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Optimizing Diagnostic Asset Lifecycle Management: From Health-System Objectives to Asset Performance through an ISO 55000-Informed Adaptive Framework

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Abstract: Investment in molecular diagnostic technologies has expanded testing capacity in resource-constrained health systems, yet equipment availability does not necessarily translate into sustained diagnostic value. This study examines how lifecycle management influences the performance and value realization of quantitative polymerase chain reaction (qPCR) diagnostic assets. A mixed-methods, multi-site assessment of approximately twenty qPCR devices combined technical inspections, environmental measurements, maintenance and operational records, diagnostic activity data, direct observation, and stakeholder interviews. More than 3,000 diagnostic test records were examined. Although most devices were nominally functional, effective performance varied substantially. Average utilization was approximately 40%, while partial module failures, reagent interruptions, environmental and power constraints, reactive maintenance, fragmented asset information, and limitations in quality assurance reduced effective diagnostic capacity. These findings indicate that diagnostic asset performance emerges from interactions among equipment, infrastructure, users, consumables, laboratory processes, quality systems, information, and governance rather than from technical functionality alone. The empirical findings were interpreted against a structured review of evidence on healthcare technology management, medical equipment lifecycle management, laboratory quality, and ISO 55000 asset-management principles. The resulting Adaptive Diagnostic Asset Lifecycle Management Framework (ADALM) introduces the Dynamic Performance Gap (DPG) as the difference between expected and observed asset-system performance. Identified gaps are interpreted through risk and value considerations and translated into adaptive lifecycle decisions. ADALM establishes a line of sight between health-system objectives, asset-management objectives, lifecycle decisions, diagnostic service performance, and health-system value. The framework offers a context-sensitive approach for improving strategic, operational, health, economic, and environmental performance of critical medical assets.

Keywords: *Asset Management; ISO 55000; Diagnostic Assets; qPCR; Lifecycle Management; Health Technology Management; Performance; Risk; Value Realization; LMIC.*

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I. INTRODUCTION

Medical technologies are fundamental to healthcare delivery, supporting diagnosis, treatment, monitoring, surveillance, and clinical decision-making. In resource-constrained health systems, governments and development partners have invested substantially in advanced diagnostic technologies, including decentralized molecular platforms. These technologies can expand diagnostic access and shorten the time between specimen collection and actionable clinical information [1–3].

Equipment availability, however, does not necessarily produce effective diagnostic capacity. Medical technologies require appropriate selection, infrastructure, installation, trained users, maintenance, consumables, quality assurance, information management, and eventual replacement or decommissioning [4–8]. Studies from low-resource environments have repeatedly identified equipment that is

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unavailable, underused, poorly maintained, or unsuitable for its operating context [9–13]. Procurement decisions that fail to consider infrastructure, maintenance, human resources, training, and lifecycle costs can contribute to persistent underperformance.

This problem is particularly important for molecular diagnostic assets. Their effective performance depends not only on equipment condition but also on electrical and environmental stability, reagent availability, competent users, testing procedures, quality systems, and reliable information. Evidence from molecular diagnostic networks shows that calibration, quality-control practices, method verification, environmental monitoring, and external quality assurance may vary considerably among facilities.

ISO 55000 offers a broader perspective by positioning asset management around value realization, organizational objectives, lifecycle thinking, risk-informed decision-making, information, and continual improvement [14–17]. Applied to healthcare, this implies that equipment functionality should not constitute the endpoint of performance assessment. Asset performance must ultimately be interpreted according to its contribution to health-service objectives.

➢ *The Research Question Addressed is Therefore:*

- *How Can ISO 55000 Principles be Operationalized to Transform Observed Lifecycle Performance Gaps in Diagnostic Medical Assets into Adaptive Decisions that Improve Health-System Value?*

The study aims to: (1) identify lifecycle determinants of diagnostic asset performance; (2) interpret observed performance gaps through an ISO 55000-informed asset-management perspective; and (3) develop an adaptive framework linking health-system objectives, asset performance, risk, and lifecycle decisions.

II. CONCEPTUAL BACKGROUND

➢ *From Equipment Management to Asset Value*

Healthcare technology management traditionally encompasses needs assessment, procurement, inventory, installation, maintenance, user support, and decommissioning [4–8]. These functions are essential but can remain organizationally fragmented.

