Annals of Medical and Health Research
An International Journal

OPEN ACCESS

Systematic Review

Check for updates

Quality Management Practices and Quality Assurance Systems in Philippine Clinical Laboratories: A Systematic Review

Chanelie Bacacao Tabliga*, **Kerstine Marie T. Yara-Castro**, **and Jemimah May B. Llanto**

Department of Medical Technology, College of Allied Medical Sciences, Cebu Doctors' University, Mandaue City, Cebu, Philippines

Corresponding author: **Chanelie Bacacao Tabliga** | E-mail: **chanelietabligacducamsmt@gmail.com**

Citation: Chanelie Bacacao Tabliga, Kerstine Marie T. Yara-Castro, and Jemimah May B. Llanto (2026). Quality Management Practices and Quality Assurance Systems in Philippine Clinical Laboratories: A Systematic Review. *Annals of Medical and Health Research: An International Journal.*
DOI: https://doi.org/10.51470/ARMHR.2026.5.1.66

Received 11 February 2026 | Revised 14 March 2026 | Accepted 08 April 2026 | Available Online 13 May 2026

Abstract

Background: *Reliable clinical laboratory services are essential to patient management, disease surveillance, and public health planning. Quality management systems (QMS) and quality assurance (QA) mechanisms support accurate, consistent, and timely laboratory results. In the Philippines, however, evidence describing the implementation of these quality practices remains dispersed across different sources.*

Objective: *This systematic review synthesized available evidence on quality management practices and quality assurance systems in Philippine clinical laboratories.*

Methods: *The review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 guidelines and was registered in PROSPERO (CRD420261427427). Searches were conducted in PubMed, Scopus, Google Scholar, ERIC, Philippine E-Journals, and relevant government and regulatory websites. Eligible studies examined QMS, QA, quality control, accreditation, external quality assessment, proficiency testing, laboratory information systems, or related quality improvement activities in Philippine clinical laboratories. Methodological quality was evaluated using the Joanna Briggs Institute Critical Appraisal Tools and the Mixed Methods Appraisal Tool, where applicable. Findings were narratively synthesized because of methodological heterogeneity.*

Results: *Nine studies met the eligibility criteria. Evidence showed increasing implementation of quality management practices, favorable perceptions of QA among laboratory personnel, and greater participation in accreditation and external quality assessment programs. Laboratory information systems improved workflow, minimized errors, and supported service delivery. However, resource shortages, infrastructure limitations, competency concerns, implementation costs, and pre-analytical errors remained important challenges. Limited evidence was available on accreditation outcomes, digital quality management technologies, and nationwide laboratory quality assessments.*

Conclusion: *Philippine clinical laboratories have progressed in strengthening QMS and QA practices. Sustained investment in workforce development, infrastructure, accreditation, and continuous quality improvement is needed to enhance laboratory reliability, patient safety, and national healthcare outcomes.*

Keywords: *Clinical laboratories, quality management systems, quality assurance, laboratory accreditation, Philippines, systematic review.*

INTRODUCTION

Clinical laboratories constitute an essential part of modern healthcare systems because they generate diagnostic evidence used in disease identification, clinical management, therapeutic monitoring, and population-level health surveillance [1]. The accuracy and dependability of laboratory findings are strongly influenced by how laboratory operations are managed and by the effectiveness of established quality assurance (QA) and quality control (QC) procedures [2]. According to the World Health Organization (WHO), a Laboratory Quality Management System (LQMS) comprises coordinated activities designed to guide and regulate laboratory processes so that results are accurate, dependable, timely, and reproducible [3]. Laboratory quality management extends beyond analytical testing and incorporates organizational governance, staff competence, equipment management, process control, information systems, occurrence management, and continuous improvement. Together, these components support the quality, consistency, and safety of laboratory services [4].

International standards provide important frameworks for establishing and evaluating quality in medical laboratories. The International Organization for Standardization (ISO) 15189:2022 outlines specific requirements for quality and competence within medical laboratory settings [5].

Its provisions integrate managerial and technical aspects of laboratory practice, including workforce competence, risk-based management, equipment validation, monitoring of quality indicators, process evaluation, and continual improvement [5]. Adherence to ISO 15189 and comparable quality frameworks is increasingly recognized as an important measure of laboratory performance and contributes to greater confidence in diagnostic findings among clinicians, patients, regulators, and other stakeholders [5]. In parallel, WHO promotes laboratory quality through the Quality System Essentials framework. This framework consists of twelve interconnected areas: organization, personnel, equipment, purchasing and inventory, process control, information management, documents and records, assessment, process improvement, customer service, facilities, and safety [3].

Laboratories differ according to their ownership, relationship with healthcare institutions, range of diagnostic services, and complexity of testing procedures [6]. Within the Philippines, clinical laboratories are commonly classified as primary, secondary, or tertiary according to the scope and complexity of examinations provided [7, 8]. Laboratory quality is evaluated through several complementary mechanisms, including internal audits, external quality assessment (EQA), proficiency testing, accreditation inspections, monitoring of quality indicators, and regulatory licensing assessments [9]. These processes examine conformity with established requirements involving staff qualifications, equipment functionality, specimen handling, analytical procedures, biosafety, documentation, and the implementation of corrective and preventive measures [10]. Taken together, such assessment activities help determine whether laboratory management processes are functioning effectively and whether QA and QC standards are consistently observed [11].

