ADDIS ABABA UNIVERSITY

COLLEGE OF HEALTH SCIENCES

SCHOOL OF BIOMEDICINE AND LABORATORY SCIENCE

DEPARTMENT OF MEDICAL LABORATORY SCIENCE

IMPLEMENTATION OF ISO 15189:2022 AMONG PRIVATE AND GOVERNMENTAL HOSPITALS AND DIAGNOSTIC LABORATORIES IN ADDIS ABABA, ETHIOPIA.

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This is to certify that the thesis prepared by Melkamu Kassaw, entitled: implementation of ISO 15189:2022 standard among private and government hospitals and diagnostic laboratories in Addis Ababa, Ethiopia, and submitted in Partial fulfilment of the requirements for the Degree of Master of Science in Clinical Laboratory Sciences (Clinical Laboratory Management and Quality Assurance specialty track) complies with the regulations of the University and meets the accepted standards with respect to originality and quality.

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Table of Contents

Contents page

Acknowledgment ii
Table of Contents iii
List of figures v
List of tables v
List Abbreviations vi
Abstract vii
1. Introduction 1
1.1. Background 1
1.2. Statement of Problem 3
1.3. Significance of the Study 5
2. Literature Review 6
2.1. Status of accreditation 6
2.2. Associated challenge of ISO 15189:2022 implementation 8
2.3. Conceptual Framework 12
3. Objective 13
3.1. General Objective 13
3.2. Specific Objectives 13
4. Methods and materials 14
4.1. Study setting 14
4.2. Study design and period 14
4.3. Population 14
4.3.1. Source population 14
4.3.2. Study population 14
4.4. Sample size determination 15
4.5. Sampling methods 16
4.6. Inclusion and exclusion criteria 17
4.6.1. Inclusion criteria 17
4.6.2. Exclusion criteria 17
4.7. Study variable 17
4.7.1. Dependent variable 17
4.7.2. Independent variable 17

4.8. Operational definition 17
4.9. Data collection 18
4.10. Data quality assurance 18
4.11. Data management and analysis 19
4.12. Ethical consideration 20
4.13. Dissemination of results 20
5. Results 21
5.1. Demographic data of Participant 21
5.2. Institutional and Laboratory Characters 22
5.3. Knowledge and participation in ISO 15189:2022 implementation 24
5.4. Challenges of ISO 15189:2022 Implementation. 25
5.5. Factors Associated with ISO 15189:2022 Implementation 27
5.6. Findings of the qualitative study 31
6. Discussion 34
7. Strengths and Limitations of the Study 40
7.1. Strengths of the study 40
7.2. Limitations of the Study 40
7.3. Challenge of the study 40
8. Conclusion and recommendations 41
8.1. Conclusion 41
8.2. Recommendation 42
References 43
Annex 1. Research participant information sheet. 47
Annex 2. Consent form 48
Annex 3. Data Collection clarification 48
Annex 4. Questionnaires 49
Declaration 54

List of figures

Figure 1: Conceptual framework diagram..... 12
Figure 2: Diagrammatic representation of sampling techniques. 16
Figure 3: Role of participant in laboratory services in Addia Ababa Ethiopia, Feb to Apr 2026...... 22

List of tables

Table 1: Demographic data of study participants in Addis Ababa, Ethiopia, from Feb to Apr 2026...... 21
Table 2. Institutional and Laboratory Characteristics of participants from Feb to Apr 2026 in Addis Ababa, Ethiopia. 23
Table 3: Knowledge and participation of participants in ISO implementation in Addis Ababa, Ethiopia...... 24
Table 4: Likert scale mean score and standard deviation 26
Table 5:Binary logistic and Multivariate Logistic Regression of Analysis of demographic characteristics of participants...... 27
Table 6: Factors Associated with the Implementation Status of ISO 15189:2022 among Governmental and Private Hospitals and Diagnostic Laboratories in Addis Ababa, Ethiopia, 2026...... 29

List Abbreviations

FRF	Financial and Resource Factors
EQA	External Quality Assurance
EXF	External Factors
HRF	Human Resource Factors
IAF	International Accreditation Forum
ISO	International Organization for Standardization
ILAC	International Laboratory Accreditation Cooperation
ITF	Infrastructural and Technical Factors
LQMS	Laboratory Quality Management Service
MLS	Medical Laboratory Science
POCT	Point of Care Testing
QMF	Quality Management Factors
UHC	Universal Health Coverage

Abstract

Background: Medical laboratories play a critical role in health care and contribute substantially to clinical decisions. The revised ISO 15189:2022 standard provides a framework for quality and competency in medical laboratories. However, the implementation remains challenging in low- and middle-income countries, including Ethiopia.

Objective: To assess the implementation status of the ISO 15189:2022 standards and associated challenges among hospitals and diagnostic laboratories in Addis Ababa, Ethiopia.

Methods: An institutional-based cross-sectional mixed methods study was conducted from February to April 2026. Quantitative data were collected from 344 laboratory professionals using structured questionnaires, while qualitative data were obtained through in-depth interviews with 10 key informants. The descriptive statistics and multivariate analysis were performed using SPSS version 27, and qualitative data were analyzed by thematic analysis. The final results were integrated using a triangulation approach.

Result: The study found that only 22.2% of laboratories in Addis Ababa were fully compliant with ISO 15189:2022 requirements. The findings also identified several significant challenges affecting implementation. Key challenges included shortages of trained personnel, high workload, limited staff competency, inadequate funding for EQA, training, and equipment calibration, lack of modern equipment, poor communication and managerial support, and weak collaboration with international partners. The multivariate analysis identified staff participation, availability of modern laboratory equipment, regular participation in the EQA program, facility types, adequate laboratory facilities, and international collaboration as significant predictors of implementation. This finding is also supported by the qualitative results.

Conclusion: the implementation of ISO 15189:2022 in Addis Ababa, Ethiopia, remains limited despite growing awareness and progress. Human resource constraints, financial limitations, infrastructural deficiency, and lack of organizational support were identified as barriers. To ensure the sustainable implementation, improving the identified barriers were essential.

Key term: ISO 15189:2022, implementation challenge, Laboratory Quality Management Service, Accreditation, laboratory professional.

1. Introduction

1.1.Background

The medical laboratory is one of the most important parts of examination driven from the human body for diagnosis, monitoring, management, prognosis, prevention, and control of disease and screening of health (1,2). It plays a pivotal role in epidemiological surveillance and infectious disease eradication (3). It's also essential for modern diagnostic services, with reliability, accuracy, and timeliness of test results affecting the efficiency and effectiveness of the services (4). However, Inadequate or incorrect laboratory results lead to incorrect treatment and diagnostic services (4,5). The laboratory service contributes to approximately 70% of medical diagnoses and helps to minimize infectious diseases by producing measurable results within the acceptable instructional limit, continuously and sustainably on a specific service (6,7).

To support universal health coverage (UHC), most countries have adopted the WHO's stepwise models, such as SLMTA and SLIPTA. These frameworks help laboratories in implementing ISO 15189-based quality management systems. However, in low and middle-income countries, achieving quality diagnostic services remains challenging (8–10).

Formal recognition (accreditation) of a diagnostic laboratory is according to the new requirement for medical laboratory ISO 15189: 2022 (10,11) and helps to be more accountable and receive little support from third parties (13). For the effectiveness of laboratory testing, implementing the 12 essentials of the laboratory quality management system (LQMS) is mandatory to guide medical decisions and patient care (4,10,12). It reviews all phases of the process using internal auditing, assessment tools, and evaluation of action (13).

The recently updated standard ISO 15189: 2022 requirement for medical laboratories emphasizes sample management, risk management, the role of the laboratory director, and point of care testing (POCT) alignment with ISO 17025:2017, contains minimum requirements for quality and competency of medical laboratories to strive for continuous quality improvement (1,14,15). The most existing quality systems remain valid; however introduces the most flexible approaches in how to meet the requirement, allow laboratory justification for deviation, eliminate the use of shall/should in notes, incorporate a companion standard on risk management and measurement of uncertainty, and encourage performing gap analysis (16).

This standard unified laboratory accreditation and developed compliance with ISO 9001 (12). It helps to harmonize results from abroad laboratories, minimizing measurement error and achieving

good diagnostic performance (2,4,14). The structure is built upon ISO/IEC 17025:2017(17). Also, it is less in defining "what" is required, instead determining "how" the requirement is met (18,19). It is an international benchmark and oversees the integrated principle of risk-based quality management, patient safety, and point-of-care testing (10).

Despite the international scope, some countries may have developed national standards to address local challenges and specific needs. Examples include adoption by the National Committee of Clinical Laboratory Standards (NCCLS)/ Clinical and Laboratory Standards Institute (CLSI), European Committee for Standardization (CEN) (15,20).

Laboratory ISO implementation has evolved from ensuring compliance with standards to emphasizing reliable testing, quality assurance, and continuous improvement. This transformation is supported by technological advancement and harmonizing global practice by different organizations like the International Laboratory Accreditation Cooperation (ILAC), the International Accreditation Forum (IAF), and National Accreditation Bodies across the globe, by adopting standards like ISO/IEC 17025 to emphasize a risk-based approach (21).

However, the implementation remains challenging due to multiple organizational and resource-related barriers such as, problems associated with laboratory professionals' lack of leadership, attention, resources, and commitment from management bodies, limited on-the-job training access, and high workload (5,22). Infrastructure, inadequate human resources capacity, insufficient on-site supervision, and a weak health system, including availability and accessibility, are the main causes for the low implementation level (23).

Furthermore, other factors such as top management commitment, knowledge of quality management system, monitoring and feedback, time and cost, training, and education are the main factors. Internal motivation, external environment pressure, staff commitment, customer satisfaction, employee resistance, and qualification of laboratory personnel, training, and continual professional development, in turn, affect the quality of laboratory service in reporting accurate and reliable results (23,24).

1.2.Statement of Problem

A significant portion of medical decision-making, approximately 70%, is influenced by laboratory results in the United Kingdom. However, the cost covers only 5% health system budget (25). In the Singapore health care system, medical laboratories are essential, and on average,35% of patients from inpatient, outpatient, and emergency accounts 98%, 29%, and 56% respectively had one or more laboratory tests ordered (26,27).

The global purpose of ISO 15189 implementation is to minimize laboratory error, foster continuous improvement, enhance patient safety, accurate diagnosis, and build a failure-resistant system in the medical laboratory. However, completely achieving this is difficult; commonly, in a developing country, a resource-constrained environment is the main character (28).

Globally, even in the developed countries (America and Europe), the rate of laboratory accreditation is low, which shows a maximum of 12% in Europe and 16% in America (29,30). According to a recent report of the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement (ILAC MRA), in 2024, medical testing facilities using 15189:2022 significantly increased from 93,279 in 2023 to 114,600 medical laboratories accredited (31). And above 3800 accredited medical laboratories according to the European accreditation multilateral recognition (EA MLA) (32). More than 1000 medical laboratories across Africa Medical Laboratory achieved ISO accreditation in 2023. However, there is a gap in many low and middle-income countries, including Ethiopia, but reflecting the growth momentum(33) .

In a certain country, the medical laboratory faces several challenges, specifically resource scarcity, outdated equipment, unreliable power supply, and expensive imports for scarce high-end diagnostic services. These issues not only impede the effectiveness of the laboratory but also extensively disturb the health care service in the country (34).

On the other hand, some challenges, like poor communication, staff apathy, and workload, had less effect on accreditation compared with documentation, laboratory safety measures, management support, and unavailability of reagents and outdated equipment (35).