Evidence from LMICs demonstrates the consequences of such fragmentation. Diaconu et al. found that procurement decisions frequently underestimate lifecycle costs, servicing requirements, infrastructure, and training needs [10]. Malkin and Keane showed that maintenance deficiencies contribute substantially to equipment unavailability, while sustainable maintenance requires consideration of local technical capacity and operating conditions [9,18].

ISO 55000 introduces an overarching question: what value should the organization obtain from its assets?

- *For Healthcare Technologies, this Can be Represented as:*

Health-system objectives → Asset-management objectives → Lifecycle decisions → Asset performance → Health-service performance → Health-system value.

This *line-of-sight* shifts attention from ownership of equipment toward sustained realization of value.

➢ *Diagnostic Platforms as Risk-Sensitive Asset Systems*

Diagnostic platforms have characteristics that make this distinction particularly important. Their outputs directly inform clinical decisions, while their performance depends on multiple supporting components.

- *For this Study, the Functional Diagnostic Asset is Therefore Conceptualized as:*

Equipment + Infrastructure + People + Reagents + Processes + Quality + Information + Governance.

This interpretation is consistent with laboratory quality principles and empirical evidence demonstrating that diagnostic reliability depends on much more than analyzer functionality [19–21]. For example, Abebaw et al. documented gaps involving calibration, method verification and quality practices across molecular diagnostic facilities.

The management boundary of the diagnostic asset must consequently extend beyond the physical machine.

III. METHODS

➢ *Study Design*

A mixed-methods, multi-site empirical assessment was undertaken to examine molecular diagnostic technologies within their operational environments.

Approximately twenty qPCR devices deployed across multiple laboratory facilities were assessed, together with more than 3,000 diagnostic test records.

The underlying information originated from a programmatic technical assessment. For the present study, the evidence was reorganized and interpreted through a lifecycle asset-management perspective. Countries, institutions, geographical locations, and commercial identifiers were removed.

➢ *Data Collection*

Five complementary sources of evidence were used.

Technical inspections examined equipment condition, module functionality, maintenance status, calibration-related information, and observable deficiencies.

Environmental assessment considered temperature, humidity, electrical conditions, and infrastructure relevant to equipment operation and reagent integrity.

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Documentary review covered maintenance records, diagnostic activity, stock information, quality records, and available operating procedures.

Semi-structured interviews with laboratory, managerial, technical, and supply-related stakeholders explored operational practices and constraints.

Direct observation examined interactions among equipment, users, workflow, consumables, infrastructure, and routine laboratory processes.

Triangulation was used to compare documented, reported, measured, and directly observed conditions.

➢ *Lifecycle Analytical Structure*

Evidence was organized into four lifecycle domains:

- Planning and acquisition: needs, specifications, procurement, allocation, support arrangements, and lifecycle requirements.
- Installation and commissioning: site readiness, infrastructure, environmental requirements, installation, and operational readiness.
- Operation and maintenance: utilization, availability, reliability, maintenance, consumables, competence, quality, information, and service continuity.
- Renewal and end-of-life: obsolescence, replacement, redistribution, decommissioning, and continuity planning.

➢ *Performance Dimensions*

Five dimensions were used to interpret performance:

- Strategic: alignment between asset deployment and health-system priorities;
- Operational: utilization, availability, effective capacity, reliability, and responsiveness;
- Health: diagnostic quality, continuity, and implications for clinical decision-making;
- Economic: value obtained from capital and lifecycle resources;
- Environmental: operating environment, resource use, waste-related risk, and sustainability.

➢ *Structured Evidence Review*

A structured evidence review was undertaken to contextualize the empirical findings and support framework development. Search concepts included combinations of *asset management, ISO 55000, medical equipment, health technology management, medical device lifecycle, maintenance, reliability, diagnostic equipment, molecular diagnostics, laboratory quality, LMIC, risk,* and *performance*.

Priority was given to peer-reviewed empirical studies and systematic reviews addressing medical equipment procurement, utilization, maintenance, reliability, lifecycle management, laboratory quality, and technology management in resource-constrained settings. Highly relevant normative publications from ISO and WHO were considered separately.

PRISMA 2020 informed the principles of transparent literature identification and selection but the evidence review is not presented as a standalone systematic review, because its purpose was to support interpretation and framework development rather than estimate a pooled effect or exhaustively answer an independent review question [22].

