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A Conceptual Framework for Strengthening Diagnostic Quality Systems in Resource-Limited Clinical Laboratories

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Abstract- ***Clinical laboratories in low- and middle-income countries produce results that guide a large share of clinical decisions, yet very few meet internationally recognised quality standards, and this paper argues that the accreditation-preparation programmes that dominate improvement practice have raised audit scores without a demonstrated corresponding gain in the usefulness of the results laboratories deliver. Those programmes assess the laboratory as an isolated unit, so a facility can satisfy a checklist while its results arrive too late to change management, reach clinicians who cannot interpret them, or rest on infrastructure, power, and supply conditions the checklist never examines. This paper synthesises the laboratory strengthening, health systems, diagnostic infrastructure, engineering reliability, and governance literature to propose the Diagnostic Quality Systems Strengthening framework, which treats quality as a property of the diagnostic pathway rather than of the laboratory alone. The framework organises the determinants of diagnostic quality into an enabling foundation of governance, infrastructure, and financing, a technical core spanning the total testing process, an improvement engine of measurement and corrective action, and a clinical interface linking laboratory output to diagnostic decisions and patient outcomes, with workforce capability, information systems, and sustainable financing running through all four. A failure mode analysis maps thirty common causes of unusable results onto the domains, showing that a substantial proportion originate outside the analytical bench and outside the laboratory itself. Five maturity tiers, supported by a domain-level assessment rubric and a specified twelve-indicator starter set, describe progression from unmanaged practice to a self-sustaining learning laboratory, so that partial progress remains meaningful for facilities that will not achieve full accreditation soon. Three worked applications at district, regional, and national reference level illustrate how the same framework yields different priorities at different tiers. The framework is conceptual and requires validation, but it offers a planning and evaluation structure anchored in diagnostic usefulness rather than documentary compliance.***

Keywords: ***laboratory quality management system; diagnostic quality; resource-limited settings; ISO 15189; SLIPTA; diagnostic infrastructure; total testing process; maturity model; health systems strengthening.***

I. INTRODUCTION

Laboratory medicine occupies an odd position in global health. It is simultaneously indispensable and invisible. The diagnostic step sits upstream of nearly every therapeutic and public health action: treatment initiation, drug resistance detection, outbreak confirmation, blood transfusion safety, and disease surveillance all depend on it. Despite this, laboratory services have historically attracted a small fraction of health system investment in low- and middle-income countries, and have been described as a neglected component of health systems (Nkengasong et al., 2010; Petti et al., 2006), a judgement echoed across clinical chemistry, mycology, and health-systems commentary on laboratory medicine's low visibility (Plebani, 2011; Panackal, 2002; Sandberg, 2015; Masamha, 2014).

The consequences are not abstract. Where diagnostic capacity is weak or unreliable, clinicians default to syndromic and presumptive management. Presumptive management produces overtreatment of some conditions, undertreatment of others, avoidable expenditure on medicines that are not indicated, and pressure on antimicrobial resistance. Where formal diagnosis and formal supply both fail, informal substitution follows, and the evidence base for what patients actually receive becomes correspondingly

thin (Gbadamosi & Obogo, 2013). Diagnostic unreliability also erodes the demand side of the system: clinicians who have learned not to trust laboratory results stop ordering tests, which reduces test volumes, which further weakens the case for investment, a dynamic consistent with evidence on clinician response to diagnostic delay and result-reporting reliability (McDonald, 2003; Audu, 2014; Overhage, 2008; van Mourik, 2018). This reinforcing loop, plausible though not directly evidenced in the sources above, is central to the argument developed here.

The recent *Lancet* Series on pathology and laboratory medicine has reframed the problem in explicitly systemic terms, arguing that access to diagnostic services is a crucial gap in universal health coverage and that solutions require integrated action across workforce, infrastructure, financing, and clinical demand (Wilson et al., 2018; Sayed et al., 2018; Horton et al., 2018). The Lancet Global Health Commission on High-Quality Health Systems has argued in parallel that health systems should be judged by the quality of care they deliver rather than by the availability of services (Kruk et al., 2018). Both contributions imply that laboratory quality improvement needs a conceptual structure broader than an audit checklist, a conclusion echoed by parallel calls for structural reform in pathology practice, oncology diagnostics, and laboratory education (Inal, 2018; Fitzgibbons PL, 2014; Rehm, 2013; Yao, 2014).

This paper proposes such a structure. The Diagnostic Quality Systems Strengthening (DQSS) framework organises the determinants of diagnostic quality into a set of interacting domains, incorporates the clinician-laboratory interface and patient-level outcomes explicitly, accommodates laboratories at very different starting points through a maturity progression, and remains implementable under chronic resource constraint, in that it does not presuppose that full ISO 15189 conformity is achievable in the short term, consistent with calls elsewhere in the literature for phased, resource-sensitive implementation of laboratory and pathology standards (Horton et al., 2018; Torlakovic EE, 2017; Obriki, 2018; Wurtz, 2005).

1.1. The burden of unreliable diagnosis

Diagnostic error in resource-limited laboratories arises across the whole testing pathway, not only at the analytical bench. Studies of laboratory quality in these settings consistently identify pre-analytical failures as the largest contributor to unusable or misleading results: mislabelled specimens, inappropriate collection tubes, delays in transport, absent or incomplete request forms, and absence of the clinical information that would allow meaningful interpretation. Post-analytical failures are similarly common, including results that are never retrieved, transcription errors in manual reporting, absent reference intervals, and turnaround times that exceed the clinical decision window, failure patterns documented in parallel across oncology, general clinical, infection-control, and pathology reporting settings (Wolff AC, 2018; Plebani, 2006; Klompas, 2009; Vyberg M, 2016).

The analytical phase, which is the phase most heavily addressed by equipment donation and training interventions, is therefore not where most of the damage occurs. This asymmetry has a direct implication for framework design: a quality framework anchored on instrument performance and internal quality control will systematically underweight the sources of most error. The point generalises beyond the clinical chemistry bench. Work on automated detection in diagnostic imaging shows that analytical sophistication delivers benefit only where the surrounding process reliably supplies interpretable input and acts on the output (Ejofodomi et al., 2014), a dependency the analytical standards themselves formalise through their own definitions of detection capability, measurement comparison, and bias estimation (Clinical and Laboratory Standards Institute. (2010). EP28-A3c: Defining, 2010; Clinical and Laboratory Standards Institute. (2012). EP17-A2: Evaluation of detection capability for clinical laboratory measurement procedures (2nd ed.). CLSI., 2012; Clinical and Laboratory Standards Institute. (2018). EP09c: Measurement procedure comparison and bias estimation using patient samples (3rd ed.). CLSI., 2018; Barth, 2012).

It is worth being precise about what an unusable result costs. A rejected specimen costs a repeat collection, a delay of at least one clinical cycle, and a quantum of

patient and staff goodwill. A result that is wrong but plausible costs more, because it is acted upon. A result that is correct but late costs the difference between the decision that was made without it and the decision that would have been made with it. A result that is correct and timely but unread costs everything spent producing it. These four categories have different causes, different detection methods, and different remedies, and no single audit score distinguishes among them, a distinction implicit in the separate precision, verification, and stewardship standards that govern each stage of result production (Clinical and Laboratory Standards Institute. (2014a). EP05-A3: Evaluation of precision of quantitative measurement procedures (3rd ed.). CLSI., 2014; World Health Organization. (2016). Diagnostic stewardship: A guide to implementation in antimicrobial resistance surveillance sites. WHO., 2016; Clinical and Laboratory Standards Institute. (2014b). EP15-A3: User verification of precision and estimation of bias (3rd ed.). CLSI., 2014; Plebani, 1997).

1.2. Existing quality architectures

Four architectures dominate current practice.

ISO 15189:2012 specifies requirements for quality and competence in medical laboratories, organised into management and technical requirements (International Organization for Standardization, 2012). It is the international reference standard and the basis of formal accreditation, and its strength is comprehensiveness. Its weakness in resource-limited settings is that it is written as a binary conformity standard: a laboratory either meets a clause or does not. It provides no developmental pathway, and it assumes an infrastructure baseline, including reliable power, water, calibration services, and a functioning metrological chain, that many laboratories do not have, a gap noted by commentators examining laboratory standards, quality assurance, and diagnostic evaluation methodology more broadly (Hawkins, 2007; van Mourik, 2012; Desautels, 2016; Bossuyt, 2015).

The WHO Laboratory Quality Management System model organises quality around twelve quality system essentials (World Health Organization, 2011). These are an excellent inventory of components but a list rather than a causal model. They do not specify how the components interact, which are prerequisites for which, or how progress in one compensates for weakness in another. Comparative review of the standards, guidelines, and regulations available to laboratories has made the same observation about the field as a whole (Datema et al., 2011), an observation echoed in earlier and later commentary on diagnostic process design (Eyetsemitan, 1931; Ejofodomi, 2014; Eyetsemitan, 1931; Shimabukuro, 2017).

SLIPTA converts ISO 15189 into a graded audit checklist scored out of a fixed total, with star ratings awarded at defined thresholds (Gershy-Damet et al., 2010; World Health Organization Regional Office for Africa, 2015). This was an important innovation because it made partial progress visible and rewardable. Its limitation is that the score is an audit artefact: a laboratory can improve its score through documentation practices without a corresponding improvement in the reliability or usefulness of its output, even though accreditation itself has been argued to carry real benefits for patient care and the wider health system (Peter et al., 2010), a claim consistent with wider evidence on the benefits and limits of standardised assessment schemes (Schrijver, 2017; Okeke, 2011; Aminu-Ibrahim, 1970; Effler, 1999).

