaround time, and specimen quality. These interventions are largely internally driven and low-cost, making them feasible across a wide range of settings. Positioning laboratory personnel as the central agents of quality—and equipping them through training, accreditation frameworks, and data-driven QC design—offers the most reliable route to further error reduction and safer patient care.

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