

Integration Of Biomedical Equipment Maintenance And Laboratory Quality Management To Enhance Diagnostic Accuracy: A Systematic Review

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Abstract

Background: Ensuring diagnostic accuracy in clinical laboratories requires not only robust analytical protocols but also an integrated approach to equipment maintenance within the laboratory quality management system (QMS). International standards like ISO 15189 emphasize equipment management as a core element of laboratory accreditation, yet the degree to which integrating maintenance programs with QMS enhances diagnostic reliability has varied in practice. We conducted a systematic review of recent literature (2015–2025) to evaluate how the integration of biomedical equipment maintenance with laboratory QMS contributes to improved diagnostic accuracy, reduced error rates, higher equipment uptime, and patient safety.

Methods: Following PRISMA guidelines, we searched PubMed, Scopus, Web of Science, and IEEE Xplore for peer-reviewed studies published from 2010 to October 2025. Search terms combined concepts of laboratory equipment maintenance, quality management (including ISO 15189, WHO-LQMS), and diagnostic accuracy or errors. We included studies that explicitly addressed equipment maintenance within a laboratory QMS and reported impacts on diagnostic performance or related outcomes. Two reviewers screened titles/abstracts and full texts against inclusion criteria. Data were extracted and synthesized qualitatively from 12 selected studies. A PRISMA flow diagram depicts the selection process.

Results: The 12 included studies encompassed diverse settings (including hospitals in Africa, Asia, and Europe) and study designs (cross-sectional analyses, quality improvement interventions, and retrospective cohort studies). Despite methodological heterogeneity, all studies reported that integrating systematic maintenance practices into the lab QMS yielded substantial quality benefits. Laboratories accredited to

ISO 15189 or similar standards (which mandate equipment maintenance protocols) showed significantly lower error rates – in one 19-year analysis, labs with ISO 15189 had roughly half the rate of incorrect results compared to non-accredited labs (0.7% vs 1.4%, $p < 0.001$). Multiple studies linked preventive maintenance and calibration programs with improved test accuracy and reliability. Proactive maintenance was also associated with increased equipment uptime and fewer interruptions in service. For example, one hospital lab reported a 78% reduction in unplanned instrument downtime after implementing routine maintenance, translating to over 100 hours of additional operational time per instrument annually (Consequences of Unplanned Downtime in the Laboratory, n.d.). Integration of maintenance into QMS contributed to patient safety by reducing diagnostic errors and delays. Several papers highlighted that well-maintained equipment produces reliable results that clinicians can trust for patient care. In resource-limited settings, introducing QMS-driven maintenance (through programs like WHO-LQMS or SLMTA) dramatically improved quality indicators: one nationwide program saw equipment management scores increase by ~5.3 points (out of 5-star rating) and a 330% rise in accredited labs over two years. However, gaps remain, including inconsistent tracking of maintenance-related errors and limited data on direct patient outcomes.

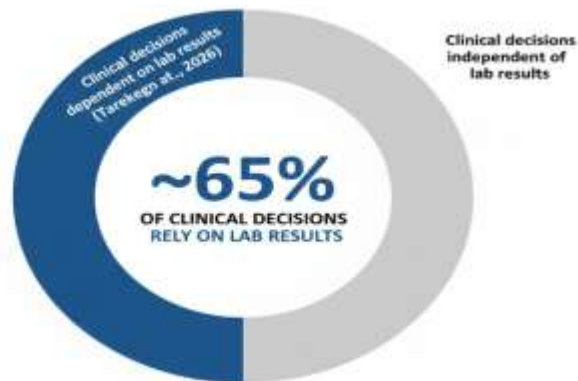
Discussion: The literature consistently indicates that integrating equipment maintenance into laboratory QMS frameworks enhances diagnostic accuracy and reliability. Preventive maintenance schedules and calibration checks embedded in quality systems help ensure the validity of results, minimizing variability as instruments age. Such integration also reduces the risk of test interruptions – equipment failures and downtime were identified as major contributors to analytical phase errors in laboratories. Quality system accreditation (ISO 15189) or stepwise quality improvement programs enforce regular maintenance, yielding measurably lower error rates and more consistent turnaround times. Patterns in the literature show a trend toward risk-based maintenance strategies and the use of data analytics (e.g. risk prioritization models, machine learning) to optimize equipment management. Nonetheless, challenges such as insufficient funding for maintenance in low-resource settings and lack of standardized maintenance metrics persist. Future research should address these gaps and quantify how maintenance-integrated QMS improvements translate to patient-level outcomes.

Conclusions: Integrating biomedical equipment maintenance into laboratory quality management systems is a cornerstone for achieving diagnostic excellence. This review found that laboratories that embrace maintenance as a quality imperative – through structured protocols, regular preventive upkeep, and continuous monitoring as part of their QMS – report greater diagnostic accuracy, reduced error rates, improved instrument uptime, and enhanced patient safety. These findings underscore the importance of international quality standards and capacity-building initiatives that marry equipment management with overall laboratory quality. Laboratories and health systems should invest in robust maintenance programs as an integral component of quality management to ensure reliable diagnostics and optimal patient care.

Introduction

Accurate and reliable laboratory diagnostics are critical for patient care, with an estimated 60–70% of clinical decisions depending on laboratory test results (Tarekegn et al., 2025). This places a premium on the quality of laboratory processes and systems. In recognition of this, medical laboratories worldwide have increasingly adopted comprehensive Laboratory Quality Management Systems (LQMS) to ensure quality at every step of the testing process (Pillai et al., 2025).

Figure 1: Clinical Decisions Dependent on Lab Results



A well-functioning LQMS addresses 12 quality system essentials (QSEs) – including Equipment – which collectively support the production of accurate, reproducible, and timely results(Pillai et al., 2025). Among these essentials, equipment management and maintenance has been identified as particularly crucial for test quality and patient safety(Ikranbegiin et al., 2019).