In Ethiopia, several barriers hinder the advancement of laboratory accreditation, such as limited financial resources, reliance on outdated equipment, the absence of a well-structured quality management system, insufficiently trained personnel and mentorship, and the increased workload placed on existing staffs to the reverse private hospitals generally possess greater financial

flexibility, allowing them to attract patients and allocate resources towards achieving and maintaining accreditation (36,37).

On the other hand, among the health facilities' funds in Addis Ababa, only 3.6% have achieved accreditation, due to barriers like equipment calibration, participation in external quality assurance, evaluation and audit, high staff turnover, gaps in the continual improvement program, and deficiency in validation and verification methods (6,7).

In Ethiopia, national guidance and strategic plans emphasize a stepwise approach to laboratory quality management systems, aligning with ISO 15189 and ISO 17025 standards. The Ethiopian Public Health Institute (EPHI) underscores the importance of ensuring minimum resources, established and documented procedures, participation in EQA, and management commitment before a laboratory can effectively implement ISO accreditation. This is positioned to progress toward accreditation, thereby institutionalizing quality and ensuring sustainability of laboratory services (3).

Despite the vital role of medical laboratories in healthcare, supporting up to 70% of medical decisions, their contribution remains unfunded and underdeveloped, especially in developing and underdeveloped countries like Ethiopia. The implementation of ISO 15189 accreditation faces major barriers such as limited resources, outdated equipment, poor documentation, lack of management support, inadequate mentorship, Availability of SOP, proper handling of documents, preventive maintenance, staff regular meetings, review of customer satisfaction, quality plan, verification of results, availability of specimen guideline, and availability of established quality indicators were predictors. In Addis Ababa, less than 4% of facilities have achieved accreditation, and 20.2% promote stepwise quality improvement (7,23).

This indicates the urgent need to know the current status of strengthening the quality management system and ISO 15189:2022 implementation to assure accuracy, reliability, and sustainability of laboratory services, and addressing the level of associated challenges faced by medical laboratories, and to the best of the investigators' knowledge, no study has assessed implementation status and associated challenges of ISO 15189:2022 among governmental and private laboratories in Addis Ababa.

1.3.Significance of the Study

Medical laboratory services play a crucial role in healthcare services. The testing laboratory is accountable for the accuracy, reliability, and sustainability of the results. So, data generated by the testing laboratory should be evidence-based and give customers confidence by implementing ISO 15189:2022. Therefore, these findings would be able

- To generate empirical, actionable insight and evidence-based recommendations on implementation, and highlight major challenges faced by the private and governmental hospital laboratories during the process of implementation.
- To provide important information to all hospitals' medical laboratories, facilitating successful accreditation, sustainable continuous improvement, and overall significant promotion of the quality and reliability of diagnostic services.
- To assist the stakeholders in strengthening medical laboratory performance and understanding the area of intervention.
- To help policymakers develop effective and targeted strategies to promote this ISO standard and baseline for further research.

2. Literature Review

2.1.Status of accreditation

According to the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement (ILAC MRA), the European accreditation multilateral recognition(EA MLA), and the ASLM 2023 report, 114,600, over 3800, and nearly 1000 medical laboratories were accredited, respectively (29,30,33).

The data obtained from the Japan accreditation board (JAB) shows that EU member countries in 2011 had 1300 implemented laboratories standard, with 482 in Germany, 276 in England, 209 in France, 100 in Czechoslovakia, etc., and the Asia-Pacific Region had 638 in Australia, 287 in India, 160 in Taiwan, and 59 in Japan (38).

The College of American Pathologists (CAP) accreditation program highlights continuous quality improvement by aligning with the ISO 15189:2022 standard as a key strategy for the laboratory. The program improves overall operation, efficiency, team morale, client satisfaction, and patient safety. The program focuses on assessment with a three-cycle methodology for accreditation, resulting in 95% of laboratories improving quality and patient safety, 87% operational efficiency, 74% feeling more valuable, and 86% having an escalation system during a pandemic like COVID-19, which means to enhance a laboratory's reputation and strategic value (39).

The study shows that in the Americas, the highest rate of 16% implemented laboratories is in Costa Rica, and the lowest 1% of accredited laboratories is in the USA and Cuba. Likewise, in 25 European Union countries, the range varies from 12% in Slovenia and 2% in the United Kingdom and Bulgaria (29,30).

According to the sixth Biennial conference of the African Society of Laboratory Medicine (ASLM) 2023, a total of 1026 laboratories achieved ISO 15189 accreditation in medical laboratory medicine across 29 African countries. This certification is coordinated under the SLIPTA by ASLM to highlight competency and integration and increase confidence in the quality of medical laboratory service across the continent, aligning with international standards. The achievement concentrated in South Africa at 61.4%, while 28% in the East Africa regions (33).

By 2020, Africa had 668 laboratories to achieve accreditation, an increase of 75% compared with 2013. However, the majority of the accredited laboratories were in South Africa (396), and Kenya (106) established a national accreditation body. Among the accredited laboratories, 113 that achieved ISO 15189 were registered under SLIPTA. This indicates participation in quality

improvement programs such as SLIPTA, SLMTA, and LQSI, driving towards ISO 15189 accreditation. This finding also requires strong national approaches like accreditation authority, adoption of standards, and a regulatory framework to forward quality management practice across the health system (35,40).

In Kenya, the Rapid result (RRI) initiative significantly improves the laboratory accreditation by advocating, providing structural mentorship, and focusing the intervention on equipment management and facility, biosafety. After implementing RRI, the progress led to 87% of the laboratories receiving ISO 15189 accreditation within two years, and similar programs like SLIPTA and SLMTA driving ISO implementation (41).

According to the study conducted in Addis Ababa, only 3.6% of medical laboratories have achieved accreditation, indicating a very low status. The identified challenges and risk factors were grouped into four categories, with the primary challenges being technical gaps such as method verification/validation, equipment calibration, and continual improvement. These challenges were broadly classified into internal and external factors that encompass all barriers to the implementation of the standard (7).

In Ethiopia, findings from accredited laboratories indicated that 82.6% (38 out of 46 laboratories) utilized their accreditation status in accordance with standard requirements. Most of the accredited laboratories were government-owned (36, 78.3%), and the majority were located in Addis Ababa(42).

2.2.Associated challenge of ISO 15189:2022 implementation

Globally, the rate of laboratory accreditation remains low, and limited progress in the process. The key challenges include inadequate training, inadequate financial and human resources, poor documentation, weak institutional commitment, insufficient awareness of accreditation benefits, and a lack of a continuous quality improvement culture. These challenges exposed the laboratory to risk in reliability, quality, and credibility of laboratory results (29,30).

Accreditation of pathology laboratories in Europe according to ISO 15189 is becoming increasingly standard; the process itself presents practical challenges. The problem is not the lack of accreditation but rather the critical points and practical difficulties that arise during its implementation (30).

According to Avedis Donabedian, accreditation programs in Iran face various challenges and factors. Commonly classified into three: structural (accreditation program, platform, culture, evaluation team, and motivation), process (program comprehensiveness, financial resources, implementing level and protocol, knowledge translation, training, and system design), and outcome challenges (43).

A systematic review on key success factors for the implementation of quality management systems in developing countries identified 10 factors for medical laboratories to strive for ISO 15189 accreditation. The review concludes three common factors. The first is preparing for change, which requires hospital management dedication, staff training, and personnel commitment. The second, resource availability, which requires physical facility, sufficient staff, and a strategic implementation plan like SLIPTA, and the third, effective project management with personnel management, motivation, and mentorship. This review concludes that achieving quality improvement and full compliance with standards requires resolving systemic, policy-level issues and government commitment, and needs internal effort (44).

Laboratory services in sub-Saharan Africa showed that, among 49 countries, 37 (75%) had no internationally recognized accredited medical laboratory in 2013. Despite this, the expansion and strengthening of accreditation improvement processes remain promising for enhancing the quality of services. The major contributing factors include an insufficient workforce, unequal distribution, low levels of qualification, and inadequately equipped personnel and facilities (45).

The systematic review conducted in Nigeria identified several challenges specifically for developing and underdeveloped countries. These challenges include inadequate infrastructure,

outdated equipment, a lack of a uniform guide framework, poor staff motivation, and poor working conditions. But, focusing not only on technological and infrastructural improvements but also on policy, workforce development, and staff welfare to enhance the overall quality of medical laboratory services in the country (34).

The other observation from Rwanda shows laboratory quality improvement in lower resource settings; SLMTA improves laboratory performance during ISO 15189 implementation. Sustaining laboratory quality is lacking ongoing mentorship and assessment. Within a limited time, intervention is challenging; rather, it requires institutionalized mentorship, regular assessment, and systematic quality improvement planning with the health system (46).

According to a study conducted in Tanzania, the implementation of ISO 15189 standards in the resource-limited setting faced multiple non-conformances. Which is inadequate financial resources, shortage of trained personnel, high staff turnover, poor infrastructure, supply interruption, weak documentation practices, limited mentorship, and resistance to quality management procedures among staff. However, improvement on external quality assessment, reducing sample rejection, turnaround time, and contamination rate were addressed by adequate mentorship, financial investment, and staff motivation, achieving ISO 15189 accreditation (47).

Tembo et al. report that implementation and transition from 15189:2012 to 15189:2022 improved laboratory performances through strengthened. The major concern that hinged on the implementation related to financial resources, human resources, and training continued. However, documentation, staff competency, quality culture, and teamwork were improved (48).

A review published in Somaliland shows significant challenges, such as limited accredited laboratories, weak governance, and inadequate national health policy. The review emphasizes the need to propose total quality management, urgently reform international standards, leadership, and compliance with ISO benchmarks, and foster international collaboration to enhance practices, ultimately achieving laboratory excellence (49).

The research conducted in Kenya shows that the application of quality assurance through accreditation by ISO 15189 was a significant challenge due to funding, government support, equipment, training opportunities, and poor infrastructure. From which the limited resource setting is the most influential challenge (46).

The study reported in South Africa shows that the implementation faces significant challenges. Among the high costs of accreditation are limited laboratory resources, a shortage of competent

staff, problems related to calibration and maintenance of laboratory equipment, documentation and record burden, and training limitation(50).

Based on the systematic review conducted in 2023, the practice of Ethiopia on medical laboratory quality management is limited. These face many factors, primarily, Problems associated with laboratory professionals, inadequate support from management, high workload, and limited access to training are listed. The other identified factor that affects laboratory results is the shortage of supplies and reagents, lack of equipment, lack of harmonized facility activity, and absence of a quality manual, compromising implementation and application of LQMS (5).

The study conducted in Dire Dawa, Eastern Ethiopia, concludes the challenge in four categories. The first organizational challenge includes a lack of staffing, leadership commitment, and poor organizational culture, which leads to workload, turnover, and lack of incentives. The second behavioral challenge includes a lack of staff skill, inadequate awareness, and a lack of ownership. The third technical challenge includes the absence of a standard form, shortage of supplies, repeated system breakdowns, and unreliable power and network. The last, external challenge includes poor collaboration between stakeholders and dependence on the NGO. However, with this challenge, it improves the quality of services (36).

Based on the case study of Bethzatha Advanced Medical Laboratory, the implementation of ISO 15189, extensive staff training on standard quality essentials, and development of a comprehensive QMS from the ground up, external partnership (metrological traceability and proficiency test), which requires sourcing and securing consistent support, are key challenges. However, commitment of both staff and management hinges on successful implementation (13).

According to the study conducted in Ethiopia, Oromia, on challenges and risk factors for implementing ISO 15189 standards in medical laboratories, various obstacles have been extensively documented and identified, including limited resources, inadequate staff training, and insufficient infrastructure. Furthermore, researchers have highlighted the importance of strong leadership and organizational support for successful implementation. Risk factors that may hinder compliance include a lack of awareness of quality standards, high staff turnover, and poor communication between laboratory personnel and management. Addressing these challenges and mitigating risks is crucial for improving the quality of laboratory services and ensuring the reliability of test results (23).

