Development of a Risk-Based Conceptual Framework for Improving Diagnostic Accuracy and Quality Management in Clinical Laboratories

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Abstract

Laboratory results inform a large share of clinical decisions, yet errors continue to occur across the total testing process (TTP). Most of these errors arise outside the analytical phase, in test request, specimen collection, result communication and interpretation. Traditional quality control (QC) and quality assurance models remain focused on analytical performance and on uniform, rule-based compliance, which leaves important sources of diagnostic error insufficiently addressed. The 2012 revision of ISO 15189 and the publication of ISO 22367:2020 require laboratories to identify, evaluate and control risks to patients, but they do not provide an integrated model for doing so. This study aimed to develop a risk-based conceptual framework that links risk management activities to every phase of the TTP and makes explicit how these activities improve diagnostic accuracy and quality management in clinical laboratories. A conceptual framework analysis approach was applied. Literature on laboratory error, risk management, Six Sigma, statistical QC design, patient-based real-time QC, quality indicators and international standards published between 1997 and 2020, complemented by cross-sector frameworks from occupational and process safety, aviation, asset integrity, pharmaceutical quality, internal audit and information governance, was mapped, deconstructed into concepts, integrated, synthesised and theoretically validated against established models from patient safety and quality science. The resulting Risk-Based Total Testing Process Quality Framework (RB-TTPQF) has four elements: a foundation layer of leadership, safety culture, competence and standards; the five-phase TTP as the domain in which risk arises; a five-stage risk management cycle (identification, assessment, control, monitoring and improvement) applied to each phase; and proximal and distal outcomes connected by a feedback loop. Six testable propositions describe the expected relationships among these elements, and a stepwise implementation guide is proposed, with adaptations for resource-limited settings. The RB-TTPQF provides a coherent structure for moving from compliance-driven QC to proportionate, patient-centred risk management. It is intended to guide laboratory practice, accreditation preparation and future

empirical research on the relationship between laboratory risk management and diagnostic accuracy.

Keywords: Risk management; total testing process; diagnostic accuracy; diagnostic error; quality management; quality control; Six Sigma; ISO 15189; ISO 22367; quality indicators; patient safety; clinical laboratory

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1. Introduction

Clinical laboratory testing occupies a central position in modern medicine. It is frequently stated that laboratory results influence a majority of medical decisions, and laboratory data are essential to diagnosis, prognosis, treatment selection and monitoring (Hallworth, 2011). Because so much clinical reasoning depends on laboratory data, the accuracy of those data is a direct determinant of diagnostic accuracy. The National Academies of Sciences, Engineering, and Medicine (2015) identified diagnostic error as a major and under-recognised threat to patient safety, and it highlighted failures in test ordering, performance and interpretation as recurrent contributors.

The capacity of a health system to deliver accurate diagnoses also depends on the physical and organisational infrastructure in which testing takes place. Sustainable diagnostic laboratory infrastructure models for resource-constrained health systems, capital project delivery models for high-risk healthcare facilities and infrastructure-driven expansion of diagnostic access to underserved regions have been described (Aminu-Ibrahim et al., 2018; Aminu-Ibrahim et al., 2019; Aminu-Ibrahim et al., 2020). Laboratory spatial planning has been linked to diagnostic accuracy, safety and throughput, and regulatory-compliant design systems have been proposed for molecular and pathology laboratories, alongside sustainable materials and energy strategies for laboratory facilities (Ogbete et al., 2018; Ogbete et al., 2019; Ogbete et al., 2020). These studies show that quality is shaped long before a specimen reaches an analyser.

Over the past five decades, laboratory medicine has achieved substantial improvements in analytical quality through automation, standardisation, internal quality control (IQC) and external quality assessment (EQA). Analytical error rates have fallen considerably, and the analytical phase is now the most controlled part of the testing pathway (Plebani, 2006). Studies conducted from the late 1990s onward have consistently shown that the majority of laboratory errors occur in the pre-analytical phase, followed by the post-analytical phase, with the analytical phase accounting for a comparatively small proportion (Plebani and Carraro, 1997; Bonini et al., 2002; Carraro and Plebani, 2007). Lundberg (1981) described the brain-to-brain loop, and Plebani (2010) later extended this into the concept of the TTP, which includes the pre-pre-analytical steps of test selection and ordering and the post-post-analytical steps of interpretation and clinical action.

In parallel, regulators and standard-setting bodies have moved toward risk-based thinking. ISO 15189:2012 requires medical laboratories to evaluate the impact of work processes and potential

failures on examination results that affect patient safety (International Organization for Standardization [ISO], 2012). The Clinical and Laboratory Standards Institute (CLSI) guideline EP23-A introduced risk management principles for laboratory QC (CLSI, 2011), and in the United States the Individualized Quality Control Plan (IQCP) gave laboratories a risk-based option for meeting QC requirements (Centers for Medicare and Medicaid Services [CMS], 2014). In 2020, ISO 22367 was published as a dedicated standard for the application of risk management to medical laboratories (ISO, 2020).

Despite this progress, several gaps persist. First, risk management is often applied in a fragmented way, for example as a single failure mode and effects analysis (FMEA) of an analyser, without connection to pre-analytical or post-analytical processes. Second, QC practice in many laboratories remains uniform, using the same control rules and frequencies for assays with very different analytical performance and clinical risk (Westgard and Westgard, 2014). Third, quality indicators are collected but are not always used to re-assess risk or drive improvement (Sciacovelli et al., 2017). Fourth, the link between laboratory risk management and the ultimate outcome of interest, accurate diagnosis, is seldom made explicit. Finally, practical guidance for laboratories in low- and middle-income countries, where resources and accreditation coverage are limited, remains scarce.

These gaps are particularly visible in resource-limited clinical laboratories. A conceptual framework for strengthening diagnostic quality systems in such laboratories emphasises the need for integrated rather than isolated interventions (Yusuf and Abdulrazaq, 2018). Integrated laboratory information systems have been proposed to improve infection detection accuracy, multi-laboratory reporting networks have been used to strengthen antimicrobial resistance surveillance, and evaluations of integrated disease surveillance have highlighted weaknesses in data quality (Abdulrazaq et al., 2019; Ekemezie et al., 2018; Yusuf et al., 2020). Conceptual work also explains why scientific innovation fails to improve patient outcomes without effective health system delivery (Ilodigwe and Adesemoye, 2019b), which is equally true of laboratory innovation.

This paper responds to these gaps by developing a risk-based conceptual framework that integrates the TTP, the risk management cycle and laboratory quality tools into a single model. The objectives are to: (1) identify and define the core concepts that underpin risk-based quality management in clinical laboratories; (2) integrate these concepts into a coherent framework that shows how risk management activities improve diagnostic accuracy; (3) formulate propositions that can be tested empirically; and (4) outline a practical pathway for implementation.

2. Research Method

The framework was developed using the conceptual framework analysis method described by Jabareen (2009), which is a grounded, qualitative and iterative procedure for building conceptual frameworks from multidisciplinary literature. This method was selected because the phenomenon of interest, risk-based quality management, draws on laboratory medicine,

industrial quality engineering, patient safety science and regulatory standards. The eight phases of the method were adapted as shown in Table 1.

Table 1. Phases of conceptual framework development

Phase	**Activity**	**Application in this study**
1	Mapping data sources	Peer-reviewed literature (1997 to 2020) on laboratory error, risk management, Six Sigma, QC design and quality indicators; cross-sector safety, quality, audit and governance frameworks; ISO, CLSI and CMS documents; IFCC working group outputs.
2	Extensive reading and categorising	Sources grouped into error epidemiology, risk tools, analytical quality, extra-analytical quality, monitoring and governance.
3	Identifying and naming concepts	Candidate concepts extracted (for example, TTP, risk priority number, Sigma metric, residual risk, quality indicator).
4	Deconstructing and categorising concepts	Each concept described by its attributes, role and ontological status (structure, process or outcome).
5	Integrating concepts	Overlapping concepts merged into higher-order constructs (for example, IQC design, PBRTQC and autoverification merged as risk control).
6	Synthesis	Constructs arranged into a layered model with directional relationships.
7	Validation	Theoretical validation against Donabedian structure-process-outcome model, Reason's accident causation model, the PDCA cycle and ISO 22367 requirements.
8	Rethinking	Framework refined to address resource-limited settings and to formulate testable propositions.

Literature was identified through searches of PubMed, Scopus and Google Scholar using combinations of the terms "laboratory error", "total testing process", "risk management", "failure mode and effects analysis", "Six Sigma", "quality control", "patient-based real-time quality control", "quality indicators" and "ISO 15189". Reference lists of key reviews were hand-searched. Because the aim was conceptual synthesis rather than effect estimation, a formal systematic review protocol and meta-analysis were not undertaken. The framework is therefore theoretical and is presented for subsequent empirical testing.

Because risk-based thinking is more mature in several high-hazard and regulated sectors than in laboratory medicine, the search was extended to conceptual frameworks from occupational and process safety, aviation safety oversight, asset integrity, pharmaceutical quality, internal audit and information governance. Frameworks from these sectors were treated as analogical sources and mined for constructs, such as hazard identification, barrier management, risk-based inspection and risk-based internal control, that could be transferred to the clinical laboratory. The methodological approach is consistent with conceptual framework studies in safety, quality and regulatory science that build integrated models from multidisciplinary literature (Adeyelu, 2019; Agboada et al., 2019; Akomolafe and Agu, 2019a; Aneke and Adesemoye, 2020; Arumosoye and Obriki, 2020; Asibor and Isong, 2019; Obriki and Arumosoye, 2018; Obriki and Arumosoye, 2020).