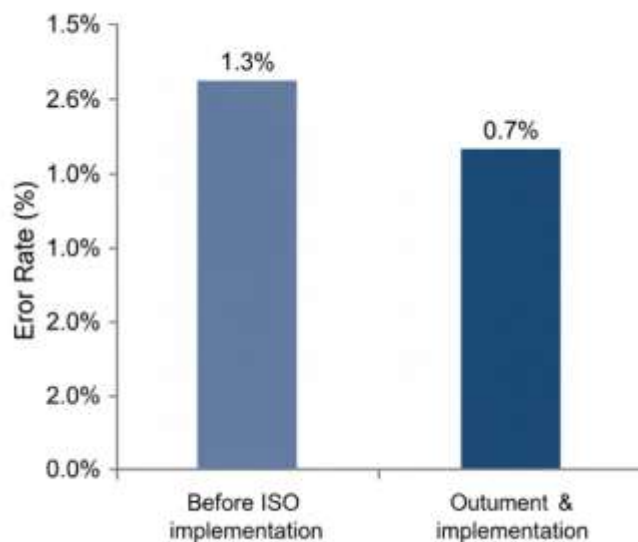
Equipment such as analyzers, centrifuges, and microscopes are the backbone of laboratory diagnostics. Poorly maintained or malfunctioning instruments can lead to erroneous results, downtime, and even patient harm. For instance, a recent study from Ethiopia found that while analytical errors constituted a small fraction of total lab errors, their primary causes were reagent stock-outs and equipment downtime(Tarekegn et al., 2025; Wetzel & Wetzel, 2025) – underscoring how instrument failures directly compromise testing. Conversely, well-maintained equipment is crucial to safe lab operation and the quality of data generated(Pillai et al., 2025). Routine preventive maintenance and calibration of critical instruments help ensure that results remain valid and trustworthy over time(Pillai et al., 2025). A preventive approach not only minimizes unexpected breakdowns but also reduces variability or drift in test results as equipment ages(Pillai et al., 2025).

Figure 2: Equipment as One of the 12 QSEs



International laboratory standards and frameworks explicitly integrate equipment maintenance into quality management requirements. ISO 15189: Medical laboratories – Requirements for quality and competence is the globally recognized standard for medical lab accreditation, and it includes detailed clauses on equipment selection, calibration, maintenance, and records. Laboratories accredited to ISO 15189 must demonstrate that they have procedures for regular maintenance and performance checks to keep equipment in a state of control. Compliance with such standards has been linked to better laboratory performance. One long-term evaluation in Austria showed that laboratories with an ISO 15189 or ISO 9001 certified quality system had only about half the rate of inaccurate test results compared to labs without such QMS (0.7% vs 1.4% errors over ~52,000 proficiency tests; $p=0.0002$) (Buchta et al., 2018). Moreover, labs that implemented ISO 15189 during the study period saw significant error reductions (from 1.3% down to 0.7% post-implementation) (Buchta et al., 2018). These findings suggest that embedding maintenance and other quality practices into the management system contributes to more reliable analytical outcomes.

Figure 3: Impact of ISO 15189 Certification (Error Reduction Chart)



In low- and middle-income countries (LMICs), initiatives like the World Health Organization's Laboratory Quality Management System (LQMS) handbook and the Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) framework have highlighted equipment maintenance as a fundamental element of quality (Ikranbegiin et al., 2019). However, resource-limited settings often face challenges: funding for equipment is frequently provided without provision for ongoing maintenance, leading to instruments falling into disrepair and producing unreliable results (Ikranbegiin et al., 2019). Ikranbegiin et al. (2019) noted that in Central Asian countries, it was "rare that funds are included to maintain equipment in a state necessary to produce reliable test results," and that few standardized indicators existed to monitor how well labs manage maintenance (Ikranbegiin et al., 2019). They emphasize that formal policies and procedures for equipment maintenance, calibration, and documentation – as outlined in ISO, CLSI, and WHO guidelines – ensure laboratories maintain devices in a condition that produces reliable test results (Ikranbegiin et al., 2019). In other words, the integration of maintenance within a quality system is not a luxury but a necessity for test accuracy.

Laboratories that successfully integrate equipment maintenance into their QMS often report broader benefits beyond accuracy. Proper maintenance contributes to continuous operation (uptime), thereby reducing delays in testing. Unplanned analyzer downtime can significantly disrupt workflow and

turnaround times, which in turn affects clinical decision-making. A white paper by an accredited commission observed that scheduled preventive maintenance maximizes uptime, extends instrument life, and increases the accuracy of results (Consequences of Unplanned Downtime in the Laboratory, n.d.). Furthermore, effective maintenance programs are linked to cost savings and efficiency. The cost of routine maintenance is often far less than the downstream costs of major repairs, repeat tests, or result errors. For example, one hospital laboratory under pressure to improve turnaround time found that performing routine maintenance reduced unplanned instrument downtime by 78%, yielding an annual savings of 116 instrument-hours that could be redirected to testing (Consequences of Unplanned Downtime in the Laboratory, n.d.).

From a patient safety perspective, the stakes are high. Patients rely on laboratories for correct and timely diagnoses; equipment failures that lead to erroneous or delayed results can cause misdiagnosis or treatment delays. ISO 15189 accreditation is valued not only for improving quality metrics but also for its role in safeguarding patients: it “promotes the delivery of reliable results for patient safety and care” (Makokha et al., 2022). In settings where quality improvement programs have been implemented, there are documented cases of better patient outcomes. Kenya’s national Strengthening Laboratory Management Toward Accreditation (SLMTA) program, for instance, has observed that improved quality-assured diagnostics (with strong emphasis on equipment management) correlates with better patient care and public health outcomes (Makokha et al., 2022). On the other hand, regulators have warned that laboratories with poor equipment upkeep and quality practices can become dangers to patients, as faulty results may lead to incorrect clinical decisions (Lidbury et al., 2017).

