CODEN (USA): IJPB07 ISSN: 2320-9267

Indian Journal of Pharmaceutical and Biological Research (IJPBR)
Journal homepage: www.ijpbr.in

Research Article DOI: https://doi.org/10.30750/ijpbr.7.4.5

Emerging Approaches to Quality Management in Resource-Limited Clinical Laboratories: A Critical Review of Diagnostic Reliability and Patient Safety

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ARTICLE INFO:

Article history:
Received: 17 September 2019
Received in revised form:
22 November 2019
Accepted: 24 November 2019
Available online: 31 December 2019

Keywords:
Quality management system, resource-limited settings, laboratory accreditation, SLIPTA, SLMTA, Sigma metrics, external quality assessment, diagnostic reliability, patient safety, total testing process, conceptual model

Abstract

Clinical laboratories generate information that informs a large share of medical decisions, yet in low- and middle-income countries laboratory services have historically been underfunded, weakly regulated and poorly integrated into health systems. Unreliable results translate directly into misdiagnosis, inappropriate therapy and avoidable harm. This critical review examines the quality management approaches that have emerged for resource-limited clinical laboratories, appraises the evidence that they improve diagnostic reliability and patient safety, and identifies gaps that limit their impact. A structured critical narrative review of peer-reviewed literature, international standards and normative guidance published between 2000 and 2019 was undertaken, with emphasis on clinical biochemistry and general diagnostic laboratories in sub-Saharan Africa, South Asia and comparable settings, supplemented by a cross-disciplinary corpus on pharmaceutical traceability, industrial and aviation safety, process standardization, maintenance engineering, procurement, data governance and surveillance. Stepwise accreditation frameworks, notably the WHO Regional Office for Africa Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) and the Strengthening Laboratory Management Toward Accreditation (SLMTA) programme, have produced measurable gains in audit scores and a growing number of accredited facilities. Analytical tools adapted from high-income settings, including multirule internal quality control, Sigma metrics, risk-based quality control and patient-based real-time quality control, offer efficient ways to target scarce resources. However, the evidence base is dominated by process measures; few studies link quality interventions to patient outcomes. Pre-analytical and post-analytical phases, where most errors arise, remain under-monitored, and the rapid expansion of point-of-care testing has outpaced quality oversight. Sustainability is threatened by dependence on donor funding, equipment downtime, supply chain failures and workforce shortages. Quality management in resource-limited laboratories has progressed from aspiration to structured practice, but the field must now shift from checklist compliance to outcome-oriented, risk-based and nationally owned systems. Priorities include harmonized quality indicators across the total testing process, affordable external quality assessment, quality frameworks for decentralized testing and rigorous studies that measure effects on diagnostic accuracy and patient safety. An integrated conceptual model, the Integrated Laboratory Quality and Patient Safety (ILQPS) model, is proposed to link enabling foundations, quality management systems and testing process controls to diagnostic reliability and patient outcomes, with six testable propositions.

1. Introduction

Laboratory medicine underpins the diagnosis, staging, monitoring and screening of disease. In clinical biochemistry alone, measurements such as glucose, creatinine, electrolytes, liver enzymes and cardiac markers guide decisions that range from insulin dosing to renal drug adjustment and emergency triage. When these results are wrong, the error propagates silently into clinical care, and in many cases neither the clinician nor the patient is aware that the decision rested on an unreliable value (Bonini et al., 2002; Plebani, 2006).

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In resource-limited settings the problem is amplified. More than a decade ago, laboratory medicine in Africa was described as a barrier to effective health care, characterized by inadequate infrastructure, few trained personnel, unreliable supplies and little quality assurance (Petti et al., 2006). Clinicians who distrust laboratory results tend to treat empirically, which wastes resources, promotes antimicrobial resistance and delays correct diagnoses (Nkengasong et al., 2010; Petti et al., 2006). The 2018 *Lancet* series on pathology and laboratory medicine reinforced that the gap in access to quality-assured diagnostics remains one of the most neglected barriers to universal health coverage in low- and middle-income countries (Sayed et al., 2018; Wilson et al., 2018). A parallel body of health systems scholarship argues that scientific innovation fails to improve patient outcomes unless it is embedded in functioning delivery systems (Ilodigwe & Adesemoye, 2019b).

Over the past fifteen years, considerable investment, much of it initially linked to HIV, tuberculosis and malaria programmes, has driven the development of quality management approaches specifically designed for laboratories with limited resources (Alemnji et al., 2014; Nkengasong et al., 2010). Conceptual frameworks for sustainable diagnostic laboratory infrastructure and for diagnostic quality systems in resource-limited laboratories have been proposed, alongside reviews of health insurance financing and provider payment reform that shape how laboratory services are funded (Aminu-Ibrahim et al., 2018; Ilodigwe & Adesemoye, 2019a; Yusuf & Abdulrazaq, 2018). These include stepwise accreditation pathways, structured management training, adapted statistical quality control, novel external quality assessment models and early efforts to govern point-of-care testing. Their proliferation raises a critical question that has received comparatively little scrutiny: to what extent have these approaches actually improved the reliability of diagnostic results and the safety of patients, as opposed to improving documentation and audit performance?

This review addresses that question. It (i) summarizes the dimensions of the quality problem in resource-limited laboratories; (ii) describes and critically appraises the principal emerging approaches across the total testing process; (iii) examines the evidence linking those approaches to diagnostic reliability and patient safety; (iv) proposes an integrated conceptual model with testable propositions; and (v) sets out implications for practice and policy and an agenda for future research. Following this introduction, Section 2 describes the research method, Section 3 presents and discusses the results, including the conceptual model, implications, limitations and future research directions, and Section 4 concludes.

2. Research Method

2.1 Review Design

This study is a critical review, a review type that goes beyond description to evaluate the quality and meaning of the literature and to generate a new conceptual contribution (Grant & Booth, 2009). A critical narrative design was chosen rather than a systematic review with meta-analysis because the evidence on laboratory quality management in resource-limited settings is heterogeneous in design, setting and outcome, and because a central aim was conceptual integration. The reporting of the review was guided by the quality criteria for narrative reviews set out in the SANRA scale, namely justification of importance, explicit aims, description of the literature search, referencing, scientific reasoning and appropriate presentation of evidence (Baethge et al., 2019).

2.2 Information Sources and Search Strategy

Sources were identified through searches of PubMed/MEDLINE and African Journals Online, supplemented by hand-searching of the reference lists of key papers and by normative documents from the World Health Organization (WHO), the International Organization for Standardization (ISO), the Clinical and Laboratory Standards Institute (CLSI) and the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). Search terms combined concepts of laboratory quality (quality management system, accreditation, quality control, external quality assessment, proficiency testing, quality indicators, laboratory error, Sigma metrics) with setting descriptors (resource-limited, low- and middle-income countries, sub-Saharan Africa, developing countries).

Because laboratory quality management increasingly borrows from other regulated and high-reliability sectors, the search was supplemented by a curated cross-disciplinary seed corpus drawn from a consolidated peer reference list. Seed works were selected when they were directly related to laboratory diagnostics and health systems, or semi-related through transferable concepts: pharmaceutical traceability, aviation and industrial safety management, process standardization, audit and internal control, maintenance and reliability engineering, procurement, data protection and cybersecurity, workforce development and public health surveillance.

2.3 Eligibility Criteria

Eligibility criteria are summarized in Table 1. All sources were restricted to publications up to and including 2019, consistent with the timeframe of the review.

2.4 Selection and Data Extraction

Titles and abstracts were screened against the eligibility criteria, followed by full-text review of potentially relevant sources. For each included source, the following were extracted: setting and laboratory tier; quality approach or intervention; study design; phase of the total testing process addressed; and the level of outcome reported. Because the review is narrative and the corpus heterogeneous, no attempt was made to compute pooled numbers or effect sizes.