This approach avoids overstating the role of the literature component while maintaining a transparent evidence base.

IV. RESULTS

Most evaluated platforms were technically operational at the time of assessment. Nominal functionality, however, concealed important differences in effective service capacity.

Partial module failures reduced throughput without necessarily rendering the complete platform non-functional. Binary classification as *functional/non-functional* therefore provided an incomplete representation of available capacity.

Average utilization was approximately 40%, with substantial variation among facilities. Low utilization could not be attributed to a single cause. Reagent availability, technical downtime, local testing demand, referral arrangements, workflow, staffing, and alternative testing capacity interacted to determine actual use.

Maintenance was predominantly reactive in several settings. Preventive maintenance was inconsistent and maintenance histories were fragmented. Centralized support arrangements could also delay corrective interventions.

Reagent and consumable availability emerged as part of the functional asset system. Technically operational equipment could provide no diagnostic service during stock interruptions.

Environmental and infrastructure conditions, including temperature and electrical stability, were not uniformly controlled. These conditions introduced potential risks to equipment reliability and reagent integrity.

Finally, asset-related information remained fragmented. Maintenance events, diagnostic activity, errors, supplies, and quality information were generally not consolidated into a single lifecycle view.

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Table 1 Empirical Lifecycle Performance Gaps

Lifecycle domain	Expected condition	Observed condition	Performance gap	Main implication	Performance affected
Planning/allocation	Capacity aligned with service needs	Large variation in utilization	Capacity–need gap	Underuse or localized saturation	Strategic, economic, health
Infrastructure	Stable utilities and controlled environment	Variable environmental/power conditions	Readiness gap	Reliability and quality risk	Operational, health
Functionality	Full usable capacity	Partial module failures	Effective-capacity gap	Reduced throughput	Operational, health
Utilization	Appropriate use of installed capacity	Mean utilization ≈40%	Utilization gap	Reduced investment value	Strategic, economic
Maintenance	Planned preventive and timely corrective maintenance	Preventive maintenance inconsistent; support often reactive	Maintenance gap	Downtime and deterioration	Operational, economic
Reagents	Continuous availability and appropriate storage	Stock interruptions and storage vulnerabilities	Supply gap	Testing interruption	Operational, health
Quality	Continuous assurance of diagnostic quality	Uneven quality-assurance practices	Assurance gap	Diagnostic reliability risk	Health
Information	Integrated lifecycle information	Maintenance, testing, stock and error data fragmented	Information gap	Weak decision support	Strategic, operational
Renewal	Defined renewal/decommissioning criteria	Limited prospective planning	Renewal gap	Obsolescence/unplanned replacement	Strategic, economic
Environment	Controlled operations and appropriate waste management	Uneven environmental controls	Environmental gap	Safety and sustainability risk	Environmental, health

➢ *ISO 55000 Interpretation*

The empirical findings were mapped against relevant asset-management concepts rather than treated as independent technical deficiencies.

Table 2 Mapping Empirical Findings to an ISO 55000-Informed Asset-Management Logic

Asset-management concept	Healthcare interpretation	Empirical manifestation	Management response
Value	Contribution to diagnostic and health objectives	Functional equipment did not always provide expected service capacity	Measure realized service value
Alignment	Connection between health priorities and asset deployment	Large differences in utilization	Align capacity with service demand
Lifecycle	Coordinated decisions from acquisition to end-of-life	Earlier decisions affected later performance	Integrate lifecycle decisions
Risk	Technical, operational, clinical, economic and environmental consequences	Multiple interacting vulnerabilities	Multidimensional risk prioritization
Decision-making	Evidence informs interventions	Fragmented information constrained decisions	Integrate asset evidence
Performance evaluation	Measurement reflects realized value	Binary functionality masked effective capacity	Use multidimensional indicators
Information	Reliable lifecycle evidence supports decisions	Maintenance, errors, activity and stocks separated	Integrated information management
Continual improvement	Evidence generates corrective adaptation	Recurrent gaps did not always produce system change	Feedback and reassessment

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Financial/non-financial alignment	Investment and service outcomes considered jointly	Underutilization reduced investment value	Connect lifecycle cost and health value

V. DISCUSSIONS

The central finding is that technical functionality is an insufficient measure of diagnostic asset performance.

A platform can remain technically operational while generating limited health-system value because installed capacity is underused, reagents are unavailable, modules have failed, environmental conditions are unstable or supporting information and quality processes are inadequate.