At the broader health-system level, dependable laboratory services are indispensable to patient safety, evidence-informed clinical practice, epidemiological surveillance, and the development of resilient healthcare systems [1, 12]. Laboratory findings contribute to a considerable proportion of clinical decisions and are particularly important in detecting and managing both infectious and non-communicable conditions [13]. Weaknesses in laboratory quality processes can contribute to incorrect diagnoses, treatment delays, unnecessary healthcare expenditures, inappropriate antimicrobial prescribing, and unfavorable patient outcomes [14]. Moreover, recent international health emergencies have demonstrated the critical function of laboratory networks in early outbreak recognition, epidemiological monitoring, and coordinated public health interventions [15]. For these reasons, improving laboratory quality management continues to be an important global health priority for systems seeking safer and more effective healthcare delivery [3].

Studies conducted across different healthcare environments indicate that comprehensive laboratory quality management systems can strengthen operational performance, increase diagnostic reliability, decrease testing-related errors, and improve conformity with accreditation and regulatory standards [16, 17]. Laboratories that adopt systematic quality frameworks have also been reported to demonstrate more efficient operations, stronger institutional cultures of quality, and improved preparedness for formal accreditation processes [2, 17]. Nevertheless, the level at which these systems are adopted and maintained differs substantially among countries and laboratory settings. Such disparities are particularly evident in low- and middle-income countries, where financial limitations, shortages of skilled personnel, and inadequate infrastructure may restrict the effective implementation of quality management activities [18].

In the Philippines, the Department of Health (DOH) regulates clinical laboratory services and establishes requirements governing licensing, laboratory operations, and quality assurance through Administrative Order No. 2021-0037 and associated regulatory policies [7]. Clinical laboratories are expected to establish appropriate quality management procedures, participate in external quality assurance activities, and comply with regulatory standards intended to safeguard the reliability of laboratory findings [7, 17]. Alongside mandatory regulatory requirements, a growing number of laboratories are seeking ISO 15189 accreditation to strengthen their quality systems and demonstrate conformity with internationally accepted standards [19]. However, laboratory institutions vary in terms of organizational capability, financial and material resources, workforce competence, and administrative support. These differences may affect the degree to which LQMS principles and QA and QC requirements are implemented across Philippine laboratory settings [20].

Despite the availability of individual research studies, institutional reports, accreditation evaluations, and regulatory assessments addressing laboratory quality in the Philippines, the overall body of evidence remains fragmented [20, 21]. Previous investigations have explored different dimensions of laboratory quality, such as LQMS implementation, accreditation activities, proficiency testing outcomes, EQA participation, institutional preparedness, quality indicators, and the knowledge, attitudes, and practices of laboratory professionals toward quality assurance [20, 22, 23, 24]. Although these investigations provide important information on specific quality components, their findings are distributed across diverse laboratory environments and quality domains. A comprehensive synthesis characterizing the broader status of quality management practices and quality assurance systems in Philippine clinical laboratories remains lacking [17, 20, 21]. As a result, the collective strengths of current systems, persistent implementation difficulties, and areas requiring further quality improvement have not been clearly consolidated.

This evidence gap may limit informed decisions concerning laboratory quality improvement, accreditation preparedness, professional capacity development, and the formulation of institutional and national laboratory policies.

Accordingly, this systematic review aims to synthesize and critically assess the available evidence concerning quality management practices and quality assurance systems in Philippine clinical laboratories. Specifically, the review seeks to: (1) characterize the quality management practices currently applied in Philippine clinical laboratories; (2) assess the implementation of QA and QC mechanisms, including quality management systems, accreditation programs, external quality assessment schemes, proficiency testing activities, and quality indicators; (3) examine the knowledge, attitudes, practices, and perceptions of laboratory personnel toward quality management and quality assurance; (4) determine the barriers and facilitating factors that affect the adoption and implementation of quality management and quality assurance systems in Philippine clinical laboratory settings; and (5) identify existing evidence gaps and formulate recommendations to strengthen laboratory quality systems, accreditation preparedness, policy development, and future research in the Philippines.

METHODOLOGY

Study Design and Protocol Registration

A systematic review design was adopted to integrate the existing literature concerning quality management practices and quality assurance systems within Philippine clinical laboratories. The review process followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 recommendations to promote a transparent, rigorous, and reproducible approach to evidence synthesis [25]. Prior to completion of the review, the protocol was registered in the International Prospective Register of Systematic Reviews (PROSPERO) with registration number CRD420261427427.

Eligibility Criteria

Study eligibility was determined using prespecified inclusion and exclusion criteria. The review considered observational, cross-sectional, descriptive, and mixed-methods investigations, as well as program evaluations, policy analyses, and other research reports addressing laboratory quality. Studies examining quality management systems (QMS), quality assurance (QA), quality control (QC), laboratory accreditation, external quality assessment (EQA), proficiency testing, laboratory information systems (LIS), or comparable quality improvement activities in Philippine clinical laboratories were considered potentially eligible.

Studies were included when they: (1) were undertaken in the Philippines; (2) investigated clinical, medical, hospital-based, or diagnostic laboratory settings; (3) presented findings concerning laboratory quality management, quality assurance, accreditation, proficiency testing, regulatory compliance, or laboratory performance; and (4) were written in English and available as accessible full-text publications. Studies conducted outside the Philippines or in non-clinical laboratory environments were excluded. Conference materials, editorials, commentaries, letters to the editor, opinion articles, dissertations, theses, study protocols, and publications for which the complete text could not be accessed were likewise excluded.

Information Sources and Search Strategy

The literature search was performed on June 15, 2026, across PubMed, Scopus, Google Scholar, and ERIC. Supplementary searches were undertaken in Philippine E-Journals and on relevant government and regulatory agency websites, particularly those of the Department of Health (DOH) and the Research Institute for Tropical Medicine (RITM). Reference lists and citation records of eligible publications were also manually examined to identify additional potentially relevant studies. Publications issued between January 2002 and June 2026 were eligible for consideration.