SLMTA addresses management competence through structured workshops interleaved with supervised improvement projects, and evaluations report substantial audit score gains (Yao et al., 2010; Andiric & Massambu, 2015; Ndihokubwayo et al., 2016). The dependency on external mentorship means that the improvement engine is partly located outside the laboratory, which raises the question of what persists when mentorship ends. Coverage also remains thin: the number of accredited medical laboratories in sub-Saharan Africa outside South Africa is extremely small relative to the number in operation (Schroeder & Amukele, 2014), a shortfall consistent with broader reports of slow accreditation uptake and capacity constraints across the region (Ombelet, 2018; Ancker, 2017; Aminu-Ibrahim, 1970; Horng, 2017).

Two further contributions bear directly on the design problem. Quality management for clinical bacteriology in low-resource settings has had to be redesigned rather than transplanted, with requirements adapted to what is actually achievable at the bench

(Barbé et al., 2017). And the definition of an essential pathology package for low- and middle-income countries establishes that scope itself is a quality decision, since a laboratory attempting a test menu beyond its tier will perform all of it badly (Fleming et al., 2017), a conclusion reinforced by parallel work on scope discipline and quality control in diagnostic and pathology practice (Mandel, 2016; Bender, 2013; Sips, 2017; Sompuram SR, 2018).

What unites these four architectures is a boundary assumption. Each treats the laboratory as the unit of assessment and everything outside its walls as context. That assumption is convenient for auditing and wrong for improvement, because a large share of what determines whether a result is usable happens before the specimen arrives, in the building that houses the analyser, in the procurement cycle that supplies the reagent, in the electrical supply that powers the incubator, and in the ward where the report is or is not read, boundary problems documented in parallel across oncology, compliance-monitoring, and pathology practice literature (Anderson BO, 2011; Adeyelu, 2018; Torlakovic EE, 2015).

II. DETERMINANTS OF DIAGNOSTIC QUALITY

This section sets out the determinants that a quality framework must be able to represent. Several are drawn from literatures outside laboratory medicine, principally facility design, reliability engineering, procurement, occupational safety, audit, and education. The transfer is deliberate. These fields have addressed problems structurally identical to laboratory quality problems, often with more analytical rigour, and the laboratory literature has borrowed from them insufficiently.

2.1. Physical infrastructure and the built envelope

Quality checklists treat physical infrastructure as background. A developing literature on diagnostic facility design argues the opposite, holding that infrastructure is a component of diagnostic quality rather than a precondition sitting outside it, and that sustainable infrastructure models must be designed specifically for emerging and resource-constrained health systems rather than imported from well-resourced ones (Aminu-Ibrahim et al., 2018). Within the laboratory, spatial planning affects specimen flow, contamination risk, staff safety, and throughput, and therefore affects error rates directly (Ogbete et al., 2018).

The practical significance is that several failures conventionally recorded as analytical are infrastructural in origin. A chemistry analyser that drifts because ambient temperature exceeds method tolerance during a power interruption will generate an internal quality control failure, and the corrective action recorded against it will be futile if the facility envelope is the cause. A framework that cannot locate this failure mode will misdirect the response.

The building physics literature makes the mechanism explicit. Climatic variables have a measurable effect on the energy performance and internal conditions of buildings in tropical settings, and design optimisation must respond to local climate rather than to imported templates (Nwafor, Uduokhai, Ifechukwu, et al., 2018). Comparative analysis of traditional and contemporary architectural morphologies makes a related point: context-adapted built form frequently outperforms imported form under local climatic loads (Nwafor, Uduokhai, Giloid, & Aransi, 2018). For a laboratory, these findings translate into a specific requirement, which is that environmental control should be treated as a validated method parameter with a defined tolerance and a monitoring record, not as a comfort matter.

Affordability and sustainability of the built environment are themselves determined by socioeconomic conditions rather than by design intent alone (Gil-Ozoudeh, Aransi, Nwafor, & Uduokhai, 2018). Applied to laboratory infrastructure, this cautions against specifying facilities whose operating costs the health system cannot meet. A laboratory built to a specification it cannot afford to run will degrade to a lower effective specification within a few years, and the quality system will be calibrated to a standard the building no longer delivers.

2.2. Power, environmental control, and equipment reliability

Intermittent electrical supply is among the most consequential and least discussed determinants of

analytical quality in low-resource laboratories. Its effects are not limited to downtime. Voltage instability and the transient behaviour of distributed generation affect the quality of supply reaching sensitive equipment, and control strategies exist to manage this at the point of connection (Oshevire, Eyenubo, & Amayo, 2017). Analysers, centrifuges, and cold chain equipment subjected to unstable supply fail earlier and drift between failures, which surfaces in the quality system as unexplained control failures and shortened calibration intervals.

Two responses appear in the engineering literature. The first is generation: integration of solar power in small-scale industrial settings in Nigeria has been examined as a route to supply stability where grid reliability is poor (Sunday & Omoegun, 2018), and statistical estimation of daily solar radiation provides the planning input such installations require (Odejobi & Ahmed, 2018a). For a district laboratory, the equivalent planning question is which specific loads, typically the cold chain and one or two analysers, must remain powered continuously, and what generation and storage that implies.

The second response is maintenance strategy. Predictive maintenance and condition monitoring in critical power and energy infrastructure shift the maintenance regime from calendar-based to condition-based, using observed parameters to anticipate failure (Adaramola, Fadero, & Gideon, 2018). Laboratory practice conventionally follows a calendar model, with servicing scheduled annually and unplanned repair in between. A condition-based logic is available even without instrumentation, since control chart drift, increasing repeat rates, and lengthening warm-up times are all observable indicators of impending failure that a laboratory already collects or could collect cheaply.

The framework consequence is that equipment reliability belongs in the quality system as an active domain with its own indicators, not as an inventory list. Downtime days, mean time between failures, and control failures attributable to environmental excursion are all measurable at low cost and are more informative than a maintenance contract that may or may not be honoured.

2.3. Procurement, inventory, and reagent security

A laboratory without reagents produces no results, and a laboratory with intermittently available reagents produces results whose comparability over time is uncertain, since lot changes, substitutions, and emergency purchases from unqualified suppliers all introduce variability that internal quality control may not detect.

The procurement literature treats this as a solvable optimisation problem. Strategic procurement optimisation frameworks developed for capital-intensive operations address supplier qualification, contract structure, and demand forecasting as a single system rather than as separate transactions (Okonkwo, Ogunwole, & Okeke, 2018a). Models linking inventory availability to plant uptime formalise the relationship this paper needs, namely that the availability of consumables is a determinant of productive capacity rather than an administrative detail (Okonkwo, Ogunwole, & Okeke, 2018b). Substituting reagent for spare part and test throughput for plant uptime, the model transfers directly.

The transfer suggests three practical requirements for a laboratory quality system. Consumption forecasting should be based on recorded test volumes rather than on historical allocation. Minimum stock levels should be set per item against lead time and its variance, not as a uniform buffer. And stock-out should be recorded as a quality event with a defined indicator, since its consequence is diagnostic unavailability, which is a clinical harm even though no incorrect result was issued.

2.4. Biosafety, occupational risk, and the working environment

Safety and quality are frequently separated in laboratory management, with safety treated as a regulatory obligation and quality as a technical one. The occupational safety literature suggests the separation is artificial. Data-driven approaches to occupational safety risk control in large-scale infrastructure operations treat hazard identification, monitoring, and control as a continuous analytical process rather than a periodic inspection (Obriki & Arumosoye, 2018), which is the same logic the

improvement engine applies to quality nonconformities.

Thermal conditions provide a concrete link. Integrated heat stress risk modelling for industrial operations in extreme environments quantifies the effect of thermal load on worker physiology and performance (Arumosoye & Obriki, 2018). A laboratory operating at high ambient temperature without functioning climate control imposes the same load on staff performing repetitive, attention-dependent tasks such as microscopy and manual pipetting. The predicted consequence is elevated error rates in exactly the tasks least likely to be covered by an automated check.

This yields a framework requirement that is easy to state and rarely implemented: environmental monitoring records should serve both the safety system and the quality system, and unexplained clusters of analytical error should prompt inspection of environmental records before instrument records.

2.5. Workforce competence and training under constraint

Competence is the enabler most often assumed and least often measured. The common practice of treating training attendance as evidence of competence is defensible only where training is well matched to learner need and workplace conditions, which in resource-constrained settings it frequently is not.

Work on pedagogical strategy for learners with differing needs in resource-constrained educational settings offers a transferable principle, which is that instructional design must be adapted to the learner and the setting rather than delivered uniformly, and that assessment must be of demonstrated capability rather than of exposure (Bobga, Boakye, Ogbona, & Yeboah, 2018). For laboratory competency systems, this argues for direct observation of practice, blind rechecking of a sample of work, and periodic reassessment, rather than certificates of attendance.

It also argues for realism about who is being trained. In many district laboratories the staff performing high-volume manual tests are assistants rather than qualified technologists, and training designed for the latter will not reach the former. A competency framework that does not distinguish roles will overstate capability at exactly the point where most volume is processed.

2.6. Information systems, records, and data governance

A laboratory result has no value until it is recorded, retrieved, and interpreted. The information layer is therefore part of diagnostic quality rather than an administrative adjunct.

Where digital systems are adopted, they introduce obligations as well as capability. Legal and ethical risk modelling in enterprise data protection governance sets out the structure required to make those obligations operational rather than nominal, covering lawful basis, access control, retention, and accountability (Mbonu, Aliliele, Iwuanyanwu, & Oluoha, 2018). For a laboratory holding identifiable clinical data, this belongs inside the quality system, since a confidentiality breach is a nonconformity in the same sense that a mislabelled specimen is.