3. Results and Discussion

The results of the conceptual framework analysis are presented in two parts: the literature synthesis that produced the core constructs (Section 3.1) and the resulting conceptual model (Section 3.2). These are followed by the discussion of the findings (Section 3.3), their implications (Section 3.4), the limitations of the study (Section 3.5) and directions for future research (Section 3.6).

3.1 Literature synthesis

The synthesis drew together the literature that informed the framework. It moves from the laboratory-specific evidence on error and quality control to cross-sector evidence on risk, safety, assurance, digital governance and system context, and closes with a summary of the gaps that the conceptual model is designed to address.

3.1.1 The total testing process and laboratory error

The TTP describes testing as a continuous sequence that begins with the clinical question and ends with a clinical action based on the result (Plebani, 2010). Errors can occur at every step. Early studies in a stat laboratory reported that about 68% of errors were pre-analytical, 13% analytical and 19% post-analytical (Plebani and Carraro, 1997), and a follow-up study a decade later found a broadly similar distribution, although overall error rates had declined (Carraro and Plebani, 2007). Pre-analytical problems such as haemolysis, inappropriate container, insufficient volume and patient misidentification remain the dominant causes of unsuitable specimens (Lippi et al., 2011). Importantly, errors in the pre-pre-analytical phase (inappropriate test requests) and the post-post-analytical phase (misinterpretation or failure to act) are less frequently measured but may have the greatest effect on diagnosis (Plebani, 2010; Hickner et al., 2008).

Advances in diagnostic technology reinforce the importance of TTP-wide control. Automated image-based detection methods, for example template matching in mammography, show that diagnostic accuracy depends on how data are acquired and processed as well as on the measurement itself (Ejofodomi et al., 2014). Similarly, the value of integrated laboratory

information systems for infection detection rests on correct specimen identification, transmission and interpretation of results (Abdulrazaq et al., 2019).

3.1.2 Risk and risk management in the laboratory

In the context of medical laboratories, risk is defined as the combination of the probability of occurrence of harm and the severity of that harm (ISO, 2020). Risk management is the systematic application of policies, procedures and practices to analysing, evaluating, controlling and monitoring risk. ISO 14971, originally written for medical device manufacturers, introduced this cycle (ISO, 2019), and it was adapted for laboratories by CLSI EP23-A and EP18 and later by ISO 22367 (CLSI, 2011; ISO, 2020). Njoroge and Nichols (2014) noted that risk management allows laboratories to focus resources on the failure modes with the greatest potential for patient harm rather than applying the same controls everywhere.

FMEA is the most widely used tool for proactive risk identification and assessment. Each failure mode is scored for severity, occurrence and detectability, and the product of these scores gives a risk priority number (RPN) used to rank risks (Chiozza and Ponzetti, 2009). Root cause analysis and fault tree analysis are complementary retrospective and deductive tools. Risk is never eliminated completely; the remaining risk after controls are applied (residual risk) must be judged against predefined acceptability criteria.

Lessons from other high-hazard sectors are directly relevant. In occupational and construction safety, systematic reviews have examined hazard identification and risk control practices and the use of near-miss and hazard observation data (Arumosoye and Obriki, 2019; Obogo et al., 2019c), which provide models for how laboratories can learn from events that did not cause harm. Conceptual risk management models for heavy lifting and crane operations, data-driven occupational safety risk control and integrated heat stress risk models show how complex tasks can be decomposed into failure points and controls, which parallels process mapping of the TTP (Arumosoye and Obriki, 2018; Obogo et al., 2020b; Obriki and Arumosoye, 2018).

Governance models for contractor safety performance and construction safety risk governance demonstrate how risk responsibilities can be allocated across organisational boundaries (Arumosoye and Obriki, 2020; Obogo et al., 2019b), a challenge that also arises between laboratories, wards and referring clinics. Reviews of occupational safety management systems, operational integrity frameworks that balance productivity with safety compliance, and internal QHSE audit systems show the value of integrating risk control into routine management systems (Nwangwu et al., 2018; Obogo et al., 2020a; Obogo et al., 2020c). Human error is central in all of these settings, and a conceptual framework for human error causation in high-risk activities provides a structure that can be applied to mislabelling, transcription and interpretation errors in the laboratory (Obriki and Arumosoye, 2020). A risk-based process engineering framework for reliability in complex gas infrastructure similarly illustrates the use of risk ranking to prioritise engineering controls (Asibor and Isong, 2019).

Aviation offers a mature model of risk-based oversight. Predictive compliance monitoring based on consumer complaint data, adaptive safety management system implementation in developing economies, and AI-driven risk quantification models (Adeyelu, 2018; Adeyelu, 2019; Adeyelu, 2020) map closely onto laboratory complaint management, accreditation in low-resource settings and quantitative risk assessment. Risk modelling approaches developed for data-limited environmental settings show how risk can still be estimated when data are sparse (Azeez and Badmus, 2018; Lamidi and Olamide, 2018), and decision frameworks reconciling chemical safety with operational targets are relevant to the handling of hazardous laboratory reagents (Okojie and Abioye, 2020).

3.1.3 Six Sigma and risk-based statistical quality control

Six Sigma provides a common metric for process performance. In the laboratory, the Sigma metric of an assay is calculated as (TEa minus |bias|) divided by CV, where TEa is the allowable total error, bias is the systematic error and CV is the imprecision, all expressed in percentage (Westgard and Westgard, 2014). Assays with high Sigma values (6 or greater) can be controlled with simple rules and few control measurements, whereas assays with low Sigma values require multirule procedures, more frequent QC or method improvement. The Westgard Sigma Rules translate the Sigma value directly into a QC strategy (Westgard et al., 2018).

Parvin (2008) introduced a patient-risk perspective to QC design by estimating the expected number of unreliable final patient results, known as Max E(Nuf), that may be reported between a QC failure and its detection. This approach links QC frequency and run size directly to patient harm and was subsequently incorporated into CLSI C24 guidance (Yundt-Pacheco and Parvin, 2013; CLSI, 2016). Patient-based real-time quality control (PBRTQC), which uses moving averages or other statistics of patient results, adds continuous monitoring between conventional QC events and can detect errors that are not visible in control materials (Badrick et al., 2019).

Process improvement and standardisation approaches developed outside the laboratory are relevant to quality control design. Reviews of digital transformation in operations management describe the role of automation, analytics and process redesign (Agboada et al., 2018), while standard operating procedures have been conceptualised as change infrastructure for sustaining improvement (Agboada et al., 2019). Procedural standardisation in high-volume services, maturity models for standardising support operations and governance alignment in regulated multi-stakeholder operations show how consistency can be achieved across sites and teams (Anyanwu, 2019; Eyetsemitan et al., 2020; Uchechi et al., 2018). Risk-based decision-making in good manufacturing practice provides a close regulatory analogue to accredited laboratory quality systems (Aneke and Adesemoye, 2020).

Analysers and automation lines are engineered assets, and reliability engineering therefore provides useful concepts for the analytical phase. Reliability engineering and failure analysis in complex systems, risk-based inspection, reliability and integrity management, reliability-centred maintenance, condition-based maintenance and integrity assurance through inspection and

monitoring have all been described (Gideon et al., 2019; Obetta and Ninduwezuor-Ehiobu, 2018; Obetta and Ninduwezuor-Ehiobu, 2019; Obetta, 2018; Obetta, 2019; Obetta, 2020). The transition from reactive to predictive maintenance, predictive maintenance and condition monitoring of critical infrastructure, and NDT-based integrity and corrosion risk assessment show how equipment risk can be anticipated before it affects output (Adaramola et al., 2018; Atta et al., 2020; Obetta et al., 2020; Sunday et al., 2020). Predictive models for resource scaling and demand forecasting illustrate the statistical forecasting methods that also underpin moving-average and patient-based QC (Ahmed et al., 2020; Aifuwa et al., 2020).

3.1.4 Quality indicators and continual improvement

Quality indicators (QIs) quantify the performance of key processes and are required by ISO 15189. The IFCC Working Group on Laboratory Errors and Patient Safety developed a Model of Quality Indicators (MQI) covering all TTP phases, together with harmonised definitions and performance specifications (Sciacovelli et al., 2017). QIs function as the "eyes" of a risk management system: they reveal whether controls are working and whether new or changed risks are emerging. The Plan-Do-Check-Act (PDCA) cycle provides the improvement logic that links measurement to action.

Indicator-based monitoring depends on reliable data and on decision systems that turn data into action. Conceptual work on data-driven executive decision systems and on data quality in disease surveillance shows that indicators improve performance only when they are accurate and linked to clear responsibility for action (Ekemezie et al., 2018; Lawal and Oduleye, 2019b). Data-informed digital learning platforms in healthcare and STEM settings, and offline-first designs for low-connectivity environments, show how the same indicator logic can be applied to staff training and competence in settings with limited infrastructure (Orise and Niniola, 2020; Unamma et al., 2018).

3.1.5 Organisational and human factors

Reason (2000) argued that adverse events typically result from the alignment of latent conditions and active failures across several defensive layers. In the laboratory, latent conditions include staffing shortages, poor information system design and unclear procedures, while active failures include mislabelling or incorrect result entry. The Donabedian (1988) model, which relates structure, process and outcome, offers a complementary lens: risk management processes can only produce improved outcomes if supported by adequate structures such as leadership, trained staff and infrastructure. Both perspectives informed the layered architecture of the proposed framework.

