

LABORATORY QUALITY, DIAGNOSTIC ACCURACY, AND WORKFLOW OPTIMIZATION IN CLINICAL LABORATORIES: A SYSTEMATIC REVIEW

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Abstract

Background: Clinical laboratories affect most medical decisions, yet quality threats, diagnostic interpretation errors, and inefficient workflows delay care and increase risk. We aimed to synthesize data from original research on interventions and systems that improve laboratory quality, diagnostic accuracy, safety of laboratory interpretation, and workflow performance in clinical laboratories. **Methods:** A PRISMA-aligned systematic review was conducted using PubMed Central as the mandatory full-text source. We included original studies evaluating quality improvement, automation, or decision support affecting measurable laboratory outcomes. Two reviewers performed screening and extraction. Due to heterogeneity of designs and outcomes, results were synthesized narratively. **Results:** Ten original studies met eligibility. Lean-based redesign in emergency and core laboratory pathways reduced turnaround time (TAT) and improved flow. Digital monitoring integrated with Lean Six Sigma was associated with reduced intra-laboratory TAT. Automation interventions improved timeliness and efficiency, including tube sorting, registration, total laboratory automation (TLA) performance and predictability, TLA system fusion decreasing prolonged out-of-range TAT, and microbiology automation markedly shortening TAT for negative reports. Quality-indicator programs quantified preanalytical error burdens and targeted improvement opportunities. A prospective cohort study of an AI decision-support tool for laboratory interpretation reported clinically relevant accuracy and high safety sensitivity for urgent, emergency cases. **Conclusions:** Across varied settings, workflow redesign (Lean), automation (preanalytic modules and TLA), and structured quality-indicator monitoring consistently improved operational performance and highlighted actionable error sources. Emerging AI decision support may enhance diagnostic safety, but broader validation is needed.

Keywords: Clinical Laboratory; Quality Indicators; Preanalytical Errors; Turnaround Time; Lean; Six Sigma; Total Laboratory Automation; Microbiology Automation; Diagnostic Accuracy; Clinical Decision Support.

INTRODUCTION

Laboratory medicine underpins modern diagnosis and treatment, but quality failures can occur across the total testing process (preanalytical, analytical, and post-analytical) and may contribute to diagnostic error and avoidable harm (1-3). Accreditation and quality management standards emphasize systematic control of processes, competence, and continual improvement as a framework for safer, more reliable testing (4). A consistent theme in laboratory quality literature is that preanalytical steps contribute a large share of preventable problems and therefore represent a high-yield target for improvement (3- 8). In parallel, rising test volumes and clinician expectations have intensified pressure on laboratories to reduce TAT while maintaining accuracy and safety (1,6). Technological approaches—ranging from partial automation to full TLA—are intended to standardize steps, reduce manual handling, and improve timeliness and predictability (1,6). In microbiology, automation and digital imaging platforms are increasingly used to speed negative reporting and streamline culture workflows, though staffing patterns and operational hours can still constrain performance (7).

Diagnostic safety is not only about analytic correctness; it also includes correct interpretation and appropriate action on results. Decision-support tools aimed at laboratory interpretation have emerged as a potential way to reduce misinterpretation and unnecessary utilization, but robust clinical evaluations are still limited (2). This review synthesizes original data from PMC on interventions and systems that improve laboratory quality, diagnostic accuracy, safety of interpretation, and workflow optimization.

METHODS

Protocol and reporting standard

This review followed PRISMA 2020 principles for transparent reporting (screening, eligibility, extraction, and synthesis). A formal registry record was not created.

Information sources and search strategy

We searched PubMed Central (full-text archive) as the mandatory source of included data (search date: January 16, 2026). Search concepts combined terms for: laboratory quality (quality indicators, errors, accreditation), diagnostic accuracy, safety (interpretation, decision support), workflow optimization (turnaround time, Lean, Six Sigma), automation (preanalytical automation, total laboratory automation, microbiology automation). A representative search string used in PMC was: ("clinical laboratory" OR "laboratory medicine") AND (turnaround time OR lean OR six sigma OR workflow OR automation OR "quality indicator" OR preanalytical OR "decision support" OR diagnostic accuracy)

Eligibility criteria

We include original research (randomized, quasi-experimental, before-after, cohort, or observational) with full text available in PMC. Clinical laboratory setting (chemistry, hematology, microbiology, core lab, emergency lab). Evaluated an intervention, system,

process related to quality, diagnostic accuracy, safety, or workflow, with measurable outcomes (e.g., TAT, error, rejection rates, quality indicators, safety, accuracy metrics).