2.5 Appraisal and Synthesis

Evidence was appraised qualitatively for study design, risk of bias and transferability, and classified by a three-level outcome hierarchy: Level 1, process outcomes (audit scores, documentation, training completion); Level 2, analytical and service performance (EQA results, Sigma metrics, error rates, turnaround time, downtime); and Level 3, patient and health system outcomes (diagnostic accuracy in practice, adverse events, treatment decisions, surveillance quality). This hierarchy deliberately distinguishes evidence that an intervention changes laboratory processes from evidence that

it changes the accuracy of results or the safety of care, since conflating these is a recurring weakness of the literature.

Table 1: Eligibility criteria for the review

Criterion	Included	Excluded
Time frame	Published 2000 to 2019 (core); 2018 to 2019 for the cross-disciplinary seed corpus	Published after 2019
Setting	Clinical and public health laboratories in low- and middle-income or resource-limited settings; high-income evidence where it defines methods or standards	Research-only laboratories with no clinical reporting, unless methods were transferable
Topic	Quality management systems, accreditation, quality control, EQA, quality indicators, laboratory error, POCT quality, enabling conditions; transferable quality and safety concepts from other sectors	Purely technical assay development without a quality or safety dimension; unrelated sectors with no transferable concept
Source type	Peer-reviewed studies, reviews, conceptual frameworks, international standards and normative guidance	Opinion pieces without supporting reasoning, news items
Language	English	Other languages

Synthesis proceeded in two stages. First, a thematic synthesis organized the literature by system layer (enabling conditions, quality management system, testing process controls) and by phase of the total testing process (Sections 3.1 to 3.8). Second, the themes and the gaps identified in the appraisal were integrated into a conceptual model with explicit, testable propositions (Section 3.9). Cross-disciplinary seed sources were used to inform the model and to identify transferable approaches; many are conceptual frameworks rather than empirical studies and were weighted accordingly.

3. Results and Discussion

This section presents the results of the review and discusses them. Sections 3.1 to 3.8 synthesize the literature in eight themes, moving from the nature of the quality problem through the main families of quality approaches to the enabling conditions on which they depend, and ending with an appraisal of the evidence linking these approaches to diagnostic reliability and patient safety. Section 3.9 presents the conceptual model derived from the synthesis, Section 3.10 discusses the findings, and Sections 3.11 to 3.13 set out the implications, limitations and directions for future research.

3.1 The Quality Problem in Resource-limited Laboratories

3.1.1 Structural Constraints

The constraints faced by laboratories in resource-limited settings are interlocking. Many facilities operate with intermittent electricity and water, inadequate cold chains and buildings not designed for laboratory use (Petti et al., 2006; Wilson et al., 2018). Equipment is frequently donated without service contracts, spare parts or local technical support, and analyzers may remain non-functional for weeks or months (Fonjungo et al., 2012). Reagent stock-outs interrupt testing, and procurement of quality control and calibration materials is often deprioritized when budgets are tight (Elbireer et al., 2011; Nkengasong et al., 2009). Workforce shortages are severe, with low numbers of laboratory scientists and pathologists per capita, limited continuing education and high attrition (Sayed et al., 2018; Wilson et al., 2018).

The physical environment of the laboratory is itself a quality variable. Spatial planning influences specimen flow, contamination risk, safety and throughput, and therefore diagnostic accuracy (Ogbete et al., 2018). Molecular and pathology laboratories require regulatory-compliant design for controlled environments (Ogbete et al., 2019), and building envelope design must account for the heat and humidity typical of many tropical settings (Nwafor et al., 2018). Capital project delivery models for high-risk healthcare infrastructure, and analytical frameworks for efficient public infrastructure delivery, determine whether new facilities open on time and remain functional (Aminu-Ibrahim et al., 2019; Nwafor et al., 2019). Unreliable grid power, a frequent cause of analyzer failure and sample loss, can be mitigated through solar and hybrid installations, which have been modelled for small-scale facilities in Nigeria and other developing economies (Sunday & Omoegun, 2018, 2019).

Equipment weaknesses follow a similar pattern. Predictive maintenance and condition monitoring, together with reliability engineering and failure analysis, are well established in energy and engineering sectors but are rarely applied in public laboratories (Adaramola et al., 2018; Gideon et al., 2019). Workforce constraints, in turn, call for explicit competency frameworks, structured onboarding and deliberate talent development of the kind described for professional services and technology workforces in emerging markets (Ukadike, 2018; Wikiri, 2019).

These structural weaknesses are reflected in the accreditation landscape. A 2014 survey identified only a few hundred laboratories in sub-Saharan Africa meeting internationally recognized quality standards, and the large majority of them were located in South Africa (Schroeder & Amukele, 2014). For most countries in the region, accredited clinical laboratories numbered in single figures, often concentrated in research or donor-supported facilities rather than in the public hospitals that serve most patients (Alemnji et al., 2014; Schroeder & Amukele, 2014).

3.1.2 Errors Across the Total Testing Process

Modern thinking about laboratory quality is framed by the total testing process, which extends from the clinical decision to request a test through sample collection, transport, analysis, reporting and the interpretation of the result by the clinician (Lippi et al., 2010; Plebani, 2006). Studies from well-resourced laboratories have consistently shown that the analytical phase now accounts for a minority of errors, while the pre-analytical and post-analytical phases account for most (Table 2) (Bonini et al., 2002; Carraro & Plebani, 2007; Plebani, 2006).

Table 2: Approximate distribution of laboratory errors across the phases of the total testing process, as reported in studies from well-resourced laboratories

Phase	Share of errors	Typical error sources
Pre-analytical	About 46% to 68%	Inappropriate test request, patient misidentification, incorrect tube or container, haemolysed, clotted or insufficient samples, delayed or unrefrigerated transport
Analytical	About 7% to 13%	Equipment malfunction, calibration error, undetected quality control failure, reagent deterioration, interference
Post-analytical	About 18% to 47%	Transcription error, delayed or lost reports, failure to communicate critical results, misinterpretation by the clinician

Ranges summarized from Plebani (2006), with consistent patterns reported by Carraro & Plebani (2007) and Bonini et al. (2002). Equivalent systematic data from resource-limited laboratories are scarce.

It would be a mistake to assume that this distribution transfers unchanged to resource-limited laboratories. Where internal quality control is irregular, reagents are stored improperly and instruments are poorly maintained, analytical error is likely to contribute a substantially larger share than in high-income laboratories (Amukele et al., 2012; Petti et al., 2006). At the same time, pre-analytical risks are intensified by long specimen transport distances, ambient temperatures, manual patient identification and handwritten request forms (Lippi et al., 2011). Integrated laboratory information systems have been proposed to improve the accuracy of infection detection, illustrating the gains available when the whole process is managed rather than the analyzer alone (Abdulrazaq et al., 2019). The practical consequence is that resource-limited laboratories must manage elevated risk in every phase simultaneously, with fewer resources than any other type of laboratory. Any credible quality management approach must therefore prioritize, and the remaining sections evaluate how well emerging approaches do so.

3.2 Systems-level Approaches: Standards and Stepwise Accreditation

3.2.1 ISO 15189 and the WHO Laboratory Quality Management System

ISO 15189 specifies requirements for quality and competence in medical laboratories and is the reference standard for accreditation worldwide (International Organization for Standardization, 2012). Its comprehensiveness is both a strength and a barrier: for a laboratory starting from a low baseline, direct preparation for ISO 15189 can appear unattainable. To bridge this gap, WHO, together with the US Centers for Disease Control and Prevention and CLSI, developed the Laboratory Quality Management System (LQMS) handbook, organized around twelve quality system essentials: organization; personnel; equipment; purchasing and inventory; process control; information management; documents and records; occurrence management; assessment; process improvement; customer service; and facilities and safety (World Health Organization, 2011). The LQMS translates the standard into practical, teachable components and has become the common vocabulary of quality training in many low- and middle-income countries.