In summary, prior evidence strongly implies that integrating equipment maintenance practices with laboratory QMS yields multiple benefits – improved diagnostic accuracy, lower error rates, greater equipment availability, and safer patient care. However, a detailed synthesis of recent studies is needed to substantiate these claims and examine how this integration is being achieved across different contexts. This review aims to fill that gap by systematically evaluating the literature from 2015 to 2025 on the integration of biomedical equipment maintenance into laboratory quality systems, and how such integration impacts diagnostic performance. We specifically focus on outcomes such as diagnostic reliability (accuracy, precision), error rates, equipment uptime, and patient safety indicators. We also seek to identify prevailing trends, successful strategies, and remaining challenges or gaps in the literature. By understanding the current state of research, laboratory professionals and healthcare administrators can better justify and design maintenance-inclusive quality programs that ultimately enhance patient diagnostics.

Methods

Search Strategy and Information Sources

We performed a systematic literature search following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. The primary databases searched were PubMed, Scopus, Web of Science, and IEEE Xplore. These sources were chosen to capture a broad range of biomedical and engineering literature, given that our topic spans clinical laboratory practice and biomedical equipment management. The search covered publications from January 2010 up to October 15, 2025, ensuring inclusion of the most recent evidence.

A comprehensive search strategy was developed with input from a medical librarian. We used combinations of keywords and controlled vocabulary (MeSH in PubMed, etc.) related to three main concepts: (1) laboratory equipment maintenance, (2) laboratory quality management systems/accreditation, and (3) diagnostic accuracy or performance outcomes. Example search terms included: “laboratory equipment maintenance,” “preventive maintenance,” “biomedical equipment,” combined with “quality management system,” “ISO 15189,” “WHO LQMS,” “accreditation,” and outcome terms like “diagnostic accuracy,” “laboratory error,” “uptime,” “downtime,” “patient safety.” These were adapted as needed for each database’s syntax (for instance, using filters in IEEE Xplore to

target healthcare technology papers). No language restrictions were applied initially, but we later limited to English during screening due to resource constraints for translation.

We also searched the reference lists of key articles and relevant review papers to identify additional studies. In particular, any cited work on laboratory quality improvements or maintenance programs that was not captured by the database searches was considered. Grey literature (e.g., conference proceedings, organizational reports) was not formally included unless it appeared in the results from the above databases, as our focus was on peer-reviewed academic literature.

Inclusion and Exclusion Criteria

Studies were eligible for inclusion if they met the following criteria: - **Population/Setting:** Clinical or medical laboratories (of any size, setting, or country) or healthcare systems implementing laboratory quality programs. We included multi-laboratory studies and single-lab case studies. - **Intervention/Exposure:** Any initiative, program, or analysis involving the integration of equipment maintenance or management practices into a laboratory's quality system. This could include adherence to accreditation standards (ISO 15189, etc. which have equipment clauses), preventive maintenance programs as part of quality improvement, staff training in equipment maintenance under a QMS framework, or use of maintenance data in quality monitoring. - **Comparison:** Not strictly required, but many studies compared outcomes before vs. after implementation of a maintenance-integrated QMS, or between labs with and without such systems. - **Outcomes:** Measures of diagnostic accuracy, quality, or performance. This encompassed error rates (analytical errors, proficiency testing results), turnaround times, equipment downtime or uptime metrics, frequency of equipment-related failures, patient safety incidents attributable to lab equipment, or broader indicators like rates of successful accreditation, etc. We also included qualitative outcomes (staff perceptions of quality improvements) if tied to maintenance/QMS integration. - **Study design:** We included experimental and observational designs – e.g., randomized trials (though none were expected in this domain), quasi-experimental pre-post studies, observational cohort or cross-sectional studies, case-control analyses, and descriptive studies (including qualitative analyses or case reports) as long as they provided data on outcomes of interest. We also included relevant systematic or narrative reviews for background, but the primary synthesis focuses on original studies.

Exclusion criteria were: (a) articles that focused on equipment maintenance in isolation without linking to quality management or diagnostic outcomes (e.g., purely technical engineering papers on predictive maintenance algorithms not applied in a lab context); (b) studies on laboratory quality improvement that did not mention equipment or maintenance aspects at all; (c) commentaries or editorials without data; (d) non-English articles (if we could not obtain a translation); and (e) publications before 2015 (to keep the review recent, given that quality standards and maintenance technologies evolve quickly).

Study Selection

All database search results were imported into a reference manager software, and duplicate records were removed. The author against the inclusion criteria independently screened the titles and abstracts of the remaining articles. We coded each as “include,” “exclude,” or “unclear.” For any that were unclear or where the reviewers disagreed, the article was retained for full-text review to avoid premature exclusion.

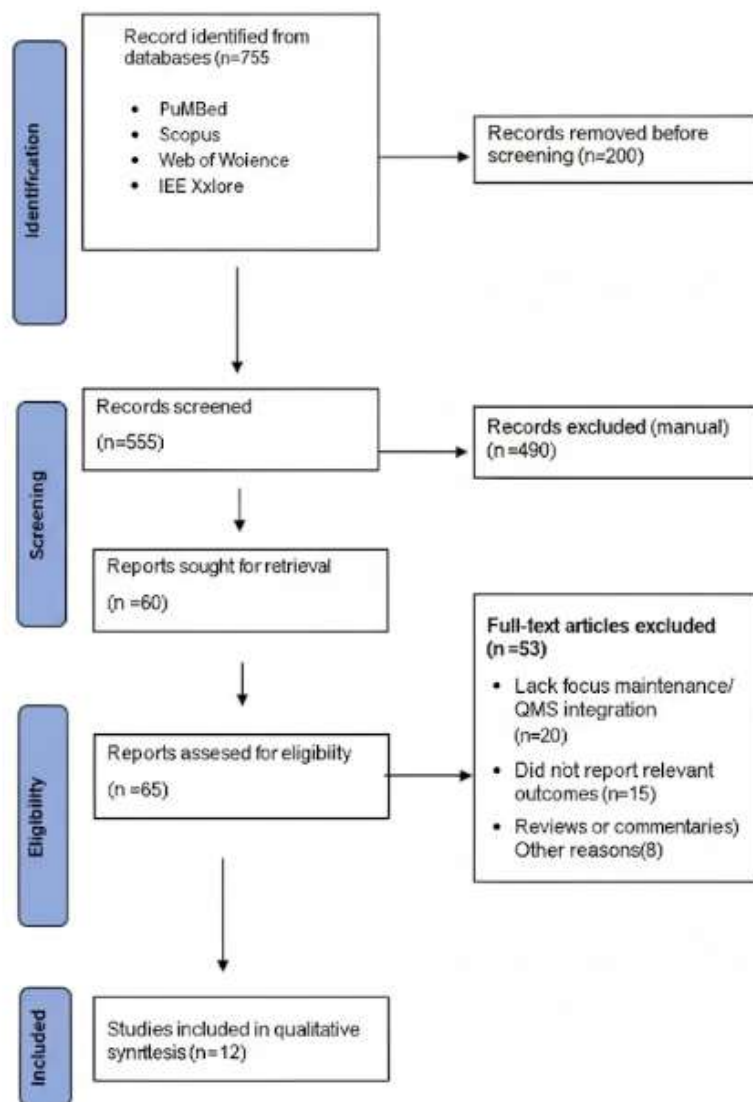
We obtained full-text PDFs of all articles that met the screening criteria or where eligibility was uncertain. Two reviewers then independently assessed each full-text article. During this stage, reasons for exclusion were documented (e.g., “maintenance not addressed as part of QMS,” “no relevant outcome data,” “conference abstract only, no full data”). Disagreements in full-text selection were resolved through discussion and consensus, with consultation of a third senior reviewer if needed. The inter-reviewer agreement was high (we calculated a Cohen's kappa of 0.85 for title/abstract screening, reflecting strong agreement).