Leadership and culture are repeatedly identified as the foundation of safety performance. Leadership-driven safety culture transformation and the link between management safety walkthroughs and safety culture outcomes support the foundation layer of the proposed framework (Obogo et al., 2019a; Obriki and Arumosoye, 2019). Competency frameworks and onboarding redesign, talent development and capability building, structured recruitment and

integration, performance management, industry-academia collaboration and professional development for staff competence show how competence can be built and maintained (Akhigbe et al., 2020; Falemi et al., 2020; Nwangwu et al., 2019; Ukadike, 2018; Ukadike, 2019; Wikiri, 2019; Yeboah et al., 2019). Ethics and compliance training frameworks designed to change culture and behaviour (Anichukwueze et al., 2020), and information-security awareness among records staff (Onche et al., 2020), illustrate the behavioural dimension of risk control.

Risk-based internal audit offers a further model for assurance. Conceptual models for enhancing internal audit quality through technology-enabled risk assessment, risk-based internal control, data-driven risk evaluation and integrated governance and compliance (Akomolafe and Agu, 2018; Akomolafe and Agu, 2019a; Akomolafe and Agu, 2019b; Akomolafe and Agu, 2019c) are directly relevant to internal laboratory audits and management review. Work on accounting systems for transparency and compliance, reconciliation control and workflow redesign, statutory compliance reporting, compliance analytics, risk assessment models and automated risk assessment for regulatory deliverables shows how controls can be designed, tested and documented (Bola-Sadipe et al., 2019; Dogbatsey and Ebhojie, 2018; Dogbatsey et al., 2019; Lawal and Oduleye, 2018b; Lawal and Oduleye, 2019a; Uchechi and Ominyi, 2020). Business continuity and disaster recovery preparedness during the COVID-19 pandemic (Fadero et al., 2020) highlights continuity planning as part of risk management, a lesson laboratories learned directly during 2020.

3.1.6 Information governance and digital risk

Modern laboratories depend on laboratory information systems, middleware and interfaces, so digital risk is now part of diagnostic risk. Legal and ethical risk modelling in data protection governance, comparative data protection regulation and secure cloud implementation, identity and access management, and privacy-centric security engineering provide design principles for protecting laboratory data (Mbonu et al., 2018; Mbonu et al., 2019a; Mbonu et al., 2020c; Okoruwa et al., 2020; Oshoba et al., 2019). A governance framework for platform management in regulated healthcare environments and models for data integration show how clinical data systems can be controlled (Badmus et al., 2019a; Badmus et al., 2019b). Security audit and enterprise risk assessment, risk-based cybersecurity assurance of data availability, insider threat modelling, intrusion detection, log analytics and automated incident response, and the security assessment of critical systems are relevant to the availability and integrity of results (Akeju et al., 2018; Dosunmu and Ogundele, 2019; Dosunmu and Ogundele, 2020; Fadayomi et al., 2019; Ladapo et al., 2018; Mbonu et al., 2019b). Further work on IT risk and ISO compliance controls, infrastructure governance, compliance and audit trails for configuration management, secure architectures, operational technology security and continuity of IT support extends these principles to the automation and network infrastructure on which laboratories rely (Adegbite et al., 2020; Ahmed and Odejobi, 2018a; Anyanwu, 2020; Mbonu et al., 2020a; Mbonu et al., 2020b; Oshoba et al., 2020).

3.1.7 Supply chain and health system context

Reagents, calibrators and consumables are prerequisites for reliable testing, and supply failures can force method changes or delay results. A conceptual framework for traceability and chain-of-custody integrity in pharmaceutical distribution is directly relevant to laboratory supplies (Aneke and Adesemoye, 2019). Supply chain risk management models, strategic procurement, inventory availability and uptime improvement, vendor governance, digitally enabled procurement, sustainable procurement and contractual resilience in supply chains offer further tools for managing supply risk (Agbabiaka et al., 2019; Ahiaeke Patrick et al., 2020; Okojie et al., 2020; Okonkwo et al., 2018a; Okonkwo et al., 2018b; Okonkwo et al., 2019; Uchechi et al., 2020).

Finally, laboratories operate within health systems whose design influences how laboratory quality translates into patient outcomes. Reviews of health insurance financing and provider payment reform, pharmacy-led delivery and access models, and capital equipment financing and risk management in healthcare technology procurement show how financing and procurement decisions shape the equipment and services available to laboratories (Ilodigwe and Adesemoye, 2019a; Ilodigwe and Adesemoye, 2020; Okoli et al., 2020). Analytical frameworks for efficient public infrastructure delivery reinforce the importance of planning and governance for laboratory networks (Nwafor et al., 2019b).

3.1.8 Summary of the synthesis

Four conclusions emerge from the synthesis. First, the laboratory literature has well-developed tools for analytical risk (Sigma metrics, patient-risk QC design, PBRTQC) but weaker and less integrated tools for the extra-analytical phases where most errors arise. Second, high-hazard sectors such as construction, process industries and aviation offer mature constructs for hazard identification, near-miss learning, barrier management, risk-tiered oversight and safety culture that can be transferred to the TTP. Third, regulated quality systems, reliability engineering and risk-based internal audit show how risk assessment can be tied to control design, maintenance and assurance. Fourth, digital, supply chain and health system factors increasingly determine whether reliable results reach clinicians. No existing model brings these strands together around the single outcome of diagnostic accuracy, which is the gap addressed by the conceptual model in Section 3.2.

3.2 Conceptual model

3.2.1 Core concepts

Table 2 summarises the principal concepts identified through the analysis, their definitions and their role within the framework.

Table 2. Core concepts of the risk-based framework

Concept	**Working definition**	**Role in framework**
Total testing process	The full sequence from test selection to clinical action on the result.	Domain in which risk arises
Hazard and failure mode	A potential source of harm; the manner in which a process step can fail.	Unit of risk identification
Risk	Combination of probability and severity of harm to the patient.	Object of assessment
Detectability	Likelihood that an existing control detects a failure before harm.	Modifier of risk; target of control
Sigma metric	Analytical process capability relative to TEa.	Quantitative risk input for analytical phase
Risk control measure	Any action that reduces probability, severity or increases detection.	Process element
Residual risk	Risk remaining after control measures.	Decision criterion
Quality indicator	Measurable element of performance for a TTP process.	Monitoring element
Safety culture	Shared values that encourage error reporting and learning.	Foundation element
Diagnostic accuracy	Correct and timely diagnosis supported by reliable laboratory information.	Distal outcome

3.2.2 Structure of the RB-TTPQF

The synthesis produced the Risk-Based Total Testing Process Quality Framework (RB-TTPQF), shown in Figure 1. The framework is organised in four interacting layers.

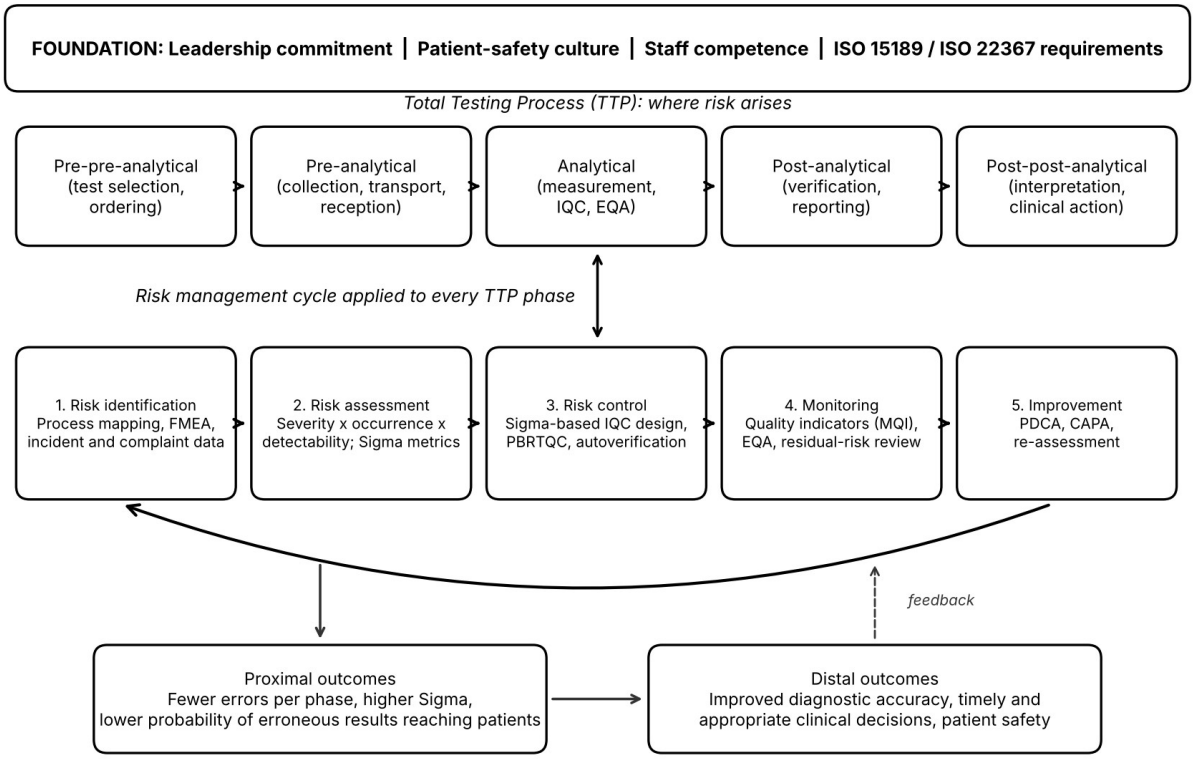


Figure 1. The Risk-Based Total Testing Process Quality Framework (RB-TTPQF). IQC, internal quality control; EQA, external quality assessment; FMEA, failure mode and effects analysis; PBRTQC, patient-based real-time quality control; MQI, Model of Quality Indicators; PDCA, Plan-Do-Check-Act; CAPA, corrective and preventive action.