3.2.2 SLIPTA: Stepwise Recognition

The WHO Regional Office for Africa launched SLIPTA to provide a graduated route toward accreditation (Gershy-Damet et al., 2010). Laboratories are audited against a checklist derived from ISO 15189 and are awarded between zero and five stars according to their score. The stepwise design acknowledges incremental progress, provides motivation and allows ministries of health to benchmark laboratories nationally (Gershy-Damet et al., 2010; Ndihokubwayo et al., 2016). Implementation reports describe expansion across many African countries and an increasing number of laboratories achieving star ratings (Ndihokubwayo et al., 2016).

A critical appraisal of SLIPTA raised important concerns, including variation in how auditors interpret checklist items, the absence of a clear institutional home for sustained programme management and the risk that a star system becomes an end in itself rather than a means to accreditation (Datema et al., 2012). Because the checklist weights documentation heavily, a laboratory can, in principle, gain points through written procedures and records without commensurate improvement in the accuracy of the results it produces. This does not invalidate the approach, since documentation is a precondition for control, but it means that star ratings should not be read as direct measures of diagnostic reliability.

3.2.3 SLMTA: Management Training for Change

SLMTA is a competency-based, task-oriented programme that pairs short workshops with improvement projects carried out at the bench, followed by audits to track progress (Yao et al., 2010, 2014). Its distinctive contribution is the recognition that quality failures in resource-limited laboratories are often failures of management (organization of work, inventory

control, supervision) rather than of technical knowledge. Reviews of the SLMTA literature report substantial and consistent improvements in SLIPTA audit scores across participating countries and laboratories, together with documented improvements in specific areas such as inventory management, turnaround time and customer satisfaction (Luman et al., 2014; Yao et al., 2014).

Mentorship appears to be a key active ingredient. Laboratories that received structured on-site mentorship in addition to training achieved greater improvements than those receiving training alone (Maruta et al., 2012). Single-site experiences, including the implementation of a quality management system in a Nigerian reference laboratory, illustrate both the feasibility of the approach and the sustained commitment it requires from leadership (Audu et al., 2012).

3.2.4 Critical Appraisal of Systems-level Approaches

Three limitations temper the enthusiasm generated by SLIPTA and SLMTA. First, most published evaluations use before-and-after designs without control groups, and many are authored by programme implementers, which raises the risk of both secular-trend confounding and reporting bias (Datema et al., 2012; Luman et al., 2014). Second, the dominant outcome measure is the audit score, a process indicator. Although audit scores plausibly correlate with result quality, very few studies have measured analytical performance (for example, external quality assessment scores or Sigma metrics) or clinical outcomes before and after implementation (Peter et al., 2010). Third, sustainability after external support ends is poorly documented. Reports of laboratories that lose star levels after funding or mentorship withdrawal underscore that these approaches have not yet been fully absorbed into national budgets and regulatory frameworks (Alemnji et al., 2014; Nkengasong et al., 2009).

Accreditation is associated with benefits for patient care and health systems in the conceptual and descriptive literature (Peter et al., 2010), but the causal chain from a higher audit score to fewer misdiagnoses has rarely been tested. Closing this evidential gap is arguably the single most important research need in the field.

Work from outside the laboratory sector sharpens this critique. Standard operating procedures function as change infrastructure only when they are actively maintained and linked to performance, not merely written for an audit (Agboada et al., 2019). Procedural standardization and workflow optimization in high-volume service clinics, and maturity models for standardizing support operations across distributed sites, show how consistent processes can be scaled (Anyanwu, 2019; Uchechi et al., 2018). Technology-enabled and risk-based internal audit and internal control models, together with integrated governance and compliance strategies, offer ways to make laboratory audits more discriminating and less dependent on individual auditor judgement (Akomolafe & Agu, 2018, 2019a, 2019b).

3.2.5 Lessons From Other Regulated Quality Systems

Pharmaceutical distribution operates under quality regimes conceptually close to ISO 15189, and frameworks for traceability and chain-of-custody integrity in pharmaceutical distribution translate directly to specimen and result traceability in the laboratory (Aneke & Adesemoye, 2019). Aviation offers a further model: adaptive safety management systems have been designed for aerodromes in developing economies, and predictive compliance monitoring has been used to detect systemic safety risks from routine reports (Adeyelu, 2018, 2019). Both sectors combine mandatory standards with risk-based oversight and graded implementation, which is precisely the balance that stepwise laboratory accreditation seeks to achieve.

Lean and Six Sigma methods, discussed in Section 3.3 for analytical quality, also have a wider role in process redesign (Gras & Philippe, 2007). Reviews of digital transformation in operations management describe how automation, analytics and process redesign reduce cycle time and variation, problems that correspond closely to laboratory turnaround time and specimen handling (Agboada et al., 2018). Sustaining such gains depends on maintained standard operating procedures and on standardized workflows (Agboada et al., 2019; Uchechi et al., 2018).

3.3 Analytical Quality: Adapting Statistical Tools to Scarcity

3.3.1 Internal Quality Control and Multirule Procedures

Internal quality control (IQC) remains the foundation of analytical reliability. The multirule approach described by Westgard and colleagues combines control rules such as 1-3s, 2-2s, R-4s and 4-1s to increase error detection while limiting false rejection (Westgard et al., 1981). In resource-limited laboratories, however, the binding constraint is often not knowledge of the rules but access to control materials, their cost, their stability under local storage conditions and the time needed to plot and interpret charts manually. A laboratory that runs a single control level once a day on an analyzer used for hundreds of samples is accepting a large, unquantified risk.

The emerging response is not to abandon IQC but to design it rationally, so that the frequency, number of levels and choice of rules reflect the actual performance of each method and the clinical consequences of error.

3.3.2 Analytical Performance Specifications

Rational QC design requires a definition of how good a method needs to be. The 2014 Milan Strategic Conference of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) established three models for setting analytical performance specifications: those based on the effect of analytical performance on clinical outcomes; those based on components of biological variation; and those based on the state of the art (Ceriotti et al., 2017; Sandberg et al., 2015). Biological variation data, long promoted as a practical basis for quality goals (Fraser, 2001), are particularly relevant for clinical biochemistry. For resource-limited settings, the Milan framework is useful because it allows laboratories to justify fit-for-purpose goals explicitly, rather than adopting regulatory limits from other jurisdictions without examination.

A critical caveat is that most biological variation and outcome data derive from populations in high-income countries, and their transferability to populations with different disease burdens, nutritional status and genetic backgrounds has not been well studied.

3.3.3 Sigma Metrics

Six Sigma methodology, adapted for the laboratory, expresses method performance on a single scale: Sigma = (TEa − |bias|) / CV, where TEa is the allowable total error, bias is the systematic error and CV is the imprecision, all in percentage units (Gras & Philippe, 2007; Westgard & Westgard, 2006). Methods performing at six Sigma or above can be controlled with simple rules and few control measurements, whereas methods below three Sigma are unreliable and require extensive control or replacement (Westgard & Westgard, 2006; Westgard et al., 2018).

This approach is arguably more valuable in resource-limited laboratories than in well-funded ones. By identifying which assays are robust and which are fragile, the laboratory can concentrate scarce control materials, staff time and troubleshooting effort where risk is highest. It also generates objective evidence for procurement decisions and for negotiations with suppliers. The limitations are practical: Sigma calculations require reliable estimates of bias, which in turn depend on access to external quality assessment or reference materials, and on stable imprecision data, which depend on consistent IQC. In laboratories where these inputs are weak, Sigma metrics can create a false impression of precision. Reliability engineering practice, which links failure analysis to targeted corrective design, suggests that Sigma assessment is most useful when it is coupled with explicit analysis of the controllable causes of poor performance (Gideon et al., 2019).