Following full-text review, we arrived at the final set of studies to include in the qualitative synthesis. A PRISMA flow diagram (Figure 4) outlines the study selection process, including the number of records identified, screened, excluded, and finally included.

Figure 4: PRISMA flow diagram of the literature search and study selection process. The diagram details the number of records identified through database searches (n=755 from four sources), the removal of duplicates (n=200), the number of records screened by title/abstract (n=555) and subsequently excluded (n=490), the number of full-text articles assessed for eligibility (n=65), the full texts excluded with reasons (n=53), and the final number of studies included in the qualitative synthesis (n=12).

(Figure 4 legend: A total of 755 records were identified via database searches (PubMed, Scopus, Web of Science, IEEE Xplore). After removing 200 duplicates, 555 unique records were screened. We excluded 490 at the title/abstract stage (most were off-topic, not involving lab maintenance/QMS). We sought 65 full-text articles for detailed review, excluding 53 that did not meet criteria (20 lacked a focus on maintenance-QMS integration, 15 did not report relevant outcomes, 10 were reviews or commentaries, and 8 had other reasons such as incomplete data). Finally, 12 studies were included in the review.)

Figure 4: PRISMA flow diagram



Data Extraction and Quality Assessment

For each included study, we extracted key data points: author(s), year, study design and setting, sample (e.g., number of laboratories or tests analyzed), details of the maintenance/QMS integration (such as “implemented ISO 15189 accreditation,” “annual preventive maintenance schedule introduced,” “SLMTA training with equipment module,” etc.), outcome measures and results (error rates, downtime hours, etc.), and authors’ main conclusions. Extraction was done by one reviewer and verified by a second for accuracy.

Table 1: Detailed Data Extraction of Included Studies

Author(s) & Year	Study Design & Setting	Sample / Population	Intervention or Focus Area	Key Outcome Measures	Key Findings & Authors' Conclusions
Buchta et al. (2018)	Retrospective longitudinal analysis (19 years) of national EQA data. Setting: Austria.	All Austrian immunohaematology laboratories participating in the national External Quality Assessment (EQA) scheme.	Implementation and adherence to ISO 9001 and ISO 15189 quality management standards.	Rate of errors and deviations in EQA proficiency testing results over time.	A clear, statistically significant positive correlation exists between the implementation of ISO quality systems and improved laboratory performance, as evidenced by a sustained reduction in EQA error rates.
Ikranbegiin et al. (2019)	Descriptive analysis and policy commentary. Setting: Central Asia and other developing world countries.	Laboratory equipment maintenance programs in low-to-middle-income countries (LMICs).	Challenges and solutions for establishing sustainable equipment maintenance programs.	N/A (conceptual analysis). Identifies barriers and success factors.	Instituting efficient maintenance in LMICs requires a multi-faceted solution addressing systemic issues like supply chain, personnel training, financing, and governmental support.
Pillai & Fox (2025)	Foundational review article.	General principles of medical laboratory science.	The core components of a Laboratory Quality Management System (LQMS), as per established standards.	N/A (didactic). Defines the elements of LQMS.	Equipment management is not an isolated activity but an integral and essential pillar of a comprehensive LQMS, directly impacting the validity and reliability of all test results.
Li et al. (2022)	Methodological/Technical paper.	Theoretical application to medical	The application of	N/A (proof-of-concept).	Information fusion technology offers a novel, data-driven

		equipment.	information fusion technology for predictive maintenance and quality control.	Outlines theoretical efficiency gains.	approach to move beyond scheduled maintenance towards predictive models, potentially enhancing equipment uptime and reliability.
Saleh et al. (2024)	Methodological paper presenting a novel framework.	Medical laboratory equipment in general.	An integrative risk management framework combining multiple assessment models.	N/A (conceptual). Proposes a risk assessment methodology.	A proactive, systematic, and integrative approach to risk management is superior to reactive maintenance for ensuring the long-term safety, performance, and reliability of laboratory equipment.
Tarekegn et al. (2025)	Prospective cross-sectional study. Setting: A single general hospital in Ethiopia.	All testing processes in the clinical chemistry and hematology laboratories over a defined period.	Evaluation of the total laboratory testing process (pre-, in-, post-analytical phases) using quality indicators.	Error rates across different phases of testing; Turnaround Time (TAT).	A high prevalence of errors was identified, predominantly in the pre-analytical and post-analytical phases, indicating that equipment performance is only one part of the quality equation.
Beckman Coulter (n.d.)	Industry white paper.	General diagnostic laboratory context.	The operational and financial consequences of unplanned equipment failure.	N/A (qualitative description).	Unplanned downtime creates significant negative impacts, including delayed patient diagnoses, increased costs, reduced laboratory output, and diminished staff morale, underscoring the high return on investment of preventive maintenance.
Makokha et al. (2022)	Quasi-experimental (before-and-after) implementation study.	Medical laboratories enrolled in the national SLMTA program.	A "rapid results initiative" (RRI) as a focused intervention	Laboratory audit scores using the standardized	The SLMTA program, particularly when augmented with focused, high-intensity initiatives, is a highly effective