The other study conducted in 2019, “Factors affecting implementation of laboratory quality management system in Addis Ababa public health laboratories, Addis Ababa, Ethiopia,” identified specific challenges and risk factors grouped into three root causes. The first, technical and process-related challenge (method validation/verification, equipment maintenance, EQA, measurement of uncertainty analysis, and evaluation. The second, resource and management related challenge (budget constraint and management), and the third, personnel related challenge (turnover, competency, workload, and adherence to quality document) (6).

Due to multiple challenges, 17% (8 out of 46) of laboratories in Ethiopia did not utilize their accreditation status. Factors significantly associated with this included personnel incompetence, absence of an appointed quality officer, inadequate follow-up by regulatory bodies, limited access to affordable calibration services, insufficient training, staff resistance due to perceiving accreditation as an unnecessary burden, and lack of management commitment (41).

2.3.Conceptual Framework

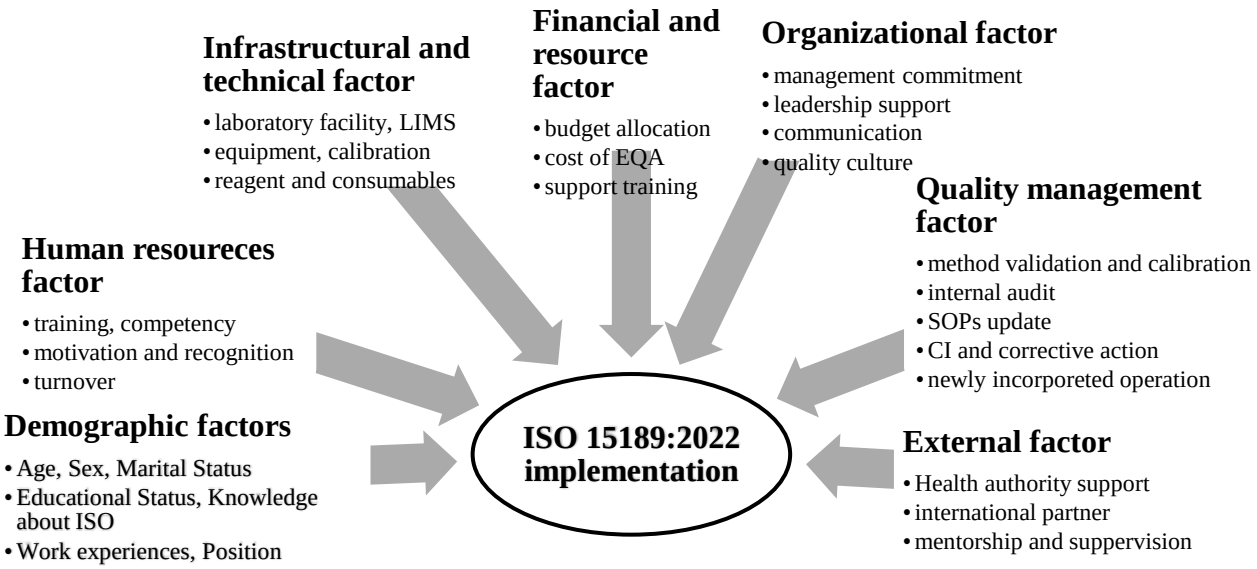


Figure 1: Conceptual framework diagram

The implementation of ISO 15189:2022 is influenced by multiple factors that collectively impact the sustainability and quality of the laboratory, which can be grouped into seven major categories. This framework starts with demographic factors such as age, sex, gender, education status, and knowledge about ISO.

Secondly, human resource factors include adequate on-the-job training, staff competence, workload, staff motivation and recognition, formal staff competency, staff turnover, staff shortages, and CPD/training. Third, financial resource factors such as budget, cost of EQA, and organizational support for training. Fourth, infrastructural and technical factors, including laboratory facility, equipment, LIMS, reagents, and consumables, and quality assurance. Fifth, organizational factors include management and administration that facilitate implementation, communication between staff and management, and quality improvement culture.

Sixth, quality management factor including risk management practice, POCT alignment, patient safety priority, continuous improvement and corrective action, SOPs updated and practiced, internal audit and review, EQA conduct, and method validation and verification. Seventh, external factors like regulatory or health authority, international partner collaboration, and mentorship. Collectively, these factors significantly affect the sustainability and overall quality of laboratory services.

3. Objective

3.1. General Objective

- To assess the implementation status and associated challenges of ISO 15189:2022 among governmental and private hospitals and diagnostic laboratories in Addis Ababa, Ethiopia, in 2026.

3.2. Specific Objectives

- To assess the implementation status of the ISO 15189:2022 standard among private and governmental hospitals and diagnostic laboratories.
- To assess the associated challenges with the implementation of the ISO 15189:2022 QMS standard among private and governmental hospitals and diagnostic laboratories.

4. Methods and materials

4.1.Study setting

Addis Ababa, the capital city and geographic center of Ethiopia, covers an area of 540 square kilometers. It is situated at 9°10′48″N latitude and 38°44′24″E longitude, at an elevation of about 3,000 meters above sea level. The city has a three-tier administrative structure(city, sub-city, and wereda), consisting of 11 sub-cities and 120 woredas (51).

There are huge number of healthcare facility such as 847 speciality clinic(828 private, 13 NGO, and 6 governmental), 748 clinic, 103 health center, 31 homecare service center, 50 diagnostic and imaging center, 10 medical office practice and consultancy office, 5 telecenter, 4 primary hospital(only private), 33 General Hospital (2 Federal, 5 under the city, and 26 Private), 8 Comprehencive and Referral Hospital (1 Private, 1 AAC, 6 Federal) and 2 Research institute organization in the city (52).

This research was conducted at 24 hospital and diagnostic laboratory, which is 12 public diagnostic and hospital laboratory and 12 Private diagnostic and hospital laboratories.

4.2.Study design and period

An institution-based cross-sectional mixed study was conducted (quantitative for measurable prevalence and extent of these associated challenges of medical laboratory accreditation in private and government hospitals and diagnostic laboratories in Addis Ababa, Ethiopia, from February to April 2026.

4.3.Population

4.3.1. Source population

All public and private hospitals and diagnostic laboratories found in Addis Ababa were included, from which all laboratory professionals who work in these laboratories as technical staff, quality officer, laboratory head, laboratory consultant/advisor, and laboratory manager in Addis Ababa, Ethiopia, from February to April 2026 were the source of the population

4.3.2. Study population

The target population consisted of all laboratory professionals working in public and private hospitals and diagnostic laboratories available during the study period. This includes technical staff, quality officers, laboratory heads, advisors, and laboratory managers who are involved in laboratories that are in withdrawal, undergoing, or completed ISO 15189:2022 accreditation between February and April 2026.

4.4.Sample size determination

For the first objective, the sample size was determined using the single population proportion formula, 80% power, 95% CI, and the proportion taken from the previous study, which shows 82.3% (≈ 83%) were utilized implementation maintained standard requirements (41).

$$n = \frac{Z^2\ P(1-P)}{d^2},\ n = \frac{1.96^2\ \times 0.83(1-0.83)}{0.05^2}$$

n=217

Where n – minimum sample, P – Proportion, q = 1-p, Z – Significance level at confidence interval of 95%, Zα/2 = value of the standard normal distribution corresponding to the significance level of α 0.05, which is 1.96

For the second objective (challenges of not utilizing), the sample size was determined using the single population proportion formula, 80% power, 95% CI, and the proportion taken from the previous study, which shows 16.7% (≈ 17%) were not utilizing accreditation with standard requirements (41).

$$n = \frac{1.96^2\ \times 0.17(1-0.17)}{0.05^2}$$ n=217

However, the number of professionals found in the not implemented this ISO was less than the calculated sample size. The finite population correction formula was applied. Where n = adjusted sample size, no = initially calculated sample size (217), and N = total sample size 190).

$$n = \frac{no}{1+\frac{no-1}{N}},\ n = \frac{no}{1+\frac{no-1}{N}} =$$ $$n = \frac{217}{1+\frac{217-1}{190}}$$ = 101.4 ≈ 102

By adding two, the calculated sample size is 319, and a 10% non-respondent rate is 32. The final sample size was 351.

The private and public hospitals and diagnostic laboratories were employed using simple random sampling; the sample size for each stratum is calculated based on the proportional allocation.

$$K1 = \frac{N1}{Th}$$ $$K2 = \frac{N2}{Th}$$

$K1 = \frac{249}{579}$ = 0.4300, $K2 = \frac{102}{190}$ =0 .5368

Where K1 = Common multiplication Ratio for implementing, and K2= for not implemented, N1 = sample size implement ISO 15189:2022, N2 = sample size not implement ISO 15189:2022, Th = total population (private and public). The total sample size per organization was also calculated using common multiplication ratios of 0.4300 and 0.5368, respectively.

For qualitative, the sample size was ten (5 from private, 5 from public), considering the concept of information richness and the principle of data saturation, informed by knowledgeable, direct experience, and the ability to highlight their perspectives directly.

4.5.Sampling methods

A flow diagram sampling strategy was employed to select the sample. This approach integrated simple random sampling and purposive sampling to align the mixed methods design of the study. All sampling procedures were conducted proportionally to the number of hospitals in each category to ensure fair representation.

First, Hospitals and diagnostic laboratories were classified based on ownership type, which created two subgroups with administrative characteristics to ensure resource allocation and adequate service acknowledgment. Category one, public hospitals and diagnostic laboratories labeled as G1 to G12, and category two, private hospitals and diagnostic laboratories labeled P1 to P12.

The participant was calculated by the proportion formula to ensure fair representation of both institutions (The total sample size per organization was common, with multiplication ratios of 0.4300 and 0.5368 for implemented and withdrawal, respectively). For the qualitative component, the participants were selected by using purposive sampling based on roles, experience, and relevance to the study objectives. For mare detail figure 2.

List of all Diagnostic and Hospital Laboratory(n=81)

	Private Diagnostic & Hospital Laboratory(n=12)												Public Diagnostic & Hospital Laboratory(n=12)											
Participant inst. code	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	P11	P12	G1	G2	G3	G4	G5	G6	G7	G8	G9	G10	G11	G12
Total Lab/ insti.	15	23	22	23	18	18	14	15	13	19	13	9	54	65	18	52	42	38	43	23	22	36	68	50
Unit Sample/insti.	7	11	11	12	9	9	7	9	7	11	7	5	24	30	8	23	19	16	20	13	12	18	32	31

Figure 2: Diagrammatic representation of sampling techniques.

4.6. Inclusion and exclusion criteria

4.6.1. Inclusion criteria

Laboratory inclusion criteria: Hospitals and diagnostic laboratories located in Addis Ababa that had implemented, were implementing, or had withdrawn from ISO 15189:2022 compliance.
Participant inclusion criteria: Laboratory personnel who had worked for at least six months, were available during the study period, held roles such as technical staff, quality team member, laboratory head/director, or consultant, and were willing to participate and provide the required information.

4.6.2. Exclusion criteria

The laboratories that didn't apply for assessment under ISO 15189:2022, with Ethiopian accreditation services, and management gaps that didn't have either the laboratory head or the quality officer, unwilling to provide complete data, and not hospital or diagnostic laboratories were excluded.

4.7. Study variable

4.7.1. Dependent variable

- ✓ Implementation status of ISO 15189:2022 among laboratories.

4.7.2. Independent variable

- ✓ Demographic factors
- ✓ Human resources factors
- ✓ Infrastructural and technical factors
- ✓ Financial and resource factors
- ✓ Organizational factors
- ✓ Quality management factors
- ✓ External factor

4.8.Operational definition

ISO 15189:2022 implementation status: - the level or stage of compliance with the requirements of ISO 15189:2022 within a laboratory, as reflected in the established, documented, and consistently practiced standard clauses and requirements.