The search approach incorporated both controlled vocabulary and free-text keywords representing laboratory quality management and quality assurance concepts. Key terms included “clinical laboratory,” “medical laboratory,” “quality management system,” “quality assurance,” “quality control,” “laboratory accreditation,” “ISO 15189,” “external quality assessment,” “proficiency testing,” “laboratory information system,” and “Philippines.” The Boolean operators AND and OR were applied to combine search concepts and were adapted according to the requirements of each information source. No date filters were imposed when the electronic searches were executed. An example of the PubMed search string was: ("quality management system" OR "quality assurance" OR "quality control" OR accreditation OR "ISO 15189") AND ("clinical laboratory" OR "medical laboratory") AND Philippines.

Study Selection

All records identified through the searches were transferred to a screening spreadsheet, after which duplicate entries were identified and removed. Two reviewers independently evaluated the titles and abstracts of the remaining records using the established eligibility criteria. Articles considered potentially relevant at this stage were obtained for full-text assessment. Both reviewers independently evaluated the complete articles for final inclusion. Differences in eligibility judgments were discussed until consensus was reached. Studies satisfying all inclusion requirements were retained in the final evidence synthesis. The identification, screening, eligibility assessment, and inclusion of studies were documented using a PRISMA 2020 flow diagram.

Data Extraction

A structured and standardized extraction form was prepared to ensure consistent collection of information from the eligible studies. The variables extracted comprised author(s), publication year, geographical location, research design, laboratory setting, study population, quality management or quality assurance components investigated,

principal findings, reported outcomes, identified barriers and facilitating factors, and recommendations for improving laboratory quality.
Two reviewers independently extracted the required information from each included study to improve the accuracy and consistency of the dataset. Any differences between the extracted data were reviewed and resolved through discussion and mutual agreement.

Quality Assessment

The methodological rigor of each included study was independently evaluated by two reviewers using the Joanna Briggs Institute (JBI) Critical Appraisal Tool appropriate to the respective study design. Studies employing mixed-methods designs were appraised using the Mixed Methods Appraisal Tool (MMAT). The appraisal process examined methodological quality, study validity, and possible sources of bias.
Based on the proportion of applicable appraisal criteria fulfilled, studies were classified into three methodological quality categories. Studies meeting at least 80% of the relevant criteria were regarded as high quality, those satisfying 60–79% were classified as moderate quality, and studies meeting fewer than 60% were categorized as low quality. Differences in appraisal judgments were addressed through reviewer discussion and consensus. The quality assessment findings were summarized and taken into account when interpreting the overall evidence.

Data Synthesis and Analysis

A narrative synthesis was undertaken because substantial variation existed among the included studies in terms of research designs, methodological approaches, and outcome measures. Evidence was grouped into thematic domains reflecting major dimensions of quality management and quality assurance in Philippine clinical laboratories. The domains comprised: (1) laboratory quality management practices; (2) accreditation and regulatory compliance; (3) external quality assessment and proficiency testing; (4) laboratory information systems; (5) laboratory personnel knowledge, attitudes, and practices; (6) factors that hinder or facilitate implementation; and (7) reported effects on laboratory performance and patient care.
The findings were integrated descriptively and reported through tabular presentations and narrative summaries. This approach was used to identify recurring themes and patterns, areas in which evidence remains limited, and potential opportunities for strengthening laboratory quality systems within the Philippines.

Ethical Considerations

Institutional ethical approval was not required for this review because all analyses were based exclusively on previously published studies and documents available in the public domain. The review did not directly recruit human participants or access individual patient records, identifiable data, or confidential information.

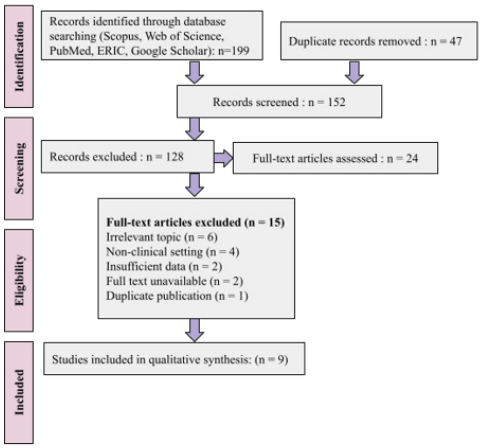

Figure 1: PRISMA 2020 Flow Diagram

The literature search yielded 199 records from Scopus, Web of Science, PubMed, ERIC, and Google Scholar. After removing 47 duplicate records, 152 articles remained for title and abstract screening. Of these, 128 records were excluded for not meeting the eligibility criteria. Twenty-four full-text articles were assessed for eligibility, and 15 were excluded due to irrelevance to Philippine clinical laboratory quality assurance practices, focus on non-clinical laboratory settings, insufficient methodological information, unavailable full texts, or duplicate publication. Ultimately, 9 studies were included in the qualitative synthesis.