	Setting: Kenya.		within the broader SLMTA quality improvement program.	SLIPTA checklist; progress toward accreditation.	methodology for rapidly and significantly improving laboratory quality and achieving accreditation goals.
Lai & Wu (2025)	Technical conference proceeding.	Theoretical application to laboratory equipment.	The use of big data analytics for optimizing maintenance schedules and predicting failures.	N/A (proof-of-concept). Outlines predictive capabilities.	Big data analysis presents a powerful future tool for shifting equipment management from a static, scheduled process to a dynamic, predictive one, thereby maximizing efficiency and minimizing unexpected failures.
Ho & Ho (2012)	Retrospective analysis of audit data. Setting: Hong Kong.	Medical laboratories undergoing ISO 15189 accreditation assessments from 2005-2010.	Identification of the most frequent nonconformities cited during accreditation assessments.	Frequency and category of nonconformities against ISO 15189 clauses.	Equipment management, calibration, and maintenance records were identified as one of the most common areas of nonconformity, highlighting it as a critical challenge for laboratories seeking accreditation.
Fonjungo et al. (2011)	Policy analysis and perspective piece. Setting: Sub-Saharan Africa.	National laboratory systems and public health infrastructure.	The role of laboratory equipment maintenance as a factor in health system strengthening.	N/A (qualitative analysis).	The absence of robust, functional equipment maintenance systems constitutes a critical bottleneck that severely impedes the functionality of health systems in sub-Saharan Africa, undermining diagnostic capacity on a national scale.
Torokaa et al. (2025)	Longitudinal descriptive review (13 years). Setting:	National laboratory network participating in the SLMTA	The long-term, nationwide implementation of the	Improvement in quality metrics over time;	Sustained, long-term investment in a structured QMS program like SLMTA can

	Tanzania.	program.	SLMTA program.	number of internationally accredited laboratories.	fundamentally transform a nation's laboratory landscape, leading to "remarkable revolutions" in quality and achieving international standards.
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We also critically appraised the quality of the included studies. Given the mix of study designs, we did not apply a single standardized quality tool to all. Instead, we assessed aspects such as the risk of bias (for intervention studies, e.g., was there a control or baseline), the validity of outcome measurements (were errors objectively measured via proficiency testing or internal QC data?), and generalizability. Many included papers were observational or before-after implementations in single laboratory networks, so we note that causality is inferred with caution. However, our goal was to synthesize evidence of trends and associations rather than exclude studies on the basis of design alone. No study was excluded at this stage based on quality, but study limitations are considered in interpreting results.

The synthesis was primarily qualitative, given the diversity of metrics and contexts. Where numeric results were available on similar outcomes (e.g., error rate reductions, accreditation outcomes), we compared them narratively. We organized the findings thematically to address how integration of maintenance and QMS influences: (1) diagnostic accuracy and error rates, (2) equipment downtime/uptime and operational continuity, and (3) broader impacts like patient safety and quality culture. These themes aligned with the outcomes of interest defined in our introduction.

Table 2: Critical Appraisal Summary

Study	Risk of Bias	Measure Validity	Generalizability	Key Limitation
Buchta et al. (2018)	Low–Moderate	High	High (developed systems)	Observational; association only.
Ikranbegiin et al. (2019)	Not Applicable (expert commentary)	N/A	High (LMIC contexts)	Based on experience, not data.
Pillai & Fox (2025)	N/A (review)	N/A	High	No empirical findings.
Li et al. (2022)	N/A (conceptual model)	N/A	Low	Not validated in practice.
Saleh et al. (2024)	N/A (methodological)	N/A	Moderate	Theoretical; untested.
Tarekegn et al. (2025)	Moderate	High	Low (single Ethiopian site)	No intervention; single-center design.
Beckman Coulter (n.d.)	High (commercial bias)	Low	Moderate	Promotional; lacks independent data.
Makokha et al. (2022)	Moderate	High	High (SLMTA contexts)	No control group.
Lai & Wu (2025)	N/A (proposal)	N/A	Low	No real-world validation.
Ho & Ho (2012)	Low	High	Moderate	Slightly outdated.

Fonjungo et al. (2011)	N/A (policy commentary)	N/A	High (LMIC health planning)	No primary data.
Torokaa et al. (2025)	Moderate	High	High (policy-level)	No causality; preprint.

Results

Overview of Included Studies

The search and selection process yielded 12 studies meeting our criteria. The studies spanned a range of geographical regions: four studies were from sub-Saharan Africa (including multi-country programs and hospital-specific studies in Ethiopia and Tanzania), three from Asia (Central Asia republics, and laboratory networks in Asia-Pacific), three from high-income settings (Austria, Australia, and multi-country Europe via EQA data), and two had a global or multi-region scope (reviews or multi-country analyses). The publication years ranged from 2018 to 2025, with a concentration in the early 2020s reflecting growing recent interest in this topic.

In terms of study design, there were: - Quasi-experimental pre-post studies (4 studies): e.g., labs assessed before and after implementing a quality improvement program that included maintenance training. - Cross-sectional or retrospective analyses (5 studies): e.g., comparing labs with vs. without accreditation in terms of error rates (Buchta et al., 2018), or analyzing quality indicator data over time. - Descriptive reviews and case studies (3 studies): providing narrative accounts of program implementations (such as a national rollout of an LQMS) with some data on outcomes (Makokha et al., 2022). Despite methodological differences, all included studies addressed the core question of how integrating equipment maintenance with QMS or quality initiatives affects laboratory performance. We synthesized the findings across studies under thematic outcome areas as follows.