3.3.4 Risk-based Quality Control

CLSI guideline EP23-A introduced quality control based on risk management, in which the laboratory identifies failure modes for each test system, estimates their likelihood and severity and designs a control plan that mitigates the most important risks (Clinical and Laboratory Standards Institute, 2011). Risk-based approaches are attractive for resource-limited settings because they make explicit the hazards that are locally prominent, such as power fluctuation, reagent exposure to heat or operator turnover, and because they integrate manufacturer-built controls with conventional IQC. The weakness is that a risk assessment is only as good as the competence of those performing it, and without structured training and templates it can degenerate into a paper exercise.

High-hazard industries offer well-developed tools for making risk assessment real. Systematic use of near-miss and hazard observation data, and data-driven occupational risk control, allow failures to be detected before they cause harm (Arumosoye & Obriki, 2019; Obriki & Arumosoye, 2018). Systematic reviews of hazard identification and risk control, and risk governance models for settings with many contractors, show how responsibility for risk can be distributed and audited (Obogo et al., 2019b, 2019c). Safety culture research shows that visible leadership and management walkthroughs change frontline practice (Obogo et al., 2019a; Obriki & Arumosoye, 2019), and frameworks for operational integrity show how productivity and safety compliance can be balanced, a familiar tension in busy laboratories (Nwangwu et al., 2018). Risk-based process engineering and risk-based inspection in gas and offshore infrastructure provide structured templates for laboratory failure mode analysis (Asibor & Isong, 2019; Obetta, 2018).

3.3.5 Patient-based Real-time Quality Control

Patient-based real-time quality control (PBRTQC) uses the results of patient samples themselves, through moving averages, moving medians or related algorithms, to detect shifts in analytical performance continuously (Badrick et al., 2019). Its appeal for resource-limited laboratories is evident: it requires no purchased control material, operates on every run and can detect errors that occur between scheduled IQC events. A 2019 review and set of recommendations from an IFCC working group clarified how PBRTQC should be configured and validated (Badrick et al., 2019). The approach does have prerequisites that many resource-limited laboratories do not yet meet, including adequate daily test volumes for stable averages, a laboratory information system or middleware capable of computing the statistics, and staff able to interpret alarms. It is therefore best seen as a complementary tool for higher-volume reference and hospital laboratories rather than a universal replacement for IQC.

PBRTQC belongs to a broader movement toward data-driven quality surveillance. Data-driven executive decision systems and ETL and data integration architectures illustrate the information infrastructure such tools require (Badmus et al., 2019a; Lawal & Oduleye, 2019), and automated log analytics with structured incident response, developed for security operations, provides a model for handling quality alarms consistently (Mbonu et al., 2019b).

3.4 External Quality Assessment: Access, Affordability and Scope

External quality assessment (EQA), or proficiency testing, provides an independent check of accuracy and is a requirement for accreditation (International Organization for Standardization, 2012). In resource-limited settings, participation has been constrained by cost, by the logistics of shipping stable materials across borders and by delays in feedback. Where participation has been studied, performance has been variable; a review of clinical research laboratories in sub-Saharan Africa showed that even well-supported laboratories experienced unsatisfactory results, highlighting the need for sustained monitoring and corrective action (Amukele et al., 2012).

Several emerging models seek to improve access. Regional and national EQA providers reduce shipping costs and align challenge materials with locally relevant analytes. Inter-laboratory comparison and split-sample exchange between nearby laboratories offer low-cost alternatives where formal schemes are unavailable, although they provide weaker evidence of trueness. Programmes that use dried or lyophilized specimens improve stability during transport. Each of these offers a pragmatic route forward, but their commutability (the degree to which EQA materials behave like real patient samples) is often unverified, which complicates the interpretation of bias.

A further and important development is the extension of EQA beyond the analytical phase to include pre-analytical and post-analytical performance, for example through assessment of sample acceptability decisions, report interpretation or result

communication (Badrick et al., 2017). Given the error distribution discussed earlier, this broader scope is highly relevant to patient safety and deserves adaptation for resource-limited laboratories.

3.5 Beyond the Analyzer: Pre-analytical and Post-analytical Quality

3.5.1 Quality Indicators

The IFCC Working Group on Laboratory Errors and Patient Safety developed a model of harmonized quality indicators covering all phases of the total testing process, with the aim of allowing laboratories to measure and benchmark error rates in a consistent way (Plebani et al., 2014; Sciacovelli & Plebani, 2009). Indicators include the proportion of misidentified samples, haemolysed or clotted samples, samples with insufficient volume, turnaround time compliance and timely notification of critical values (Plebani, 2012; Shahangian & Snyder, 2009). Their adoption in resource-limited laboratories remains limited, partly because data collection is manual and partly because quality programmes have concentrated on audit checklists rather than on measured error rates.

A selective, feasible set of indicators, collected with simple tally sheets or basic spreadsheet tools, would allow resource-limited laboratories to identify their dominant error sources and to monitor the effect of interventions. A proposed core set is shown in Table 3. Indicator design can draw on established reviews of laboratory quality indicators (Shahangian & Snyder, 2009) and on safety management systems in aviation, which use routine data to detect systemic risk before harm occurs (Adeyelu, 2018, 2019).

Table 3: A proposed minimum set of quality indicators for resource-limited clinical laboratories

Phase	Indicator	Rationale for priority
Pre-analytical	Percentage of requests with incomplete patient identification or clinical information	Misidentification is a direct and severe patient safety hazard
Pre-analytical	Percentage of samples rejected (haemolysis, clotting, wrong container, insufficient volume)	Captures collection and transport failures, especially for clinical biochemistry
Pre-analytical	Percentage of samples received outside defined transport time or temperature limits	Long transport distances and heat are typical of resource-limited settings
Analytical	Percentage of IQC runs performed as scheduled and percentage of runs rejected	Measures whether analytical control is actually happening
Analytical	EQA performance (percentage of acceptable results) and corrective action closure	Independent indicator of accuracy
Analytical	Equipment downtime (days per analyzer per quarter) and reagent stock-out days	Structural causes of testing interruption and unreliable results
Post-analytical	Turnaround time compliance for priority tests	Delays compromise clinical decision-making
Post-analytical	Percentage of critical results communicated and documented within a defined time	Failure to act on critical values causes avoidable harm
Post-analytical	Percentage of reports with transcription errors on audit	Manual transcription remains common

Indicator definitions should be aligned with the IFCC model (Plebani et al., 2014; Sciacovelli & Plebani, 2009) to allow future benchmarking.

3.5.2 Specimen Collection and Transport

Sample quality is a principal determinant of result reliability in clinical biochemistry, with haemolysis, inappropriate anticoagulant use and delayed separation among the most common causes of spurious results (Lippi et al., 2011, 2019). In resource-limited settings, specimen referral networks that move samples from peripheral facilities to central laboratories have become an important quality intervention in their own right. Innovative transport options, including motorcycle courier networks and, experimentally, unmanned aerial vehicles, have been explored; a 2015 study found that common chemistry and haematology analytes were not meaningfully affected by drone transport, supporting further evaluation (Amukele et al., 2015). Frameworks for integrating unmanned aerial vehicles into national inspection programmes, and reviews of UAV methods and challenges, though developed for power grids, address the regulatory and operational issues that drone-based specimen transport will face (Dagodzo, 2018a, 2018b). Traceability and chain-of-custody frameworks from pharmaceutical distribution provide a ready model for specimen referral systems (Aneke & Adesemoye, 2019). The critical point is that transport systems are rarely evaluated for their effect on sample integrity under local temperature and time conditions, and the quality benefit should not be assumed.