RESULTS

The database and supplementary searches identified 199 records from PubMed, Scopus, Google Scholar, ERIC, and additional information sources. Following the removal of 47 duplicate entries, 152 unique records remained for title and abstract screening. Of these, 128 were excluded because they did not satisfy the predefined eligibility requirements. The full texts of 24 potentially relevant publications were subsequently reviewed. Fifteen articles were excluded at this stage because they did not specifically address laboratory quality management, were conducted in non-clinical laboratory environments, provided inadequate methodological details, or were unavailable in full text. Consequently, nine studies fulfilled the inclusion criteria and were incorporated into the qualitative synthesis (Figure 1).
The evidence from Philippine clinical laboratory settings indicated a generally substantial adoption of quality management and quality assurance practices. In hospital laboratories located in Region XII, Villena and Coronica [17] documented a very high degree of Laboratory Quality Management System (LQMS) implementation. Among the assessed components, Process Management achieved the strongest implementation ratings, whereas Facilities and Safety Management received the lowest scores. Comparable findings were presented by Arada et al. [20], who observed that medical technologists working in selected Level III hospitals in Davao City generally expressed favorable attitudes toward quality assurance and reported adherence to established QA practices.

Nevertheless, the respondents identified financial costs, the need for additional professional training, and the time required to perform QA-related activities as major obstacles to implementation.

Findings from studies examining external quality assessment indicated variability in laboratory proficiency. Mondoy et al. [26] observed an improvement in the proportion of passing performance among laboratories enrolled in the National External Quality Assessment Scheme (NEQAS) for Bacteriology between 2009 and 2015. However, despite this positive trend, a considerable number of participating laboratories continued to demonstrate unsatisfactory performance. Limitations in staff competence, resource availability, and the effective application of quality assurance procedures were identified as contributing factors. Similarly, Galit et al. [27] reported that numerous laboratories participating in Diagnostic Medical Parasitology proficiency testing did not attain the required passing score. Particular difficulties involved the accurate identification of parasites and estimation of malaria parasite density. In blood service facilities, Punzalan et al. [28] documented aberrant findings in serological and malaria examinations, indicating the occurrence of both random and systematic analytical errors.

Studies focusing on laboratory quality indicators further demonstrated areas requiring continued improvement. Aquino and Damian [29] found a specimen rejection rate of 5.78% for hematology samples in a tertiary government hospital. Clotted specimens and insufficient sample volume represented the leading reasons for rejection, with emergency and intensive care units demonstrating comparatively higher rejection frequencies. From a patient-centered perspective, Gulapa [30] documented generally high satisfaction with the technical competence and professionalism of laboratory personnel and the accessibility of laboratory services. However, communication practices and laboratory turnaround times remained aspects in which further improvement was needed.

The available evidence also indicated that technological innovations and accreditation-focused initiatives may contribute to improved laboratory quality. Antonio et al. [31] found that introducing a Laboratory Information System was associated with fewer transcription errors, shorter turnaround times, more effective communication, and greater confidence in reported laboratory findings. Dayrit et al. [32] developed conformity assessment instruments intended to facilitate adherence to ISO 15189 accreditation requirements and improve laboratory equipment management processes. Furthermore, historical and regulatory evidence indicates that laboratory quality systems in the Philippines have progressively evolved through the development of accreditation mechanisms, licensing standards, and national quality assurance policies [7, 8, 33].

Evidence Gaps Identified

Several limitations in the existing Philippine evidence base were identified through the review. First, the geographical coverage of most studies was restricted to particular hospitals or regions, thereby limiting the extent to which the findings can represent laboratory quality practices nationwide. Second, few investigations have examined whether ISO 15189 accreditation produces sustained improvements in laboratory performance or measurable benefits to patient outcomes. Third, research concerning Laboratory Information Systems and other digital approaches to quality management remains limited. Fourth, multicenter investigations comparing quality management implementation across different clinical laboratory classifications are notably lacking. Finally, insufficient evidence is available regarding the cost-effectiveness, long-term feasibility, and sustainability of quality improvement interventions implemented within clinical laboratory services.

DISCUSSION

The evidence synthesized in this review demonstrates considerable advancement in the adoption of quality management and quality assurance systems among clinical laboratories in the Philippines. Villena and Coronica [17] documented a very high degree of Laboratory Quality Management System (LQMS) implementation, with process management emerging as the most strongly implemented component. This finding indicates that quality principles have increasingly become embedded within routine laboratory processes. Consistent with this observation, Arada et al. [20] reported generally favorable perceptions of quality assurance among medical technologists, together with reported adherence to established QA practices. Taken together, these findings reflect a growing recognition among laboratory professionals of the role of structured quality systems in producing dependable, accurate, and timely diagnostic information.

Nevertheless, the widespread acceptance of quality principles does not necessarily translate into complete or uniform implementation. Arada et al. [20] identified financial demands, the requirement for further training, and the additional time associated with QA activities as notable constraints. Villena and Coronica [17] similarly observed weaker implementation in facilities and safety management, suggesting that infrastructure and resource availability remain areas of concern. These observations indicate that personnel awareness alone may be insufficient to maintain effective quality systems without adequate institutional commitment, financial investment, and operational support. Comparable obstacles, particularly funding limitations, workforce training needs, and inadequate infrastructure, have also been documented in Ghana, Ethiopia, Malawi, and other low- and middle-income settings [9, 14, 16]. Thus, the difficulties experienced by Philippine clinical laboratories appear to reflect broader challenges encountered internationally when comprehensive laboratory quality systems are introduced and sustained.

The findings also underscore the central role of external quality assessment in evaluating laboratory competency and revealing deficiencies that may not be readily detected through routine internal monitoring. Mondoy et al. [26] showed progressive improvement in bacteriology proficiency testing among laboratories participating in the National External Quality Assessment Scheme (NEQAS). Despite this improvement, unsatisfactory performance persisted in several laboratories and was associated with limitations in staff competence, available resources, and the implementation of quality assurance procedures. In diagnostic parasitology, Galit et al. [27] likewise identified continuing performance difficulties, particularly in the correct identification of specific parasites and the estimation of malaria parasite density. Punzalan et al. [28] further documented aberrant findings in external quality assessment results from blood service facilities, indicating the occurrence of both systematic and random testing errors. Collectively, these findings demonstrate that EQA programs provide more than a measure of laboratory proficiency; they also generate evidence that can guide corrective measures, targeted competency development, and continuous quality improvement.