Architecture matters as well as policy. Conceptual work on scalable and secure architectures for enterprise systems addresses the trade-offs between accessibility, resilience, and control that a laboratory information system faces in miniature (Ahmed & Odejobi, 2018a). The insider threat literature adds the observation that the most probable source of data compromise is an authorised user rather than an external attacker, and that classification and risk assessment should be built accordingly (Akeju et al., 2018). And experience from offline assessment of security-critical systems demonstrates that meaningful assurance is achievable without continuous connectivity (Ladapo, Dosunmu, Jooda, & Abolaji, 2018), which is directly relevant to laboratories operating with intermittent network access.

Connectivity itself is a determinant of post-analytical performance. Where results are transmitted electronically, network quality determines delivery reliability, and deployment planning determines network quality (Amayo & Popoola, 2017b). A laboratory that reports electronically over an unreliable link has not eliminated the delivery failure mode; it has changed its form.

The framework position is therefore technology-agnostic. A well-designed paper register with a

reliable retrieval method outperforms an unreliable digital system, and premature digitisation without process discipline reproduces disorder at greater cost.

2.7. Financial governance and budget accountability

Recurrent quality costs are small in absolute terms and highly vulnerable in practice. External quality assessment enrolment, control materials, calibration services, and maintenance contracts are the first items cut when budgets are compressed, because their benefit is diffuse and their omission is not immediately visible.

Systematic review of budget compliance and statutory reporting in sub-Saharan Africa identifies the structural reasons this occurs, including weak linkage between budget formulation and execution, limited reporting discipline, and absent accountability for non-execution (Dogbatsey & Ebhojie, 2018). The implication for laboratory quality is that securing a budget line is insufficient; what matters is whether the line is executed and whether non-execution is visible to anyone.

This supports a specific framework element. A laboratory at higher maturity should be able to report the execution rate of its quality budget line as an indicator in its own right, alongside its technical indicators, because a laboratory whose quality budget is approved but not released is in a materially different position from one whose budget is genuinely absent, and the two require different remedies.

2.8. Audit, assurance, and complaint-driven risk detection

Internal audit in laboratory practice is typically periodic, manual, and checklist-driven, which makes it expensive per unit of information and slow to detect emerging problems.

Work on enhancing internal audit quality through technology-enabled risk assessment describes the alternative, in which audit effort is directed by risk indicators rather than distributed uniformly, and in which routine data substitutes for some manual testing (Akomolafe & Agu, 2018). A laboratory can apply this at low cost by directing audit attention to the areas where its indicators are deteriorating rather than auditing all twelve quality system essentials at equal depth annually.

A second contribution comes from an unexpected source. Predictive compliance monitoring using consumer complaint data has been shown capable of surfacing systemic safety risk in aviation oversight, on the argument that complaints constitute an under-exploited signal about system failure (Adeyelu, 2018). The laboratory analogue is the clinician complaint, which is usually handled as an interpersonal matter and rarely aggregated. Systematically logging and analysing clinician complaints about results, turnaround, and rejections would convert an existing but discarded signal into a diagnostic instrument for the quality system.

2.9. Decision-making under data scarcity

A recurring objection to indicator-based quality management in low-resource laboratories is that the data required do not exist. The objection has force, but it is not decisive, and the environmental risk modelling literature explains why.

Spatially explicit risk modelling frameworks have been developed specifically for tracking contaminant migration in data-limited remediation contexts, on the premise that structured inference from sparse observations is preferable to no inference at all (Lamidi & Olamide, 2018). Related work on predicting subsurface contamination pathways demonstrates the same principle in a data-driven form (Azeez & Badmus, 2018), with the additional relevance for laboratories that waste stream management is a genuine environmental obligation and not merely an analogy.

Transferred to laboratory quality, the principle supports sampling rather than census. A laboratory that cannot review every request form can review twenty per month and obtain a defensible estimate of completeness. A laboratory that cannot track every result to the patient record can audit thirty charts per quarter. The framework accordingly specifies sampled indicators wherever a census would be infeasible, and treats an estimate with a known method as superior to an assumption with none.

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2.10. Summary of coverage gaps

Table 1 sets out how the dominant architectures cover the determinants described above.

Table 1. Coverage of existing quality architectures against key determinants of diagnostic quality

Determinant	ISO 15189	WHO LQMS	SLIPTA	SLMTA
Analytical performance	Strong	Strong	Strong	Moderate
Documentation and records	Strong	Strong	Strong	Strong
Pre-analytical process outside the laboratory	Weak	Moderate	Weak	Weak
Physical infrastructure and built envelope	Weak	Moderate	Weak	Absent
Power supply quality and continuity	Weak	Weak	Weak	Absent
Equipment reliability and maintenance strategy	Moderate	Moderate	Moderate	Weak
Procurement and reagent security	Weak	Moderate	Weak	Weak
Biosafety linked to analytical performance	Moderate	Moderate	Moderate	Weak
Workforce competence as demonstrated capability	Moderate	Moderate	Moderate	Moderate
Information systems and data governance	Moderate	Moderate	Moderate	Weak
Budget execution and financial accountability	Absent	Weak	Absent	Weak
Clinician ordering appropriateness	Absent	Weak	Absent	Absent
Result interpretation and clinical action	Absent	Weak	Absent	Absent
Developmental sequencing for low-baseline laboratories	Absent	Absent	Moderate	Moderate
Linkage to patient outcomes	Absent	Absent	Absent	Absent

Three gaps stand out. The first is the treatment of quality as a property of the laboratory rather than of the diagnostic pathway. The second is the absence of a sequencing logic that tells a laboratory director at a district hospital with two technologists and intermittent electricity what to do first. The third is the absence of any outcome anchor, which leaves improvement efforts accountable to auditors rather than to patients.

III. METHOD AND FRAMEWORK DEVELOPMENT

This is a conceptual paper and no primary data were collected. The framework was constructed in five steps.

Structured narrative review. Literature was reviewed across six streams: laboratory systems strengthening and accreditation in low- and middle-income countries; diagnostic and healthcare facility infrastructure; reliability, power, and maintenance engineering; procurement and inventory management; governance, audit, and financial accountability; and health systems and quality of care theory. Peer-

reviewed sources were identified through PubMed and the African Journal of Laboratory Medicine, supplemented by engineering and management journals for the transferred literatures and by guidance documents from the World Health Organization and its Regional Office for Africa. The review was narrative rather than systematic, since the objective was conceptual synthesis rather than effect estimation.

Deconstruction of existing standards. ISO 15189:2012 clauses, the twelve WHO quality system essentials, and the SLIPTA checklist sections were mapped against the total testing process and against the WHO health system building blocks to identify uncovered territory (International Organization for Standardization, 2012; World Health Organization, 2011; Datema et al., 2011).

Failure mode enumeration. A list of failure modes producing unusable, misleading, late, or unread results was assembled from the reviewed literature and from the standards themselves. Each was then classified by the phase in which it occurs and by the system component that causes it. This step was used as the primary test of framework adequacy: a candidate domain structure was rejected if any enumerated failure mode could not be located within it.

Theoretical anchoring. Candidate theoretical lenses were assessed against three criteria: capacity to represent causal structure, capacity to represent developmental progression, and capacity to represent feedback and adaptation.

Synthesis and internal validation. Domains, enablers, maturity tiers, and indicators were drafted, tested against the failure mode inventory, and revised. The result was checked for parsimony, for compatibility with ISO 15189 rather than competition with it, and for feasibility at a low resource baseline, taking feasibility to mean implementable by a laboratory with no additional staff and no additional recurrent budget beyond external quality assessment enrolment.

3.1. Theoretical grounding

Donabedian's structure-process-outcome model remains the most durable account of how healthcare quality can be observed (Donabedian, 1966). Applied to the laboratory, structure comprises facilities, equipment, staff, and reagents; process comprises the total testing process; and outcome comprises diagnostic accuracy, clinical action, and patient health. Existing laboratory quality architectures are overwhelmingly structure-focused and partly process-focused, and almost entirely silent on outcome. The framework retains the triad but insists that the outcome limb be measured, even imperfectly.

The WHO health system building blocks situate the laboratory inside the health system rather than beside it. This matters because several dominant constraints on laboratory quality, notably procurement, human resource policy, and budget allocation, are not under the control of the laboratory manager. A framework that addresses only what the laboratory manager controls will misattribute failure, and will generate improvement plans that fail for reasons the plan cannot name.

Capability maturity modelling, originating in software process improvement, supplies the developmental logic that binary conformity standards lack. Maturity models describe ordered stages in which each stage stabilises the gains of the previous one. This is the right shape for laboratories that cannot leap to full conformity, because it makes partial progress meaningful and defines what consolidation looks like. It also makes regression visible, which a pass-or-fail standard does not.

Reliability and risk-based thinking, drawn from the engineering literature reviewed above, contributes two ideas. The first is that failure is a property of a system under load rather than of a component in isolation, which is why environmental and power conditions belong in the analytical quality account (Adaramola et al., 2018; Oshevire et al., 2017). The second is that assurance effort should be allocated in proportion to risk rather than uniformly, which is the principle underlying risk-directed audit (Akomolafe & Agu, 2018).