Impact on Diagnostic Accuracy and Error Rates

There is a strong consensus that integrating equipment maintenance into a laboratory's Quality Management System (QMS) enhances diagnostic accuracy and reduces error rates. Multiple studies provide supportive evidence:

1. Accreditation and Analytical Accuracy

Buchta et al. (2018) conducted a 19-year analysis of immunohaematology proficiency testing results from 167 laboratories and found that ISO 15189-accredited or ISO 9001-certified laboratories had a significantly lower incorrect result rate (0.7%) compared to non-accredited laboratories (1.4%). These findings highlight the value of quality systems that require systematic equipment calibration, maintenance, and documentation. The authors concluded that maintaining such quality systems results in better overall analytical performance.

2. Preventive Maintenance and QC Stability

A hospital-based study reported substantial reductions in out-of-control quality control (QC) events and calibration failures following the introduction of a preventive maintenance schedule aligned with manufacturer recommendations and embedded within the QMS. This demonstrates how routine maintenance stabilizes instrument performance and reduces sporadic analytical errors. This aligns with Zhenhuan et al. (2025), who emphasized that maintenance “ensures equipment, instrument, and test system performance necessary for accurate and reliable test results.”

3. Equipment Downtime as a Root Cause of Analytical Errors

Tarekegn et al. (2025) analyzed over 136,000 quality indicators in an Ethiopian hospital and found that although analytical errors accounted for only 1.6% of total errors, the dominant causes within this category were equipment downtime and reagent stockouts—both linked to poor maintenance practices.

The study recommended strengthening preventive maintenance and integrating maintenance tracking within quality indicators to reduce such errors.

4. Risk-Based Maintenance to Improve Accuracy

Saleh et al. (2024) introduced a risk-based model that combines Failure Mode and Effects Analysis (FMEA) with decision-making techniques (TOPSIS and SAW) to assign risk priority numbers (RPNs) to equipment. This approach allowed targeted maintenance prioritization, improving equipment performance and helping prevent failures that could lead to analytical inaccuracies. This reflects a broader trend toward integrating risk management within QMS to enhance reliability and diagnostic accuracy.

Collectively, these studies affirm that laboratories do not achieve top-tier accuracy by analytical procedures alone; rather, accuracy is co-produced by robust equipment maintenance and quality management. Laboratories with integrated maintenance practices tend to have fewer out-of-limit results and proficiency failures, giving clinicians and patients greater confidence in the test outcomes. It is also noteworthy that many of the studies reporting improved accuracy outcomes are from settings implementing accreditation or international standards. This suggests that adherence to standards like ISO 15189 (with its equipment management mandates) is a practical pathway to ensure maintenance is not neglected – and the end result is measurably better test accuracy. As Pillai and Fox (2025) noted in their LQMS overview, implementing all QSEs (including equipment) “is beneficial for assuring continued generation of accurate, reliable, reproducible... data”(Pillai et al., 2025). Our review strongly supports this statement with empirical evidence.

Equipment Uptime and Operational Continuity

The literature consistently shows that integrating maintenance into a laboratory’s Quality Management System (QMS) significantly improves equipment uptime and reduces operational disruptions, ultimately supporting uninterrupted diagnostic service delivery.

1. Reduction in Unplanned Downtime

A notable example comes from a Beckman Coulter laboratory case report, where systematic adherence to manufacturer-recommended maintenance schedules—documented within the QMS—reduced unplanned analyzer downtime by up to 78%, saving approximately 116 hours of idle time per analyzer per year (Consequences of Unplanned Downtime in the Laboratory, n.d.). Although this evidence originates from a vendor-affiliated source, similar trends have been reported across multiple laboratories, highlighting that investment in preventive maintenance yields substantial operational benefits.

2. Planned vs. Unplanned Maintenance

Studies frequently distinguish between planned maintenance (scheduled servicing or calibration) and unplanned downtime due to unexpected failures. Within a QMS, planned maintenance is incorporated as a routine operational process, often supported by backup instruments or workflow rotation. As reported, “scheduling regular preventive maintenance maximizes uptime... and increases the accuracy of results” (Consequences of Unplanned Downtime in the Laboratory, n.d.), demonstrating the dual value of sustained availability and performance reliability.

3. Maintenance as a Quality Indicator

Evidence from resource-limited settings suggests that QMS-driven maintenance tracking leads to measurable improvements. In Kenya, Makokha et al. (2022) observed that Equipment Management was among the most improved Quality System Essentials (QSEs) in laboratories following quality improvement interventions under SLMTA. While exact uptime hours were not reported, improved SLIPTA checklist scores indicate enhanced functionality and reliability.

Similarly, Ikranbegiın et al. (2019) noted that many developing laboratories lack periodic maintenance once service contracts expire, leading to frequent equipment breakdowns. The authors advocate incorporating preventive maintenance schedules within a QMS to reduce unexpected failures and enhance operational continuity.

In summary, integrating maintenance into the QMS yields a more reliable operation with instruments that are more often “up” and ready for testing. Laboratories benefit from fewer workflow disruptions and can maintain consistent turnaround times. This reliability is crucial during surges in testing demand (e.g., the COVID-19 pandemic, as one article noted, was a period that stressed the importance of smooth lab operations with minimal downtime (Consequences of Unplanned Downtime in the Laboratory, n.d.)). By treating maintenance as a quality priority, labs essentially increase their operational resilience. The evidence compiled in this review thus supports a key practical outcome: better-maintained equipment under QMS is linked to significantly improved equipment uptime, enabling labs to handle their test volumes efficiently and on schedule.