Implementation challenge: – the obstacle or problem encountered by the laboratory during implementation of ISO 15189:2022.

Staff competency: The knowledge, skills, training, and experience of laboratory personnel required to perform assigned tasks according to ISO 15189:2022 requirements.

High workload: A condition in which the volume of laboratory tasks exceeds available staff capacity, potentially affecting quality management activities and ISO implementation.

Staff turnover: The departure and replacement of laboratory personnel during the implementation or maintenance of ISO 15189:2022.

Financial support: The availability of organizational funds for ISO 15189:2022 implementation activities, including training, EQA participation, equipment maintenance, and accreditation costs.

Adequate laboratory facility: The availability of sufficient workspace, safety measures, environmental conditions, and infrastructure necessary to meet ISO 15189:2022 requirements.

Modern and functional equipment: Laboratory equipment that is operational, properly maintained, calibrated, and suitable for intended testing purposes.

External Quality Assessment (EQA): A system of external performance evaluation in which a laboratory's testing results are compared with those of other laboratories or reference standards.

Continuous improvement: An ongoing process of identifying, correcting, and preventing quality-related problems to enhance laboratory performance.

Method validation/verification: The documented process of confirming that a test method is fit for its intended use and performs according to specified requirements.

Management support: The commitment and involvement of laboratory management in providing resources, leadership, and oversight for ISO 15189:2022 implementation.

Effective communication: The timely and accurate exchange of information between laboratory staff and management regarding quality management activities.

International collaboration: Partnerships with external organizations that provide technical assistance, mentorship, training, funding, or quality improvement support for ISO 15189:2022 implementation.

Basic knowledge of ISO 15189:2022: Awareness and understanding of the principles, requirements, and objectives of the ISO 15189:2022 standard.

Dichotomization- dividing the Likert scale into two groups, Agree (agree, strongly agree) and Disagree (disagree, neutral, and strongly disagree).

4.9.Data collection

Consent was obtained from the participant with full orientation of the aim of the study. A trained data collector were participated at all public and private hospitals and diagnostic laboratories during working hours from February to April 2026.

Quantitative phase: - well-structured and pre-tested questionnaire was developed, in an appropriate format, and incorporated items on all anticipated challenges related to ISO 15189:2022. The questionnaire was consists of open-ended, closed-ended, and a Likert scale format to address all the independent variables.

Qualitative phase: - semi-structured questionnaires were offered to selected participants and a guide in flexible interviews to gain insight and an in-depth exploration of experience and perception. All interviews were conducted in Amharic, and audio-recorded with the participants' consent to ensure accuracy and completeness of the data.

The data collector had a minimum of a BSC in medical laboratory sciences, over 6 months of experience, a certificate of training at ISO 15189:2022 standards, and involvement in ISO 15189:2022 implementation. The quantitative data were collected by trained data collectors, while the qualitative data were collected by the principal investigator.

4.10. Data quality assurance

Before the data collection, pilot-tests were conducted at the AHRI laboratory and the Ethiopia Public Health Institution (EPHI) capacity building team to ensure clarity, logical sequence, and reliability. Following this pre-test, the finalized questionnaire was administered to the selected participants, accompanied by clear instructions provided by trained data collectors, which was trained for one day by the Principal investigator.

The principal investigator checked all data completeness and double-entry into the software to ensure accuracy. And also regularly checked, supervised, and monitored the selection process and completeness of the standard questionnaire throughout the study period to avoid bias and incomplete information and maintain clarity and accuracy. The data collector was given a unique ID for each participant. Each participant was required to submit data after filling in all data, unless the data was rejected. The PI was approved and saved in a cloud or flash disk as a backup file.

4.11. Data management and analysis

After checking, the data were exported from the KoboToolbox and cleaned for a SPSS-suitable format.

The data is also analyzed in two categories.

For the quantitative phase, IBM SPSS version 27 was used to analyze descriptive statistics (frequency, mean, standard deviation, table, graph, and percentages) to summarize socio-demographic and associated factors. It was also used for inferential statistics regression analysis to identify significant factors to implement ISO 151889:2022 associated with the level and severity of that challenge. Variables with p-value ≤0.25 in binary analysis were entered into multivariate logistic regression.

The results were presented using words, graphs, charts, and tables. In addition, bivariate and multivariate logistic regression analyses were performed. Variables with a p-value < 0.05 at a 95% confidence interval were considered statistically significant.

The reliability of the study assessment material was assessed using Cronbach's alpha coefficient (α=0.892), indicating excellent internal consistency among questionnaire items measuring factors related to ISO 15189:2022 implementation. The predictive strength of the logistic regression model was evaluated using the model summary Nagelkerke R^2, which yielded 0.432. This indicates that approximately 43.2% of the variance in the dependent variable is explained, which is moderate explanatory power. Furthermore, the goodness-of-fit model (Hosmer and Lemeshow) test produced a p-value of 0.094, which is greater than the threshold value called good. In addition, the threshold of p-value ($p \leq 0.05$) was determined to indicate the statistical significance of variables.

The implementation of ISO 15189:2022 challenges were assessed across six major domains using a five-point Likert Scale. These responses were dichotomized for logistic regression analysis purposes with “Strongly agree and Agree” as “Agree,” and “Strongly disagree, Disagree, and Neutral” as “Disagree.” Since the mean score is above 3, indicating positive perception, and below 3, a high challenge for implementation. For negative worded statements, a high mean score reflects greater implementation challenges.

For the qualitative phase, audio-recorded data were first transcribed verbatim and translated from Amharic into English. Then, using a systematic thematic approach, the data were analyzed through

familiarization, coding, reviewing, defining, and naming themes, followed by reporting participant quotes. The findings were manually linked under each theme.

Finally, the quantitative and qualitative findings were integrated and interpreted using a triangulation approach.

4.12. Ethical consideration

Ethical clearance of this study was obtained from the Department of Research and Ethical Review Committee (DRERC/828/25/MLS) of the Department of Medical Laboratory Science, College of Health Science, Addis Ababa University, Addis Ababa City Administration health bureau IRB, and the private hospital and diagnostic IRB (Oral permission). The objective of the study was clearly explained to each study participant, and informed consent was obtained before data collection. Participation in the study was entirely voluntary, and participants had the right to refuse or withdraw from the study at any stage without any consequence. Participants who did not provide consent were excluded from the study. The confidentiality and data integrity were prioritized, beginning with assigning a unique identification code for each hospital laboratory and participant to all questionnaires. Finally, the respondents were maintained throughout the study. The collected data were used only for the purposes stated before the analysis.

4.13. Dissemination of results

The study findings will be presented to AAU-CHS-DMLS. It will also be shared with the Addis Ababa City Administration health bureau (AACAHB), public and private hospitals, and the diagnostic laboratory where the research was conducted to support improvement efforts, as well as with the regulatory body responsible for accreditation, policymakers, professional associations, and non-governmental organizations for conference presentations. Finally, the results were submitted to both local and international publishers.

5. Results

5.1.Demographic data of Participant

Out of the calculated sample size of 351, a total of 344 laboratory professionals participated in the study, representing a response rate of 98%. This high response rate strengthens the representativeness and reliability of findings. Among the participants, 206 (59.6%) were male. The majority of participants, 165 (48%), were aged between 30 and 39 years, and the least were above 50 years, 8 (2.3%).

Regarding the educational qualification, the majority, 243 (70.6%), hold a BSc. The work experience varied among participants, with 113 (32.8%) having fewer than 5 years of experience, while only 23 (6.7%) had more than 20 years of service. Detailed information in Table 1.

Table 1: Demographic data of study participants in Addis Ababa, Ethiopia, from Feb to Apr 2026.

Variable	Category	Frequency (n=344)	Percent (%)
Gender	Male	206	59.6
	Female	138	40.1
Age	≥29	118	34.3
	30-39	165	48.0
	40-49	53	15.4
	≤50	8	2.3
Marital Status	Single	126	36.6
	Married	189	54.9
	Divorced/separated	26	7.6
	Widowed	3	0.9
Educational Status	Diploma	11	3.2
	BSC\degree	243	70.6
	MSc	87	25.3
	PhD	3	0.9
Work Experience	≤5	113	32.8
	6-10	88	25.6
	11-15	81	23.5
	16-20	39	11.9
	≥21	23	6.7

The majority of the respondents were technical staff 260 (75.6%), followed by laboratory quality officers 40 (11.6%), while laboratory consultants accounted for the smallest proportion 4 (1.2%). The participants worked in various laboratory sections, with the highest proportion in hematology 72 (20.9%), clinical chemistry 71 (20.65%), and quality management responsibility 71 (20.6%), with molecular biology 37 (10.8%), microbiology 45 (13.1%), while support and specialty centers accounted for 48 (14%). The detailed information in Figure 3.

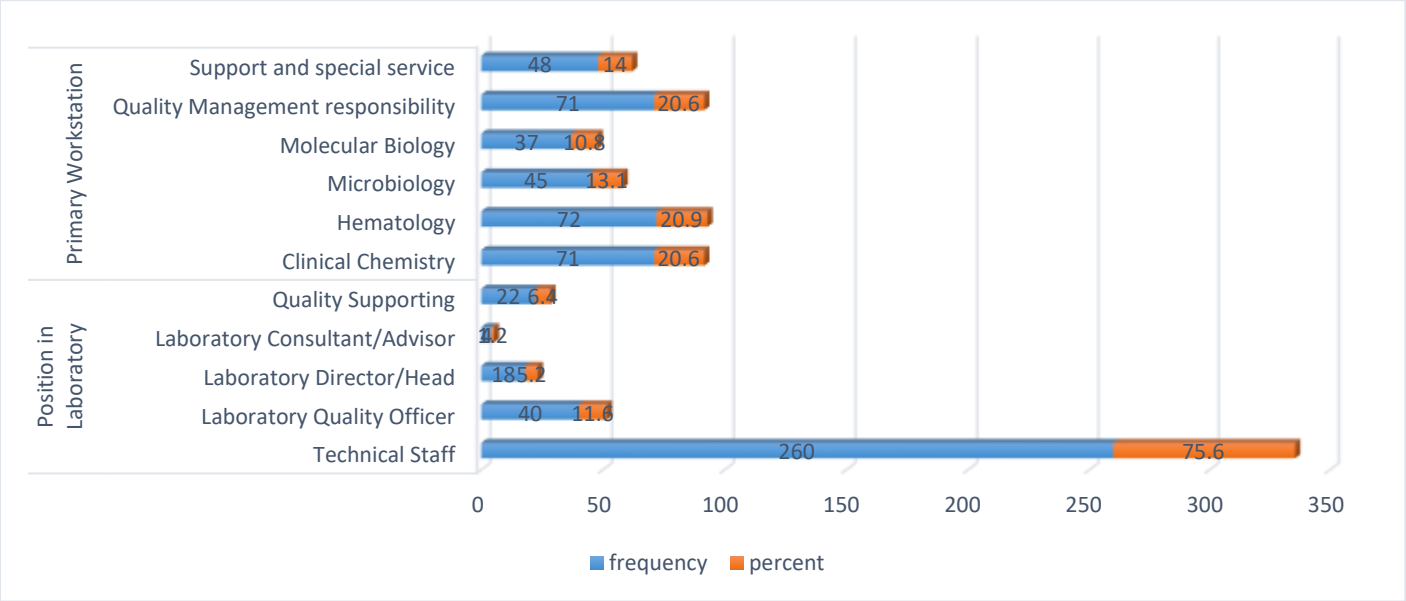


Figure 3: Role of participant in laboratory services in Addia Ababa Ethiopia, Feb to Apr 2026.