The use of quality indicators provides another important approach for identifying weaknesses across the total testing process. Aquino and Damian [29] reported a specimen rejection frequency higher than rates described in several international investigations, with clot formation and inadequate specimen volume representing the predominant causes of rejection. The greater occurrence of rejected specimens in emergency and intensive care environments further highlights the vulnerability of the pre-analytical phase in high-pressure clinical settings. These findings emphasize the importance of improving specimen collection procedures, strengthening staff competency, and routinely monitoring pre-analytical indicators. Quality assessment should also consider the experiences of patients receiving laboratory services. Gulapa [30] observed generally high levels of satisfaction with laboratory services but identified communication and turnaround time as continuing concerns. Accordingly, laboratory improvement strategies should not focus exclusively on analytical performance but should also incorporate service-related and patient-centered measures that influence the overall quality of care.

Digital technologies represent a further opportunity to strengthen laboratory operations and reduce preventable errors. Antonio et al. [31] demonstrated that the introduction of a Laboratory Information System was associated with reduced transcription errors, faster specimen processing, improved communication across departments, and increased confidence in laboratory reports. These operational improvements may facilitate more timely and informed clinical decisions and contribute to better patient management. Similarly, Dayrit et al. [32] demonstrated the usefulness of equipment conformity assessment instruments in facilitating alignment with ISO 15189 accreditation requirements. Structured approaches to equipment evaluation may improve equipment management processes while also supporting institutional preparedness for accreditation.

The progress observed in Philippine laboratories must also be considered within the context of the country's evolving regulatory and quality assurance framework. Maramba [8] described the historical development of laboratory accreditation and quality assurance mechanisms in the Philippines, reflecting sustained regulatory efforts to improve the reliability of laboratory services. This regulatory commitment is reinforced by Department of Health Administrative Order No. 2021-0037, which establishes requirements related to laboratory licensing, personnel qualifications, equipment, and compliance with quality assurance standards. In addition, the National External Quality Assessment Scheme Guidelines issued by the Research Institute for Tropical Medicine emphasize participation in EQA as an integral component of laboratory quality assurance and regulatory compliance [33]. Collectively, these regulatory mechanisms establish an important foundation for promoting standardized laboratory practice, continuous improvement, and greater preparedness for accreditation.

Overall, the available evidence indicates that Philippine clinical laboratories have achieved meaningful progress in establishing quality management and quality assurance practices. However, persistent limitations involving workforce competency, laboratory infrastructure, financial and material resources, pre-analytical errors, and the long-term sustainability of quality systems continue to require attention. Addressing these concerns will require sustained competency development, systematic performance monitoring, greater use of appropriate laboratory technologies, adequate institutional investment, and continued regulatory support. Strengthening these areas may further improve laboratory performance, support compliance with accreditation standards, enhance patient safety, and contribute to the delivery of more reliable and high-quality healthcare services in the Philippines.

CONCLUSION

The findings of this systematic review indicate that Philippine clinical laboratories have made significant progress in implementing quality management systems and quality assurance practices aimed at ensuring the accuracy, reliability, and timeliness of laboratory services. The reviewed studies demonstrated substantial adoption of quality management initiatives, including accreditation programs, external quality assessment participation, laboratory information systems, quality indicators, and continuous quality improvement activities. These measures have contributed to improved laboratory performance, enhanced patient safety, increased operational efficiency, and greater confidence in diagnostic results. However, several challenges continue to hinder the full implementation and sustainability of quality systems, including resource limitations, infrastructure constraints, workforce competency issues, implementation costs,

and persistent pre-analytical and analytical errors. The findings further highlight the importance of regulatory compliance, external quality assessment programs, technological innovations, and ongoing professional development in strengthening laboratory quality practices. Overall, maintaining robust quality management systems requires continuous monitoring, institutional commitment, adequate resource allocation, and adherence to national and international standards. Strengthening these areas will further enhance the quality of laboratory services in the Philippines and support improved healthcare outcomes for patients.

Strengths of the Review

This review has several strengths. To the best of our knowledge, it is the first systematic review specifically synthesizing evidence on quality management practices and quality assurance systems in Philippine clinical laboratories. The review incorporated studies from multiple quality domains, including accreditation, external quality assessment, laboratory information systems, patient-centered indicators, and personnel practices. Furthermore, the review followed PRISMA 2020 guidelines and utilized established quality appraisal tools to evaluate methodological rigor.

LIMITATIONS

Several limitations should be considered when interpreting the findings of this systematic review. The relatively small body of published research specifically addressing quality management systems and quality assurance practices in Philippine clinical laboratories limited the scope of evidence available for synthesis. Considerable variation was also observed among the included studies with respect to research design, methodological approaches, laboratory settings, and reported outcomes, thereby limiting direct comparison of findings across studies. In addition, much of the available evidence originated from individual institutions, selected geographic regions, or specific laboratory environments. Consequently, the findings may not accurately reflect quality management and quality assurance practices across all clinical laboratories in the Philippines.

The review was further dependent on literature retrieved from the selected information sources. Relevant unpublished research, institutional documents, and other forms of gray literature may therefore have been missed during study identification. Moreover, substantial methodological and outcome heterogeneity among the eligible studies prevented the statistical pooling of results through meta-analysis. A narrative synthesis was therefore used to integrate and interpret the available evidence. Despite these constraints, this review offers an important synthesis of the existing evidence on laboratory quality management and quality assurance in the Philippines and identifies priority areas for further investigation and continued quality improvement.