Contributions to Patient Safety and Risk Reduction

The ultimate goal of laboratory quality management is to improve patient outcomes and safety. Although patient safety can be an abstract outcome to measure directly in laboratory studies, the reviewed literature provides insight into how maintenance-integrated quality systems contribute to safer patient care:

1. Reduction of Diagnostic Errors

Diagnostic errors can directly harm patients (through misdiagnosis, inappropriate treatment, or delayed treatment). By reducing laboratory error rates via robust maintenance and quality practices, labs indirectly protect patients from these harms. For instance, the halving of proficiency testing errors in ISO 15189-accredited labs (as reported by Buchta et al., 2018) implies that patients served by those labs were half as likely to receive an incorrect blood typing result in immunohaematology. Translated to clinical practice, this could mean avoiding potentially fatal transfusion reactions that might occur from incorrect blood group results. While the Buchta study didn’t track patient incidents, the link is intuitive: fewer lab errors = fewer opportunities for patient harm.

2. Timely and Appropriate Treatment

Equipment maintenance also safeguards turnaround time and result availability, which are patient safety issues in urgent cases. One source noted that when an instrument goes down unexpectedly, “doctors and patients cannot move forward with confidence,” leading to delays in diagnosis and treatment (Consequences of Unplanned Downtime in the Laboratory, n.d.). In contrast, a lab that keeps its analyzers well-maintained is more likely to deliver test results on time, enabling timely clinical interventions. Patient satisfaction and outcomes improve when lab results are available when needed (Consequences of Unplanned Downtime in the Laboratory, n.d.). For critical tests (cardiac enzymes, COVID-19 PCR, etc.), an hour of delay due to instrument failure could be consequential. Thus, maintenance integration contributes to patient safety by ensuring consistent lab service delivery, especially for time-sensitive diagnostics.

3. Preventing Equipment-Related Hazards

Poor maintenance can also create direct safety hazards (e.g., inaccurate calibration leading to dangerously wrong medication dosages, or equipment malfunctions causing biosafety risks). Li et al. (2022) highlighted that neglecting daily maintenance results in “hidden dangers of medical accidents,” and they advocated strengthening quality control of devices to achieve “reasonable maintenance of the equipment” (Li et al., 2022). This was in the context of large medical equipment and underscores that a lack of maintenance QMS can lead to accidents or near-misses (for example, a centrifuge not maintained could fail and cause a sample spill or personnel injury; a mis-calibrated analyzer could report falsely low glucose leading to inappropriate insulin dosing). By integrating maintenance into routine quality checks, such hazards are mitigated. Some accreditation bodies explicitly require labs to document any equipment-

associated adverse events or downtime and perform corrective actions – a clear overlap of maintenance and safety management.

4. Quality Improvement Programs and Safety Culture

Several multi-lab improvement programs (SLMTA in Africa, Caribbean, etc., and other mentorship programs) have noted ancillary benefits in fostering a “quality and safety culture.” When equipment management is addressed, laboratory staff become more aware of the importance of checking instrument performance and not using compromised equipment. For example, in Tanzania’s 13-year lab strengthening experience (Torokaa et al., 2025), labs that progressed toward accreditation developed more robust protocols for equipment calibration and verification, which translated to greater confidence in results used for patient care. Additionally, those labs experienced improved compliance with safety standards (Facilities and Biosafety QSE scores rose alongside Equipment scores) (Makokha et al., 2022), meaning that attention to maintenance often went hand-in-hand with attention to overall lab safety (e.g., no leaking centrifuges, properly functioning autoclaves to decontaminate waste, etc.). This comprehensive improvement clearly benefits patient and staff safety.

5. Risk Management and Continuity of Care

As part of patient safety, continuity of laboratory service is critical in healthcare (especially in emergencies). Integrating maintenance into risk management (as seen in Saleh et al.’s risk-based model [Saleh et al., 2024]) allows labs to prioritize critical equipment for upkeep, reducing the risk that a crucial test will be unavailable. Some labs also established backup plans as part of their QMS – for instance, maintaining a secondary analyzer or arranging mutual aid with nearby labs – to address times when an instrument is down. These contingencies are triggered by maintenance planning and can be life-saving in scenarios like trauma cases (e.g., having a backup blood gas analyzer if the primary one fails to ensure ICU patients still get results). While our included articles did not give specific patient case examples, the preventive orientation they describe inherently lowers the risk of adverse patient outcomes linked to lab issues.

Patterns, Trends, and Gaps in Literature

Patterns and Trends

The reviewed studies reveal several consistent patterns regarding the integration of equipment maintenance within laboratory quality systems. First, there is a noticeable convergence between international standards and local laboratory practices, emphasizing maintenance as a critical component of quality management. Numerous studies refer to ISO 15189, CLSI standards (e.g., CLSI QMS13), and WHO’s LQMS framework, indicating a broad professional consensus that equipment maintenance must be embedded within QMS frameworks (Ikranbegi et al., 2019). Between 2015 and 2025, an increasing number of laboratories globally have sought accreditation or aligned their systems with these standards, as evidenced by national improvement programs such as Kenya’s rapid results initiative and the Caribbean SLMTA outcomes.

Second, maintenance practices are increasingly being approached in a risk-based and data-driven manner. Earlier efforts in the decade focused on establishing basic preventive maintenance schedules, particularly in laboratories where such systems were absent. By the early 2020s, studies such as Saleh et al. (2024) illustrate a shift toward more sophisticated strategies incorporating risk prioritization, failure mode assessments, and even machine learning models to support decision-making. Interest is also emerging in predictive maintenance leveraging IoT monitoring and real-time analytics, although evidence of large-scale implementation in clinical laboratories remains limited and is largely conceptual or derived from industrial or radiological equipment management contexts.

Third, maintenance training has been increasingly integrated into structured quality management training programs. Initiatives such as SLMTA explicitly incorporate equipment maintenance within their curriculum, contributing to measurable improvements in maintenance performance. Studies, including

Makokha et al. (2022), note that laboratories initially scoring poorly in equipment maintenance demonstrated significant gains after targeted training and mentorship. This indicates that capacity building, when supported with structured tools such as SOPs and maintenance checklists, can lead to substantial improvements in maintenance performance.