5.2.Institutional and Laboratory Characters

According to the data obtained from the Ethiopian Accreditation Service (EAS), a total of 81 public and private hospitals and diagnostic laboratories in Addis Ababa were identified at the time of study, comprising 8 comprehensive hospital laboratories, 4 primary hospital laboratories, 33 general hospital laboratories, 34 private diagnostic laboratories, and 2 research and public diagnostic laboratories. Out of these laboratories, only 18 (22.2%) hospitals and diagnostic laboratories are implemented according to compliance with ISO 15189:2022 requirements, underscoring the limited, but growing, number in Addis Ababa. The study engaged 24 organizations, achieving an organizational response rate of 96%. Among the participating institutions, 70.8% (17/24) of laboratories are accredited, 8.3% (2/24) of laboratories are ongoing, and 20.8% (5/24) of laboratories are withdrawn from the implementation of ISO 15189:2022.

The institutional profile of the participants: the majority of participants were from public hospitals and diagnostic laboratories (68.6%), and the largest proportions of the participants were general hospital laboratories and comprehensive hospital laboratories staff members, accounting for 39.5% and 38.7%, respectively. Among the total, 57.3% of professionals work under the jurisdiction of Ethiopia's Minister of Health, whereas the remainder were affiliated with the Addis Ababa City Administration Health Bureau. With respect to workforce size, over half, 50.9% of the respondents worked in large laboratories with more than 30 staff members, and a small portion of the respondents 7.6% worked with 10 or fewer employees, whereas the others were 11-19 and 21-29 employees, working in the laboratory are 22.4% and 19.2%, respectively. For more detail table 2.

Table 2. Institutional and Laboratory Characteristics of participants from Feb to Apr 2026 in Addis Ababa, Ethiopia.

Variable	Category	Frequency(n=344)	Percent(%)
Types of institutions	Public laboratory	236	68.6
	Private laboratory	108	31.4
Responsibility to	AACHB	147	42.7
	MoH	197	57.3
Facility types	GHL	136	39.5
	CHL	133	38.7
	PPDL	75	21.8
Number of Employee	≤10	20	7.6
	11-20	77	22.4
	21-30	66	19.2
	≥31	175	50.9

Abrevation: AACHB, Addis Ababa City Health Bureau; MoH, Minister of health of Ethiopia; GHL, General Hospital Laboratory; CHL, Comprehensive Hospital Laboratory; PPDL, Public and private diagnostic laboratory.

5.3.Knowledge and participation in ISO 15189:2022 implementation

Among the 344 participants, 93.9% (323) had basic knowledge of ISO 15189:2022, indicating a relatively high level of awareness among laboratory professionals in Addis Ababa. Despite this encouraging awareness, active participation in implementation activities was considerably lower; only 45.6% (157/344) were involved in implementation activities, including 52,9% (83/157) in document preparation and review, 9.6% (15/157) in training and mentorship, 3.9% (6/157) in audit and assessment implementation, and 4.7% (7/157) in leadership activities. Additionally 28.9% (45/157) respondents reported involvement in multiple implementation tasks.

The remaining participants, 54.4% (187/344), were not involved in the implementation process. The reasons cited for non-participated included 36.9% (69/187) lack of opportunity, 20.8% (39/187) lack of interest, 13.5% (25/187) lack of training, 14.9% (28/187) workload, 5.3% (10/187) organizational barrier, and 8.6% (16/187) personal or unknown reasons.

Accordingly, 27.9% (96/344) of participants are from withdrawn laboratories, 17.7% (61/344) are from ongoing, and 54.4% (187) of respondents are from fully implemented laboratories. The majority of the participants were from facilities implemented in multiple disciplines (more than one discipline of accreditation), 50% (94/187), molecular biology 20% (37/187), clinical chemistry 19% (36/187), hematology 7% (13/187), and microbiology 4% (7/187). The following Table 3 summarizes the knowledge and participation of laboratory professionals in ISO 15189:2022 implementation.

Table 3: Knowledge and participation of participants in ISO implementation in Addis Ababa, Ethiopia.

Variables	Category	Frequency	Percent
Basic knowledge about ISO 15189:2022?	Yes	323	93.9
	No	21	6.1
Participation in the ISO 15189:2022 implementation process	Yes	157	45.6
	No	187	54.4
Participants from	Implemented organization	187	54.4
	Withdrawn organization	96	27.9
	Ongoing organization	61	17.7

Participant from disciplines of implementation	Clinical chemistry	36	19.0
	Hematology	13	7.0
	Microbiology	7	4.0
	Molecular biology	37	20.0
	Multiple disciplines	96	50.0

5.4.Challenges of ISO 15189:2022 Implementation.

The overall mean score distribution of the six major factors varies in levels of challenge to the ISO 15189:2022 implementation among surveyed laboratories. Among the assessed factors, the quality management factor (QMF) has relatively stronger implementation challenges than the financial and resources factor (FRF) and the organizational factor (OF), whereas the infrastructural and technical factor (ITF) and the external factors (EXF) also remained challenges. For detailed information Table 4.

Among the six challenge categories assessed, HRF (X=3.5) had a high mean score. Within this categories, participants reported organizations' inadequate support for CPD and training (X=2.87, SD=0.993), the absence of effective staff motivation and recognition (X=2.87, SD=0.993), the presence of high workload (X=3.41, SD=0.915), and high turnover rate (X=3.53, SD=0.846) was identified as a significant concern, with both its negative impact on implementation and maintaining (X=3.45, SD=0.893) organization to ISO implementation.

Similarly, the majority of the laboratory struggles against inadequate funding (FRF). These findings indicate that budget insufficiency (X=2.74, SD=0.968) and supporting training(X=2.88, SD=0.994). Other than this, budget constraints delay implementation practices (X=3.24, SD=0.973) and the cost of the EQA program is a barrier (X=3.38, SD=0.925) to implementing the new standard.

Among ITF, Equipment breakdown, and consumable products and supply shortages are major hindrances (X=3.65, SD=0.765) to effectively implement the standard. Whereas OF was a major gap, which organizational support and the communication between management and staff (X=2.97, SD=1.001) is failing.

Among the QMF (X=3.7), successful transition and risk-based thinking required by the new standard risk management practice(X=3.51, SD=0.864), POCT alignment (X=3.71, SD= 0.706),

and giving patient safety priority(X=3.71, SD=0.706) were at an appreciable level. However, the major gap was functionality of continuous improvement and corrective action(X=2.97, SD=1.001). The last, EXF category (X = 3.3, SD=0.77) indicated that regulatory support, international partnership, and regular mentorship were moderate challenges. For more detail summarized into table 4.

Table 4: Likert scale mean score and standard deviation

Categ-ory	Variable/Domain	Mean score (X)	Disagree n (%)	Agree n (%)	Overall Mean	SD
HRF	High workload on staff is a significant barrier to implementation	3.41	76 (22.1)	268 (77.9)	3.5	0.62
	Organization staff motivation and recognition program	2.87				
	Staff turnover hurts the implementation of standards	3.53				
	Staff turnover hurts the maintenance of implementation	3.45				
	The organization has an adequate CPD/training	2.74				
FRF	The organization allocated sufficient budget for standard implementation	2.74	150 (43.6)	194 (56.4)	3.2	0.69
	Budget constraints delay the implementation process	3.24				
	The cost of EQA is a barrier to implementing ISO	3.38				
	The organization's adequate support for staff training	2.88				
ITF	Equipment breakdown and reagent supply are major hindrances to implementation	3.65	199 (57.6)	145 (42.4)	3.8	0.56
OF	The organization has effective communication between staff and management about the quality improvement process.	2.97	75 (21.8)	269 (78.2)	3.2	1.09
QMF	The laboratory has functional continuous improvement and corrective action	2.97	171 (49.7)	173 (50.3)	3.7	0.58
	Operating SOP is a Challenge in the laboratory	2.92				
EXF	Your organization have effective international partner collaboration.	3.10	151 (43.9)	193 (56.1)	3.30	0.77
	The regulatory authority facilitating your implementation activity.	3.07				

***Abbreviations**: HRF, Human resource factor; FRF, Financial and resources factor; ITF, Infrastructural and technical factor; OF, Organizational factor; QMF, Quality management factor; EXF, External factors.*

5.5.Factors Associated with ISO 15189:2022 Implementation

Binary logistic regression analysis was performed as a screening step, with variables yielding p-values ≤0.25 being candidates for multivariable analysis. In the Final multivariate logistic regression analysis, six variables were statistically significantly associated with ISO 15189:2022 implementation at a threshold p-value <0.05 and CI 95%.

Facility types were statistically significant predictors for implementation status of ISO 15189:2022 (p-value=0.018, AOR=3.1, CI=1.220-8.237). Public and private diagnostic laboratories were 3.1 times more likely to successfully implement the standard compared to general hospital laboratories.

The laboratories with active involvement of staff on the ISO implementation process were statistically significant predictors. The laboratory with active participation of staff on ISO 15189:2022 implementation was 4.1 times more likely to have successful implementation than laboratories with limited staff involvement (p-value <0.001, AOR=4.1, CI=1.945-8.750).for detail table 5.

***Table 5:*Binary logistic and Multivariate Logistic Regression of Analysis of demographic characteristics of participants.**

Variable	Category	Implementation Status (N=344)		COR (CI 95%)	p-value	AOR (CI 95%)	P-value
		Yes	No				
Educational	Diploma	9	2	1			
	BSc	124	119	4.3(0.914-20.401)	0.065	2.4(0.413-15.138)	0.319
	MSc	52	35	3.0(0.617-14.867)	0.172	3.8(0.550-27.141)	0.174
	PhD	2	1	2.3(0.130-38.811)	0.577	2.9(0.094-93.707)	0.536
Types of Institution	Public	135	101	1			
	Private	52	56	1.4(0.911-2.274)	0.118	1.3(0.591-3.066)	0.479
Facility Types	GHL	88	48	1			
	CHL	64	69	1.97(1.212-3.224)	0.006	1.9(0.839-4.543)	0.121
	PPDL	35	40	2.09(1.18-3.720)	0.012	3.1(1.220-8.237)	0.018**
Number of Employees	<10	16	10	1			
	11-20	41	36	1.4(0.567-3.484)	0.852	1.0((0.310-3.496)	0.949
	21-30	19	47	3.9(1.526-10.264)	0.129	1.5(0.436-5.442)	0.502
	>30	111	64	0.9(0.395-2.154)	<0.001	0.5(0.173-1.612)	0.262
Responsible to	AACHB	67	80	1			
	MOH	120	77	0.5(0.349-0.828)	0.005	1.8(0.820-4.024)	0.142
Work Experiences	≤5	52	61	1			

	6-10	53	35	0.6(0.320-0.990)	0.360	0.8(0.252-3.116)	0.851
	11-15	47	34	0.6(0.347-1.097)	0.747	0.6(0.183-2.209)	0.476
	16-20	22	17	0.6(0.316-1.371)	0.889	0.9(0.294-3.287)	0.979
	≥21	13	10	0.6(0.266-1.619)	0.173	1.2(0.361-4.647)	0.692
Position	TS	132	128	2.5(0.981-6.816)	0.05	0.7(0.237-2.551)	0.777
	QO	25	15	1.6(0.541-4.982)	0.417	1.0(0.242-4.412)	1.000
	LD	11	7	1.6(0.447-6.439)	0.437	0.9(0.166-4.887)	0.904
	LC	3	1	0.9(0.077-10.300)	0.925	0.3(0.22-6.396)	0.501
	QS	16	6	1			
Participation in implementation	Yes	110	47	1			
	No	77	110	3.3(2.134-5.238)	<0.001	4.1(1.945-8.750)	<0.001**

Abbreviation: D (disagree), A (agree), AACHB (addis ababa city healyh bureau), MoH (minister of health), PPDL (public and private diagnostic laboratory), CHL (comprehensive hospital laboratory), GHL (General Hospital laboratory), TS (technical staff), QO (Quality officer), LD (Lab. Director), LC (lab. Consultant), and QS (Quality support).