RECOMMENDATIONS

Based on the evidence synthesized in this review, further efforts are needed to reinforce quality management systems and quality assurance practices across clinical laboratories in the Philippines. Laboratory leaders and institutional administrators should prioritize sustained workforce capacity development by providing regular training, periodic competency evaluations, and continuing professional education. These initiatives are essential for keeping laboratory personnel updated on evolving quality standards, accreditation requirements, and advances in laboratory technology. Quality improvement programs should also address the entire testing pathway by strengthening pre-analytical, analytical, and post-analytical procedures to reduce preventable errors and enhance the consistency and reliability of laboratory findings.

Healthcare institutions and relevant policymakers should ensure sufficient financial, technical, and operational support for laboratory quality initiatives. Priority investments should include improvements in laboratory facilities, preventive equipment maintenance, Laboratory Information Systems, and activities required for accreditation preparedness and maintenance. Broader and sustained participation in external quality assessment schemes and accreditation programs should also be encouraged to promote adherence to national and internationally recognized standards and to embed continuous quality improvement within routine laboratory operations. Regulatory authorities and professional organizations should further strengthen technical support, performance monitoring, and capacity-building activities that assist laboratories in maintaining acceptable standards of service quality.

The limited body of published Philippine evidence on laboratory quality management and quality assurance also demonstrates the need for additional research. Future investigations should encompass laboratories from a broader range of geographic locations, institutional settings, classifications, and laboratory disciplines to generate a more representative understanding of quality practices nationwide. Further studies should evaluate the measurable effects of specific quality improvement strategies, determine the short- and long-term outcomes of accreditation, and examine how emerging digital and laboratory technologies influence operational performance and patient safety. Strengthening the national evidence base may support more informed policy formulation, guide context-appropriate quality improvement interventions, and contribute to the continued advancement of clinical laboratory services throughout the Philippines.

Table 1: Characteristics of Included Studies (n = 9)

Author(s), Year	Study Design	Setting/Location	Participants/Sample	Main Findings
Arada et al. (2021)	Descriptive quantitative study	Level III hospitals, Davao City, Philippines	Medical technologists	Respondents demonstrated positive attitudes and good compliance with laboratory quality assurance practices; cost and time were identified as barriers.
Mondoy et al. (2017)	Retrospective program evaluation	National External Quality Assessment Scheme (NEQAS), Philippines	Participating laboratories	Improvement in bacteriology proficiency testing performance over time; deficiencies remained in personnel competency and quality assurance implementation.
Galit et al. (2019)	Program evaluation study	NEQAS Diagnostic Parasitology Program, Philippines	Participating laboratories	Laboratories demonstrated variable proficiency in parasite identification and malaria parasite quantification.
Punzalan et al. (2019)	Descriptive evaluation study	Blood service facilities, Philippines	Participating facilities	External quality assessment identified random and systematic errors affecting testing performance.
Aquino & Damian (2025)	Retrospective observational study	Philippine tertiary hospital laboratory	Blood specimens	Clotted specimens and insufficient sample volume were the leading causes of specimen rejection.
Antonio et al. (2024)	Mixed-methods study	Valenzuela Medical Center, Philippines	Healthcare professionals	Laboratory Information System implementation improved workflow efficiency, reduced errors, and enhanced patient outcomes.
Dayrit et al. (2023)	Descriptive evaluation study	Clinical laboratories, Philippines	Laboratory equipment/processes	Equipment conformity assessment supported ISO 15189 compliance and accreditation readiness.
Villena & Coronica (2025)	Descriptive survey study	Clinical laboratories, Region XII, Philippines	Laboratory personnel	High levels of quality management system implementation were reported, particularly in process management.
Maramba (2002)	Historical and policy review	Philippines	Clinical laboratory sector	Described the development of laboratory accreditation and quality assurance systems in the Philippines.

Table 2: Methodological Quality Assessment of Included Studies

Author(s), Year	Study Design	Appraisal Tool	Score*	Quality Rating
Arada et al. (2021)	Descriptive quantitative study	JBI Analytical Cross-Sectional Checklist	6/8	Moderate
Mondoy et al. (2017)	Retrospective program evaluation	JBI Quasi-Experimental/Observational Checklist	6/9	Moderate
Galit et al. (2019)	Program evaluation study	JBI Quasi-Experimental/Observational Checklist	6/9	Moderate
Punzalan et al. (2019)	Descriptive evaluation study	JBI Analytical Cross-Sectional Checklist	6/8	Moderate
Aquino & Damian (2025)	Retrospective observational study	JBI Analytical Cross-Sectional Checklist	7/8	High
Antonio et al. (2024)	Mixed-methods study	Mixed Methods Appraisal Tool (MMAT)	4/5	High
Dayrit et al. (2023)	Descriptive evaluation study	JBI Analytical Cross-Sectional Checklist	6/8	Moderate
Villena & Coronica (2025)	Descriptive survey study	JBI Analytical Cross-Sectional Checklist	7/8	High
Maramba (2002)	Historical and policy review	Narrative Review Appraisal Tool	4/6	Moderate