Complex adaptive systems theory contributes the recognition that laboratory quality is not linear in inputs. Feedback loops dominate. The trust loop described above, offered as a plausible mechanism rather than a directly evidenced one, in which unreliable results reduce ordering, which reduces volume, which reduces investment and skill maintenance, can trap a laboratory in a low-quality

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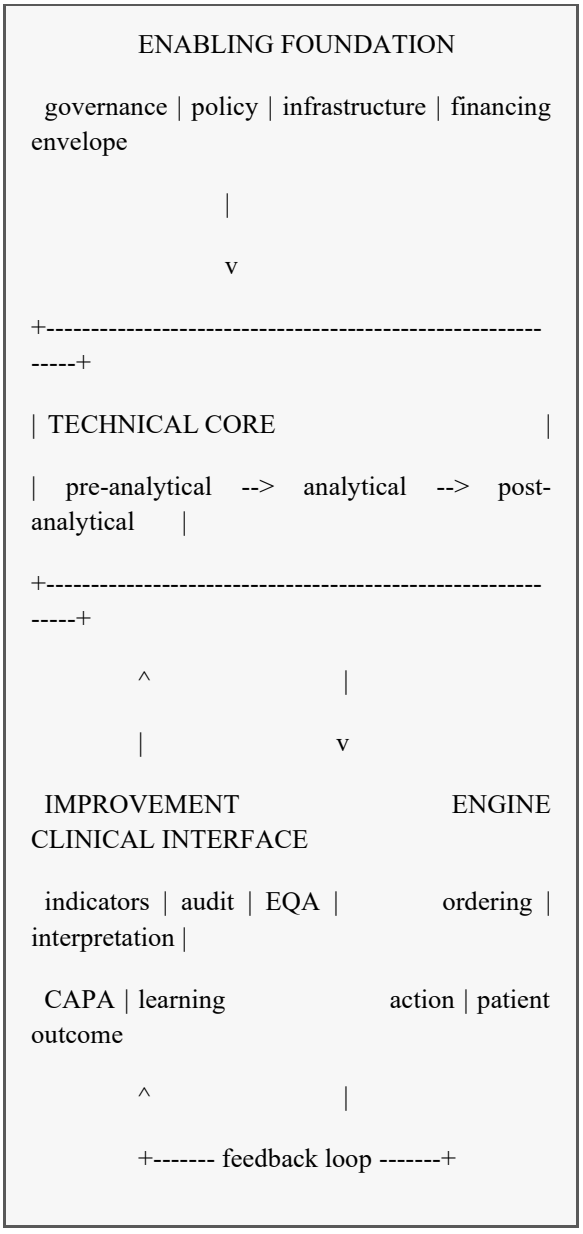
equilibrium regardless of how much equipment is donated. Interventions must be designed to break loops, not only to add inputs. The corollary is that the highest-return intervention is often not the largest one, but the one placed at the point where a reinforcing loop can be interrupted.

3.2. Overall structure

The framework consists of four domains arranged as a value chain, three cross-cutting enablers, and five maturity tiers.

Figure 1. Structure of the DQSS framework



The arrangement is deliberate. The Foundation sets the conditions under which anything else is possible. The Technical Core is where the technical work happens. The Clinical Interface is where value is realised or lost. The Improvement Engine is the mechanism by which the system observes itself and corrects, drawing signal from the Clinical Interface as well as from the Technical Core. The feedback arrow from the Clinical Interface back to the Improvement Engine is the feature that most distinguishes this framework from checklist-based models.

3.3. The Enabling Foundation

This domain covers the conditions external to daily technical work that determine whether quality is possible at all.

Legal and policy basis. A national laboratory policy and strategic plan, with the network defined by tier and mandated test menu. National strategic plans have been argued to be the necessary starting point for laboratory system strengthening (Nkengasong et al., 2009), and scope decisions should follow an explicit view of what belongs at each tier (Fleming et al., 2017).

Governance and accountability. A designated national laboratory authority, defined reporting lines, and a laboratory director with real decision rights over staffing, procurement requisitions, and process change. Where the director cannot change anything, quality management is ceremonial.

Physical infrastructure and facility lifecycle. Facilities designed for the methods performed, with spatial arrangement, environmental control, and maintenance treated as quality parameters rather than as estate matters (Aminu-Ibrahim et al., 2018; Ogbete et al., 2018), and with design responsive to local climatic

load rather than to imported templates (Nwafor, Uduokhai, Ifechukwu, et al., 2018).

Power and utility continuity. A defined critical load list, generation and storage sized against it, and monitoring of supply quality at the point of connection (Oshevire et al., 2017; Sunday & Omoegun, 2018; Odejobi & Ahmed, 2018a).

Tiered network design. Explicit definition of which tests are performed at which tier, with referral pathways and specimen transport arrangements. Attempting an inappropriate test menu at a low tier is a common and underrecognised source of poor quality.

Financing envelope and budget execution. A budget line for quality activities specifically, including external quality assessment enrolment, calibration, and control materials, together with visibility of whether that line is executed (Horton et al., 2018; Dogbatsey & Ebhojie, 2018).

Regulatory and biosafety baseline. Licensing, waste management, and safety requirements establishing the floor below which a laboratory should not operate, with occupational risk managed analytically rather than by periodic inspection alone (Obriki & Arumosoye, 2018).

The Foundation is placed first because interventions in the Technical Core and the Improvement Engine attempted without it tend not to survive. A laboratory that improves through mentorship but has no budget line for control materials will regress the moment mentorship ends, and a laboratory whose building cannot hold temperature will fail controls whatever its procedures say.

3.4. The Technical Core

This domain covers the total testing process, from the clinical question to the delivered result.

3.4.1. Pre-analytical components

Test request practice, patient and specimen identification, collection technique and container selection, labelling, storage and transport conditions, acceptance and rejection criteria, and documented rejection rates. The framework explicitly places specimen collection inside the quality domain even when it is performed on the ward by nursing staff who do not report to the laboratory. This is a deliberate boundary expansion, justified by the concentration of error in this phase.

The organisational difficulty is real. A laboratory manager has no line authority over ward staff and cannot discipline collection practice. The framework's response is that the laboratory's obligation is to measure and report, not to command. A rejection log disaggregated by originating ward, reviewed with clinical leadership, converts an authority problem into an information problem, which is tractable.

3.4.2. Analytical components

Standard operating procedures that are current, accessible, and actually used; method verification appropriate to the setting; internal quality control with defined rules and documented action on failure; equipment function verification, maintenance, and calibration traceability; reagent and consumable inventory management with stock-out prevention; and environmental control sufficient for the methods in use. Adaptation of method and control expectations to what is achievable locally, rather than wholesale transplantation of high-resource protocols, is essential (Barbé et al., 2017).

Two components deserve emphasis because they are conventionally underweighted. Maintenance should move as far toward condition-based logic as local instrumentation allows, using observable proxies where sensors are absent (Adaramola et al., 2018). And inventory should be managed against forecast consumption and lead time variance rather than against historical allocation, with stock-out recorded as a quality event (Okonkwo, Ogunwole, & Okeke, 2018b).

3.4.3. Post-analytical components

Result review and authorisation, reference intervals appropriate to the local population where feasible, critical value definition and communication, turnaround time measured against clinically defined thresholds, result delivery with confirmation of receipt, and archiving. Where delivery is electronic, the reliability of the transmission path is part of the delivery control and must be monitored rather than assumed (Amayo & Popoola, 2017b).

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The framework requires that each of the three phases carry at least one measured indicator. A common failure of practice is that analytical quality is measured intensively while pre-analytical and post-analytical quality are managed by assumption.

3.5. The Improvement Engine

This domain is the self-correction mechanism. It converts observation into change.

Indicator system. A small, deliberately minimal set of quality indicators with defined numerators, denominators, collection responsibility, and review frequency. A laboratory that collects six indicators reliably and acts on them outperforms one that nominally collects thirty and acts on none. Where a census is infeasible, sampled estimation with a documented method is preferred to assumption (Lamidi & Olamide, 2018).

External quality assessment and inter-laboratory comparison. Participation is treated as non-negotiable at every maturity tier, since it is the only external check on analytical truth. Where commercial schemes are unaffordable, structured specimen exchange within the tiered network serves as an interim substitute.

Risk-directed internal audit. Periodic self-assessment against a defined standard, with audit effort concentrated where indicators are deteriorating rather than distributed uniformly across all quality system essentials (Akomolafe & Agu, 2018).

Occurrence management and corrective action. A non-punitive mechanism for recording nonconformities, near misses, and complaints, with root cause analysis proportionate to severity and documented closure. The non-punitive character is essential: in hierarchical institutional cultures, error reporting collapses if reporting is followed by blame.

Complaint analytics. Systematic logging and periodic analysis of clinician complaints about results, turnaround, and rejections, treating complaint data as a signal about systemic risk rather than as an interpersonal matter to be settled case by case (Adeyelu, 2018).

Management review and learning. A scheduled forum at which indicator data, external assessment performance, audit findings, complaint patterns, and corrective action status are reviewed and decisions recorded.

the Foundation and the Technical Core can be built by external technical assistance. The Improvement Engine is what makes improvement endogenous, and it is therefore the domain most predictive of sustainability. Its weakness is the most plausible explanation for the score regression observed after programme support tapers (Yao et al., 2010; Ndihokubwayo et al., 2016).

3.6. The Clinical Interface

This domain is largely absent from existing architectures and is where the framework departs most from current practice.

Demand shaping and ordering appropriateness. Clinician awareness of the available test menu, guidance on indications, and monitoring of ordering patterns for both under-ordering and inappropriate ordering.

Request quality. Completeness of clinical information on request forms, which conditions the laboratory's ability to interpret results and to flag implausible values.

Result comprehensibility. Report format, units, reference intervals, interpretive comments where competence permits, and flagging of critical values.

Clinical action. Whether results are retrieved, read, and acted upon within the clinical decision window, sampled through chart review even where information systems are absent.

Trust and feedback. Structured, periodic dialogue between laboratory and clinical staff, and a route by which clinicians can raise concerns about results.

Patient-level outcome proxies. Selected tracer conditions in which the diagnostic contribution to management is traceable, for example time from specimen collection to initiation of appropriate antimicrobial therapy in suspected bacteraemia, or proportion of treated malaria episodes with a confirmatory test result.