3.5.3 Reporting and Communication

Post-analytical errors, such as transcription mistakes, lost reports and failure to communicate critical values, are less visible but no less dangerous (Plebani, 2006). Laboratory information systems reduce transcription errors and support audit trails, but their adoption is limited by cost, power reliability and technical support. Lower-cost interventions, including standardized report templates, critical value call logs and electronic or SMS-based result delivery to peripheral sites, are increasingly reported, but rigorous evaluations of their effect on time to treatment or on errors are uncommon. Integrated laboratory information systems can improve

detection accuracy and support audit trails (Abdulrazaq et al., 2019), and governance frameworks for platform management in regulated healthcare environments show how such systems can be administered safely (Badmus et al., 2019b).

3.5.4 Data Governance, Cybersecurity and Information Integrity

As laboratories digitize, the integrity, confidentiality and availability of results become patient safety issues in their own right. Legal and ethical risk modelling for enterprise data protection, and comparative reviews of data protection regulation and secure cloud implementation, provide the policy scaffolding for exchanging laboratory data (Mbonu et al., 2018, 2019a). Secure cloud architectures and identity and access management for distributed and federated systems address the reality that laboratories increasingly share data with peripheral sites and programmes (Ahmed & Odejobi, 2018; Oshoba et al., 2019).

The threat environment is real. Insider threat models, security audit and enterprise risk assessment frameworks, and risk-based cybersecurity assurance focused on data availability describe risks that could take a laboratory information system offline or corrupt its records (Akeju et al., 2018; Dosunmu & Ogundele, 2019; Fadayomi et al., 2019). Automated log analytics and incident response architectures offer practical ways to monitor these systems (Mbonu et al., 2019b).

3.6 Decentralized and Point-of-care Testing

Point-of-care testing (POCT) has expanded rapidly in resource-limited settings, driven by rapid diagnostic tests for malaria and HIV, glucometers, haemoglobin meters and, increasingly, portable chemistry analyzers (Pai et al., 2012; Peeling & Mabey, 2010). POCT brings testing closer to patients and can shorten the time to treatment, but it also moves testing outside the controlled environment of the laboratory and into the hands of operators who often have little laboratory training (Engel et al., 2015; Pai et al., 2012).

The quality challenges are well characterized: lack of IQC, variable storage of test kits, inadequate operator training and supervision, poor documentation and weak links between POCT results and patient records (Engel et al., 2015; Pai et al., 2012). Qualitative research in India illustrated that barriers to effective POCT extend beyond the device to include workflow, trust, regulatory oversight and the fit with clinical practice (Engel et al., 2015). Emerging approaches include national POCT policies that assign oversight responsibility to a supervising laboratory, operator certification, simplified EQA panels for rapid tests and connected devices that transmit results and QC data to central databases. Automated diagnostic image analysis, such as template-matching detection of architectural distortion in mammograms, illustrates how automated and decentralized diagnostics are expanding faster than their quality frameworks (Ejofodomi et al., 2014). Offline-first design for digital tools in low-connectivity environments is relevant to POCT data capture and operator training (Unamma et al., 2018). The evidence base for these approaches is at an early stage, and the governance of POCT is, in this author's assessment, the area in which quality management is most clearly lagging behind service expansion.

3.7 Enabling Conditions: Infrastructure, Supply, Workforce and Governance

Quality management systems cannot compensate for absent infrastructure. Equipment maintenance has been identified as a critical bottleneck, with analyzers frequently out of service because of lack of preventive maintenance, spare parts or trained engineers (Fonjungo et al., 2012). Strategies such as equipment harmonization across a national network, reagent rental agreements that bundle service and consumables, and regional biomedical engineering capacity have been proposed to address this problem (Elbireer et al., 2011; Fonjungo et al., 2012). Predictive maintenance and condition monitoring, condition-based maintenance concepts and reliability and integrity management reviews from energy infrastructure offer transferable methods for keeping analyzers in service (Adaramola et al., 2018; Obetta & Ninduwezuor-Ehiobu, 2018; Obetta, 2019). Models linking inventory availability to plant uptime address the same problem from the supply side (Okonkwo et al., 2018b).

3.7.1 Supply Chains for Reagents and Consumables

Reliable testing requires reliable supply. Supply chain risk management models, strategic procurement optimization and cost reduction through contract negotiation and vendor governance, although developed for oil, gas and engineering projects, are directly relevant to the management of reagents and control materials (Agbabiaka et al., 2019; Okonkwo et al., 2018a, 2019). Laboratory networks face the same risks of single-supplier dependence, long lead times and weak inventory visibility (Fonjungo et al., 2012; Nkengasong et al., 2009), and traceability frameworks from pharmaceutical distribution show how supply integrity can be assured end to end (Aneke & Adesemoye, 2019).

3.7.2 Infrastructure Governance and Financing

Capital project delivery models for high-risk healthcare infrastructure, and frameworks for efficient public infrastructure delivery, are emerging tools for planning laboratory networks (Aminu-Ibrahim et al., 2019; Nwafor et al., 2019). On the financing side, health insurance financing and provider payment reform determine how laboratory services are paid for and whether quality investments can be sustained (Ilodigwe & Adesemoye, 2019a), and the persistent gap between scientific innovation and patient outcomes is often a gap in delivery systems rather than in technology (Ilodigwe & Adesemoye, 2019b).

At the governance level, national laboratory policies and strategic plans establish the institutional basis for quality, define tiered networks and allocate responsibility for regulation and accreditation (Nkengasong et al., 2009). The 2008 Maputo Declaration called on governments to develop such policies and to strengthen laboratory systems (Nkengasong et al., 2010). Subsequent progress has been substantial in some countries but uneven across the region (Alemnji et al., 2014). Workforce development, including pre-service curricula that embed quality management and career pathways that retain trained staff, is a further prerequisite (Sayed et al., 2018). Lessons from research laboratories, where good clinical laboratory practice frameworks have been implemented with external support, show that high standards

are achievable in resource-limited settings, but also that they are expensive to maintain (Ezzelle et al., 2008).

3.7.3 Workforce Competence and Education

Competency frameworks and redesigned onboarding, and conceptual frameworks for talent development in emerging markets, can be adapted to laboratory staffing (Ukadike, 2018; Wikiri, 2019). Gamification in talent and performance management has been associated with lower attrition and greater engagement, which matters where trained staff are scarce (Ukadike, 2019). Industry-academia collaboration for modernizing technical learning centres is relevant to the training of laboratory scientists (Nwangwu et al., 2019), and offline-first digital learning supports training where connectivity is poor (Unamma et al., 2018).

3.7.4 Laboratories Within Surveillance Systems

Laboratory quality has consequences beyond the individual patient. The quality of surveillance data is limited by the quality of the laboratory data feeding it, as an evaluation of integrated disease surveillance and DHIS2 data quality in Benue State, Nigeria showed (Ekemezie et al., 2018). Outbreak detection, disease surveillance and antimicrobial resistance monitoring all presuppose reliable laboratory confirmation (Nkengasong et al., 2010; Petti et al., 2006).

3.8 Synthesis of Evidence: Linking Quality Management to Diagnostic Reliability and Patient Safety

The central question of this review is whether emerging quality approaches make results more reliable and patients safer. Table 4 summarizes a critical appraisal of the main approaches against this standard.