3.2.3 Layer 1: Foundation

The foundation layer contains the structural conditions without which risk management cannot function: leadership commitment, a non-punitive patient-safety culture, competent and adequately staffed personnel, and alignment with ISO 15189 and ISO 22367. Leadership defines risk acceptability criteria, allocates resources and holds management reviews. Safety culture determines whether incidents and near misses are reported and therefore whether risk identification draws on real data. Competence assessment ensures that staff can perform and interpret risk tools correctly.

3.2.4 Layer 2: The total testing process

The second layer defines the scope of risk management as the entire TTP. Each of the five phases is mapped into process steps, and each step becomes a candidate location for failure modes. Explicitly including the pre-pre-analytical and post-post-analytical phases extends the responsibility of the laboratory into areas shared with clinicians, which requires interdisciplinary teams and communication channels such as demand management and interpretive commenting.

3.2.5 Layer 3: The risk management cycle

The third layer is a five-stage cycle that is applied to every TTP phase. Table 3 lists representative tools and outputs for each stage.

- **Risk identification** uses process mapping, FMEA brainstorming, incident reports, complaints, EQA failures and literature to compile a register of hazards and failure modes for each phase.
- **Risk assessment** scores each failure mode for severity, occurrence and detectability. For the analytical phase, Sigma metrics and Max E(Nuf) provide quantitative estimates of occurrence and detection. Risks are then ranked and compared with acceptability criteria using a risk matrix.
- **Risk control** applies measures in order of effectiveness: inherent safety by design (for example, closed tube systems, barcoded positive patient identification), protective measures (Sigma-based QC rules and frequency, PBRTQC, delta checks, autoverification rules, specimen integrity indices), and information for safety (training, standard procedures, critical result policies).
- **Monitoring** tracks QIs from the IFCC MQI, EQA performance, Sigma trends and incident rates to confirm that residual risks remain acceptable and to detect emerging risks.
- **Improvement** uses PDCA and corrective and preventive action to address unacceptable performance, after which risks are re-assessed. The cycle restarts whenever processes, equipment, staff or clinical needs change.

Table 3. Tools and outputs at each stage of the risk management cycle by TTP phase

TTP phase	Typical high-priority failure modes	Assessment inputs	Example controls	Example indicators
Pre-pre-analytical	Inappropriate or missing test requests; incomplete clinical details	Audit of requests; clinician feedback	Order sets, electronic decision support, demand management rules	Inappropriate request rate
Pre-analytical	Misidentification; haemolysis; wrong tube; delays	Incident data; rejection logs; FMEA	Barcoding at bedside, phlebotomy training, transport monitoring, serum indices	Misidentification rate; haemolysed sample rate

TTP phase	**Typical high-priority failure modes**	**Assessment inputs**	**Example controls**	**Example indicators**
Analytical	Systematic shift; random error; calibration failure	Sigma metric; Max E(Nuf); EQA bias	Westgard Sigma Rules, QC frequency by run size, PBRTQC	Sigma per assay; EQA unacceptable results
Post-analytical	Transcription error; delayed critical results; wrong reference interval	Audit; turnaround time data	Interfacing, autoverification, delta checks, critical result call-back	Critical result notification time; amended reports
Post-post-analytical	Misinterpretation; failure to act	Clinician surveys; case review	Interpretive comments, reflex and reflective testing, education	Follow-up of critical results; clinician satisfaction

3.2.6 Layer 4: Outcomes and feedback

The framework distinguishes proximal outcomes, which are directly measurable within the laboratory (lower error rates per phase, higher Sigma, fewer unreliable results released), from distal outcomes, which concern patients and clinical care (improved diagnostic accuracy, appropriate and timely decisions, avoidance of harm). A feedback loop links distal outcome information, such as clinician-reported diagnostic problems, back to risk identification, so that the system learns from consequences and not only from internal process data.

3.2.7 Propositions

To allow empirical testing, the relationships in the framework are expressed as six propositions.

- **P1.** Laboratories with stronger foundation elements (leadership commitment, safety culture and competence) will identify a greater number of extra-analytical failure modes and report more near misses.
- **P2.** Applying the risk management cycle across all five TTP phases, rather than to the analytical phase alone, will produce a greater reduction in total laboratory error rate.
- **P3.** Sigma-based and patient-risk-based QC design will reduce the number of unreliable patient results reported, with no increase, or a decrease, in QC cost compared with uniform QC practice.
- **P4.** Use of harmonised quality indicators linked to explicit risk re-assessment will be associated with sustained improvement in indicator performance over time.

- **P5.** Reductions in proximal error outcomes will be associated with improvements in measures of diagnostic accuracy, such as fewer diagnostic delays or misdiagnoses attributed to laboratory information.
- **P6.** Proportionate application of the framework, prioritising the highest-risk failure modes, will yield measurable benefit in resource-limited laboratories without full accreditation.

3.3 Discussion

The RB-TTPQF integrates several strands of laboratory quality science that are frequently applied separately. Its main contribution is to place the risk management cycle inside the TTP and to link both to the outcome that matters most to patients and clinicians: accurate and timely diagnosis. In doing so, it moves the focus of quality management from demonstrating conformity to reducing the probability of patient harm.

The framework is consistent with the direction of international standards. ISO 15189:2012 requires risk evaluation, and ISO 22367:2020 provides the process requirements, but neither prescribes how risk management should be connected with QC design, quality indicators and the extra-analytical phases. The framework offers this connection. It also accommodates newer QC approaches: Sigma metrics and Max E(Nuf) quantify analytical risk, while PBRTQC and autoverification serve as control measures whose effectiveness can be monitored through indicators.

Several benefits are expected. By prioritising risks, laboratories can allocate limited resources to the failure modes with the greatest consequence, which may reduce unnecessary QC repetition for high-Sigma assays and strengthen control for low-Sigma ones. By explicitly including the pre-pre-analytical and post-post-analytical phases, the framework encourages collaboration with clinicians on test selection and interpretation, areas where diagnostic errors linked to laboratory testing are common (Hickner et al., 2008). By closing the loop from monitoring to improvement, it supports continual improvement rather than one-off risk assessments.

3.4 Implications

3.4.1 Implications for laboratory practice

A phased approach is recommended so that laboratories can implement the framework incrementally.

Table 4. Stepwise implementation of the RB-TTPQF

Step	Action	Responsible	Deliverable
1. Prepare	Secure management commitment, define risk acceptability criteria, form a multidisciplinary risk team.	Laboratory director, quality manager	Risk management policy and plan

Step	Action	Responsible	Deliverable
2. Map	Map the TTP for priority tests, including links to wards and clinics.	Risk team with clinicians	Process maps
3. Identify and assess	Conduct FMEA per phase; calculate Sigma metrics for analytes.	Risk team, section heads	Risk register with RPN and Sigma values
4. Control	Implement controls for unacceptable risks; redesign IQC using Sigma rules; configure autoverification and delta checks.	Section heads, LIS staff	Updated procedures and QC plans
5. Monitor	Select QIs from the IFCC MQI; set targets; report monthly.	Quality manager	QI dashboard
6. Review and improve	Hold management review; perform CAPA; repeat assessment at least annually or after change.	Management	Review minutes; revised register

In resource-limited settings, including many laboratories in sub-Saharan Africa, the framework can be applied proportionately. Laboratories may start with a small number of high-volume or high-impact tests, use simple paper-based FMEA and risk matrices, prioritise patient identification and specimen quality, and use EQA data to estimate bias where peer data are limited. Stepwise accreditation programmes such as the WHO SLIPTA (Stepwise Laboratory Quality Improvement Process Towards Accreditation) already provide an entry point into which risk-based activities can be integrated (Gershy-Damet et al., 2010).

Evidence from comparable settings supports this proportionate approach. Diagnostic quality system frameworks and sustainable laboratory infrastructure models designed for resource-constrained health systems, expansion of diagnostic access to rural regions, and evaluations of surveillance data quality all suggest that targeted, high-yield interventions can achieve measurable gains without large investment (Aminu-Ibrahim et al., 2018; Aminu-Ibrahim et al., 2020; Ekemezie et al., 2018; Yusuf and Abdulrazaq, 2018).

3.4.2 Implications for accreditation bodies, regulators and policy makers

For accreditation bodies, the framework offers a structure against which the risk management requirements of ISO 15189 and ISO 22367 can be assessed consistently, moving assessment from checking the existence of an FMEA to evaluating whether risks across all TTP phases are identified, controlled and monitored. Regulators and ministries of health can use the framework to set national quality indicator panels, to support risk-based options for QC similar to the IQCP approach, and to prioritise investment in high-impact controls such as positive patient identification, laboratory information systems and EQA participation. In health systems that are

expanding laboratory networks, the framework can be built into the planning of facilities, procurement and supply chains so that risk control is designed in rather than added later.