Table 3: Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Studies focused on quality management systems (QMS), quality assurance (QA), quality control (QC), accreditation, external quality assessment (EQA), or laboratory quality improvement	Studies not related to laboratory quality management or quality assurance
Studies conducted in clinical, medical, diagnostic, or hospital laboratories in the Philippines	Studies conducted outside the Philippines
Original research articles, evaluation studies, observational studies, mixed-methods studies, and survey studies	Editorials, commentaries, conference abstracts, letters to the editor, and opinion papers
Articles published in peer-reviewed journals	Non-peer-reviewed publications
Full-text articles available in English	Articles without accessible full text or published in languages other than English
Studies published within the specified search period	Duplicate publications or duplicate records
Studies reporting outcomes related to laboratory quality practices, accreditation, proficiency testing, laboratory performance, patient satisfaction, or laboratory information systems	Studies not reporting findings relevant to quality management or quality assurance in clinical laboratories

REFERENCES

1. Adekoya, A., Okezue, M. A., & Menon, K. (2025). Medical laboratories in healthcare delivery: A systematic review of their roles and impact. *Laboratories*, 2(1), 8. ttps://doi.org/10.3390/laboratories2010008
2. Pillai, S. P., & Fox, E. (2025). Laboratory quality management system fundamentals. *Frontiers in Bioengineering and Biotechnology*, 13, 1578654. https://doi.org/10.3389/fbioe.2025.1578654
3. World Health Organization [WHO], (2023). Laboratory quality management system training toolkit. Retrieved May 23, 2026, from https://extranet.who.int/hslp/content/LQMS-training-toolkit
4. Clinical and Laboratory Standards Institute [CLSI], (2018, August 10). Quality management in the laboratory. https://clsi.org/resources/insights-blog/quality-management-in-the-laboratory/
5. International Organization for Standardization. (2022). Medical laboratories—Requirements for quality and competence (ISO Standard No. 15189:2022). International Organization for Standardization.
6. Department of Health. (2007, August 22). Revised rules and regulations governing the licensure and regulation of clinical laboratories in the Philippines (DOH Administrative Order No. 2007-0027). Republic of the Philippines. Supreme Court E-Library – DOH Administrative Order No. 2007-0027
7. Department of Health. (2021, June 18). Administrative Order No. 2021-0037: New rules and regulations governing the regulation of clinical laboratories in the Philippines. Republic of the Philippines. https://bit.ly/DOHAO2021-0037
8. Maramba, T. P. (2002). Accreditation of clinical laboratories in the Philippines. *Southeast Asian Journal of Tropical Medicine and Public Health*, 33(Suppl. 2), 79–82. PMID: 12755273.
9. Sorvor E, Dzodzomenyo M, Nonvignon J, Aryeetey GC (2026) Assessment of compliance with quality laboratory standards in medical laboratories within the Kumasi Metropolis, Ghana. *PLoS One* 21(3): e0335380. https://doi.org/10.1371/journal.pone.0335380
10. Department of Health. (2020). Administrative Order No. 2020-0031 [PDF]. Department of Health, Republic of the Philippines. https://law.upd.edu.ph/wp-content/uploads/2020/08/DOH-AO-2020-0031.pdf

