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REVIEW ARTICLE

REVIEW OF LABORATORY MANAGEMENT AND QUALITY IMPROVEMENT: CURRENT SCOPE, EMERGING TRENDS, AND FUTURE DIRECTIONS

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ABSTRACT: Clinical laboratories generate a substantial proportion of the data used in medical decision making. In the past, "quality" in the laboratory mostly meant instrument quality control but over the past decades the understanding has changed, and quality is now understood to span the total testing process, from pre-analytical phase to post-analytical phase. This review aims to describe where laboratory management and quality improvement stand today and what new trends are appearing and how they can be implemented in low- and middle-income countries (LMICs). This is a narrative review, and literature was gathered from peer-reviewed journals, systematic reviews, and guidance documents from bodies such as ISO, CAP, CLIA, WHO and IFCC. Modern laboratory quality management combines accreditation (ISO 15189, CAP, CLIA), quality indicators, internal quality control (IQC) and external quality assessment (EQA), risk management, and improvement tools like Lean and Six Sigma. Digital tools, including laboratory information systems, and artificial intelligence, are becoming more common but are not yet accessible to every part of the world, and the evidence for some of the newer technologies is still limited. Resource-limited settings face additional challenges, but programs like SLIPTA and SLMTA show that stepwise progress is possible even without full accreditation. Additionally, cybersecurity is becoming a bigger concern as laboratories become more digital. Laboratory quality management needs to emphasize especially in connecting quality measures to real patient outcomes, and in making sure new technologies are properly tested before wide use.

Keywords: Laboratory quality management; ISO 15189; quality indicators; external quality assessment; Six Sigma; artificial intelligence in laboratory medicine.

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INTRODUCTION:

Clinical laboratory testing influences a substantial proportion of medical decisions, even though they usually take up a small part of the overall healthcare budget [1,2]. For a long time, quality was perceived in terms of how precise and accurate the instruments were. Although important, it turned out to not be the whole story. Studies have shown that most errors in the laboratory take place before or after the analytical step itself; for example, when a sample is mislabeled or when a result is not communicated to the doctor quickly enough [3,4].

This wider way of thinking is usually called the "total testing process" (TTP), sometimes also called the "brain-to-brain loop," a term that has been used since it was first proposed by Lundberg and later expanded by Plebani and colleagues. This means that laboratory quality is thought to start when a doctor decides to order tests and end when that doctor uses the test results to make a decision, not just the part in between where the sample is physically tested [3].

This review examines the main topics in laboratory management: quality management systems, accreditation standards, quality indicators, quality control, risk management, improvement methods such as Lean and Six Sigma, staff and leadership issues, digital tools including AI, and some of the specific challenges faced in resource-limited settings. It also highlights where the evidence is still weak or where there is disagreement in the literature, rather than only listing what has been published. It aims to provide laboratory professionals with information about the current picture, emerging trends and future direction of laboratory management and quality improvement process.

EVOLUTION OF LABORATORY MANAGEMENT:

Quality Management Systems and Accreditation

From around the 1990s, laboratories started to adopt broader quality management ideas, often influenced by ISO 9001 and general "total quality management" thinking. This led to more structured, document-based quality systems, and eventually to the first international standard specifically for medical laboratories, ISO 15189, first published in 2003 and has been updated several times, most recently in 2022 [5,6].

Total Testing Process

Starting in the 2000s, there was a move toward thinking about quality across the whole testing process rather than only the analytical part. This period also saw the development of quality indicators to measure performance in the pre-analytical, analytical, and post-analytical phases [4].

Digital Transformation

More recently, especially since around 2015 and even more after the COVID-19 pandemic, laboratories have been adopting more digital tools: laboratory information systems with built-in decision support, automated testing lines, digital pathology, and some early use of machine learning for quality control and workflow planning [7,8].

PRINCIPLES OF LABORATORY QUALITY MANAGEMENT SYSTEMS (QMS):

A laboratory QMS is usually organized around a set of essential items like organization, personnel, equipment, purchasing, process control, documents and records, handling of nonconformances, internal assessments, process improvement, and facility/safety [9]. This gives laboratories a checklist to follow, although some authors have pointed out that this can end up encouraging a "tick-box" mentality rather than genuine improvement [10,11].

One issue that comes up in the literature is that having a documented QMS, or even being accredited, does not automatically mean a laboratory performs better in ways that matter to patients. Some studies suggest accredited laboratories do better on EQA performance or have less variation in turnaround time, but it is hard to know how much of this is really caused by accreditation itself, since laboratories that can

afford accreditation may already have more resources and better management to begin with [12,13].