3.4.3 Implications for clinicians and laboratory education

Because the framework extends into the pre-pre-analytical and post-post-analytical phases, it requires shared responsibility between laboratory professionals and clinicians for test selection, specimen quality, critical result communication and interpretation. Training curricula for laboratory scientists, pathologists and clinical biochemists should therefore include risk assessment methods, Sigma metrics, QC design and quality indicators, and continuing education for clinicians should address appropriate test use and interpretation.

3.4.4 Implications for theory

Theoretically, the framework connects laboratory quality science with patient safety theory and with the risk management literature of other high-hazard sectors. It reframes laboratory quality as a property of the whole diagnostic process rather than of the analytical method, and it specifies propositions that link structure, process and outcome in the sense of Donabedian. This provides a basis for theory testing and refinement through empirical research.

3.5 Limitations

The framework has several limitations. First, it is conceptual and has not yet been empirically validated; its propositions remain to be tested. Second, risk scoring with FMEA is partly subjective, and RPN values can be inconsistent between assessors; structured scoring guides and team-based consensus can reduce, but not eliminate, this weakness. Third, measuring distal outcomes such as diagnostic accuracy is methodologically difficult because many factors outside the laboratory affect diagnosis, which makes attribution of outcomes to laboratory risk management uncertain. Fourth, part of the synthesis draws on analogical evidence from non-laboratory sectors, and constructs transferred from construction, process industries, aviation or finance may behave differently in clinical settings. Fifth, the literature search was not a formal systematic review, so relevant studies may have been missed. Finally, implementation requires time, data systems and trained staff, which may be limited in some settings and could constrain the generalisability of the framework.

3.6 Future research

Several directions for future research follow from the framework and its propositions.

- **Empirical validation.** Multi-site studies should compare laboratories before and after implementing the framework, using interrupted time-series analysis of quality indicators to test propositions P2 and P4.
- **Risk-based QC outcomes.** Studies should evaluate whether Sigma-based and patient-risk-based QC design reduces unreliable results and QC costs compared with uniform QC, testing proposition P3.

- **Linking laboratory and diagnostic outcomes.** Validated measures are needed that link laboratory error rates to diagnostic delays, misdiagnoses and patient harm, testing proposition P5.
- **Culture and leadership.** Survey and mixed-methods studies should measure safety culture and leadership in laboratories and relate them to near-miss reporting and risk identification, testing proposition P1.
- **Resource-limited settings.** Implementation studies in low- and middle-income countries should examine which elements give the greatest benefit at lowest cost, testing proposition P6.
- **Digital and automated controls.** Research should assess the effectiveness of autoverification, PBRTQC and machine learning tools as risk controls, together with the new risks they introduce.
- **Instrument development.** A validated maturity or audit instrument based on the framework would allow laboratories and accreditation bodies to benchmark progress.

4. Conclusion

Diagnostic accuracy depends on the reliability of every step in the total testing process, not only on analytical performance. The Risk-Based Total Testing Process Quality Framework proposed in this paper integrates a foundation of leadership and safety culture, the five phases of the TTP, a five-stage risk management cycle and an outcome-feedback loop into a coherent model. It aligns with ISO 15189 and ISO 22367, incorporates Six Sigma and patient-risk QC principles, and uses harmonised quality indicators for monitoring. The framework offers clinical laboratories a practical structure for prioritising and controlling risk, and it provides researchers with testable propositions on how laboratory risk management contributes to safer and more accurate diagnosis.

Conflict of Interest

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References

1. Abdulrazaq, K., Yusuf, H. D., Osinem, H. E., & Eribenne, F. (2019). A model for improving infection detection accuracy through integrated laboratory information systems. Iconic Research and Engineering Journals, 3(6), 650-675. https://doi.org/10.64388/IREV3I6-1723089
2. Adaramola, T. S., Fadero, S., & Gideon, E. N. (2018). Predictive maintenance and condition monitoring in critical power and energy infrastructure. Iconic Research and Engineering Journals, 2(5), 454-477. https://doi.org/10.64388/IREV2I5-1722489

3. Adegbite, M. P., Adebayo, A., & Ahmed, M. O. (2020). Securing operational technology networks in electric utilities: A systematic review of NERC CIP compliance and architectural threat mitigation. International Journal of Engineering and Modern Technology, 6(3), 103-146. https://doi.org/10.56201/ijemt.vol.6.no3.2020.pg103.146
4. Adeyelu, O. O. (2018). A predictive compliance monitoring framework for detecting systemic safety risks through aviation consumer complaint data. Iconic Research and Engineering Journals, 1(8), 250-276. https://doi.org/10.64388/IREV1I8-1718478
5. Adeyelu, O. O. (2019). An adaptive safety management system implementation model for aerodromes in developing economy contexts. Iconic Research and Engineering Journals, 3(4), 628-654. https://doi.org/10.64388/IREV3I4-1718479
6. Adeyelu, O. O. (2020). An artificial intelligence-driven conceptual model for wildlife strike risk quantification and aircraft airworthiness impact assessment at high-traffic African airports. Iconic Research and Engineering Journals, 4(1), 339-368. https://doi.org/10.64388/IREV4I1-1718482
7. Agbabiaka, J., Okonkwo, C. S., Ogunwole, O., Mayo, W., & Okeke, O. T. (2019). Supply chain risk management model for EPC and gas processing projects. Iconic Research and Engineering Journals, 3(2), 968-980. https://doi.org/10.64388/IREV3I2-1713124
8. Agboada, P., Ezeako, R., Okoli, I. E., & Uzondu, C. S. (2018). Digital transformation in operations management: A review of advances in automation, analytics, and process redesign. International Journal of Engineering Technology Research & Management, 2(11), 109-134.
9. Agboada, P., Ezeako, R., Okoli, I. E., & Uzondu, C. S. (2019). Standard operating procedures as change infrastructure: A conceptual framework for sustaining operational improvement. Iconic Research and Engineering Journals, 3(6), 706-730. https://doi.org/10.64388/IREV3I6-1723313
10. Ahiaeke Patrick, M. C., Okonkwo, C. S., Mayo, W., & Okeke, O. T. (2020). A GIS enabled framework for modern ERP procurement processes. International Journal of Multidisciplinary Research and Growth Evaluation, 1(5), 499-508. https://doi.org/10.54660/IJMRGE.2020.1.5.499-508
11. Ahmed, K. S., & Odejobi, O. D. (2018a). Conceptual framework for scalable and secure cloud architectures for enterprise messaging. IRE Journals, 2(1), 1-15.
12. Ahmed, K. S., Odejobi, O. D., & Oshoba, T. O. (2020). Predictive model for cloud resource scaling using machine learning techniques. Journal of Frontiers in Multidisciplinary Research, 1(1), 173-183.
13. Aifuwa, S. E., Oshoba, T. O., Ogbuefi, E., Ike, P. N., Nnabueze, S. B., & Olatunde-Thorpe, J. (2020). Predictive analytics models enhancing supply chain demand forecasting accuracy and reducing inventory management inefficiencies. International Journal of Multidisciplinary Research and Growth Evaluation, 1(3), 171-181. https://doi.org/10.54660/.IJMRGE.2020.1.3.171-181
14. Akeju, B., Edivri, J., Ogbole, J. I., Okoruwa, P. O., Fadayomi, O., & Abolaji, T. O. (2018). Conceptual model for insider threat classification and risk modeling in complex digital

systems. Iconic Research and Engineering Journals, 1(9), 476-492. https://doi.org/10.64388/IREV1I9-1713778

15. Akhigbe, R., Wikiri, M., & Udeh, C. A. (2020). Strategic recruitment and employee integration in emerging-market enterprises: A framework for building workforce capacity. International Journal of Multidisciplinary Research and Growth Evaluation, 1(5), 1265-1278. https://doi.org/10.54660/.IJMRGE.2020.1.5.1265-1278
16. Akomolafe, O., & Agu, M. U. (2018). A conceptual model for enhancing internal audit quality through technology-enabled risk assessment frameworks. Iconic Research and Engineering Journals, 1(9), 458-475.
17. Akomolafe, O., & Agu, M. U. (2019a). A conceptual framework for developing risk-based internal control models in the insurance and banking sectors. Iconic Research and Engineering Journals, 2(8), 335-354.
18. Akomolafe, O., & Agu, M. U. (2019b). A review of data-driven risk evaluation models for emerging market financial institutions. Iconic Research and Engineering Journals, 3(6), 433-448.
19. Akomolafe, O., & Agu, M. U. (2019c). Advances in financial resilience through integrated governance and compliance strategies. Iconic Research and Engineering Journals, 2(10), 607-620.
20. Aminu-Ibrahim, A. Y., Ogbete, J. C., & Ambali, K. B. (2018). Developing sustainable diagnostic laboratory infrastructure models for emerging and resource constrained health systems. Iconic Research and Engineering Journals, 1(8), 118-132. https://doi.org/10.64388/IREV1I8-1713586
21. Aminu-Ibrahim, A. Y., Ogbete, J. C., & Ambali, K. B. (2019). Capital project delivery models for high risk healthcare infrastructure in developing national health systems. Iconic Research and Engineering Journals, 2(10), 626-649. https://doi.org/10.64388/IREV2I10-1713588
22. Aminu-Ibrahim, A. Y., Ogbete, J. C., & Ambali, K. B. (2020). Infrastructure driven expansion of diagnostic access across underserved and rural healthcare regions. International Journal of Multidisciplinary Research and Growth Evaluation, 1(5), 691-706. https://doi.org/10.54660/IJMRGE.2020.1.5.691-706
23. Aneke, O. B., & Adesemoye, A. C. (2019). Toward an integrated conceptual framework for traceability and chain-of-custody integrity in pharmaceutical distribution. Iconic Research and Engineering Journals, 3(4), 655-672.
24. Aneke, O. B., & Adesemoye, A. C. (2020). A conceptual framework for risk-based decision-making in good manufacturing practice environments. Iconic Research and Engineering Journals, 4(6), 325-341.
25. Anichukwueze, C. C., Osuji, V. C., & Oguntegbe, E. E. (2020). Designing ethics and compliance training frameworks to drive measurable cultural and behavioral change. International Journal of Multidisciplinary Research and Growth Evaluation, 1(3), 205-220.