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The Clinical Interface closes the loop identified in the introduction. It makes explicit that a technically perfect result arriving too late, or not understood, or not trusted, has produced no quality at all, which is the mechanism through which accreditation is thought to reach patients in the first place (Peter et al., 2010). It also provides the argument laboratory managers need when competing for domestic budget, because it expresses laboratory performance in terms that clinical and financial decision-makers recognise (Horton et al., 2018).

3.7. Cross-cutting enablers

Workforce capability. Adequate establishment, defined competency requirements per role, documented initial competency assessment and periodic reassessment, continuing education, supervision, and retention conditions. Competency assessment is distinguished from training attendance, and the framework treats attendance records as insufficient evidence. Assessment should be by demonstrated capability, differentiated by role, and adapted to the learner and the setting rather than delivered uniformly (Bobga et al., 2018).

Information systems. Any reliable mechanism for capturing, retrieving, and analysing test data, ranging from a well-designed paper register through spreadsheets to a laboratory information system. Where digital records are adopted, the legal and ethical obligations attaching to patient data become part of the quality system rather than separate from it (Mbonu et al., 2018), architecture must balance accessibility against control (Ahmed & Odejobi, 2018a), insider risk should be assessed explicitly rather than assumed away (Akeju et al., 2018), and assurance must remain achievable under intermittent connectivity (Ladapo et al., 2018).

Sustainable financing. Progressive transition from donor-financed to domestically financed recurrent quality costs, cost analysis of the test menu, integration of laboratory quality costs into facility budgeting, and monitoring of budget execution rather than budget approval alone (Horton et al., 2018; Dogbatsey & Ebhojie, 2018). Specification should be constrained by what the system can afford to operate, since a facility built beyond its sustainable operating cost will degrade to a lower effective standard (Gil-Ozoudeh et al., 2018).

3.8. Failure mode analysis

Table 2 enumerates common failure modes producing unusable, misleading, late, or unread results, and locates each within the framework. The table is the framework's principal adequacy test: every mode has a home, and the distribution shows that a minority originate at the analytical bench.

Table 2. Failure mode inventory mapped to domains

Failure mode	Phase	Primary domain	Detection route
Specimen unlabelled or mislabelled	Pre-analytical	Technical Core / Clinical Interface	Rejection log
Wrong container or anticoagulant	Pre-analytical	Technical Core / Clinical Interface	Rejection log
Insufficient specimen volume	Pre-analytical	Technical Core / Clinical Interface	Rejection log
Haemolysed or clotted specimen	Pre-analytical	Technical Core / Clinical Interface	Rejection log
Transport delay beyond stability limit	Pre-analytical	Foundation / Technical Core	Receipt time record

Failure mode	Phase	Primary domain	Detection route
Transport temperature excursion	Pre-analytical	Foundation / Technical Core	Transport monitoring
Request form missing clinical detail	Pre-analytical	Clinical Interface	Sampled form audit
Test ordered without indication	Pre-analytical	Clinical Interface	Ordering pattern review
Indicated test not ordered	Pre-analytical	Clinical Interface	Tracer condition audit
SOP absent, outdated, or unused	Analytical	Technical Core	Internal audit
Method not verified for local conditions	Analytical	Technical Core	Internal audit
Internal control not run	Analytical	Technical Core / Improvement Engine	Control record
Control failure not acted upon	Analytical	Improvement Engine	Control record review
Calibration lapsed or untraceable	Analytical	Technical Core	Equipment record
Instrument drift from ambient temperature	Analytical	Foundation	Environmental log
Instrument failure from unstable power	Analytical	Foundation	Downtime record
Reagent stock-out suspending a test	Analytical	Foundation / Technical Core	Stock-out indicator
Lot-to-lot variation undetected	Analytical	Technical Core / Improvement Engine	Control charting
Reagent from unqualified emergency supplier	Analytical	Foundation	Procurement record
Operator error under thermal or workload stress	Analytical	Foundation / enabler	Error clustering review
Operator not competent for assigned task	Analytical	Enabler	Competency assessment
Transcription error in manual reporting	Post-analytical	Technical Core	Sampled report audit
Reference interval absent or inappropriate	Post-analytical	Technical Core / Clinical Interface	Report format audit

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Failure mode	Phase	Primary domain	Detection route
Critical value not communicated	Post-analytical	Technical Core / Clinical Interface	Critical value log
Turnaround exceeds decision window	Post-analytical	Technical Core / Clinical Interface	Turnaround indicator
Electronic delivery fails on unreliable link	Post-analytical	Enabler	Delivery confirmation
Report not filed in patient record	Post-analytical	Clinical Interface	Chart audit
Report filed but not read	Post-analytical	Clinical Interface	Chart audit
Result read but not acted upon	Post-analytical	Clinical Interface	Tracer condition audit
Result distrusted and disregarded	Post-analytical	Clinical Interface	Complaint analytics

Of the thirty modes, nine are pre-analytical, twelve analytical, and nine post-analytical. Only four are addressed wholly within the conventional analytical quality control apparatus. Nine sit primarily in the Clinical Interface, which no existing architecture assesses, and five sit primarily in the Foundation, where the laboratory manager has limited authority. This distribution is the empirical case for the framework's boundary choices.

3.9. Maturity tiers

Table 3. DQSS maturity tiers

Tier	Descriptor	Defining characteristic	Typical evidence
1	Unmanaged	Testing occurs; practice is individual and undocumented	No SOPs in use; no records; no external quality assessment
2	Basic control	Core safety, identification, and documentation established	SOPs present and used; specimen identification reliable; safety baseline met; EQA enrolled
3	Measured	The laboratory routinely measures its own performance	Indicator set collected; internal quality control documented with action on failure; internal audit conducted
4	Improving	Measurement reliably drives change	Corrective action closure demonstrated; management review functioning; indicator trends improving; EQA performance acceptable

Tier	Descriptor	Defining characteristic	Typical evidence
5	Learning and integrated	Quality extends across the clinical interface and is self-sustaining	Clinical Interface indicators in routine use; domestic financing of recurrent quality costs; improvement continues without external mentorship

Two rules govern the tiers. Progression is cumulative, so a tier is claimed only when the previous tier is stable, since regression is more costly than slow advance. And the tiers are not equivalent to SLIPTA stars, although they could in principle be mapped to SLIPTA star ratings with appropriate validation: Tier 5 in particular has no SLIPTA equivalent, because it includes clinical interface performance and financing sustainability, neither of which the checklist assesses.

3.10. Domain-level assessment rubric

Because the tiers describe the laboratory as a whole, a laboratory may sit at different levels in different domains, and usually does. Table 4 disaggregates the tiers by domain so that assessment produces a profile rather than a single score. The overall tier is the lowest domain level attained, which enforces the cumulative rule and prevents a laboratory from claiming maturity on the strength of its strongest domain. Where Table 2 attributes a failure mode to two domains at once, that mode is attributed to both for the purposes of this rubric: it can depress either domain's level, depending on which domain's evidence the specific instance falls under during assessment.

Table 4. Domain-level maturity rubric

Level	Enabling Foundation	Technical Core	Improvement Engine	Clinical Interface
1	No policy basis; no quality budget; facility unsuited to methods	Practice undocumented and individual	No records of error or performance	No contact beyond specimen and report
2	Policy exists; safety and licensing baseline met; critical loads identified	SOPs in use for main tests; identification reliable; EQA enrolled	Nonconformities recorded, if not analysed	Report format defined; critical values listed
3	Quality budget line exists; environmental and power conditions monitored	All three phases carry an indicator; controls run and recorded	Indicators collected on schedule; first internal audit completed	Request completeness measured; complaints logged
4	Budget line executed; maintenance moving to condition-based; procurement forecast-driven	Control failures reliably acted upon; stock-outs rare and recorded	Corrective actions closed; audit risk-directed; management review functioning	Turnaround measured against clinical thresholds; laboratory-clinical review meeting established
5	Domestically financed and resilient to supply and power interruption	Performance stable across lot, staff, and season	Improvement continues without external mentorship	Tracer outcome indicators in routine use and acted upon

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3.11. Indicator specification

Table 5 specifies the starter indicator set. Each entry gives numerator, denominator, and source, because indicators without specified denominators are not comparable across periods and are the most common reason indicator systems collapse. All twelve are collectable manually, and five are sampled rather than census.

Table 5. Specification of the twelve starter indicators

Indicator	Numerator / denominator	Source	Frequency
Specimen rejection rate	Specimens rejected / specimens received	Rejection log	Monthly
Request form completeness	Forms with required clinical fields / forms sampled	Sampled forms (n = 20)	Monthly
Internal control acceptance	Control runs within limits / control runs performed	Control record	Weekly
Reagent stock-out days	Days a listed test was unavailable / days in period	Stock register	Monthly
Equipment downtime	Days instrument non-functional / days in period	Equipment log	Monthly
Environmental excursion	Days outside method temperature tolerance / days in period	Environmental log	Monthly
Turnaround within threshold	Priority tests within threshold / priority tests reported	Register timestamps	Monthly
Critical value communication	Critical values communicated within target / critical values identified	Critical value log	Monthly
External assessment performance	Acceptable results / results submitted	EQA report	Per round
Corrective action closure	Actions closed within target / actions raised	Occurrence register	Quarterly
Result filed in record	Reports located in chart / reports traced	Chart audit (n = 30)	Quarterly
Tracer clinical action	Episodes with confirmatory result / episodes treated	Chart audit (n = 30)	Monthly

A thirteenth indicator, quality budget execution rate, is added at Tier 4 where the laboratory has visibility of its own budget line, computed as funds released divided by funds approved for quality activities in the period (Dogbatsey & Ebhojie, 2018). It is placed late because most laboratories below Tier 4 cannot obtain the figures.