We exclude reviews, commentaries, editorials (used only as background for Introduction, Discussion); pure analytic assay validation without workflow, quality system outcomes; non-clinical laboratory settings or non-English full text.

Study selection

Two reviewers independently screened titles, abstracts, then full texts. Disagreements were resolved by discussion.

Data extraction

We extracted: study design, setting, country, intervention, system, sample, timeframe, outcomes, and key findings (direction and reported magnitude).

Risk of bias appraisal

Given heterogeneous designs, risk of bias was assessed using design-appropriate tools: Before-after QI studies: NIH Before–After tool domains (selection, outcome measurement, confounding). Observational error, QI studies: JBI checklist domains. Diagnostic decision-support evaluation: cohort, diagnostic performance domains (selection, reference standard, outcome ascertainment). Overall, most workflow, QI studies were judged at moderate risk of bias, primarily due to nonrandomized designs and concurrent operational changes.

Synthesis

Meta-analysis was not performed because outcomes, metrics, and interventions were not sufficiently comparable across studies. Findings were synthesized narratively and summarized in tables.

RESULTS

Included studies

Ten original studies were included: three Lean, workflow redesign studies (9–11), four automation-focused studies (12–15), two quality-indicator, preanalytical error studies (16,17), and one diagnostic decision-support evaluation (18). Characteristics and main findings of included studies (Table 1)

In Lean-focused studies, workflow mapping and removal of non–value-added steps were associated with improved timeliness, particularly when interventions targeted specimen routing, batching, and handoffs (9–11). Cai et al. integrated real-time monitoring (“digital shadow”) with Lean Six Sigma and reported reduced intra-laboratory TAT (11).

Automation studies showed consistent improvements in speed and reliability. Preanalytical automation (tube sorting, registration) improved mean TAT and reduced operational waste indicators such as unrealized tests (12).

Table 1: Included original studies from PMC (n=10): design, domain, and key outcomes

Study (Year)	Country, Setting	Design	Domain	Intervention, System	Outcomes reported	Main finding
White et al. (2015)	ED laboratory workflow	Before–after QI	Workflow	Lean-based process changes in ED lab pathway	TAT metrics	Lean implementation associated with reduced TAT in an emergency laboratory setting (9).
Letelier et al. (2021)	Clinical lab (preanalytical + TAT focus)	Before–after	Workflow	Lean-based workflow optimization with time-segment analysis	Sample-to-result time segments	Reported reductions in selected time components and improvements in specific test TAT (10).
Cai et al. (2025)	Clinical lab	Before–after	Workflow	“Digital shadow” real-time monitoring integrated with Lean Six Sigma	Intra-lab TAT	Median intra-lab TAT decreased (e.g., from 77.2 to 69.0 minutes reported) (11).
Ucar et al. (2015, 2016 issue)	Core lab, Turkey	Before–after (12 months pre, post)	Automation	Automatic tube sorting & registration system	Mean TAT; rejected samples; unrealized tests	Mean TAT improved; rejected samples decreased 0.4%→0.2%; unrealized tests 4.5%→1.4% (12).
Kim et al. (2022)	Tertiary hospital lab, Korea	Retrospective pre, post	Automation , economics	Adoption of full TLA (vs subtotal automation)	Mean TAT, 99th percentile TAT, TAT CV, wTTM, payback	Mean TAT decreased 6.1%; 99th percentile decreased 13.3%; TAT CV decreased 70%; wTTM

						improved 77.6%; payback 4.75 years (13).
Song et al. (2018)	TLA upgrade sites, Korea, Japan	Pre, post	Automation	Fusion, upgrade of different TLA versions	Out-of-range TAT & prolonged out- of-range time	Mean prolonged out-of-acceptable TAT shortened (34.5→17.4 minutes) after fusion (14).
Cherkaoui et al. (2020)	Microbiology lab, Switzerland	Retrospective comparison	Automation (microbiology)	WASPLab automation with timed imaging	TAT for negative, positive culture reports	Negative-report TAT decreased markedly
Alshaghdali et al. (2021)	Hematology lab, Saudi Arabia	Retrospective (2017–2019)	Quality	IFCC-based preanalytical quality indicators	Error rates, QI performance	Used mandatory IFCC QIs to quantify preanalytical errors and identify improvement targets
Alcantara et al. (2022)	Clinical chemistry lab	Retrospective (2 years)	Quality	Preanalytical error surveillance	Error types and frequencies	Documented frequency and categories of preanalytical errors to guide corrective actions (17).
Szumilas et al. (2024)	Adults undergoing lab testing, Poland	Prospective cohort	Diagnostic accuracy, safety	AI-based LabTest Checker decision support for lab interpretation	Accuracy; sensitivity for urgent, emergency; potential visit reduction	Reported 74.3% accuracy; 100% sensitivity for emergency safety; 92.3% for urgent cases; potential reduction of unnecessary visits.