26. Anyanwu, K. C. E. (2019). Developing a maturity model for standardizing IT support operations across geographically distributed multi-office organizations. Iconic Research and Engineering Journals, 3(5)., 580-598.
27. Anyanwu, K. C. E. (2020). Balancing cost and operational continuity in hybrid remote and on-site IT support for multi-branch SMEs. International Journal of Economics and Financial Management, 5(2), 132-148. https://doi.org/10.56201/ijefm.v5.no2.2020.pg132.148
28. Arumosoye, O. M., & Obriki, O. D. (2018). Development of an integrated heat stress risk conceptual model for industrial operations in extreme environments. Iconic Research and Engineering Journals, 1(12), 141-160. https://doi.org/10.64388/IREV1I12-1714415
29. Arumosoye, O. M., & Obriki, O. D. (2019). Systematic review of near-miss and hazard observation data utilization in industrial safety management. Iconic Research and Engineering Journals, 3(2), 981-999. https://doi.org/10.64388/IREV3I2-1714417
30. Arumosoye, O. M., & Obriki, O. D. (2020). A governance-oriented conceptual model for contractor safety performance in multi-contract industrial projects. International Journal of Multidisciplinary Research and Growth Evaluation, 1(5), 728-740. https://doi.org/10.54660/.IJMRGE.2020.1.5.728-740
31. Asibor, E., & Isong, D. E. (2019). Risk-based process engineering framework for strengthening reliability across complex natural gas infrastructure systems. Iconic Research and Engineering Journals, 3(2), 1020-1060. https://doi.org/10.64388/IREV3I2-1723153
32. Atta, S., Tofah, P., Kankam, M. A., & Adenuga, O. M. (2020). A critical review of NDT-based integrity management and corrosion risk assessment strategies for refinery process equipment. International Journal of Engineering and Modern Technology, 6(2), 19-46. https://doi.org/10.56201/ijemt.vol.6.no2.2020.pg19.46
33. Azeez, L. O., & Badmus, O. B. (2018). Data-driven framework for predicting subsurface contamination pathways in complex remediation projects. Iconic Research and Engineering Journals, 2(5), 312-335.
34. Badmus, O., Dosunmu, A. A., & Ozowara, D. E. (2019a). A conceptual model for ETL design and data integration in Salesforce-centric enterprise architectures. Iconic Research and Engineering Journals, 3(5).
35. Badmus, O., Dosunmu, A. A., & Ozowara, D. E. (2019b). A governance framework for Salesforce platform management in regulated healthcare environments. Iconic Research and Engineering Journals, 3(6).
36. Badrick, T., Bietenbeck, A., Cervinski, M. A., Katayev, A., van Rossum, H. H., and Loh, T. P. (2019). Patient-based real-time quality control: review and recommendations. *Clinical Chemistry*, 65(8), 962-971.
37. Bola-Sadipe, D., Aliliele, C., & Eboh, E. E. (2019). Conceptual model for strategic accounting systems strengthening financial transparency and regulatory compliance. IRE Journals, 3(6), 535-564. https://doi.org/10.64388/IREV3I6-1715327
38. Bonini, P., Plebani, M., Ceriotti, F., and Rubboli, F. (2002). Errors in laboratory medicine. *Clinical Chemistry*, 48(5), 691-698.

39. Carraro, P., and Plebani, M. (2007). Errors in a stat laboratory: types and frequencies 10 years later. *Clinical Chemistry*, 53(7), 1338-1342.
40. Centers for Medicare and Medicaid Services. (2014). *Individualized Quality Control Plan (IQCP): A new quality control option*. Baltimore, MD: CMS.
41. Chiozza, M. L., and Ponzetti, C. (2009). FMEA: a model for reducing medical errors. *Clinica Chimica Acta*, 404(1), 75-78.
42. Clinical and Laboratory Standards Institute. (2011). *Laboratory quality control based on risk management; Approved guideline* (CLSI document EP23-A). Wayne, PA: CLSI.
43. Clinical and Laboratory Standards Institute. (2016). *Statistical quality control for quantitative measurement procedures: Principles and definitions* (4th ed., CLSI guideline C24). Wayne, PA: CLSI.
44. Dogbatsey, E. A., & Ebhojie, O. (2018). Budget compliance and statutory reporting in Sub-Saharan Africa: A systematic review of frameworks, gaps, and reform pathways. Zenodo. https://doi.org/10.5281/zenodo.20446859
45. Dogbatsey, E. A., Ebhojie, O., & Oyeleye, A. O. (2019). Reconciliation control and financial workflow redesign in emerging market organizations: A conceptual framework. Zenodo. https://doi.org/10.5281/zenodo.20447103
46. Donabedian, A. (1988). The quality of care: How can it be assessed? *JAMA*, 260(12), 1743-1748.
47. Dosunmu, A. A., & Ogundele, P. O. (2019). Security audit and enterprise risk assessment frameworks for resilient information systems. Iconic Research and Engineering Journals, 3(5), 434-447. https://doi.org/10.64388/IREV3I5-1713225
48. Dosunmu, A. A., & Ogundele, P. O. (2020). Intrusion detection and prevention models for enhancing organizational cyber defense effectiveness. Iconic Research and Engineering Journals, 4(6), 310-324. https://doi.org/10.64388/IREV4I6-1713226
49. Ejofodomi, O. A., Gideon, E. N., Oladipo, G. O., & Oshomah, E. R. (2014). Automated detection of architectural detection in mammograms using template matching. International Journal of Biomedical Science and Engineering, 2(1), 1-6. https://doi.org/10.11648/j.ijbse.20140201.11
50. Ekemezie, U. C., Ohunyon, G., & Sydney, E. (2018). Evaluating IDSR implementation in Benue State, Nigeria: DHIS2 data quality and surveillance capacity. Iconic Research and Engineering Journals, 2(6).
51. Eyetsemitan, R. A., Ambali, K. B., Oyeleye, A. O., & Fadayomi, O. (2020). Multi-stakeholder governance alignment in joint venture operations: A conceptual framework for coordinating business processes in highly regulated environments. Iconic Research and Engineering Journals, 4(4), 418-441. https://doi.org/10.64388/IREV4I4-1716955
52. Fadayomi, O., Abolaji, T. O., Edivri, J., Ogbole, J. I., Okoruwa, P. O., & Akeju, B. (2019). Risk-based cybersecurity assurance and data availability: Limitations, advances and future research opportunities. Iconic Research and Engineering Journals, 2(12), 602-617. https://doi.org/10.64388/IREV2I12-1713779

53. Fadero, S., Jooda, D., Oyesiji, S. O., & Nwakamma, S. (2020). Business continuity and disaster recovery preparedness in African financial services: Lessons from the COVID-19 pandemic. Iconic Research and Engineering Journals, 3(9), 525-544. https://doi.org/10.64388/IREV3I9-1722620
54. Falemi, A., Akhigbe, R., & Akin-Oluyomi, O. T. (2020). A conceptual supply chain talent development model for capability building across distributed operations. International Journal of Multidisciplinary Research and Growth Evaluation, 1(5), 439-456. https://doi.org/10.54660/.ijmrge.2020.1.5.439-456
55. Gershy-Damet, G. M., Rotz, P., Cross, D., Belabbes, E. H., Cham, F., Ndihokubwayo, J. B., et al. (2010). The World Health Organization African region laboratory accreditation process: Improving the quality of laboratory systems in the African region. *American Journal of Clinical Pathology*, 134(3), 393-400.
56. Gideon, E. N., Adaramola, T. S., & Fadero, S. (2019). Reliability engineering and failure analysis in complex engineering systems. Iconic Research and Engineering Journals, 2(11), 703-727. https://doi.org/10.64388/IREV2I11-1722490
57. Hallworth, M. J. (2011). The "70% claim": what is the evidence base? *Annals of Clinical Biochemistry*, 48(6), 487-488.
58. Hickner, J., Graham, D. G., Elder, N. C., Brandt, E., Emsermann, C. B., Dovey, S., and Phillips, R. (2008). Testing process errors and their harms and consequences reported from family medicine practices: a study of the American Academy of Family Physicians National Research Network. *Quality and Safety in Health Care*, 17(3), 194-200.
59. Ilodigwe, L., & Adesemoye, A. C. (2019a). A critical review of health insurance financing mechanisms and provider payment reform strategies for balancing coverage expansion and financial protection in emerging markets. International Journal of Health and Pharmaceutical Research, 5(2), 31-55. https://doi.org/10.56201/ijhpr.vol.5.no2.2019.pg31.55
60. Ilodigwe, L., & Adesemoye, A. C. (2019b). From molecules to health systems: A conceptual model explaining why scientific innovation fails to improve patient outcomes without effective healthcare delivery infrastructure. International Journal of Health and Pharmaceutical Research, 5(2), 56-79. https://doi.org/10.56201/ijhpr.vol.5.no2.2019.pg56.79
61. Ilodigwe, L., & Adesemoye, A. C. (2020). Advances in pharmacy-led delivery and access models for strengthening primary healthcare systems and expanding medicine availability in emerging markets. International Journal of Health and Pharmaceutical Research, 5(3), 78-96. https://doi.org/10.56201/ijhpr.vol.5.no3.2020.pg78.96
62. International Organization for Standardization. (2012). *ISO 15189:2012 Medical laboratories: Requirements for quality and competence*. Geneva: ISO.
63. International Organization for Standardization. (2019). *ISO 14971:2019 Medical devices: Application of risk management to medical devices*. Geneva: ISO.
64. International Organization for Standardization. (2020). *ISO 22367:2020 Medical laboratories: Application of risk management to medical laboratories*. Geneva: ISO.
65. Jabareen, Y. (2009). Building a conceptual framework: philosophy, definitions, and procedure. *International Journal of Qualitative Methods*, 8(4), 49-62.