The laboratory, which has adequate facilities such as adequate workspace, safety system, ventilation, and well-arranged, was independently associated with ISO implementation. Laboratories with adequate physical facilities were 2.1 times more likely to implement and maintain the implementation activity effectively than those with poor facility arrangements (p-value=0.012, AOR=2.1, CI=1.185-4.0.68).

Similarly, laboratories equipped with modern, functional, and well-maintained equipment were 3.4 times more likely to successfully implement ISO 15189:2022 (p-value=0.008, AOR=3.4, CI=1.393-8.692).

The vital predictors of the technical requirement of laboratory service, which include regular participation in the External quality assurance (EQA) program, were also the most significant predictor for the successful implementation of ISO 15189:2022 (p-value=<0.001, AOR=3.2, CI=1.609-6.470). The laboratory with consistent participation in the EQA program was 3.2 times more likely to improve the success of implementing readiness, competency, and compliance requirements than inconsistent participants.

The other prominent predictor was the status of facility collaboration with international partners, which is statistically significant. Laboratories with strong partnerships with national and international organizations were 1.9 times more likely to implement ISO 15189:2022 by leveraging training access, technical assistance, mentorship, and quality-strengthening programs (p-value=0.050, AOR=1.9, CI=0.999-3.967). For detail Table 6.

Table 6: Factors Associated with the Implementation Status of ISO 15189:2022 among Governmental and Private Hospitals and Diagnostic Laboratories in Addis Ababa, Ethiopia, 2026.

Variable	category	Implementation status		COR (95%, CI)	P-value	AOR (95%, CI)	P-value
		Yes	No				
The laboratory has sufficient, qualified, and significantly competent staff to meet the requirements of ISO	Disagree	47	55	1.6(1.008-2.558)	0.046	0.5(0.258-1.077)	0.079
	Agree	140	102	1			
High workload on staff is a barrier to implementation) In your laboratory.	Disagree	60	31	1			
	Agree	127	126	1.9(1.166-3.162)	0.010	1.8(0.940-3.595)	0.075
adequate on-the-job training in preparing staff for ISO 15189:2022 implementation.	Disagree	86	92	1.7(1.083-2.551)	0.020	0.9(0.471-2.076)	0.976
	Agree	101	65	1			
A strong staff motivation and recognition program is in place to drive commitment for implementation.	Disagree	93	101	1.8(1.181-2.815)	0.007	1.4(0.746-2.804)	0.275
	Agree	94	56	1			
Staff turnover negatively affects your ISO implementation.	Disagree	56	24	1			
	Agree	131	133	2.3(1.387-4.047)	0.002	2.2((0.928-5.328)	0.073
Staff turnover significantly affects your ability to maintain ISO15189:2022.	Disagree	66	28	1			
	Agree	121	129	2.5(1.514-4.172)	<0.001	1.1(0.541-2.597	0.670
Adequate refresher training or CPD frequency related to ISO 15189:2022	Disagree	106	110	1.8(1.143-2.798)	0.011	1.7(0.786-3.921	0.170
	Agree	81	47	1			
Your organization's financial support for staff training and CPD required by ISO is sufficient.	Disagree	107	86	1.1(0.720-1.693)	0.131	0.5(0.259-1.153)	0.112
	Agree	80	71	1			
Adequate laboratory facility (staff, space, safety, and environment) to meet ISO15189:2022.	Disagree	74	74	1.3(0.886-2.091)	0.159	2.1(1.185-4.068)	0.012**
	Agree	113	83	1			
Your laboratory equipment is modern, functional, and maintained regularly.	Disagree	35	20	1			
	Agree	152	137	1.6(0.869-2.862)	0.134	3.4(1.393-8.692)	0.008**
Your laboratory consistently has available essential reagents and consumables.	Disagree	79	77	1.3(0.859-2.016)	0.207	0.7(0.397-1.504)	0.448
	Agree	108	80	1			
Consistently performed equipment calibration and preventive maintenance as per your laboratory schedule.	Disagree	38	46	1.6(0.991-2.666)	0.055	1.1(0.563-2.435)	0.672
	Agree	149	111	1			
The communication between laboratory staff and management on quality issues is very effective	Disagree	84	94	1			
	Agree	103	63	1.8(1.190-2.812)	0.006	0.5(0.292-1.197	0.144
Continuous improvement and corrective action systems are in place and functional	Disagree	30	39	1.7(1.01-2.946)	0.044	0.8(0.402-1.933)	0.752
	Agree	157	118	1			
	Disagree	50	72	2.3(1.478-3.644)	<0.001	1.9(0.920-3.328)	0.088

The process of method validation or verification is straightforward.	Agree	137	85	1			
The laboratory consistently uses a policy, SOP, and documentation that are updated and practiced daily.	Disagree	28	37	1.7(1.015-3.020)	0.044	1.6(0.738-3.853)	0.215
	Agree	159	120	1			
The frequency and thoroughness of internal audits or reviews as part of the quality improvement tool are highly effective	Disagree	44	54	1.7(1.063-2.731)	0.027	1.7(0.818-3.640)	0.152
	Agree	143	103	1			
External Quality Assessment (EQA) programs are regularly conducted.	Disagree	43	80	3.5(2.191-5.525)	<0.001	3.2(1.609-6.470)	<0.001**
	Agree	144	77	1			
Collaboration with international partners strengthens accreditation efforts.	Disagree	73	81	1.6(1.083-2.557)	0.020	1.9(0.999-3.967)	0.050**
	Agree	114	76	1			
The regulatory framework is facilitating ISO 15189 implementation support.]	Disagree	75	85	1.7(1.148-2.707)	0.010	0.8(0.452-1.640)	0.649
	Agree	112	72	1			

5.6.Findings of the qualitative study

The in-depth interviews were conducted with 10 selected respondents from private and public hospitals and a diagnostic laboratory, primarily laboratory quality officers (QOs). All participants had sufficient training, knowledge, and experience in ISO 15189:2022 implementation. However, 4 respondents of the QOs were from facilities that had withdrawn from implementation. For confidentiality and privacy of the respondent and institutions, the interviewees are coded letters from Q1 to Q10, corresponding to their participant codes.

The participants reported major human resources-related challenges, including a shortage of trained laboratory professionals, limited training, and competency in ISO 15189:2022 requirements. Moreover, high workload, high staff turnover, inadequate motivation and recognition from the organization, and resistance from staff to implement are also the common challenges as mentioned by respondents.

Interviewee Q1 reported that a "*shortage of qualified and trained personnel, particularly on POCT, risk mitigation, and updated on ISO 15189:2022. Comparatively high workload on staff, and inadequate refreshment and retraining program from the organization were our major human resource-related factors."* Another respondent Q2, stated that "*the laboratory had a shortage of staff who were aware of updated ISO 15189:2022. Even the laboratory head and quality officer had limited experience."* Similarly, Q4 reported that "*limited competency of laboratory leadership was a major problem for implementation. The replacement of staff lost through turnover with qualified personnel was a challenge we faced"*.

In other cases, the laboratories identified staff resistance, and ineffective utilization of staff members as critical challenges. Interviewee Q5 reported that, "*During the transition program, some staff resisted the implementation of the new standard. However, after on-the-job training, this was improved.*" Another respondent, Q7, said that "*the laboratory has faced countless challenges inncluding ineffective utilization of competent staff and poor motivation systems. New employees become busy immediately due to a high turnover rate*." Respondent Q10 noted that *"the laboratory faced the least challenges related to inadequate CPD-integrating training and staff resistance.*" In contrast, Q9 reported that "*the laboratory mainly faced a problem of high workload and a shortage of staff only.*"

As a developing country, Ethiopia faces major financial and resource-related challenges. The participants reported inadequate budget allocation and high costs associated with EQA participation, training-related accommodation, calibration services, procurement, and audit expenses as major barriers to ISO 15189:2022 implementation. Respondent Q1 stated that "*the laboratory budget allocation was insufficient to cover the expenses of EQA participation, updated training, consumable procurement, and assessment auditor expenses*". Similarly, Q2 explained that "*the laboratory had a major gap in financial support from management for the expenses of accreditation-related activity, and training*". Q7 further reported that "*the laboratory had a limited budget allocation over years for the EQA participation, modern equipment procurement, and professional training*".

However, some laboratories reported that their organizations allocated sufficient budget for laboratory services. The interviewee Q6 reported that "*the organization allocates an adequate budget and procures modern and updated laboratory equipment*". Similarly, Q10 reported that "*the organizations did not have problems with budget allocation for training, procurement, and quality improvement activity. However, the problem lies in effective mobilization of funds, the high cost of EQA, and the absence of calibration services.*"

Regarding infrastructural and technical factors, the major problems were equipment calibration, inadequate facilities, reagent stock-out, and internet interruption for effective integration of LIMS within the laboratory services. Q2 stated that "*to implement updated ISO, the major problem was equipment calibration.*" Q5 reported that "*the laboratory facility space, ventilation, and illumination were problems for effective implementation*". Likewise, Q8 said that *"the infrastructural problems were a major hindrance for the laboratory to effectively implement the new ISO, such as calibration issues, inadequate supply and consumables, weak POCT integration, and inadequate EQA sample."*

On the other hand, Q3 reported that "*the laboratory had an adequate infrastructural setup to implement ISO 15189:2022 without any limitation.*" Similarly, Q6 reported that "*the laboratory infrastructure was adequate for implementation. However, for emergency preparedness, the laboratory didn't have adequate facilities.*" Exceptionally, Q9 reported that "*to create adequate facility types, the laboratory should renovate the working area. However, this renovation condition was one of the major reasons for withdrawal from implementation."*

Organizational factors, such as management commitment and administration support to facilitate ISO 15189:2022 implementation, showed improvement overall; However, communication between staff and management is often ineffective. The respondent Q3 reported that "*the organizational leadership and management strongly supported effective implementation and maintenance of laboratory standards.*" The majority of respondents (Q4, Q5, Q7, Q9, and Q10) also reported that there is strong management and administration support. In contrast, Q1 indicated that "*the management support was weak, and there was pressure to implement the standard without adequate support, which negatively affected quality procedures*". Q2 similarly stated that "*the administration provided weak support and lacked responsibility towards sustaining implementation.*"

Other factors related to quality management also presented gaps, particularly in corrective action, occurrence management, documentation, internal audit, and review practices. In this regards, Q1 stated that "*the laboratory quality team had weaknesses such as failing to conduct internal audit according to schedule, not taking appropriate corrective action, and not conducting root cause analysis when an occurrence happens. This delayed the implementation of the laboratory."* Q2 likewise reported that "*poor documentation practices, weak internal auditing, and a poor occurrence recording system delayed the laboratory implementation activities.*"

However, Q4, Q5, and Q10 reported that their laboratory quality teams had improved overall quality culture and quality improvement activities. Exceptionally, Q9 explained that "*the laboratory's quality improvement activities were deprioritized due to renovation activities and national instability.*"

The main external challenges included inadequate mentorship, weak regulatory body support, lack of international integration and collaboration, and limited external technical assistance, all of which negatively affected the implementation process. Q1, Q2, Q8, and Q10 reported that "*the laboratory faced challenges related to inadequate guidance and support, lack of mentorship, and lack of external partnerships.*"

However, Q3, Q4, and Q7 reported that *"the laboratory had strong national and international partnerships, including embassy affiliated cooperation, which helps to obtain supply and consumable support, technical support, and provide EQA samples.*" Separately, Q9 reported that "*the laboratory had international and national collaboration for EQA support and training; But this was not fully effective due to expired EQA sample support and limited access to training*".