A useful way to think about a QMS is to combine it with the plan-do-check-act (PDCA) cycle, so that each part of the QMS is not just written down once but is regularly reviewed and updated.

INTERNATIONAL STANDARDS AND ACCREDITATION: ISO 15189, CAP, CLIA:

ISO 15189

ISO 15189, "Medical laboratories — Requirements for quality and competence," is the main international standard used for laboratory accreditation, and it is used and referenced in most countries around the world. The most recent version, from 2022, is more closely aligned with other ISO standards and puts more emphasis on risk-based thinking, oversight of point-of-care testing, and information technology [6,14].

CAP and CLIA

In the United States, CLIA sets the basic legal requirements for laboratory testing, while CAP accreditation, based on detailed checklists, is generally considered to go beyond what CLIA requires [15].

Comparing the Standards

Table 1 gives a simple comparison between ISO 15189:2022, CAP, and CLIA. One important point is that all three of these frameworks were really designed with well-resourced health systems in mind and using them directly in a low-resource setting, without adapting them, has often been described as more of a barrier than a help, which is part of why stepwise accreditation models were developed (see Section *Quality Improvement in Resource-Limited Settings*) [6,16].

The table summarizes the key features of the three major laboratory quality and accreditation frameworks. ISO 15189:2022 provides an internationally recognized standard for competence and quality management in medical laboratories, CLIA establishes the minimum regulatory requirements for clinical laboratory testing in the United States and CAP accreditation offers a voluntary, peer-based accreditation program that exceeds CLIA requirements through more comprehensive quality and performance standards [16].

Table 1. Comparison of ISO 15189:2022, CAP accreditation, and CLIA.

Feature	ISO 15189:2022	CAP	CLIA
Governing body	National accreditation bodies (ISO-based)	College of American Pathologists	US Centers for Medicare & Medicaid Services
Geographic scope	International (70+ countries)	Primarily USA (and some international labs)	USA (federal minimum standard)
Nature	Voluntary international standard	Voluntary accreditation, deemed CLIA-compliant	Mandatory federal regulation
Update frequency	Major revisions every 5-10 years	Checklists updated annually	Amended periodically, less frequently
Prescriptiveness	Principle/risk-based requirements	Highly prescriptive discipline-specific checklists	Minimum performance standards
LMIC applicability	Used as reference; often needs adaptation	Limited direct applicability	Not applicable outside USA

QUALITY INDICATORS AND KEY PERFORMANCE INDICATORS:

The IFCC Working Group on Laboratory Errors and Patient Safety has developed a widely used set of quality indicators, covering things such as sample misidentification and hemolysis rates before testing, internal QC and EQA performance during testing, and turnaround time and critical value notification after testing. There is also a shared data platform that lets laboratories compare their own performance with others internationally [4,17].

One limitation that keeps coming up is that these indicators mostly measure the process, not the actual clinical outcome. There is a lack of strong evidence directly showing that improving a specific

quality indicator leads to fewer diagnostic delays or better patient outcomes [18]. Turnaround time is a good example of this problem: it is the KPI most laboratories report, because it is easy to measure, but it is less clear that pushing turnaround time down further, once it is already reasonably fast, changes outcomes for patients.

Quality indicators are useful for benchmarking between laboratories, but they mostly measure processes rather than outcomes; turnaround time gets more attention than its proven impact on outcomes may justify; more work is needed connecting indicators to real patient-level results.

INTERNAL QUALITY CONTROL AND EXTERNAL QUALITY ASSESSMENT:

Internal Quality Control

Internal quality control (IQC) is the main day-to-day safeguard for analytical quality. In recent years there has been more interest in individualized quality control plans and in adjusting how often QC is run based on how good the analytical performance already is (measured using sigma metrics), rather than using the same fixed QC schedule for every test [19,20].

External Quality Assessment / Proficiency Testing

External quality assessment (EQA), sometimes called proficiency testing, is an important independent check on a laboratory's performance and is usually required for accreditation. In many LMICs, access to EQA programs, and the cost and logistics of sending samples (some of which need to be kept cold) across borders, remain real obstacles. Regional programs (for example through WHO-AFRO or ASLM) have been set up partly to address this gap [21].

RISK MANAGEMENT AND PATIENT SAFETY:

ISO 15189:2022 now explicitly requires laboratories to use risk-based thinking. Common tools include failure mode and effects analysis (FMEA), used to try to predict where things might go wrong before they happen, and root cause analysis (RCA), used after an incident to understand what went wrong. ISO 22367 gives laboratory-specific guidance for applying general risk management principles [22,23].