66. Ladapo, O. O., Dosunmu, A. A., Jooda, D., & Abolaji, T. O. (2018). Lessons learned from offline assessment of security-critical systems: The case of Microsoft Active Directory. Iconic Research and Engineering Journals, 2(6), 277-299. https://doi.org/10.64388/IREV2I6-1717205
67. Lamidi, O. B. A., & Olamide, A. (2018). Spatially explicit risk modeling framework for tracking subsurface contaminant migration in data-limited remediation sites. Iconic Research and Engineering Journals, 2(6), 178-198.
68. Lawal, O. A., & Oduleye, T. E. (2018b). A review and conceptual framework for tax governance and cross-border compliance analytics. Iconic Research and Engineering Journals, 2(5).
69. Lawal, O. A., & Oduleye, T. E. (2019a). A conceptual risk assessment model for transfer pricing in multinational corporations. Iconic Research and Engineering Journals, 2(12).
70. Lawal, O. A., & Oduleye, T. E. (2019b). Conceptualizing data driven executive decision systems for strategic financial planning. Iconic Research and Engineering Journals, 3(3).
71. Lippi, G., Chance, J. J., Church, S., Dazzi, P., Fontana, R., Giavarina, D., et al. (2011). Preanalytical quality improvement: from dream to reality. *Clinical Chemistry and Laboratory Medicine*, 49(7), 1113-1126.
72. Lundberg, G. D. (1981). Acting on significant laboratory results. *JAMA*, 245(17), 1762-1763.
73. Mbonu, I. S., Aliliele, C., Iwuanyanwu, U., & Oluoha, O. M. (2018). A conceptual framework for legal and ethical risk modeling in enterprise data protection governance systems. Iconic Research and Engineering Journals, 2(2), 207-226. https://doi.org/10.64388/IREV2I2-1714911
74. Mbonu, I. S., Aliliele, C., Iwuanyanwu, U., & Uzoka, E. (2020c). A review of identity and access management integration strategies in hybrid and multi cloud environments. International Journal of Multidisciplinary Research and Growth Evaluation, 1(5), 795-810. https://doi.org/10.54660/.IJMRGE.2020.1.5.795-810
75. Mbonu, I. S., Aliliele, C., Uzoka, E., & Oluoha, O. M. (2019a). A review of comparative data protection regulations and secure cloud implementation strategies across jurisdictions. Iconic Research and Engineering Journals, 2(9), 482-501. https://doi.org/10.64388/IREV2I9-1714912
76. Mbonu, I. S., Iwuanyanwu, U., Aliliele, C., & Uzoka, E. (2020a). A conceptual framework for agile supply chain digital transformation with embedded IT risk and ISO compliance controls. Iconic Research and Engineering Journals, 3(11), 566-593. https://doi.org/10.64388/IREV3I11-1714916
77. Mbonu, I. S., Iwuanyanwu, U., Aliliele, C., & Uzoka, E. (2020b). Advances in infrastructure as code governance for secure terraform based enterprise cloud deployments. International Journal of Multidisciplinary Research and Growth Evaluation, 1(5), 811-828. https://doi.org/10.54660/.IJMRGE.2020.1.5.811-828
78. Mbonu, I. S., Iwuanyanwu, U., Uzoka, E., & Oluoha, O. M. (2019b). Advances in enterprise log analytics and automated incident response architectures using Python and SIEM

platforms. Iconic Research and Engineering Journals, 3(2), 1000-1019. https://doi.org/10.64388/IREV3I2-1714915

79. National Academies of Sciences, Engineering, and Medicine. (2015). *Improving diagnosis in health care*. Washington, DC: The National Academies Press.
80. Njoroge, S. W., and Nichols, J. H. (2014). Risk management in the clinical laboratory. *Annals of Laboratory Medicine*, 34(4), 274-278.
81. Nwafor, M. I., Uduokhai, D. O., Ifechukwu, G. O., Stephen, D., & Aransi, A. N. (2019b). Developing an analytical framework for enhancing efficiency in public infrastructure delivery systems. Iconic Research and Engineering Journals, 2(11), 657-670.
82. Nwangwu, C. V., Duvbiama-Owasanoye, O. A., & Onwumere, A. (2018). A framework for operational integrity in high-risk drilling: Balancing productivity and safety compliance. Iconic Research and Engineering Journals, 2(5), 436-453.
83. Nwangwu, C. V., Duvbiama-Owasanoye, O. A., & Onwumere, A. (2019). A strategic review of the industry-academia collaboration model for modernizing technical learning centers. Iconic Research and Engineering Journals, 3(6), 565-583.
84. Obetta, P. C. (2018). A risk-based inspection concept for fitness-for-service assessment of ageing pressure vessels on offshore joint venture facilities. Iconic Research and Engineering Journals, 2(5), 497-520. https://doi.org/10.64388/IREV2I5-1722578
85. Obetta, P. C. (2019). Reliability and integrity management of fired heaters, boilers and furnaces in upstream oil and gas: A review. Iconic Research and Engineering Journals, 3(5), 599-626. https://doi.org/10.64388/IREV3I5-1722580
86. Obetta, P. C. (2020). A reliability-centered maintenance (RCM) concept for static mechanical equipment in offshore oil and gas operations. International Journal of Multidisciplinary Futuristic Development, 1(1), 74-91. https://doi.org/10.54660/IJMFD.2020.1.1.74-91
87. Obetta, P. C., & Ninduwezuor-Ehiobu, N. (2018). A condition-based maintenance concept for CALM buoy bearings and swivels to improve offshore crude export availability. Iconic Research and Engineering Journals, 2(6), 385-410. https://doi.org/10.64388/IREV2I6-1722579
88. Obetta, P. C., & Ninduwezuor-Ehiobu, N. (2019). Integrity assurance of FSO turret mooring systems: A review of inspection, monitoring and life-extension strategies. Iconic Research and Engineering Journals, 3(6), 599-629. https://doi.org/10.64388/IREV3I6-1722581
89. Obetta, P. C., Ninduwezuor-Ehiobu, N., & Olisakwe, H. C. (2020). Corrosion management and material selection for crude oil export equipment in marine environments: A review. International Journal of Multidisciplinary Futuristic Development, 1(1), 92-110. https://doi.org/10.54660/IJMFD.2020.1.1.92-110
90. Obogo, S. F., Arumosoye, O. M., & Obriki, O. D. (2020a). Advances in internal QHSE audit systems for industrial engineering operations. Iconic Research and Engineering Journals, 4(4), 399-417. https://doi.org/10.64388/IREV4I4-1715499
91. Obogo, S. F., Arumosoye, O. M., & Obriki, O. D. (2020b). Conceptual risk management model for heavy lifting and crane installation engineering operations. Shodhshauryam,

International Scientific Refereed Research Journal, 3(4), 122-144. https://doi.org/10.32628/SHISRRJ214441