Table 4: Critical appraisal of emerging quality management approaches in resource-limited clinical laboratories

Approach	Main mechanism	Strength of evidence	Resource demand	Principal gap
SLIPTA	Graded audit and recognition	Moderate for process improvement; weak for outcomes	Moderate (auditors, travel)	Audit variability; scores not linked to result accuracy
SLMTA with mentorship	Management training and bench-level projects	Moderate for audit scores; limited for analytical and clinical outcomes	Moderate to high (trainers, mentors)	Sustainability after external support ends
ISO 15189 accreditation	Comprehensive external assessment	Strong as a benchmark; limited outcome studies in these settings	High	Cost and access for most public laboratories
Rational IQC design and Sigma metrics	Fit-for-purpose analytical control	Strong methodologically; few field studies in these settings	Low to moderate	Requires reliable bias and imprecision data
Risk-based QC (EP23)	Local failure mode analysis	Limited empirical evidence	Low to moderate	Depends on staff competence; risk of paper exercise
PBRTQC	Continuous monitoring with patient data	Emerging	Low materials cost; needs IT	Volume and information system prerequisites
Regional and alternative EQA	Independent accuracy check	Moderate	Low to moderate	Commutability; feedback delay
Quality indicators (IFCC model)	Measurement of errors across all phases	Strong conceptually; little use in these settings	Low	Manual data collection; little benchmarking
POCT governance	Oversight of decentralized testing	Weak; early stage	Moderate	Fragmented responsibility; operator competence
Lean Six Sigma process redesign	Waste and variation reduction across workflow	Moderate in other sectors; limited in laboratories	Low to moderate	Sustaining gains; change management
Industrial safety and incident learning	Near-miss reporting, human factors, safety culture	Strong in other sectors; untested in laboratories	Low	Blame culture; under-reporting
Health informatics and data governance	Integrity, security and flow of results	Mostly conceptual	Moderate to high	Cyber risk; interoperability; power and connectivity

Approach	Main mechanism	Strength of evidence	Resource demand	Principal gap
Supply chain and maintenance analytics	Predicting stock-outs and downtime	Moderate in other sectors	Moderate	Data availability; procurement rules

Strength of evidence refers to evidence from resource-limited settings that the approach improves laboratory processes, analytical performance or patient outcomes, as appraised in this review.

Direct evidence of clinical benefit exists mostly in a narrow form: studies showing that the availability of reliable laboratory testing improves diagnosis and treatment outcomes, for example in primary health care facilities in East Africa (Carter et al., 2012). Such studies demonstrate that reliable testing matters, but they do not isolate the specific contribution of quality management interventions. The more general argument that accreditation improves patient care rests on plausible mechanisms and descriptive evidence rather than controlled comparisons (Peter et al., 2010).

3.9 Conceptual Model

The synthesis suggests that the literature lacks an integrating framework that explains how investments in laboratory quality translate, or fail to translate, into reliable results and safer care. Existing frameworks either describe the components of a quality management system (International Organization for Standardization, 2012; World Health Organization, 2011) or the phases of the testing process (Lippi et al., 2010; Plebani, 2006), but rarely connect them to the enabling conditions on one side and to patient outcomes on the other. Building on the total testing process concept, the twelve quality system essentials, the diagnostic quality systems framework for resource-limited laboratories (Yusuf & Abdulrazaq, 2018) and the systems view that innovation fails without functioning delivery systems (Ilodigwe & Adesemoye, 2019b), this review proposes the Integrated Laboratory Quality and Patient Safety (ILQPS) model (Figure 1).

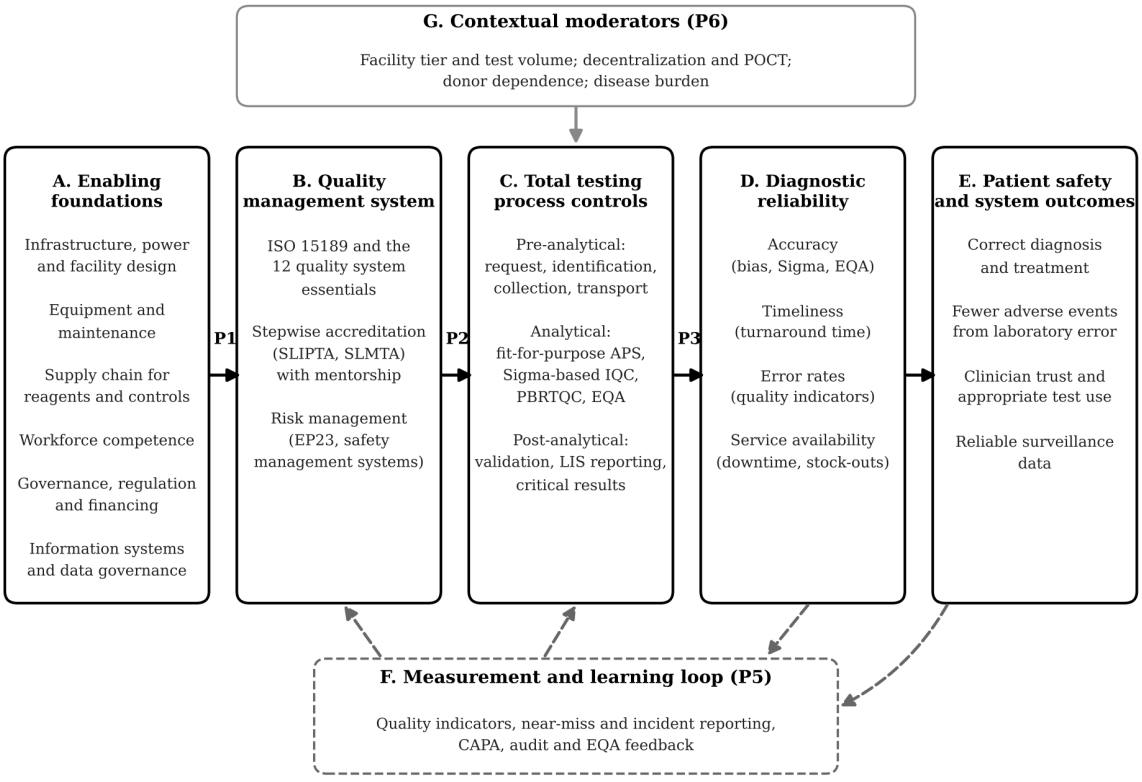


Figure 1: The Integrated Laboratory Quality and Patient Safety (ILQPS) model. Solid arrows show the hypothesized causal pathway; dashed arrows show the measurement and learning loop; P1 to P6 denote the propositions described in Section 3.9.2.

3.9.1 Model Constructs

The model has five sequential constructs, a feedback loop and a set of contextual moderators (Table 5). **Enabling foundations (A)** are the physical, material, human, financial and informational inputs without which no quality system can function: infrastructure and power, equipment and its maintenance, supply of reagents and controls, workforce competence, governance and financing, and information systems with data governance (Adaramola et al., 2018; Agbabiaka et al., 2019; Aminu-Ibrahim et al., 2018; Fonjungo et al., 2012; Nkengasong et al., 2009). The **quality management system (B)** comprises the organizational structures that standardize and control work, represented by ISO 15189 and the twelve quality system essentials, stepwise

accreditation with mentorship, and formal risk management (Clinical and Laboratory Standards Institute, 2011; Gershy-Damet et al., 2010; International Organization for Standardization, 2012; World Health Organization, 2011; Yao et al., 2014). **Total testing process controls (C)** are the specific operational controls applied in each phase of testing, from request and specimen transport through analytical control to validation, reporting and critical result communication (Plebani, 2006; Sciacovelli & Plebani, 2009; Westgard et al., 2018).