LEAN, SIX SIGMA, LEAN SIX SIGMA, AND CONTINUOUS QUALITY IMPROVEMENT:

Six Sigma

Six Sigma is a way of measuring how good (or bad) an analytical process is, expressed as a "sigma value" based on bias, imprecision, and how much error is considered acceptable for that test. It has become a common way to benchmark analytical performance and to decide how often QC needs to be run [24]. One practical problem is that the sigma value calculated for the same test can be quite different depending on which source is used to define the acceptable amount of error, and there is not full agreement in the field on which source should be used [25].

Lean

Lean methods focus on removing steps in a process that do not add value, often using tools like value stream mapping to visualize where delays happen. This has been applied in laboratories to look at specimen flow and pre-analytical bottlenecks [26]. Several reviews suggest Lean and Six Sigma projects in laboratories generally have positive results on turnaround time and cost, but the underlying studies are often "before-and-after" designs without a proper comparison group, and follow-up periods tend to be short, so the results should probably be interpreted with some caution [27].

Lean Six Sigma

Lean Six Sigma combines the waste-reduction focus of Lean with the statistical approach of Six Sigma, usually organized through the DMAIC cycle (Define, Measure, Analyze, Improve, Control). The "control" step is meant to address a

common problem with Lean projects on their own, which is that improvements are made but then fade away once the project team moves on to something else [28].

Continuous Quality Improvement as a Culture

Beyond specific tools, many authors argue that continuous quality improvement (CQI) is more about organizational culture than about any one method, requiring leadership support, staff willingness to speak up, and reasonably good data systems. Laboratories that treat these methods as a single project, rather than an ongoing way of working, seem to have less lasting success [29].

LEADERSHIP, GOVERNANCE, WORKFORCE COMPETENCY, AND STAFF TRAINING:

ISO 15189:2022 has strengthened requirements around competency assessment, moving beyond just recording that someone attended a training session, toward actually checking that they can perform the task correctly [6].

A major challenge worldwide is a shortage of trained laboratory staff, which is worse in LMICs and in rural areas of high-income countries, and has been linked in survey studies to higher error rates and more staff burnout [30].

LABORATORY INFORMATION SYSTEMS, DIGITAL PATHOLOGY, AND LABORATORY AUTOMATION:

Laboratory Information Systems

Modern laboratory information systems (LIS), support functions such as auto verification (automatically releasing results that meet certain criteria without a person checking them first), specimen tracking. Auto verification can reduce turnaround time and cut down on manual review workload, and studies generally show it works well when the rules are properly validated, but if the rules are not set up carefully, errors can pass through undetected at a larger scale than before, which is an important reminder that automation changes the type of risk rather than removing it entirely [31].

Total Laboratory Automation

Total laboratory automation, where specimen transport, sorting, and testing are all connected in one automated line, has been shown to reduce certain pre-analytical errors, like misidentification and hemolysis, and to improve turnaround time, especially in high-volume laboratories. However, the cost and space needed for such system means it is mostly limited to larger laboratories, which raises a fairness question about smaller or rural laboratories being left behind [32]. This gap is especially pronounced in LMICs, where the capital investment, reliable electricity, and stable reagent supply chains that total automation requires are often unavailable, so most laboratories in these settings continue to rely on manual or semi-automated pre-analytical workflows even as automation becomes more common in well-resourced systems.

Digital Pathology

Digital pathology, using whole-slide scanning, has grown quickly. AI-assisted tools have received regulatory clearance in various countries, moving digital pathology from a "second opinion" tool toward being used for primary diagnosis in some places. Studies comparing digital and traditional glass-slide review generally show high agreement, often above 95%, although there are still occasional disagreements [33,34]. Digital pathology also brings new quality issues that older QMS frameworks were not built to handle, such as image quality control and scanner calibration [35].

Digital tools generally make laboratories more efficient and reduce some kinds of error, but they also create new kinds of risk (for example, related to software or scanner performance) that need their own quality oversight; larger, better-resourced laboratories are currently more likely to have access to these tools than smaller ones.

ARTIFICIAL INTELLIGENCE AND MACHINE LEARNING IN LABORATORY MANAGEMENT:

AI and machine learning are being explored in several areas of laboratory management improving quality control, predicting which samples are at higher risk of pre-analytical problems like hemolysis, helping with image analysis in digital pathology and microbiology, and forecasting operational needs like staffing or reagent supply [36].