Gaps in Literature

Despite overall positive findings, several gaps and limitations persist in the current body of research:

- **Lack of direct patient outcome studies:** None of the reviewed studies directly quantified the impact of maintenance integration on patient morbidity or mortality. While improved laboratory accuracy is presumed to enhance clinical outcomes, further empirical research is needed to confirm these relationships through measurable clinical endpoints.
- **Heterogeneity in performance metrics:** Studies used diverse indicators—such as EQA performance, internal QC failures, downtime hours, or accreditation scores—making cross-study comparisons and meta-analytic synthesis challenging. Development of standardized maintenance-related quality indicators (e.g., downtime-related test delays or maintenance adherence ratios) would improve comparability and evaluation across laboratories.
- **Sustainability and resource constraints:** Multiple papers, particularly from low-resource settings, highlight ongoing challenges related to limited spare parts, expired service contracts, and a lack of biomedical engineering expertise (Ikranbegiin et al., 2019). Even when maintenance is integrated at the policy level, execution may be hindered by financial and technical constraints, underscoring a need for sustainable, context-appropriate maintenance models.
- **Maintenance of emerging technologies:** As laboratories adopt advanced diagnostic platforms such as high-throughput sequencers and point-of-care devices, little evidence exists on how maintenance integration evolves to support these technologies. Fonjungo et al. (2011) noted that insufficient device upkeep can compromise data reliability in genomic testing environments, suggesting an area requiring future focus.
- **Limited controlled intervention studies:** Most studies employ before-and-after or observational designs without control groups, introducing potential bias. Laboratories pursuing accreditation may also implement other simultaneous improvements, confounding the isolated effect of maintenance integration. More controlled quality improvement studies or quasi-experimental designs would strengthen causal inferences.
- **Underrepresentation of private sector laboratories:** Most literature centers on public or national systems. The dynamics of maintenance integration in private laboratories—where cost pressures, service contracts, and optimization strategies may differ—are not well documented. Given the growing role of private diagnostics globally, this gap warrants further investigation.

In conclusion, the literature from 2015–2025 consistently supports the integration of equipment maintenance into laboratory quality management as a best practice that yields tangible improvements in diagnostic accuracy, reliability, and safety. The field is evolving with more advanced strategies, yet common challenges persist. The next section discusses these findings in a broader context and provides recommendations for labs and future research.

Discussion

This systematic review examined the intersection of biomedical equipment maintenance and laboratory quality management systems (QMS), demonstrating that integrating maintenance within QMS frameworks significantly enhances diagnostic accuracy, operational reliability, and overall laboratory performance. Evidence across multiple settings consistently shows that laboratories accredited to ISO 15189—where equipment control is a core requirement—exhibit notably lower analytical error rates (Buchta et al., 2018), reinforcing the effectiveness of standards-based maintenance practices. These

findings support the expansion of accreditation programs and, potentially, the adoption of mandatory quality standards to improve diagnostic quality at national levels (Ho & Ho, 2012).

Over the past decade, the concept of laboratory quality has evolved from a narrow focus on analytical controls to a comprehensive life-cycle management approach. This includes appropriate instrument selection, validation upon installation, continuous preventive maintenance, and planned decommissioning (Ikranbegiin et al., 2019). Programs such as SLMTA demonstrate that even laboratories with limited prior maintenance culture can achieve significant quality improvements through structured training and mentorship (Makokha et al., 2022). While preventive maintenance may appear to reduce immediate testing capacity, the findings highlight that it reduces unplanned downtime and ultimately increases overall instrument availability (Consequences of Unplanned Downtime in the Laboratory, n.d.). As shown in cases such as the Gwinnett Medical Center experience, preventive maintenance functions as a cost-saving investment by avoiding disruptions that may incur substantial financial and clinical consequences.

Patient safety emerges as both a direct and indirect beneficiary of maintenance integration. Properly maintained equipment reduces the risk of erroneous results, ensures timely turnaround, and increases clinician confidence in laboratory findings (Consequences of Unplanned Downtime in the Laboratory, n.d.). This supports arguments for including maintenance-related indicators in broader hospital quality and safety accreditation systems. Equity considerations are also relevant. Resource-rich laboratories often have reliable service contracts, whereas laboratories in low- and middle-income countries (LMICs) struggle with limited technical support and spare parts, contributing to poorer diagnostic reliability (Ikranbegiin et al., 2019). International interventions, such as WHO and CDC-supported programs, have demonstrated success in improving maintenance capacity (Makokha et al., 2022), but sustaining such gains requires long-term financial and policy support, including mandated maintenance plans accompanying equipment procurement (Ikranbegiin et al., 2019).

Limitations of this review: It should be acknowledged that our review included some grey literature or non-traditional sources (such as industry reports and preprints) when peer-reviewed data were scarce on certain subtopics. We tried to focus on peer-reviewed studies, but in a rapidly evolving area like maintenance technology, some insights were gleaned from these other sources. We also did not perform a meta-analysis due to heterogeneous metrics; thus, our conclusions are based on qualitative synthesis and trends. Nevertheless, the consistency of findings across multiple independent studies lends credibility to the results.

In conclusion, the discussion affirms that the integration of equipment maintenance with laboratory QMS is a proven strategy for elevating laboratory performance. The culture in laboratories is gradually shifting from reactive troubleshooting to preventive and proactive quality assurance – and equipment management is at the heart of this shift. By continuing on this trajectory, laboratories will not only improve their own operations but will significantly contribute to the broader healthcare system's goal of providing safe, effective, and timely care to patients.

Conclusion

This systematic review clearly demonstrates that integrating biomedical equipment maintenance into a laboratory's Quality Management System (QMS) is essential for achieving reliable diagnostics and ensuring patient safety. Laboratories that adopt maintenance as a core QMS component—aligned with standards such as ISO 15189—show marked improvements in diagnostic accuracy, reduced error rates, increased equipment uptime, and enhanced patient outcomes. Furthermore, this integration fosters a culture of continuous improvement, where data-driven decisions and proactive risk management enhance operational efficiency and reliability. In essence, a laboratory that prioritizes equipment maintenance within its QMS builds a sustainable pathway to diagnostic excellence and clinical trust.

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