6. Discussion

This study assessed the implementation status of ISO 15189:2022 and explored the associated challenges among private and governmental hospitals and diagnostic laboratories in Addis Ababa, Ethiopia. The mixed-methods approach provided both quantitative evidence and in-depth qualitative insight into the complex factors influencing implementation. Integrating quantitative survey data from 344 laboratory professionals across 24 institutions and 10 quality officers was used as a sample for qualitative in-depth interviews. The triangulated findings provide a comprehensive and contextually grounded understanding of the barriers and enablers of laboratory ISO implementation in Ethiopia, the capital city.

Ninety-eight percent of the calculated sample size participated in the study. Findings were assessed, and a high proportion of participants (323 out of 344, 93.9%) have basic knowledge about ISO 15189:2022. This significant gap between awareness and active engagement indicates a critical implementation challenge. Knowledge of standards doesn't automatically translate into meaningful participation. To bridge this gap, organizational enablement, structural support, and dedicated time allocation are important. This suggestion was similar to a study in Rwanda and Ethiopia (23,42). The similarities are due to training, continuous mentoring, and creating awareness to improve laboratory quality and competency, and complaint implementation teams that engage all staff members.

Despite this encouraging awareness, active participation in implementation activities was considerably lower; only 157 (45.6%) were involved in implementation activities, including document preparation and review (52.9%), training and mentorship (9.55%), audit and assessment (3.8%), implementation leadership activities (4.5%), and multiple implementation tasks (38.7%).

However, the gap between awareness and active participation was significant. Only 45.6 of participants had been involved in any implementation activity. More than half of respondents, 54.4% (187 out of 344), didn't participate in the implementation process due to a lack of opportunity (36.9%), a lack of training (13.5%), workload (14.9%), and organizational barriers (5.3%) as primary reasons. This study is unique due to quantifying the reasons for not being involved in the implementation process and the kind of participation in the implementation process over the previous study conducted in Addis Ababa (6,37). This study uniquely quantifies the pattern, which indicates awareness of the standard is a necessary but insufficient condition for

implementation. To convert knowledge into practical engagement, an active, structured, and organized invitation and support are required. Similar studies have been reported in Nigeria and Dire Dawa, Ethiopia, where low levels of staff engagement and poor ownership of quality process were identified as major challenges of implementation (34,36). The similarity was due to accreditation requiring collective effort, ownership, and continuous involvement.

The study involved 24 organizations, while 20.8% of participant organizations were withdrawn from the previous ISO 15189:2012, and 8.3% were under implementation. This indicates that awareness of laboratory professionals and management regarding laboratory quality services remained limited in Ethiopia.

The overall implementation status of hospitals and diagnostic laboratories in Addis Ababa was 22.2% fully compliant with ISO 15189:2022 as of February 2026. This finding represents better improvement compared to the 3.6% rate reported by a study conducted in the same setting in 2023 (7) and the 4% estimated in the earlier study(6). The improvement may be the expansion of new ISO training, strong involvement of EAS, and growing recognition benefit among laboratory leadership. The status increment reflects the national awareness program, a stepwise framework, such as SLIPTA and SLMTA, promoted by the regulatory body MOH, EPHI, and EAS. However, the implementation rate remains low across the health system.

By comparison, this status exceeds the implementation rates reported in several developed countries relative to their total laboratory populations, such as 16% in Costa Rica, 12% in Slovenia, and 2% in both the United Kingdom and Bulgaria (29,30). Nevertheless, this comparison of an Ethiopian figure reflects only those facilities already engaged in the implementation process or withdrawn from the previous standard. The effective coverage rate falls below international benchmarks and remains far behind sub-Saharan African leaders such as Kenya, which improved 87% progress through structured rapid results initiatives (40), and South Africa, which accounts 61.4% of all African laboratories implementing the standards (33). The differences were due to resource availability, government commitment, and laboratory infrastructure between countries.

Despite implementation, 20.8% of organizations that had implemented the previous underwent the ISO 15189:2012, but withdrew from the updated ISO 15189:2022 requirements. This indicates that maintaining compliance is at least as challenging as achieving initial implementation. These findings were similar to a study conducted in Rwanda and Tanzania. Which reported initial

implementation gains are possible, but maintaining the implementation is difficult without strong mentorship, institutional commitment, and a systematic quality improvement program (44,45).

This contributed direct and actionable implications for laboratory managers and policymakers, who should create structured opportunities for all laboratory staff to engage meaningfully with implementation activity. Because laboratories with active staff involvement were four times more likely to achieve successful implementation than passive engagement.

Human-related factors (HRF, X=3.5) emerged as the most persistent category of implementation challenges in these findings. Within this factor, such as high staff workload, high staff turnover, inadequate access to training and CPD, a shortage of ISO-trained professionals, and inadequate staff motivation and recognition were significant. This finding was supported by qualitative interviews, where participants reported that trained staff leave for better opportunities, creating repeated retraining costs and loss of institutional memory. Specifically, Q1 and Q2 stressed that even laboratory leaders and quality officers often had limited experience with the new standard, which undermined effective implementation and leadership. Most reported that staff shortages, inadequate competency in the new standard requirement (Risk mitigation and POCT), and staff resistance hindered the implementation and maintenance of ISO 15189:2022 requirements. Especially, the withdrawal facilities quality officer emphasizes that these human-related factors cause workforce instability.

These links between each other summarize that workforce capacity building must be supported by a national strategy to improve standard implementation in Addis Ababa, Ethiopia. Q5 reflects common challenges in staff with high workload, and changing workflow and documentation is an additional burden, which is similar to studies conducted in developed countries (29,30). These findings align with previous studies conducted in Ethiopia (24), which identified inadequate staffing, high workload, limited training access, and poor staff motivation as barriers to laboratory quality improvement and implementation. Similarly, the results were reported in Oromia, Ethiopia, Dire Dawa, Ethiopia, Tanzania, and South Africa (23,36,47,50). This reinforces the validity of these findings across multiple geographies and study designs. The similarities were chronic shortage of qualified staff, increasing demand for services, and limited financial capacity to retain and recruit skilled personnel, and documentation task increase staff workload.

The second Factors, financial and resource factors (FRF, X==.2) were identified as the most significant challenge, such as insufficient budget allocation, high cost of EQA, inadequate

organization support for training, and delay of necessary laboratories consumable and supplies. These findings were similar in Nigeria, Tanzania, and Somaliland, collectively characterizing financial limitation as a defining challenge for laboratory quality implementation (34,47,49). The similarities were substantial costs associated with implementation and infrastructure improvements. In the low-and middle-income countries, health financing is limited to quality management initiatives.

Laboratories that participated regularly in the EQA program were 3.2 times more likely to achieve successful implementation (AOR=3.2, p-value<0.001), but the cost of this was leading to failure. However, the interviewee (Q1, Q2, Q7, Q6, and Q10) revealed that access to affordable and reliable EQA materials remained a problem, including expired EQA samples and limited availability through national providers. Similarly, insufficient budgets to cover training, calibration, consumables, and auditor costs were reported.

In Ethiopia, dependency on external funding and international support makes the health system structure fragile, including EQA participation. Compared with high-income settings, the cost of maintaining the systems and adapting new standards was a greater challenge than financial resources (29,30). The similarity was due to the EQA-identified gap, which promotes continuous quality improvement. In contrast, the differences were due to inequality in laboratory financing needs, policy responses, including government subsidization of EQA participation, collaborative procurement of laboratory consumables, and allocating implementation budget within the institution.

The third infrastructural and technical factor (ITF, X=3.8) represented the highest scoring domain, which indicates widespread difficulties with physical laboratory condition, equipment availability and maintenance, and supply chain availability. Equipment breakdown and consumable shortage were rated as major hindrances to laboratory services delivery (X=3.65, SD=.765), and multivariate analysis confirmed that laboratories with modern, functional, and regularly maintained equipment (AOR=3.4, p-value=0.008) were 3.4 times more likely to achieve successful implementation. Additionally, laboratories with adequate facility conditions were 2.1 times more likely to succeed in implementation (AOR=2.1, p-value=0.012). These findings were supported by a study conducted in Kenya, Nigeria, and sub-Saharan Africa, which reported outdated equipment, inconsistent supply chain, and inadequate infrastructure as the main challenges (34,46,49). Similarity of study results from the dependence on imported equipment and

consumables, prolonged procurement process, and limited access to local calibration and maintenance services. However, the magnitude of these appears lower than previous studies, which reflects the gradual improvement of laboratory infrastructure and the increase in investment in diagnostic services in Ethiopia during recent years.

Similarly, the interviewee (Q3, Q6) also reported that adequate infrastructure and technical capacity were more feasible, but renovation undertaken deprioritized quality activity. The interviewee (Q2, Q5, Q8) adds more specific information, such as equipment calibration, reagent stockouts, weak LIMS integration, and poor POCT device management, which were the most reported barriers. Most of the key informants from withdrawal facilities reported that calibration of equipment is the main gap. Maintaining implementation needed national accessible calibration services and framework.

Regarding the Organizational factor (OF, X=3.2), management commitment and administration support were improved. The key informants also notice strong implementation support gained. However, communication between staff and management was identified as a challenge (X=2.97, SD=1.001). These findings align with a study conducted in Iran and Ethiopia, which reported that poor organizational communication, poor quality culture, and inadequate leadership produce staff resistance and lag the implementation process (23,43).

This was supported by the qualitative finding, interviewee (Q3, Q4, Q5, Q7, Q9, Q10), who reported that strong management commitment, leadership support, and a growing quality culture in their institution. In contrast, management pressure to achieve implementation without providing operational and financial support. Effective communication is a structural requirement of ISO 15189:2022 under management system responsibility. So the regular quality review meeting, staff empowerment mechanism, and accountability were important to quality commitments.

Quality management factors (QMF, X=3.7) receive relatively high scores on risk management practices(X=3.51), POCT alignment (X=3,71), and patient safety prioritization (X=3.71). This indicates the new concept of ISO 15189:2022 was adaptive and made good progress in Addis Ababa, Ethiopia, hospitals and diagnostic laboratories. However, the major challenges were presented, such as functionality of corrective action (X=2.97, SD=1.001), and conducting daily activity according to SOPs (X=2.92, SD=0.998), which remained at a weak rate. Also, regular audits and reviews were identified as a challenge. The key informant announced that

documentation practices, corrective action, and root cause analysis remained poor components of quality improvement activity.

This was supported by in-depth interviews (Q1, Q2), which cited this as the main challenge, but Q9 reported that quality improvement was deprioritized due to renovation and national instability. This difference is due to budget allocation, where not for quality but rather for addressing services. Similar studies reported from Rwanda and Ethiopia reported that a long-term continuous improvement culture was more difficult than the initial implementation of quality improvement (24,44). The similarity was due to the introduction of risk mitigation principles, patient safety considerations, and POCT integration, which requires advanced technical expertise and organizational maturity. These findings suggest that many laboratories in Addis Ababa approach implementation as a one-time promotion and certification rather than as a framework for ongoing quality improvement.

Regarding external factors (EXF, X=3.3), significant predictors. The laboratories with strong relationships with national and international organizations were 1.9 times more likely to achieve successful implementation (AOR=1.9, p-value=0.050). These findings are confirmed by qualitative interviews; the laboratories with strong partnerships (Q3, Q4, Q7, Q9), such as embassy-affiliation, technical assistance, and access to EQA sample provision, show better implementation performance. However, even where collaboration existed, their effectiveness was sometimes undermined by limited training access and expired EQA sample (Q9).