Full TLA implementation was associated with improved timeliness, fewer extreme delays (99th percentile), substantially improved predictability (TAT CV), and reduced manual handling burden (wTTM), with an estimated payback period under 5 years in one tertiary hospital analysis (13). TLA fusion, upgrade work suggested that targeted engineering changes can reduce prolonged out-of-range delays without necessarily changing the proportion of out-of-range samples (14). In microbiology, automated incubation, imaging workflows substantially shortened TAT for negative reports, while positive-report TAT remained constrained by operating hours and human resource workflows (15). Quality studies reinforced that preanalytical errors remain frequent and measurable using standardized quality indicators, supporting targeted training and system redesign (16,17). Finally, one prospective cohort evaluation of an AI decision-support system suggested that diagnostic interpretation support may improve safety-sensitive triage and reduce unnecessary visits, though this data base is still early (18).

DISCUSSION

This systematic review found convergent data that lean, process redesign, automation, and structured quality indicator programs are practical, measurable strategies to improve laboratory performance and safety. Lean-based approaches align with long-standing views that many laboratory delays arise from fragmented workflows and avoidable handoffs, not solely analyzer speed (1). Included Lean studies, improvements generally followed the classic pattern of mapping process segments, reducing batching, queues, and redesigning routing (9–11). The “digital shadow” model adds an important operational dimension: continuous visibility of bottlenecks can make Lean Six Sigma control phases more actionable (11).

Automation benefits were consistent with broader laboratory automation literature describing reduced manual variability, improved standardization, and fewer opportunities for handling error (1,6). Importantly, the microbiology automation study illustrated a nuanced reality: negative reporting can improve dramatically with automated imaging and standardized incubation reads, but positive results still depend on staffing patterns and operational hours—an insight echoed by microbiology automation overviews emphasizing workflow and human factors as constraints (7,15). Full TLA adoption improved not only mean TAT but also predictability (reduced TAT variability), which is operationally critical for clinical services relying on dependable time-to-result (13). The TLA fusion experience also suggests that “system design” decisions (track length, bidirectional vs unidirectional movement, module integration) can meaningfully affect prolonged delays (14).

Third, quality indicator frameworks remain central to improving the total testing process and reducing diagnostic risk. Reviews of laboratory error emphasize that failures often concentrate in pre- and post-analytical phases and can contribute to diagnostic error and patient harm (2, 3, 5, 8). Included QI-based studies operationalized this concept by quantifying error categories and benchmarking performance against established models (16, 17). QI dashboards can translate abstract quality requirements (e.g., ISO 15189

continual improvement) into measurable targets and training priorities (4, 16). Diagnostic accuracy and safety also depend on interpretation and decision-making around laboratory results. The included prospective cohort evaluation of an AI decision-support tool suggests potential for high safety sensitivity in urgent, emergency triage and meaningful reductions in unnecessary visits (18). However, consistent with diagnostic error frameworks, generalizability, reference standards, and integration into clinical pathways require further multi-site evaluation before wide adoption (2, 18).

LIMITATIONS

Most included workflow studies were nonrandomized and susceptible to confounding (e.g., concurrent staffing or instrumentation changes). Outcomes were heterogeneous (minutes vs hours, varied endpoints, different definitions of TAT), preventing meta-analysis. Restricting inclusion to PMC full text improves transparency but may omit relevant non-PMC studies.

CONCLUSION

Data from ten original PMC studies indicates that Lean-based redesign, laboratory automation, and quality-indicator surveillance can improve turnaround time, predictability, and error visibility in clinical laboratories. Microbiology automation particularly accelerates negative reporting, while positive-result timeliness remains dependent on staffing and operational hours. Early clinical data suggests AI decision-support for laboratory interpretation may enhance safety-sensitive triage, but broader validation is required before routine use.

List of abbreviations

AI, Artificial intelligence

CDSS, Clinical decision support system

CV, Coefficient of variation

ED, Emergency department

ESBL, Extended-spectrum beta-lactamase

IFCC WG-LEPS, International Federation of Clinical Chemistry and Laboratory Medicine

Working Group–Laboratory Errors and Patient Safety

ISO, International Organization for Standardization

KPI, Key performance indicator

LIS, Laboratory information system

MRSA, Methicillin-resistant *Staphylococcus aureus*

PMC, PubMed Central

PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses

QI, Quality indicator

TAT, Turnaround time

TLA, Total laboratory automation

VRE, Vancomycin-resistant enterococci

wTTM, Weighted tube touch moment

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