92. Obogo, S. F., Arumosoye, O. M., & Obriki, O. D. (2020c). Critical review of occupational safety management systems in oil and gas maintenance projects. Shodhshauryam, International Scientific Refereed Research Journal, 3(4), 145-166. https://doi.org/10.32628/SHISRRJ214442
93. Obogo, S. F., Ozobu, C. O., & Uduokhai, D. O. (2019a). Advances in leadership driven safety culture transformation in large construction workforces. Iconic Research and Engineering Journals, 3(5), 507-523. https://doi.org/10.64388/IREV3I5-1715497
94. Obogo, S. F., Ozobu, C. O., & Uduokhai, D. O. (2019b). Development of a construction safety risk governance model for multi contractor high rise projects. Iconic Research and Engineering Journals, 2(9), 502-522. https://doi.org/10.64388/IREV2I9-1715495
95. Obogo, S. F., Uduokhai, D. O., & Ozobu, C. O. (2019c). Systematic review of hazard identification and risk control practices in urban construction projects. Iconic Research and Engineering Journals, 2(12), 666-681. https://doi.org/10.64388/IREV2I12-1715496
96. Obriki, O. D., & Arumosoye, O. M. (2018). Conceptual modeling of data-driven occupational safety risk control in large-scale energy infrastructure projects. Iconic Research and Engineering Journals, 1(7), 169-189. https://doi.org/10.64388/IREV1I7-1714414
97. Obriki, O. D., & Arumosoye, O. M. (2019). A conceptual framework linking management safety walkthrough frequency and coverage to safety culture outcomes in mega projects. Iconic Research and Engineering Journals, 2(8), 355-374. https://doi.org/10.64388/IREV2I8-1714416
98. Obriki, O. D., & Arumosoye, O. M. (2020). Conceptual framework for human error causation in high-risk construction and industrial activities. International Journal of Multidisciplinary Research and Growth Evaluation, 1(5), 715-727. https://doi.org/10.54660/.IJMRGE.2020.1.5.715-727
99. Ogbete, J. C., Aminu-Ibrahim, A. Y., & Ambali, K. B. (2018). Optimizing laboratory spatial planning strategies to improve diagnostic accuracy, safety, and clinical throughput. Iconic Research and Engineering Journals, 2(1), 87-113. https://doi.org/10.64388/IREV1I7-1713587
100. Ogbete, J. C., Aminu-Ibrahim, A. Y., & Ambali, K. B. (2019). Regulatory compliant design systems for molecular and pathology laboratories in highly controlled environments. Iconic Research and Engineering Journals, 3(4), 607-631. https://doi.org/10.64388/IREV3I4-1713589
101. Ogbete, J. C., Aminu-Ibrahim, A. Y., & Ambali, K. B. (2020). Sustainable materials selection and energy efficiency strategies for modern medical laboratory facilities. International Journal of Multidisciplinary Research and Growth Evaluation, 1(5), 674-690. https://doi.org/10.54660/IJMRGE.2020.1.5.674-690
102. Okojie, J. S., & Abioye, R. F. (2020). Reconciling chemical safety with circular-economy targets: A decision framework for post-consumer recycled polymers in consumer-goods

packaging balancing REACH compliance, lifecycle GHG footprint, and regulatory risk. International Journal of Multidisciplinary Research and Growth Evaluation, 1(5), 992-1006.

103. Okojie, J. S., Filani, O. M., Ihwughwavwe, S. I., & Sakyi, J. K. (2020). Sustainable procurement practices: ESG-integrated supply chain models for corporate responsibility and environmental performance. IRE Journals, 4(2).
104. Okoli, I., Agboada, P., Kinyanjui, A., Akintobi, A., & Pedro, O. (2020). Capital equipment financing and risk management in healthcare technology procurement. International Journal of Humanities and Information Technology(Special Issue 2), 12-54. https://doi.org/10.21590/ijhit.spcl.02.02
105. Okonkwo, C. S., Ogunwole, O., & Okeke, O. T. (2018a). Framework for strategic procurement optimization in oil and gas operations. Iconic Research and Engineering Journals, 1(7), 153-168. https://doi.org/10.64388/IREV1I7-1713119
106. Okonkwo, C. S., Ogunwole, O., & Okeke, O. T. (2018b). Model for inventory availability and plant uptime improvement in energy facilities. Iconic Research and Engineering Journals, 2(4), 160-172. https://doi.org/10.64388/IREV2I4-1713120
107. Okonkwo, C. S., Ogunwole, O., Okeke, O. T., & Mayo, W. (2019). Conceptual framework for cost reduction through contract negotiation and vendor governance. Iconic Research and Engineering Journals, 2(9), 468-482. https://doi.org/10.64388/IREV2I9-1713121
108. Okoruwa, P. O., Fadayomi, O., Akeju, B., Edivri, J., Ogbole, J. I., & Abolaji, T. O. (2020). Conceptual model for privacy-centric security engineering in digital and cloud computing systems. International Journal of Scientific Research in Computer Science, Engineering and Information Technology, 7(5), 371-389.
109. Onche, V. O., Ogbonna, C. S., & Adegbite, M. P. (2020). Information-security awareness and records confidentiality in Nigerian university registries: A behavioural assessment. International Journal of Multidisciplinary Research and Growth Evaluation, 1(5), 1032-1044. https://doi.org/10.54660/.IJMRGE.2020.1.5.1032-1044
110. Orise, C., & Niniola, S. (2020). Data-informed digital learning platforms: A conceptual framework for evidence-based educational technology in healthcare and STEM environments. International Journal of Multidisciplinary Research and Growth Evaluation, 1(5), 1078-1089. https://doi.org/10.54660/.IJMRGE.2020.1.5.1078-1089
111. Oshoba, T. O., Hammed, N. I., & Odejobi, O. D. (2019). Secure identity and access management model for distributed and federated systems. IRE Journals, 3(4), 550-567.
112. Oshoba, T. O., Hammed, N. I., & Odejobi, O. D. (2020). Blockchain-enabled compliance and audit trail model for cloud configuration management. Journal of Frontiers in Multidisciplinary Research, 1(1), 193-201.
113. Parvin, C. A. (2008). Assessing the impact of the frequency of quality control testing on the quality of reported patient results. *Clinical Chemistry*, 54(12), 2049-2054.
114. Plebani, M. (2006). Errors in clinical laboratories or errors in laboratory medicine? *Clinical Chemistry and Laboratory Medicine*, 44(6), 750-759.

115. Plebani, M. (2010). The detection and prevention of errors in laboratory medicine. *Annals of Clinical Biochemistry*, 47(2), 101-110.
116. Plebani, M., and Carraro, P. (1997). Mistakes in a stat laboratory: types and frequency. *Clinical Chemistry*, 43(8), 1348-1351.
117. Reason, J. (2000). Human error: models and management. *BMJ*, 320(7237), 768-770.
118. Sciacovelli, L., Lippi, G., Sumarac, Z., West, J., Garcia del Pino Castro, I., Furtado Vieira, K., et al. (2017). Quality indicators in laboratory medicine: the status of the progress of IFCC Working Group "Laboratory Errors and Patient Safety" project. *Clinical Chemistry and Laboratory Medicine*, 55(3), 348-357.
119. Sunday, E. A., Omoegun, G. O., Essien, M. A., & Oluokun, O. A. (2020). Transitioning from reactive to predictive maintenance in mechanical systems. International Journal of Scientific Research in Computer Science, Engineering and Information Technology, 6(6), 425-447.
120. Uchechi, N., & Ominyi, M. (2020). Advances in automated risk assessment frameworks for regulatory deliverables in upstream energy operations. International Journal of Multidisciplinary Evolutionary Research, 1(2), 158-175. https://doi.org/10.54660/IJMER.2020.1.2.158-175
121. Uchechi, N., Ominyi, M., & Jones, B. C. (2018). Procedural standardization and workflow optimization in high-volume dispute resolution clinics: A systematic review. Iconic Research and Engineering Journals, 2(6), 420-452. https://doi.org/10.64388/IREV2I6-1722789
122. Uchechi, N., Ominyi, M., Anichukwueze, C. C., & Jones, B. C. (2020). Force majeure and contractual resilience in global energy supply chains: A systematic review. International Journal of Multidisciplinary Research and Growth Evaluation, 1(5), 1247-1264. https://doi.org/10.54660/.IJMRGE.2020.1.5.1247-1264
123. Ukadike, C. A. (2018). Competency frameworks and onboarding redesign in professional services: A conceptual model for return on investment. International Journal of Social Sciences and Management Research, 4(9), 42-62. https://doi.org/10.56201/ijssmr.v4.no9.2018.pg.42.62
124. Ukadike, C. A. (2019). Gamification in talent and performance management: A systematic review of effects on attrition, engagement, and cost. International Journal of Social Sciences and Management Research, 5(4), 108-129. https://doi.org/10.56201/ijssmr.v5.no4.2019.pg.108.129
125. Unamma, U. M.-L., Okwesa, I. J., Iwuanyanwu, U., & Ajiga, D. (2018). An offline-first design framework for digital learning in low-connectivity environments. Iconic Research and Engineering Journals, 2(3), 192-211. https://doi.org/10.64388/IREV2I3-1722627
126. Westgard, J. O., and Westgard, S. A. (2014). *Basic quality management systems: Essentials for quality management in the medical laboratory*. Madison, WI: Westgard QC.
127. Westgard, J. O., Bayat, H., and Westgard, S. A. (2018). Planning risk-based SQC schedules for bracketed operation of continuous production analyzers. *Clinical Chemistry*, 64(2), 289-296.

128. Wikiri, M. (2019). Global technology talent development in emerging markets: A conceptual framework for preparing software professionals for international employment. Iconic Research and Engineering Journals, 3(5), 651-671. https://doi.org/10.64388/IREV3I5-1723088

129. Yeboah, T. J., Bobga, M. A., Boakye, K., & Ogbona, C. S. (2019). Professional development and teacher competence in managing exceptional learners: A Ghanaian perspective. Iconic Research and Engineering Journals, 2(12), 618-636. https://doi.org/10.64388/IREV2I12-1714177

130. Yundt-Pacheco, J., and Parvin, C. A. (2013). Validating the performance of QC procedures. *Clinics in Laboratory Medicine*, 33(1), 75-88.

131. Yusuf, H. D., & Abdulrazaq, K. (2018). A conceptual framework for strengthening diagnostic quality systems in resource-limited clinical laboratories. Iconic Research and Engineering Journals, 1(11), 145-179. https://doi.org/10.64388/IREV1I11-1723090

132. Yusuf, H. D., Abdulrazaq, K., Osinem, H. E., & Eribenne, F. (2020). Advances in antimicrobial resistance surveillance using multi-laboratory national reporting networks. International Journal of Multidisciplinary Evolutionary Research, 1(2), 176-194. https://doi.org/10.54660/IJMER.2020.1.2.176-194