Diagnostic reliability (D) is the intermediate outcome: results that are accurate, timely, error-free and available when needed, measured through EQA performance, Sigma metrics, quality indicators, turnaround time and service availability (Plebani et al., 2014; Shahangian & Snyder, 2009; Westgard & Westgard, 2006). **Patient safety and system outcomes (E)** are the final outcomes: correct diagnosis and treatment, fewer adverse events attributable to laboratory error, appropriate clinician trust and test use, and reliable surveillance data (Carter et al., 2012; Ekemezie et al., 2018; Petti et al., 2006). The **measurement and learning loop (F)** captures how information on reliability and outcomes is fed back, through quality indicators, near-miss and incident reporting, corrective action, audit and EQA feedback, to strengthen the quality system and process controls (Akomolafe & Agu, 2018; Arumosoye & Obriki, 2019; Badrick et al., 2017). **Contextual moderators (G)**, including facility tier and test volume, decentralization and point-of-care testing, donor dependence and disease burden, condition the strength of each link (Alemnji et al., 2014; Badrick et al., 2019; Pai et al., 2012).

Table 5: Constructs of the ILQPS model, example indicators and principal supporting literature

Construct	Components	Example indicators	Principal sources
A. Enabling foundations	Infrastructure and power; equipment and maintenance; supply chain; workforce; governance and financing; information systems	Analyzer downtime; stock-out days; staff competency assessment; budget line for quality	(Adaramola et al., 2018; Agbabiaka et al., 2019; Aminu-Ibrahim et al., 2018; Fonjungo et al., 2012; Ilodigwe & Adesemoye, 2019a; Nkengasong et al., 2009; Ogbete et al., 2018; Ukadike, 2018)
B. Quality management system	ISO 15189 and LQMS essentials; SLIPTA and SLMTA; risk management	SLIPTA star level; accreditation status; documented risk assessments	(Agboada et al., 2019; Clinical and Laboratory Standards Institute, 2011; Gershy-Damet et al., 2010; International Organization for Standardization, 2012; World Health Organization, 2011; Yao et al., 2014)
C. Testing process controls	Pre-analytical controls; analytical QC and EQA; post-analytical reporting controls	IQC runs performed as scheduled; sample rejection rate; critical value call log completion	(Abdulrazaq et al., 2019; Badrick et al., 2019; Plebani, 2006; Sciacovelli & Plebani, 2009; Westgard et al., 2018)
D. Diagnostic reliability	Accuracy; timeliness; error rates; availability	EQA acceptable results; Sigma per assay; turnaround time compliance; error rates per phase	(Amukele et al., 2012; Plebani et al., 2014; Shahangian & Snyder, 2009; Westgard & Westgard, 2006)
E. Patient safety and system outcomes	Correct diagnosis and treatment; adverse events; clinician trust; surveillance quality	Laboratory-related incidents; treatment changes after result correction; surveillance data quality	(Carter et al., 2012; Ekemezie et al., 2018; Peter et al., 2010)
F. Measurement and learning loop	Quality indicators; incident and near-miss reporting; CAPA; audit; EQA feedback	Near-miss reports per month; corrective actions closed on time	(Akomolafe & Agu, 2018; Arumosoye & Obriki, 2019; Badrick et al., 2017; Obriki & Arumosoye, 2019)

Construct	Components	Example indicators	Principal sources
G. Contextual moderators	Facility tier and volume; decentralization; donor dependence; disease burden	Tests per day; share of tests done at point of care; donor share of quality budget	(Alemnji et al., 2014; Pai et al., 2012; Schroeder & Amukele, 2014)

3.9.2 Propositions

The model generates six propositions that can be tested empirically:

- **P1 (foundations as necessary conditions).** Quality management interventions produce sustained gains only where enabling foundations meet a minimum threshold; without reliable power, functioning equipment, supply and trained staff, audit score improvements will not be sustained (Adaramola et al., 2018; Alemnji et al., 2014; Fonjungo et al., 2012; Sunday & Omoegun, 2018).
- **P2 (mediation through process controls).** The effect of a stronger quality management system on diagnostic reliability is mediated by the operational controls actually applied in each phase of testing; audit scores that are not accompanied by measurable process controls will show weak association with reliability (Agboada et al., 2019; Datema et al., 2012; Peter et al., 2010).
- **P3 (phase weighting).** In resource-limited laboratories, the largest reliability gains per unit of resource come from basic pre-analytical and analytical controls (specimen integrity, routine IQC, maintenance) before advanced tools are introduced (Lippi et al., 2011; Plebani, 2006; Westgard et al., 1981).
- **P4 (risk-proportionate control).** Analytical control designed on the basis of performance specifications and Sigma metrics yields greater reliability per unit of resource than uniform QC applied to all assays (Clinical and Laboratory Standards Institute, 2011; Sandberg et al., 2015; Westgard et al., 2018).
- **P5 (learning loop and sustainability).** Laboratories that routinely measure quality indicators and act on near-miss and incident reports sustain improvements longer than those relying on periodic external audit alone (Arumosoye & Obriki, 2019; Obriki & Arumosoye, 2019; Sciacovelli & Plebani, 2009).
- **P6 (contextual moderation).** Decentralization to point-of-care testing weakens the link between the laboratory quality system and diagnostic reliability unless governance, training and EQA are explicitly extended to decentralized sites; low test volume limits the applicability of data-driven QC such as PBRTQC (Badrick et al., 2019; Engel et al., 2015; Pai et al., 2012).

3.9.3 Use of the Model

The ILQPS model is intended to serve three purposes. For laboratory managers, it provides a diagnostic map for locating the weakest link in their own system, for example a laboratory with a high SLIPTA score but frequent analyzer downtime has a foundation problem, not a documentation problem. For programme designers and policymakers, it shows which indicators should accompany audit scores if quality programmes are to be judged by their effect on results. For researchers, the propositions offer a structure for studies that measure several links of the causal chain at once, which the literature has so far rarely done.

3.10 Discussion of Findings

This critical review set out to determine whether emerging approaches to quality management in resource-limited clinical laboratories improve diagnostic reliability and patient safety. The principal finding is that the field has made substantial and well-documented progress at the level of systems and processes, but that evidence at the level of analytical performance and patient outcomes remains thin. Stepwise accreditation, management training with mentorship and the adaptation of modern quality control methods have demonstrated that internationally recognized standards are attainable in settings with limited resources (Luman et al., 2014; Ndihokubwayo et al., 2016; Yao et al., 2014). What has not been demonstrated with comparable rigour is that these gains translate into more accurate results, fewer laboratory-related adverse events and better clinical decisions (Datema et al., 2012; Peter et al., 2010).

Three observations follow. First, the field has relied on a chain of inference (better systems lead to better processes, which lead to better results, which lead to better care) whose links have rarely been measured together. Second, the most patient-relevant phases of the testing process, pre-analytical and post-analytical, are those least covered by routine quality measurement in resource-limited laboratories. Third, the outcomes that matter for patient safety, such as misdiagnosis rates, adverse events attributable to laboratory error and delays in treatment, are seldom measured at all. These gaps do not mean the approaches are ineffective; they mean that their effectiveness has not been convincingly demonstrated, which weakens the case for sustained domestic investment.

Viewed through the ILQPS model, the literature has concentrated on construct B, the quality management system, and to a lesser extent on construct C, while constructs A, D and E are comparatively neglected. This imbalance matters. Where enabling foundations are weak, quality systems can become documentation exercises that satisfy auditors without changing the reliability of results; frequent equipment failure, power interruption and stock-outs are recurrent themes in the literature on resource-limited laboratories (Adaramola et al., 2018; Elbireer et al., 2011; Fonjungo et al., 2012). Conversely, the cross-disciplinary literature shows that sectors with mature safety performance, such as aviation and high-hazard industry, combine standards with continuous measurement of leading indicators, near-miss reporting and visible leadership, which together form the learning loop (construct F) that most laboratory programmes lack (Adeyelu, 2019; Arumosoye & Obriki, 2019; Obogo et al., 2019a; Obriki & Arumosoye, 2019).