3.12. Phased implementation

Phase A, stabilise (Tiers 1 to 2). Establish the non-negotiable floor: patient and specimen identification, biosafety, functional standard operating procedures for the highest-volume tests, external quality assessment enrolment, and a working register. Identify the critical electrical load and confirm what happens to it during an outage. Indicator systems should not

begin before identification and documentation are reliable, because indicators built on unreliable records generate false confidence.

Phase B, measure (Tier 3). Introduce the indicator set incrementally, starting with three indicators, one per phase of the testing process. Establish internal quality control discipline with documented action on failure, begin an environmental log, and conduct a first internal audit.

Phase C, improve (Tier 4). Establish corrective action and management review as scheduled routines, moving from data collection to documented decisions. Direct audit effort by indicator movement rather than uniformly (Akomolafe & Agu, 2018). Move maintenance toward condition-based scheduling using the observable proxies already collected (Adaramola et al., 2018). Shift procurement to forecast-driven replenishment (Okonkwo et al., 2018a). This is the phase in which external mentorship should be deliberately tapered, since the objective is endogenous capability (Andiric & Massambu, 2015).

Phase D, integrate (Tier 5). Add Clinical Interface indicators, establish laboratory-clinical review meetings, begin complaint analytics, conduct test menu cost analysis, and negotiate domestic budget lines for recurrent quality costs with execution monitored rather than approval alone.

The framework is intended to be adapted. Domains and enablers are fixed, since they represent the causal structure. Indicator definitions are local, since denominators depend on available records. Sequencing may be reordered where a specific binding constraint dominates, provided the Phase A floor is not deferred. Where power supply is the binding constraint, for instance, Foundation-level power work should precede Phase B measurement, since indicators collected during unmanaged supply interruption will attribute environmental failure to analytical causes.

3.13. Worked applications

Three vignettes illustrate how the framework yields different priorities at different tiers of a national network. All are hypothetical and are offered to demonstrate operational logic, not as evidence of effect.

3.13.1. A district hospital laboratory

A district laboratory serves a catchment of approximately 150,000 people with two technologists and three assistants, offering malaria microscopy and rapid tests, HIV testing, tuberculosis smear microscopy, basic haematology, and a limited chemistry panel. Power is intermittent and there is no laboratory information system. It participates in external quality assessment for HIV and tuberculosis through a vertical programme but not for chemistry or haematology.

A conventional SLIPTA audit would score this laboratory at zero or one star and generate a long list of nonconformities, most of which cannot be addressed with existing resources. The response is often demoralisation.

Under DQSS the profile is uneven rather than uniformly poor. The Foundation sits at level 1 to 2: a national strategic plan exists, but there is no facility quality budget and the building does not hold temperature within method tolerance during outages. The Technical Core sits at level 2 for HIV and tuberculosis, where vertical programme support has produced usable practice, and level 1 for chemistry, which has no external assessment and no documented calibration. The Improvement Engine is at level 1. The Clinical Interface is at level 1, although chart review reveals that a substantial share of malaria treatment episodes proceed without a documented confirmatory result.

The resulting plan is short. In Phase A, standardise specimen labelling and open a rejection log; secure chemistry external assessment through specimen exchange with the regional laboratory, since commercial enrolment is unaffordable; write and post procedures for the five highest-volume tests; and determine whether the refrigerator and one analyser can be moved to a protected circuit. In Phase B, collect three indicators: rejection rate, chemistry control acceptance, and malaria confirmatory testing proportion. In Phase C, establish a monthly review with the clinical officer in charge, using the malaria indicator as the shared agenda item. This last activity belongs to the Clinical Interface and is introduced early because it is inexpensive, it addresses the highest-volume clinical decision in the facility, and it

generates the clinical constituency that Foundation financing will later require.

3.13.2. A regional referral laboratory

A regional laboratory receives referrals from twelve district facilities, holds a broader chemistry and microbiology menu, and has fifteen technical staff and a functioning if under-resourced quality officer. It has attained two SLIPTA stars and has stalled there for three years.

The DQSS profile explains the plateau. The Technical Core is at level 3, with indicators collected and controls run. The Improvement Engine is at level 2 to 3: nonconformities are recorded but few are closed, and the annual internal audit covers all quality system essentials at equal depth, consuming most of the quality officer's available time for limited yield. The Foundation is at level 3 but with an approved quality budget that is not reliably released. The Clinical Interface is at level 1.

The framework directs effort to the Improvement Engine rather than to further technical work. Redirecting audit toward the three areas where indicators are deteriorating would free the quality officer's time (Akomolafe & Agu, 2018); establishing closure targets and a management review with recorded decisions would convert the existing occurrence register from an archive into a mechanism. The laboratory should also begin tracking budget execution, since its constraint is release rather than approval (Dogbatsey & Ebhojie, 2018). The referral role adds a specific pre-analytical obligation: rejection data disaggregated by originating district is the only signal the network has about collection and transport practice at facilities the regional laboratory does not control.

3.13.3. A national reference laboratory

A national reference laboratory holds accreditation for a subset of its menu, hosts the national external quality assessment scheme, and functions as the apex of the tiered network. Its own technical performance is strong.

Here the framework's contribution is at the Foundation and Clinical Interface rather than the Technical Core. As network apex, the laboratory's Foundation responsibilities extend beyond its own walls to network design, tier menu definition, and specimen referral logistics (Fleming et al., 2017; Nkengasong et al., 2009). Its Improvement Engine responsibilities include operating inter-laboratory comparison for facilities that cannot afford commercial schemes, which is the mechanism by which the network's lower tiers obtain any external check at all. Its Clinical Interface responsibility is the one most often neglected: as the institution with the analytical authority to define what a usable result looks like, it is best placed to specify report formats, reference intervals, and critical value thresholds for the network, and to aggregate complaint and turnaround data across facilities into a picture no single laboratory can see (Adeyelu, 2018).

The vignette illustrates a general property of the framework. The four domains are constant, but their relative weight shifts with the position of the laboratory in the network, which is why a single national improvement programme applying identical priorities at every tier will misallocate effort.

3.14. Scope and Boundaries of the Framework

Stating what a framework does not cover is as useful as stating what it does, since unstated scope invites misapplication.

The framework addresses the production and use of diagnostic results in clinical laboratories operating under resource constraint. It does not address anatomic pathology workflows, which involve interpretive processes and turnaround expectations sufficiently different that the technical core would need substantial revision. It does not address blood transfusion services beyond the laboratory testing component, since donor recruitment, screening policy, and inventory management for blood products constitute a distinct system. It does not address point-of-care testing performed outside any laboratory governance structure, although the pre-analytical and clinical interface domains apply to such testing and could form the basis of a derivative framework.

The framework is silent on method selection. Whether a laboratory should perform a given assay by one technique or another is a technical and economic question the framework deliberately leaves to the tier

menu definition and to the essential package literature (Fleming et al., 2017). What the framework asserts is only that the menu should be explicit and matched to the tier, since an unstated menu cannot be resourced or assessed.

The framework does not constitute an accreditation scheme and confers no recognition. It is a planning and self-assessment structure. A laboratory could reach Tier 5 on the rubric and still fail an ISO 15189 assessment on documentation requirements the framework does not enumerate, since the framework is organised by causal contribution to result usefulness rather than by clause coverage. The two are complementary, and the mapping in Table 7 is provided precisely so that a laboratory pursuing both is not asked to maintain two parallel systems.

Finally, the framework assumes a laboratory that exists and functions at some level. It has nothing to say about establishing diagnostic services where none are present, which is a facility development and workforce production problem addressed by other literatures (Aminu-Ibrahim et al., 2018). The lowest tier described, unmanaged practice, still presupposes that testing occurs.

3.15. Implementation Barriers and Mitigations

A framework's usefulness depends on whether it survives contact with the conditions it describes. Table 8 sets out the barriers most likely to defeat implementation, drawn from the reviewed literature on why quality programmes regress, together with mitigations available within the framework itself.

Table 8. Anticipated implementation barriers and framework-level mitigations

Barrier	Mechanism	Mitigation within the framework
Indicator burden exceeds staff capacity	Twelve indicators added to existing duties without any task removed	Phased introduction of three indicators at Tier 3; five of twelve sampled rather than census; audit effort reduced by risk-direction to offset collection effort
Records too poor to support indicators	Denominators unobtainable from existing registers	Phase A requires register discipline before Phase B measurement; sampled estimation accepted where census infeasible
the Clinical Interface requires authority the laboratory lacks	Laboratory cannot direct clinician behaviour	Laboratory obligation defined as measurement and reporting, not command; rejection and tracer data routed to clinical leadership
Foundation items lie outside the laboratory's control	Budget, estate, and establishment decisions sit with facility or ministry	Framework separates measurement from remedy; laboratory reports the constraint upward rather than absorbing blame for it
Improvement stalls when mentorship ends	Improvement engine located outside the laboratory	The Improvement Engine identified as the sustainability determinant; mentorship tapered deliberately during Phase C rather than withdrawn abruptly
Assessment gamed through documentation	Evidence produced for the assessor rather than for use	Rubric requires demonstrated action, not documented intent; closure and trend evidence required at level 4
Uniform national rollout misallocates effort	Same priorities applied at district, regional, and reference tiers	Domain weight shifts by network position, as set out in the worked applications

Barrier	Mechanism	Mitigation within the framework
Quality budget approved but not released	Budget formulation disconnected from execution	Budget execution rate added as an explicit indicator at Tier 4
Environmental causes misattributed to analytical ones	Control failures investigated at the bench only	Environmental log required from Tier 3; root cause procedure directs inspection of environmental records before instrument records
Staff conceal errors	Reporting followed by blame	Non-punitive occurrence management stated as a design requirement rather than an aspiration

3.16. The Data Quality of the Indicators Themselves

An indicator system inherits the reliability of the records it draws on, and in low-resource laboratories those records are frequently the weakest part of the system. Three specific threats deserve statement, since a framework that ignores them will produce confident numbers about an unmeasured reality.