11. Padmanabhan, P. (2024). Basics of quality control in a clinical laboratory. *Journal of Clinical and Laboratory Research*, 7(8). https://doi.org/10.31579/2768-0487/154
12. IMARC Group. (2026). Philippines clinical laboratory services market report by test type (human and tumor genetics, clinical chemistry, medical microbiology and cytology, and others), service provider (hospital-based laboratories, stand-alone laboratories, clinic-based laboratories), application (bioanalytical and lab chemistry services, toxicology testing services, cell and gene therapy related services, preclinical and clinical trial related services, drug discovery and development related services, and others), and region 2026–2034. https://www.imarcgroup.com/philippines-clinical-laboratory-services-market
13. World Health Organization, & United Nations Development Programme. (2019). Prevention and control of noncommunicable diseases in the Philippines: The case for investment. World Health Organization. WHO report PDF
14. Fenta, D. A., & Ali, M. M. (2020). Factors affecting quality of laboratory results during ordering, handling, and testing of the patient's specimen at Hawassa University College of Medicine and Health Science Comprehensive Specialized Hospital. *Journal of Multidisciplinary Healthcare*, 13, 809–821. https://doi.org/10.2147/JMDH.S264671
15. Barnadas, C., Stevens, L., Milhano, N., Barbosa de Lima, A. C., Struminger, B., Burke, L., & Cognat, S. (2025). WHO public health laboratories webinar series—An online platform to disseminate testing recommendations and best practices during health emergencies. *Frontiers in Public Health*, 12, 1462756. https://doi.org/10.3389/fpubh.2024.1462756
16. Tembo, D., Kaphika, J. S., Ahmadu, A., Alufandika, L., Kalilangwe, V., Kukacha, C., Kaphika, D., Lipenga, F. T., Machonjo, M., Manda, S., Masina, M., Mchoma, E. C., Mnyanga, A. C., Moyo, I. M., Mutala, F. P., Mzumara, P., Shani, D., Selemani, G. P., & Denis, B. (2026). Implementing and transitioning a laboratory quality management system from ISO 15189:2012 to ISO 15189:2022: Experience from the Malawi-Liverpool Wellcome Research Programme, Blantyre. *Wellcome Open Research*, 11, 144. https://doi.org/10.12688/wellcomeopenres.25356.2
17. Villena, J. T. S., & Coronica, L. (2025). Quality management system of Philippine hospital laboratories: An analysis based on service capability and bed capacity. *Journal of Medical and Health Studies*, 6(2), 103–109. https://doi.org/10.32996/jmhs.2025.6.2.16
18. Andiric, L. R., Chavez, L. A., Johnson, M., Landgraf, K., & Milner, D. A., Jr. (2018). Strengthening laboratory management toward accreditation: A model program for pathology laboratory improvement. *Clinics in Laboratory Medicine*, 38(1), 131–140. https://doi.org/10.1016/j.cll.2017.10.010
19. Tanasiichuk, I., Karaman, O., & Natrus, L. (2023). Key success factors for the implementation of quality management systems in developing countries. *African Journal of Laboratory Medicine*, 12(1), 2058. https://doi.org/10.4102/ajlm.v12i1.2058
20. Pant, V., Parchwani, D., Upadhyay, M., Ohkawa, R., Sherpa, M. L., & Dabla, P. K. (2026). Urgent call for action: Bridging gaps in Asia-Pacific laboratories' transition to ISO 15189:2022. *Electronic Journal of the International Federation of Clinical Chemistry and Laboratory Medicine*, 37(1), 166–170.
21. Arada, M. C. G., Caduco, D. D. D., Cho, I., Santos, D. R., Villamin, D. S O., Visitacion, E. R., & Yara, I. Y. H. (2021). Knowledge, attitude, and practices on laboratory quality assurance among medical technologists in selected Level III hospitals in Davao City. *International Journal of Progressive Research in Science and Engineering*, 2(8), 398–427. https://journal.ijprse.com/index.php/ijprse/article/view/391
22. Balderama, H. J., Tesoro, V. A., Antonio, T. J., & Ramones, R. A. (2022). Institutionalization of the Philippine Health Laboratory System (PHLS). *Philippine Journal of Pathology*, 7(2), 5–12. https://doi.org/10.21141/PJP.2022.20
23. Ulep, V. G T., Uy, J., Casas, L. D. D., & Nuevo, C. E. L. (2021). Assessment of the service capability and readiness of Philippine hospitals to provide high-quality health care (Discussion Paper Series No. 2021-32). Philippine Institute for Development Studies. https://pidswebs.pids.gov.ph/CDN/PUBLICATIONS/pidsdps2132.pdf
24. Philippine Health Insurance Corporation. (2025). Measuring hospital performance in the Philippines: Evidence on quality, efficiency, and equity from social health insurance claims (Discussion Paper No. 2025-30). https://doi.org/10.62986/dp2025.30
25. Mendoza, M. A. F., Zarsuelo, M.-A. M., Borlongan, G. R., Silva, M. E. C., Lam, H. Y., & Padilla, C. D. (2020). Moving towards evidence-informed policy development on third-party accreditation of healthcare facilities in light of the Universal Health Care Act: Policy analysis. *Acta Medica Philippina*, 54(6). https://doi.org/10.47895/amp.v54i6.2617
26. Page, M.J., et al. (2021) The PRISMA 2020 Statement: An Updated Guideline for Reporting Systematic Reviews. *Systematic Reviews*, 10, Article No. 89.https://doi.org/10.1186/s13643-021-01626-4
27. Mondoy, M., Rapanut, J. M., Bugayong, M. P., Aguinaldo, R., Navarro, R., Yap, K. J., Kapawan, M. T., Almonia, D. J., Esparar, G., Sadiasa, A., Macalalad, N., Sombrero, L., Capeding, M. R., & Lupisan, S. (2017). Proficiency testing of clinical laboratories for bacteriology in the Philippines, 2009–2015. *Philippine Journal of Pathology*, 2(2).
28. Galit, S., Tangcalagan, D., Rapanut, J. M., Sadiasa, A., Bautista, P. N., Dominguez, K. J., Bañaga, J., Roxas, C. B., Navarro, R., Bugayong, M. P., Luchavez, J., Mondoy, M., Sombrero, L., & Lupisan, S. (2019). The National External Quality Assessment Scheme for Diagnostic Medical Parasitology in the Philippines, 2009–2015. *Philippine Journal of Pathology*, 4(1), 12–17. https://doi.org/10.21141/PJP.2019.03
29. Punzalan, K. A., Yu, R., & Chamen, I. M. (2019). External quality assessment scheme for transfusion transmissible infections among blood service facilities in the Philippines, 2018. *Philippine Journal of Pathology*, 4(2). https://doi.org/10.21141/PJP.2019.17

30. Aquino, J. B., & Damian, K. B. (2025). Pre-analytical Factors Influencing Blood Sample Rejection Rate in the Hematology Laboratory of the Philippine General Hospital from 2018 to 2022: A Cross-sectional Study. *Acta Medica Philippina*, 59(11), 30–36. doi:10.47895/amp.vi0.9961.

31. Gulapa, L. (2026). Patient Satisfaction On Clinical Laboratory Services Of Tertiary Private Hospital: Basis For Quality Management Improvement. *SALETTINIAN OPEN ACADEMIC REVIEW*, 8(1), 177-191.

32. Antonio, S. M., Dancel, M. B., Lim, C. N., Roberto, J. R. A., Malang, B. P., & Malang, J. D. S. (2024). Assessing the Impact of Laboratory Information System on Clinical Workflow and Patient Outcomes. *International Journal of Multidisciplinary: Applied Business and Education Research*, 5(11).

33. Dayrit, G. B., Mok, D., Nabulsi, R., Eloyan, N., Chowdhury, S., & Ma, A. C. Y. (2023). Conformity Evaluation of Afinion 2 Analyzer Maintainability: Compliance Practicality for Philippine National Standard PNS ISO 15189:2013 Accreditation. *Acta Medica Philippina*, 57(11), 72–91.

34. Research Institute for Tropical Medicine (RITM). (2023). Guidelines for the RITM National External Quality Assessment Scheme (RITM-NEQAS) (As of August 2023). Department of Health, Philippines.