There are also concerns about whether AI tools work equally well for all groups of patients, since much of the data used to build these models comes from limited or non-representative populations, and this issue has not yet been studied well in laboratory medicine [37]. Validating these tools for real-world use raises further practical challenges beyond initial accuracy testing. One is dataset drift: a model trained on historical data from a given patient population, analyzer platform, or reagent lot may perform less reliably once instrumentation or reference ranges change over time, so performance confirmed at deployment does not guarantee performance months or years later without ongoing monitoring and periodic re-validation. Algorithmic bias is a related concern; outside laboratory medicine, a widely cited health-management algorithm was found to systematically underestimate the needs of Black patients because it used healthcare cost, rather than illness burden as a proxy for need [37]. Comparable risks could arise in laboratory AI models if training data reflect unequal access to testing or historical inequities in care, and because many of these models function as "black boxes," such problems can be difficult to detect without deliberate, ongoing bias and drift monitoring rather than a single pre-deployment validation study.

QUALITY IMPROVEMENT IN RESOURCE-LIMITED SETTINGS:

Applying standards like ISO 15189 or CAP checklists directly in many LMIC laboratories can be difficult because of problems like unreliable electricity or water supply, limited cold storage, workforce shortages, and simply the cost of pursuing accreditation. This has led to the development of stepwise accreditation approaches instead of an all-or-nothing model. The Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA), developed with WHO and CDC support, uses a star rating system from zero to five stars instead of a simple pass/fail, and has been used widely across sub-Saharan Africa. Laboratories using this system have generally shown measurable improvement over repeated audits, which is fairly encouraging evidence that structured quality improvement can work even with limited resources [38]. The related Strengthening Laboratory Management Toward Accreditation (SLMTA) program provides mentorship-based training and has also been linked to improved SLIPTA scores in several countries.

REGULATORY, ETHICAL, AND CYBERSECURITY CONSIDERATIONS:

Rules around data protection differ a lot between countries, for example the GDPR in Europe compared with HIPAA in the United States, and this creates real practical difficulties for laboratories that operate across borders or use cloud-based systems for their LIS [39].

Cybersecurity has become a much bigger issue for laboratories in recent years, following several ransomware attacks on hospital and laboratory computer systems, some of which caused services to be disrupted for days or weeks, occasionally forcing laboratories to go back to paper-based reporting temporarily [40,41]. This is a clear example of how becoming more digital can also create new risks if cybersecurity is not properly invested in it. ISO 15189:2022 and related IT security guidance now expect laboratories to have documented business continuity and disaster recovery plans in case of an LIS failure, although how well this is implemented varies a lot, and smaller laboratories often do not have dedicated IT security staff [42]. Because cybersecurity incidents typically disrupt the same LIS pathways that carry samples and results through the total testing process, an attack does not only threaten data confidentiality: it can

directly generate pre-analytical errors, such as lost or mismatched specimen-patient linkage during a system outage, and post-analytical errors, such as delayed or missing result delivery to clinicians, so cybersecurity is increasingly a patient-safety and data-integrity issue as much as an information-technology one [40,41].

CHALLENGES IN IMPLEMENTING QUALITY IMPROVEMENT PROGRAMS:

Common barriers to implementing quality improvement include not enough engagement from leadership; competing priorities within the organization; poor data systems to actually measure indicators; staff shortages and turnover, which make it hard to keep institutional knowledge of past improvement work; financial limits, and a general feeling among staff that quality improvement is an external audit burden rather than something that adds value to their daily work [43]. Implementation science frameworks, such as the Consolidated Framework for Implementation Research, have started to be applied more often to laboratory quality work since 2020, giving a more structured way to understand why some quality projects succeed and others do not, though this is still a young area specifically for laboratory medicine [44].

Future Directions and Research Opportunities

Based on the current gaps, a few research priorities stand out, such as the need for more research directly linking quality indicators to patient outcomes, rather than only measuring process performance. AI and machine learning tools used in laboratories need more studies that test them prospectively, across multiple sites, and that check for bias, before they are considered fully evidence based. Additionally, more research is needed from LMIC settings to better understand the challenges to attaining full accreditation. More research, particularly on cybersecurity for laboratory information systems, is needed, given the vulnerability of information system to cyber-attacks. Overall, the field needs more solid evidence connecting what laboratories need to do to achieve outcomes that matter to patients.

CONCLUSION:

Laboratory management and quality improvement have grown from a narrow focus on analytical quality control into a much broader field that includes the whole testing process, international accreditation, workforce and leadership, digital systems, and artificial intelligence. However, the evidence base has not always kept up with this growth. There is still not enough research clearly linking quality indicators to patient outcomes, AI tools in the laboratory are mostly still in early testing stages, and LMIC quality improvement programs need more evidence. Going forward, it is probably more useful for the field to focus on closing these evidence gaps than on continuing to introduce new frameworks and technologies without first properly testing the ones already in use.

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