This finding is consistent with broader medical-equipment literature. Reliability assessments increasingly incorporate utilization, availability, maintenance, safety, performance and cost rather than technical condition alone. Evidence from low-resource laboratory environments also demonstrates that strengthening user and biomedical engineering competencies can materially improve equipment availability and utilization.

➢ *Performance is a System Property*

The results support conceptualizing diagnostic performance as an asset-system property.

The relevant system comprises equipment, infrastructure, people, reagents, processes, quality, information, and governance. Failure in one component can reduce the value generated by the others.

This explains why isolated technical interventions may have limited impact. Repairing equipment does not correct a reagent shortage. Procuring additional capacity does not resolve poor referral pathways. Training users does not compensate for unstable electricity.

The management problem is therefore one of system alignment, rather than equipment maintenance alone.

➢ *Lifecycle Path Dependency*

Operational performance was also influenced by earlier decisions.

Technology selection affects maintenance requirements. Procurement determines contractual support. Site selection affects utilization. Infrastructure readiness affects reliability. Training arrangements affect effective use.

Research on medical-device procurement in LMICs similarly demonstrates that lifecycle costs, infrastructure, maintenance capacity and training should be considered before equipment acquisition. Frameworks developed specifically for low-resource settings likewise identify external dependencies, health technology management, cost and expected lifetime as critical dimensions of technology resilience.

These relationships create lifecycle path dependency: early decisions influence future cost, risk, reliability, and value.

➢ *Risk is Multidimensional*

The diagnostic asset also has a distinctive risk architecture:

- Technical risk: equipment or module failure.
- Operational risk: downtime, supply interruption, competence or workflow deficiencies.
- Diagnostic and patient-related risk: delayed or unreliable diagnostic information.
- Economic risk: underused investment, excessive lifecycle cost, or premature replacement.
- Environmental risk: inappropriate operating conditions, biosafety, and waste.

These risks interact. An environmental deviation can affect equipment or reagent integrity, which may subsequently influence diagnostic reliability, patient management, and economic performance.

➢ *Adaptive Diagnostic Asset Lifecycle Management Framework*

The empirical findings support an Adaptive Diagnostic Asset Lifecycle Management Framework (ADALM).

Its central mechanism is the Dynamic Performance Gap (DPG).

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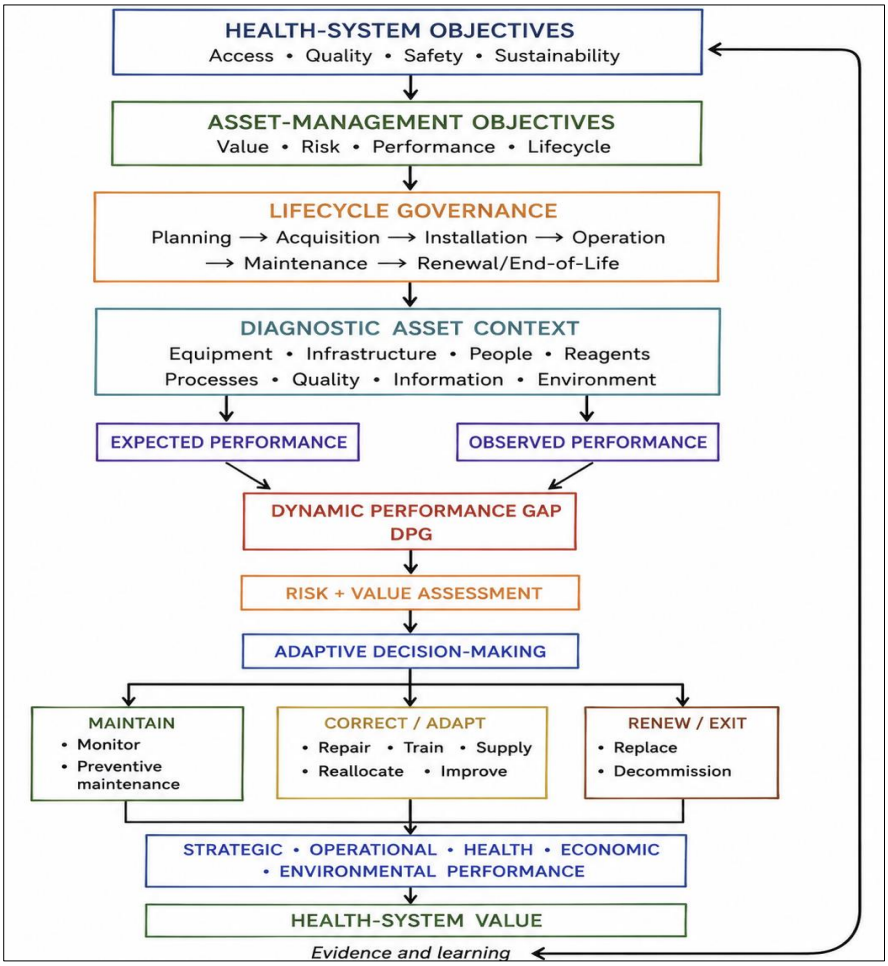