Denominator instability. This is related to, but distinct from, the denominator-availability barrier named in Table 8: Table 8 concerns whether a denominator can be obtained at all during initial implementation, whereas the threat addressed here persists after implementation, since a nominally available denominator can still be recorded inconsistently. Rejection rate is meaningless unless specimens received are counted consistently. Where reception is not a defined step with a register entry, the denominator will vary with staffing and workload, and the rate will move for reasons unrelated to collection practice. The framework's insistence that Phase A precede Phase B exists for this reason: register discipline is not preparatory to measurement, it is a component of it.

Definitional drift. Indicators collected over years by successive staff will change meaning unless numerator and denominator are documented and the documentation is used during handover. This is why Table 5 specifies both explicitly rather than naming indicators alone. Definitional drift is difficult to detect after the fact, because the resulting series looks continuous.

Observation effect and selective recording. Where an indicator is used to judge staff, recording will adjust. Rejection rates fall when rejection is discouraged rather than when collection improves, and turnaround improves when timestamps are entered at reporting rather than at receipt. The framework's non-punitive requirement for occurrence management addresses part of this, but the more robust protection is triangulation: a falling rejection rate accompanied by a rising rate of results flagged implausible is evidence of suppressed rejection rather than improved collection.

The general principle is the one drawn from risk modelling under data scarcity: structured inference from acknowledged sparse data is preferable to unstructured assumption, provided the method is documented and its limits stated (Lamidi & Olamide, 2018). A laboratory reporting that request form completeness is approximately sixty percent based on twenty sampled forms per month is in a stronger epistemic position than one reporting nothing, and a much stronger position than one asserting that completeness is adequate.

3.17. Appendix A: Minimum Record Set

The framework requires four records at Tier 3 and a fifth at Tier 4. All can be maintained on paper. Field lists are given so that a laboratory can construct them without further guidance.

3.17.1. A1. Specimen rejection log

One line per rejected specimen. Fields: date and time of receipt; specimen identifier; originating ward, clinic, or referring facility; test requested; rejection reason from a fixed list; person notified; time of

notification; whether a replacement specimen was received; date of replacement.

The fixed reason list should be short enough to be used consistently, typically: unlabelled or mislabelled; wrong container; insufficient volume; haemolysed; clotted; leaked in transit; delayed beyond stability; request form absent or unsigned. A free-text other category should exist but should be reviewed monthly, since a growing other category indicates the list needs revision.

This single record supports two indicators, supplies the pre-analytical component of the failure mode inventory, and generates the ward-disaggregated report that the Clinical Interface requires.

3.17.2. A2. Internal quality control record

One line per control run. Fields: date; test and method; control material lot; expected value and acceptance limits; observed value; in or out of limits; if out, the action taken; person taking action; whether patient results for that run were held, released, or repeated; sign-off.

The action and sign-off fields are what distinguish a quality control record from a logbook. A record showing control failures without recorded action is evidence of a Tier 2 laboratory that believes itself to be at Tier 3.

3.17.3. A3. Equipment and environment log

Two linked records. The equipment log carries: instrument identifier; date; event type from a fixed list of service, breakdown, repair, calibration, verification; description; downtime start and end; parts or reagents consumed; person responsible.

The environmental log carries: date; location; temperature at a fixed daily time or continuous minimum and maximum where a recording device exists; humidity where relevant to methods; power interruptions with start and end times; whether backup supply engaged; any method suspended as a result.

Keeping these two adjacent is deliberate, since the diagnostic value of each depends on the other. A pattern of control failures becomes interpretable only when read against the interruption and temperature record for the same days (Adaramola et al., 2018; Oshevire et al., 2017).

3.17.4. A4. Occurrence and complaint register

One line per occurrence, near miss, or complaint. Fields: date raised; source, distinguishing internal detection from clinician complaint; description; phase affected; severity from a three-level scale; immediate action; root cause where investigated; corrective action agreed; owner; target closure date; actual closure date; verification of effectiveness.

Severity should determine investigation depth. A three-level scale in which only the top level triggers formal root cause analysis keeps the register usable, since a requirement to investigate everything formally results in a register that records nothing.

The source field is what enables complaint analytics. Clinician complaints recorded in the same register as internal findings can be counted, trended, and compared by originating unit, converting an interpersonal signal into a systemic one (Adeyelu, 2018).

3.17.5. A5. Quality budget record, from Tier 4

One line per budget period per line item. Fields: item, covering external quality assessment enrolment, control materials, calibration, maintenance, and consumables reserved for quality use; amount requested; amount approved; amount released; amount spent; variance explanation.

The distinction between approved and released is the point of the record. A laboratory whose quality budget is consistently approved and inconsistently released faces a different problem from one whose budget is refused, and the two require different escalation (Dogbatsey & Ebhojie, 2018).

3.18. Appendix B: Illustrative First-Year Implementation Calendar

Table 9 sets out an illustrative twelve-month sequence for a laboratory beginning at Tier 1, on the assumption of no additional staff and no additional recurrent budget beyond external quality assessment enrolment. It is offered as a worked example of the

phasing logic, not as a prescription, since binding constraints differ by facility.

Table 9. Illustrative first-year sequence for a Tier 1 laboratory

Months	Focus	Actions	Evidence of completion
1 to 2	Identification and safety floor	Define reception as a registered step; standardise labelling; confirm biosafety and waste baseline; identify the critical electrical load	Reception register in daily use; labelling procedure posted; critical load list agreed with facility management
3 to 4	Documentation floor	Write and post procedures for the five highest-volume tests; establish document control with version and date; brief all staff	Procedures in use at the bench; staff able to locate the current version
5 to 6	External check	Enrol in external quality assessment for programme-supported tests; negotiate specimen exchange with the referral laboratory for unenrolled tests	First round submitted; exchange agreement in writing
7 to 8	First indicators	Open the rejection log and the control record; begin the environmental log; collect three indicators only	Three months of indicator data with stated denominators
9 to 10	First review and audit	Hold the first management review with recorded decisions; conduct a limited internal audit directed at the weakest indicator	Review minutes with decisions and owners; audit report with findings
11 to 12	Occurrence management	Open the occurrence register; agree the severity scale; close the first cohort of corrective actions	Register in use; at least one action closed with effectiveness verified

A laboratory completing this sequence has reached Tier 2 across all domains and Tier 3 in the Technical Core and part of the Improvement Engine, without additional staff or recurrent budget beyond external assessment enrolment. Clinical Interface work has not begun, which is intentional: the framework places it at Phase D because it requires indicator infrastructure to be trustworthy before clinical colleagues are asked to act on it. A laboratory that presents unreliable data to clinicians damages the trust relationship the domain is meant to build.

3.19. Appendix C: Glossary of Terms as Used in This Paper

Several terms in laboratory quality management are used inconsistently across the literature. The definitions below state the sense intended here.

Term	Definition as used in this paper
Diagnostic quality	The degree to which the diagnostic pathway produces a result that is correct, timely, understood, and acted upon. Distinguished from analytical quality, which concerns correctness alone.

Term	Definition as used in this paper
Total testing process	The sequence from formulation of the clinical question through specimen collection, analysis, reporting, and clinical action. Broader than the pre-analytical to post-analytical span used in most laboratory standards, in that it includes ordering and action.
Domain	One of four groupings of determinants that jointly produce diagnostic quality, defined so that every enumerated failure mode falls within one.
Enabler	A capability that conditions performance in all four domains rather than in any one, and which therefore cannot be sequenced as a domain can.
Maturity tier	An ordered developmental stage describing the laboratory as a whole, claimed only when the preceding tier is stable across all domains.
Improvement engine	The set of mechanisms by which a laboratory observes its own performance and changes it, comprising indicators, external assessment, audit, occurrence management, complaint analytics, and management review.
Clinical interface	The set of interactions through which laboratory output enters clinical decision making, including ordering, request quality, report comprehensibility, retrieval, action, and feedback.
Failure mode	A specific mechanism by which the pathway produces a result that is unusable, misleading, late, or unread.
Critical load	The subset of laboratory equipment that must remain powered continuously for diagnostic function or specimen integrity to be preserved.
Sampled indicator	An indicator estimated from a defined subset rather than a census, with the sampling method documented so the estimate is interpretable.
Condition-based maintenance	Maintenance scheduled by observed indications of deterioration rather than by elapsed time, using instrument or process proxies where sensors are unavailable.
Risk-directed audit	Internal audit in which effort is concentrated where indicator movement suggests emerging weakness, rather than distributed uniformly across requirement areas.
Tracer condition	A clinical presentation selected because the contribution of a diagnostic result to its management is traceable in the patient record.
Budget execution rate	Funds released as a proportion of funds approved for quality activities in a period, distinguished from budget approval.

IV. DISCUSSION AND CONCLUSION

The framework advances the field in four respects. It relocates the unit of quality from the laboratory to the diagnostic pathway, which brings pre-analytical activity performed outside the laboratory, infrastructure and power conditions, procurement performance, and clinical action after reporting inside the quality boundary. It supplies a developmental sequencing logic through maturity tiers with a domain-level rubric, addressing the practical question of what to do first that binary standards leave unanswered. It treats the clinical interface as a formal domain with its own indicators, which creates an outcome anchor and,

incidentally, a budget argument. And it identifies the improvement engine as the domain that determines sustainability, which reframes external mentorship as a mechanism for building that engine rather than as a substitute for it.