A second tension concerns the sequencing of technical sophistication. Tools such as Sigma metrics, risk-based QC and patient-based real-time quality control are genuinely

valuable for allocating scarce resources (Badrick et al., 2019; Clinical and Laboratory Standards Institute, 2011; Westgard et al., 2018), but each depends on data and infrastructure that many laboratories do not yet have. The model suggests that their adoption should follow, rather than precede, the consolidation of basic pre-analytical control, routine IQC and equipment maintenance (P3). This is not an argument against innovation, but for sequencing it in a way that protects patients during the transition.

A third tension concerns ownership and sustainability. The rapid spread of SLIPTA and SLMTA owed much to external funding and technical support (Alemnji et al., 2014; Yao et al., 2014). Health financing arrangements and provider payment systems determine whether quality becomes a funded function of the health system or remains a project (Ilodigwe & Adesemoye, 2019a; Nkengasong et al., 2009). Finally, the expansion of point-of-care testing and digital reporting widens the boundary of the laboratory and introduces new risks, including operator variability and threats to data integrity and availability, that current quality systems were not designed to manage (Dosunmu & Ogundele, 2019; Engel et al., 2015; Fadayomi et al., 2019; Pai et al., 2012).

3.11 Implications

3.11.1 Implications for Laboratory Practice

- **Measure the whole testing process.** Laboratories should adopt a small, harmonized set of quality indicators across all phases, such as that proposed in Table 3 and aligned with the IFCC model, and review them monthly (Plebani et al., 2014; Sciacovelli & Plebani, 2009).
- **Design analytical QC rationally.** Laboratories should define analytical performance specifications using the Milan framework, calculate Sigma metrics where data allow and adjust QC frequency and rules accordingly, directing scarce resources to the least robust methods (Sandberg et al., 2015; Westgard et al., 2018).
- **Build a learning loop.** Near-miss and incident reporting, root-cause analysis and timely corrective action should be routine, supported by leadership walkthroughs and a non-punitive culture (Arumosoye & Obriki, 2019; Obogo et al., 2019a; Obriki & Arumosoye, 2019).
- **Treat maintenance and data governance as quality functions.** Preventive maintenance schedules, power backup, and policies for data protection, access control and security audit should be included in the quality manual (Adaramola et al., 2018; Dosunmu & Ogundele, 2019; Mbonu et al., 2018; Oshoba et al., 2019; Sunday & Omoegun, 2018).

3.11.2 Implications for Policy and Health Systems

- **Shift accreditation from compliance to outcomes.** Stepwise programmes should report analytical performance (EQA results, Sigma metrics) and patient-relevant indicators alongside audit scores (Datema et al., 2012; Peter et al., 2010).
- **Secure the enabling conditions.** Ministries and funders should treat equipment service, supply chain reliability, power and workforce retention as part of laboratory quality investment (Agbabiaka et al., 2019; Fonjungo et al., 2012; Nkengasong et al., 2009; Ukadike, 2019).
- **Expand affordable EQA and govern point-of-care testing.** Regional EQA schemes with commutable materials and timely feedback, and national POCT policies that designate supervising laboratories and require operator training, should be prioritized (Badrick et al., 2017; Pai et al., 2012).
- **Build national ownership and financing.** Quality programmes should transition from donor-funded projects to budgeted government functions with regulatory backing, and national surveillance programmes should require quality-assured laboratory confirmation (Alemnji et al., 2014; Ekemezie et al., 2018; Ilodigwe & Adesemoye, 2019a; Sayed et al., 2018).

3.11.3 Theoretical Implications

The ILQPS model reframes laboratory quality management from a set of compliance requirements into a causal system with inputs, structures, processes, intermediate outcomes and final outcomes, linked by feedback. This framing aligns laboratory quality with established structure-process-outcome thinking in health care quality and with safety management theory in high-reliability sectors (Adeyelu, 2019; Arumosoye & Obriki, 2019), and it makes explicit the assumptions that current programmes leave implicit. It also positions diagnostic reliability as a distinct construct that can be measured and that mediates between laboratory systems and patient safety.

3.12 Limitations

The literature is dominated by programme reports, single-site experiences and uncontrolled before-and-after studies. Publication bias is likely, since successful implementations are more readily reported than failures. Settings vary greatly, from national reference laboratories with external support to district hospital laboratories with a single technician, which limits generalizability. Much of the published experience comes from sub-Saharan Africa and from programmes linked to HIV and tuberculosis, which may not represent clinical biochemistry services or other regions. This review is narrative and did not involve formal quality scoring of included studies or quantitative synthesis; its conclusions should be read as a structured critical interpretation rather than a pooled estimate of effect. The cross-disciplinary seed literature extends the conceptual reach of the review, but much of it consists of conceptual frameworks and narrative reviews, many drawn from adjacent sectors; it has been used to suggest transferable approaches, not as evidence of effect in clinical laboratories.

3.13 Future Research

The gaps identified in this review, and the propositions of the ILQPS model, point to a focused research agenda (Table 6). The overarching priority is to move from studies that measure a single link, usually the effect of an intervention on audit scores, to studies that measure the full chain from enabling conditions through quality systems and process controls to diagnostic reliability and patient outcomes.

Methodologically, future work should use the three-level outcome hierarchy described in Section 2.5 of the research method, report Level 2 and Level 3 outcomes wherever feasible, include cost and sustainability measures, and be designed and led by national institutions to strengthen local

ownership of the evidence. Validation of the ILQPS model itself, through structural equation modelling across a sample of laboratories or through comparative case studies, would test whether the hypothesized pathways hold in practice.

Table 6: Priority questions for future research

Research question	Suggested design	Key outcome measures
Do gains in SLIPTA scores translate into better analytical performance and fewer laboratory errors? (P2)	Controlled interrupted time series or stepped-wedge rollout across laboratories	EQA performance, Sigma metrics, quality indicator error rates
What minimum level of enabling foundations is needed for quality gains to be sustained? (P1)	Longitudinal cohort of laboratories with repeated audits after funding ends	Retention of star levels; downtime; stock-out days
Does Sigma-based or risk-based QC improve reliability at lower cost than uniform QC? (P4)	Pragmatic comparative study with cost-effectiveness analysis	Error detection, false rejection, cost per reportable result
Is PBRTQC feasible and effective in mid-volume African hospital laboratories? (P6)	Simulation using local patient data followed by prospective validation	Time to error detection; alarm burden
Do near-miss reporting and leadership walkthroughs reduce pre- and post-analytical errors? (P5)	Cluster-randomized trial of a learning-loop intervention	Reported near misses; sample rejection; critical value communication
How should POCT governance be organized to protect result quality? (P6)	Mixed-methods implementation research	POCT EQA performance; operator competency; result documentation
What is the effect of laboratory quality on patient outcomes and surveillance data? (whole model)	Linked laboratory and clinical record studies; surveillance data audits	Diagnostic accuracy in practice; adverse events; surveillance completeness and validity

4. Conclusion

Quality management in resource-limited clinical laboratories has advanced considerably. Stepwise accreditation, management training with mentorship and the adaptation of modern quality tools have shown that internationally recognized standards are attainable even where resources are scarce. Yet the evidence for these approaches largely concerns processes rather than the reliability of results or the safety of patients. The next phase of development should focus on measuring what matters across the whole testing process, applying risk-based and data-driven analytical control, extending quality oversight to decentralized testing and embedding quality within nationally owned and financed systems. Only by closing the gap between checklist performance and demonstrable diagnostic reliability can laboratory quality management fully deliver on its promise to patients.

Declarations

Conflict of interest: The author(s) declare no conflict of interest.

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Cite this article: **Nnamdi Eneh, Kazeem Abdulrazaq, Habeeb Damilola Yusuf, Olatunde Adesoji Aladegba.** Emerging Approaches to Quality Management in Resource-Limited Clinical Laboratories: A Critical Review of Diagnostic Reliability and Patient Safety. **Indian J. Pharm. Biol. Res.2019; 7(4):26-44.**

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