Fig 1 Adaptive Diagnostic Asset Lifecycle Management Framework

- *Dynamic Performance Gap*

For a defined performance domain:

The equation does not imply that heterogeneous dimensions should be aggregated into a universal numerical score. It formalizes the comparison between the performance required from an asset and that observed in practice.

✓ *Decision Priority can Conceptually be Expressed as:*

A relatively small technical gap associated with substantial patient or service risk may therefore justify greater intervention than a larger deviation with limited consequences.

- *Adaptive Decisions*

Depending on the source of the performance gap, possible actions include:

Monitor – maintain – repair – train – strengthen supply – improve infrastructure – redesign workflow – redistribute – upgrade – replace – decommission.

The appropriate response to low utilization is therefore not automatically maintenance or additional equipment.

- *Feedback and Organizational Learning*

Performance is reassessed after intervention:

Evidence → Gap → Risk/Value Assessment → Decision → Action → New Evidence

This feedback loop links operational evidence to governance and future lifecycle planning.

➢ *Research Contributions*

The study offers three principal contributions.

First, conceptually, it reframes diagnostic equipment as a strategic asset system rather than an isolated technical unit. Value depends on interactions among technology, infrastructure, users, consumables, quality, information, and governance.

Second, methodologically, the Dynamic Performance Gap provides an operational bridge between normative asset expectations and observed healthcare performance. It enables deviations to be interpreted according to their consequences rather than treated uniformly.

Third, managerially, ADALM establishes an explicit line of sight between health-system objectives and lifecycle decisions. Technical indicators such as utilization, availability, maintenance, errors, or effective capacity can therefore be interpreted according to their strategic,

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operational, health, economic, and environmental implications.

The framework may be transferable to other categories of healthcare physical assets provided that their specific value pathways and risk architecture are defined.

VI. LIMITATIONS AND FUTURE RESEARCH

The empirical assessment covers a relatively limited portfolio of diagnostic assets within a specific programmatic context. The findings should therefore be regarded as analytically transferable rather than statistically generalizable.

The assessment was predominantly cross-sectional and cannot establish longitudinal causal relationships among maintenance, degradation, utilization, and organizational decisions.

Some maintenance and operational records were incomplete. Although information fragmentation itself represents an important finding, it limited quantitative analysis.

ADALM and the Dynamic Performance Gap should also be considered an empirically informed conceptual framework, not a validated theory.

Future research should prospectively test the framework and operationalize its performance dimensions using measurable indicators. Longitudinal studies could examine whether DPG-informed decisions improve utilization, availability, service continuity, lifecycle cost, and investment value. Integration with CMMS, laboratory information systems, automated equipment data, and asset dashboards could enable continuous rather than periodic performance-gap assessment.

VII. CONCLUSION

Diagnostic medical assets generate value through more than technical functionality.

Their performance emerges from interactions among equipment, infrastructure, users, consumables, quality systems, information, and governance throughout the lifecycle. The empirical assessment revealed substantial differences between nominal functionality and realized performance, including underutilization, partial capacity loss, supply constraints, maintenance limitations, environmental vulnerabilities, and fragmented information.

The proposed ADALM framework establishes a line of sight from health-system objectives to asset-level action. Its Dynamic Performance Gap mechanism compares expected and observed performance and translates meaningful deviations into risk- and value-informed lifecycle decisions.

The resulting perspective moves healthcare technology management beyond fragmented technical intervention toward adaptive lifecycle asset governance, where the ultimate measure of asset performance is the sustainable value it contributes to health-system objectives.

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