The failure mode analysis in Table 2 supports these choices empirically rather than by assertion. If two thirds of enumerated failure modes originate outside the analytical bench, and a third sit primarily in domains that current architectures do not assess, then the boundary of the conventional quality system is drawn in the wrong place, and no amount of additional rigour inside that boundary will address the excluded modes.

4.1. Alignment with Established Standards

The framework is not a competitor to ISO 15189 and does not propose an alternative accreditation route. A laboratory reaching Tier 4 will have addressed a substantial share of the SLIPTA checklist (International Organization for Standardization, 2012; World Health Organization, 2011; World Health Organization Regional Office for Africa, 2015). The framework is best understood as a planning and evaluation layer sitting above the standards, organising them causally and extending them at the clinical interface. A laboratory pursuing accreditation loses nothing by adopting it, and gains a sequencing logic the standard does not provide.

A framework that cannot be reconciled with the standards laboratories are already assessed against will be treated as additional work and abandoned. Table 7 maps the DQSS domains and enablers onto the twelve WHO quality system essentials and onto the principal requirement areas of ISO 15189:2012, so that a laboratory can satisfy both simultaneously and can show an assessor where each requirement is addressed. Ratings here are not directly comparable to those in Table 1: Table 1 rates each architecture's general topical coverage of a determinant, whereas Table 7 rates whether a specific named DQSS sub-element has a direct textual counterpart in the WHO or ISO requirement, so a determinant rated Weak in Table 1 can still appear as Not addressed here where no specific corresponding clause exists.

Table 7. DQSS domains mapped to WHO quality system essentials and ISO 15189 requirement areas

DQSS component	WHO quality system essentials	ISO 15189:2012 requirement areas	Extends beyond both
Foundation: Legal and policy basis	Organisation	Management requirements: organisation and management responsibility	National tier and menu definition
Foundation: Governance and accountability	Organisation	Management requirements: management responsibility	Director decision rights as a stated precondition
Foundation: Infrastructure and lifecycle	Facilities and safety	Technical requirements: accommodation and environmental conditions	Facility lifecycle, climate-responsive design, affordability of operation
Foundation: Power and utility continuity	Facilities and safety	Technical requirements: accommodation and environmental conditions	Critical load definition, supply quality monitoring
Foundation: Financing and budget execution	Not addressed	Not addressed	Budget execution rate as an indicator

DQSS component	WHO quality system essentials	ISO 15189:2012 requirement areas	Extends beyond both
Foundation: Regulatory and biosafety	Facilities and safety	Technical requirements: safety	Occupational risk linked analytically to error
Technical Core: Pre-analytical	Process control	Technical requirements: pre-examination processes	Collection outside the laboratory brought inside the boundary
Technical Core: Analytical	Process control; equipment; purchasing and inventory	Technical requirements: examination processes, equipment, reagents	Condition-based maintenance; forecast-driven inventory
Technical Core: Post-analytical	Information management; process control	Technical requirements: post-examination, reporting, release of results	Transmission path reliability as a delivery control
Improvement Engine: Indicator system	Assessment; process improvement	Management requirements: quality indicators, continual improvement	Specified denominators; sampled estimation where census infeasible
Improvement Engine: External quality assessment	Assessment	Technical requirements: ensuring quality of results	Specimen exchange as a sanctioned substitute
Improvement Engine: Risk-directed internal audit	Assessment	Management requirements: internal audit	Audit effort allocated by indicator movement
Improvement Engine: Occurrence management	Occurrence management	Management requirements: nonconformity, corrective and preventive action	Explicit non-punitive design requirement
Improvement Engine: Complaint analytics	Customer service; occurrence management	Management requirements: resolution of complaints	Complaints aggregated as a systemic risk signal
Improvement Engine: Management review	Process improvement	Management requirements: management review	Review agenda specified to include Clinical Interface data
Clinical Interface: all components	Customer service, partially	Not substantively addressed	Ordering, interpretation, action, and outcome as assessed domains
Enabler: Workforce capability	Personnel	Technical requirements: personnel	Demonstrated capability differentiated by role

DQSS component	WHO quality system essentials	ISO 15189:2012 requirement areas	Extends beyond both
Enabler: Information systems	Documents and records; information management	Technical requirements: laboratory information management	Data protection obligations and insider risk
Enabler: Sustainable financing	Not addressed	Not addressed	Domestic transition and execution monitoring

Two observations follow from the mapping. First, the overlap is substantial: sixteen of the nineteen components map onto existing requirements, which means adoption is largely a matter of reorganising evidence a laboratory already generates rather than generating new evidence. Second, the three components with no counterpart, namely budget execution, sustainable financing, and the Clinical Interface in its entirety, are precisely those that determine whether technical compliance produces clinical value or is retained after external support ends.

4.2. On the transfer of methods from other sectors

Several determinants in this framework are supported by literature from facility design, power engineering, procurement, occupational safety, audit, and education rather than from laboratory medicine. This is a deliberate methodological choice and carries a known risk, which is that transferred models may not hold in a clinical setting with different constraints, incentives, and failure consequences. The justification is that the laboratory literature has documented these failure modes extensively while theorising them thinly, whereas the source literatures have addressed structurally similar problems with more analytical development. The transfers proposed here are conservative: condition-based maintenance, forecast-driven inventory, risk-directed audit, and complaint analytics are all well-established methods whose transfer requires substitution of variables rather than adaptation of logic. Where the transfer is looser, as with heat stress modelling applied to microscopy error, or with contaminant-migration risk modelling applied to indicator sampling under data scarcity (Section 2.9), the paper states it as a hypothesis rather than a finding.

4.3. Implications for practice, policy, and research

For laboratory managers, the framework offers a defensible basis for prioritisation and a language for negotiating with clinical colleagues. For national laboratory authorities, it offers a network-level planning structure in which tiered facilities can be placed at different maturity levels with differentiated support (Nkengasong et al., 2009). For funders, this framework's logic implies that investment in the Improvement Engine and the Clinical Interface, which are inexpensive relative to equipment, may yield greater durable return than further analytical inputs, consistent with the broader case for integrated investment across the diagnostic pathway made by Sayed et al. (2018). For estate and engineering functions, it makes explicit that facility, power, and maintenance decisions are clinical quality decisions and should be evaluated as such.

For researchers, the framework generates testable propositions. Four are stated in Table 6, each with a proposed test, on the argument that a conceptual framework earns its place by being falsifiable rather than by being comprehensive.

Table 6. Testable propositions arising from the framework

Proposition	Proposed test
Improvement Engine maturity at the point of mentorship withdrawal predicts retention of quality gains at 24 months, independently of audit score at withdrawal	Prospective cohort of laboratories completing a mentorship programme, with Improvement Engine rubric level and audit score both recorded at exit
Clinical Interface indicators improve in response to Technical Core improvement only where turnaround thresholds are defined against clinical decision windows	Stepped introduction of clinically defined thresholds across matched facilities, with tracer indicator as outcome
A material proportion of internal control failures in facilities with unstable supply are attributable to environmental excursion rather than to reagent or instrument causes	Paired environmental logging and control failure root cause classification over twelve months
Rejection data disaggregated by originating ward reduces rejection rates without any change in laboratory authority over collection practice	Controlled introduction of disaggregated reporting to clinical leadership in a subset of wards

4.4. Limitations

Five limitations should be stated plainly.

The framework is conceptual and has not been empirically validated. Its domains are analytically derived, and their claimed causal relationships, particularly the proposition that Improvement Engine maturity predicts sustainability, remain hypotheses. The failure mode inventory in Table 2 was assembled from the literature and from standards rather than from a prospective incident dataset, so the distribution across domains should be read as indicative rather than as an estimate of frequency.

Several supporting sources are drawn from outside laboratory medicine, and their transfer is argued rather than demonstrated. The risk of over-extension is real, particularly where the source setting differs materially in scale, regulation, or consequence of failure.

The underlying review was narrative rather than systematic and is therefore subject to selection bias, with likely over-representation of sub-Saharan African and Nigerian experience, since that is where both the SLIPTA literature and much of the transferred engineering literature is concentrated. Applicability to South and Southeast Asia, Latin America, and small island states is untested.

Clinical Interface measurement is demanding. Several proposed indicators require chart review, which consumes staff time that low-tier laboratories do not have. Sampling reduces but does not eliminate this burden, and there is a risk that the Clinical Interface becomes aspirational in practice while the technical domains absorb all available effort.

The framework does not resolve the resource problem. It offers a better allocation logic under constraint, not an escape from constraint. Laboratories without reagents cannot be improved by frameworks.

4.5. Conclusion

Diagnostic quality in resource-limited settings has been pursued largely through accreditation-preparation programmes that measure laboratories against checklists derived from a standard designed for well-resourced systems. This approach has produced real progress and remains valuable, but it treats quality as an internal property of the laboratory and leaves the endpoint defined by auditors rather than by patients.

The framework proposed here reorganises the determinants of diagnostic quality into four interacting domains, adds three cross-cutting enablers, and describes progression through five maturity tiers

supported by a domain-level rubric and a specified indicator set. Its distinguishing features are the inclusion of infrastructure, power, procurement, and the clinician-laboratory interface within the quality boundary, the identification of the improvement engine as the determinant of sustainability, and a sequencing logic that makes partial progress meaningful for laboratories that will not reach full accreditation soon. The failure mode analysis shows why these boundary choices are necessary rather than merely convenient.

The framework requires validation. Priority next steps are content validation with laboratory professionals across multiple countries, pilot application in district-level laboratories with prospective indicator collection, and tests of the four propositions set out above. Until such work is done, the framework should be treated as a structured hypothesis about how diagnostic quality is produced, offered in the expectation that it will be revised by the people who use it.

Declarations

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