These findings are similar to internationally supported initiatives such as SLIPTA, SLMTA, and RRI, which have helped achieve implementation (33,40). Rwanda is also building a well-structured external collaboration for mentorship (44). Similarly, Ethiopia benefited from external partnerships. However, the qualitative data show that collaborations are fragmented, time-limited, and insufficient to produce long-term quality improvements.

The role of MoH, EAS, and EPHI in supporting ISO implementation was moderate. The quality officer interview reported that the support was proactive engagement, including structured mentorship, accessible calibration services, subsidized EQA sample, and regular performance monitoring. The similarity of these findings with the previous studies, technical assistance, mentorship opportunity, training access, and resource mobilization provided through these partnerships. It facilitates knowledge transfer and strengthens the laboratory quality system in

resource-limited settings. Strengthen the regulatory system and develop a strategic framework to sustain quality excellence in Addis Ababa, Ethiopia.

7. Strengths and Limitations of the Study

7.1.Strengths of the study

- The study employed mixed methods, which enhanced the validity and comprehensiveness of results.
- The study included a relatively high sample size with a high response rate, which improves the representativeness of findings.
- The inclusion of both implemented and withdrawn laboratories also provided a broader perspective on factors influencing ISO 15189:2022 implementation.

7.2.Limitations of the Study

- The participants may overestimate or underestimate the actual implementation and challenges, which causes recall bias.
- The qualitative sample size is relatively low, which may not fully represent all perspectives of laboratory professionals involved in ISO 15189:2022 implementation.
- Some laboratories included in the study were in the transition phase(ongoing) during data collection. This may influence the challenge that was not directly addressed by the internal audit and review of the gap.

7.3.Challenge of the study

During the conduct of this study, several challenges were faced, such as

- Organizational bureaucracy and delay to proceding data collection, limited financial support, and global instability affected the research activities.
- Some organizations, including laboratory professionals, were unwilling to participate because previous findings did not bring practical improvement. Especially, the laboratory head and quality officer fear exposing institutional weakness and time constraints.

8. Conclusion and recommendations

8.1.Conclusion

This mixed-methods study explained that the implementation of ISO 15189:2022 among private and public hospitals and diagnostic laboratories in Addis Ababa remains limited, with only a few facilities achieving full compliance. While awareness of the standard among the laboratory professionals was high, but limited participation.

The common challenges of ISO 15189:2022 implementation were human resource constraints, financial limitations, infrastructural deficiency, poor organizational and management quality culture, and limited external mentorship, which were hindrances.

Multivariate analysis identified facility type, staff participation on implementation, adequate laboratory infrastructure, modernization and functionality of laboratory equipment, regular participation and conducting EQA, and integration of laboratory along with international and national collaboration as predictors of successful implementation.

However, the successful implementation depends not only on resources but also on leadership, staff engagement, and supporting systems within the laboratory. Targeting these areas was essential to improve the quality of services of medical laboratory science to support ultimate clinical medical decisions.

8.2.Recommendation

Regarding the findings, to improve laboratory services to align with ISO 15189:2022 implementation and sustainability in Ethiopia.

- Governing body (MoH) policy maker with EAS- develop a national collaboration strategy of ISO implementation with international organization partners for both private and public sectors, expanding and institutionalizing monitoring, supporting, and mentorship, subsidizing key services such as calibration services, EQA program, centralized procurement strategies, and expanding continuous professional Training (CPD).
- Hospital and Diagnostic Laboratories management – Allocate sufficient budget, communicate effectively with staff members, prioritize staff engagement, develop staff motivation and retention mechanisms, address training, and promote service quality.
- Academic institution and researcher- Conducting a nationwide study to assess challenges and associated factors across Ethiopia. Regarding implementation practices, further qualitative study, direct laboratory observation, and document review should be essential.
- Medical Laboratory professionals- Promoting teamwork and quality culture in your facility by actively participating in ISO 15189:2022 implementation and realizing their hidden role in the health system.

References

1. Standardization IO for. Medical Laboratories, Requirements for Quality and Competence. ISO, International Organization for Standardization; 2022.

2. Allison FI, Ojule AA, Allison I. Medical laboratories in Nigeria (Part 1): Assessment of quality management practices and accreditation status. Eur J Med Health Sci. 2024;6(2):21–9.

3. EPHI. Ethiopian Public Health Institute First Edition Ethiopian Public Health Institute Addis Ababa, Ethiopia guideline 2024. - Google Search. 2024.

4. Organization WH. Laboratory quality management system: handbook. World Health Organization; 2011.

5. Misganaw AS. A journey to accreditation: ISO 15189 laboratory accreditation possible in Ethiopia? Pan Afr Med J. 2016;24:329.

6. Sisay A, Gurmessa A, Liknew W. Factors Affecting Implementation of Laboratory Quality Management System in Addis Ababa Public Health Laboratories, Addis Ababa, Ethiopia. 2019. 2019.

7. Tesema M, Sisay A. Medical laboratory accreditation status and associated factors in selected private and government health facilities of Addis Ababa, Ethiopia. Pan Afr Med J. 2023;45(1).

8. Accreditation E. Medical Laboratories [online report]. Available from: https://eas-eth.org/directory-of-accredited-facilities/

9. Datema TAM, Oskam L, Broerse JEW, Klatser PR. Review of the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) version 2:2015. Afr J Lab Med. 2020;9(1):1068.

10. Tsimillis KC, Michael S. Accreditation of medical laboratories: What is new in ISO 15189:2022. Accreditation Qual Assur. 2024;29(2):175–82.

11. Pradhan S, Gautam K, Pant V. ISO 15189: 2022; what's new in new? J Pathol Nepal. 2023;13(1):2027–8.

12. Jülicher P, O'Kane M, Price CP, Christenson R, John AS. Health economic evaluations of medical tests: Translating laboratory information into value - A case study example. Ann Clin Biochem. 2022;59(1):23–36.

13. Abebe N. Successful ISO 15189 Accreditation in the Bethzatha Advanced Medical Laboratory in Ethiopia. EJIFCC. 2016;27(4):351–3.

14. Ireland. INAB transition plan to ISO 15189:2022. 20224. NAB transition plan to ISO 15189:2022. Available from: www.inab.inab

15. Linko S, Boursier G, Bernabeu-Andreu FA, Dzneladze N, Vanstapel F, Brguljan PM, et al. EN ISO 15189 revision: EFLM Committee Accreditation and ISO/CEN standards (C: A/ISO) analysis and general remarks on the changes. Clin Chem Lab Med. 2025;63(6):1084–98.

16. Kao Chih-Hsiung. Diagnostics [Internet]. 2024. Insights on updated accreditation guidelines ISO 15189:2022. Available from: https://diagnostics.roche.com

17. Commission IE. ISO/IEC 17025: 2017: General requirements for the competence of testing and calibration laboratories. Vol. 17025. ISO/IEC; 2017.

18. Maccurtain M. ISO/CASCO-Committee on conformity assessment. Obtenido ISOCASCO-Comm Conform Assess. 2017.

19. Pereira P. Trends in the Accreditation of Medical Laboratories by ISO 15189. In: Six Sigma and Quality Management. IntechOpen; 2023.

20. Khattar RB, Nehme ME. Emergence and evolution of standardization systems in medical biology laboratories. Adv Lab Med. 2024;5(3):261–7.

21. Dwivedi APD. Laboratory Accreditation: Evolution and Development. In: Handbook of Quality System, Accreditation and Conformity Assessment. Springer, Singapore; 2025. p. 1–18.

22. Girma M, Desale A, Hassen F, Sisay A, Tsegaye A. Survey-Defined and Interview-Elicited Challenges That Faced Ethiopian Government Hospital Laboratories as They Applied ISO 15189 Accreditation Standards in Resource-Constrained Settings in 2017. Am J Clin Pathol. 2018;150(4):303–9.

23. Mulleta D, Jaleta F, Banti H, Bekele B, Abebe W, Tadesse H, et al. The Impact of Laboratory Quality Management System Implementation on Quality Laboratory Service Delivery in Health Center Laboratories of Oromia Region, Ethiopia. Pathol Lab Med Int. 2021;13:7–19.

24. Mesganaw B, Fenta A, Hibstu Z, Belew H, Misganaw K, Belayneh M. Medical Laboratories Quality Management and Challenges in Ethiopia: A Systematic Review. Pathol Lab Med Int. 2023;Volume 15:13–26.

25. Hallworth MJ. The “70% claim”: what is the evidence base? Ann Clin Biochem. 2011;48(Pt 6):487–8.

26. O NF, A OE. Overview of the Implementation of Quality Management System in Nigerian Medical Laboratories. Univ Lagos J Basic Med Sci. 2021;6(1 & 2).

27. Kopanitsa G, Semenov I. Patient facing decision support system for interpretation of laboratory test results. BMC Med Inform Decis Mak. 2018;18(1):68.

28. Zima T. Accreditation of Medical Laboratories - System, Process, Benefits for Labs. J Med Biochem. 2017;36(3):231–7.

29. Grochau IH, Caten CS ten, de Camargo Forte MM. Current American landscape in laboratory accreditation according to ISO/IEC 17025. Accreditation Qual Assur. 2017;22(2):57–62.

30. Grochau IH, Leal DKB, ten Caten CS. European current landscape in laboratory accreditation. Accreditation Qual Assur. 2020;25(4):303–10.

31. ILAC. International Laboratory Accreditation Coopration Facts & Figures– report. 2024. ILAC; 2024.

32. Combe A. Publication of the revision of EA-4/20 Guidance for the assessment of laboratories against EN ISO 15189:2022 Point-of-Care Testing. European Accreditation [Internet]. 2022. Available from: https://european-accreditation.org/publication

33. Inc K. ASLM Announces 6th Biennial Conference in South Africa: Shaping Laboratory Systems and Diagnostic Services for the 21st Century. ASLM [Internet]. 2023. Available from: https://aslm.org/aslm-announces-6th

34. Opeyemi AA, Obeagu EI, Hassan AO. Enhancing quality healthcare in Nigeria through medical laboratory services: A review. Medicine (Baltimore). 2024;103(2):e36869.

35. Attoh S, Tetteh FKM, McAddy M, Ackah K, Kyei R, Moroti M, et al. Challenges with the pursuit of ISO 15189 accreditation in a public health laboratory in Ghana. Afr J Lab Med. 2022;11(1):1448.

36. Tolera A, Firdisa D, Roba HS, Motuma A, Kitesa M, Abaerei AA. Barriers to healthcare data quality and recommendations in public health facilities in Dire Dawa city administration, eastern Ethiopia: a qualitative study. Front Digit Health. 2024;6.

37. Girma M. Major Challenges of Medical Laboratories for ISO 15189 Accreditation in Selected Government Hospitals of Addis Ababa, Debrebrhan, and Bishoftu, Ethiopia. Addis Ababa University; 2017.

38. Watanabe K, Kubono K, Shimoda K. Current status of ISO 15189 accreditation system. Rinsho Byori. 2012;60(7):653–9.

39. CAP 15189. College of American Pathologists [online report]. CAP; 2025. CAP 15189 Accreditation Program. Available from: www.cap.org

40. Makokha EP, Ondondo RO, Kimani DK, Gachuki T, Basiye F, Njeru M, et al. Enhancing accreditation outcomes for medical laboratories on the Strengthening Laboratory Management Toward Accreditation programme in Kenya via a rapid results initiative. Afr J Lab Med. 2022;11(1):1614.

41. AOAC Africa Scientific Committee, Riungu A. The AOAC Africa Laboratory Performance Benchmarking Program. Int J Conform Assess. 2024;3(1).

42. Tanasiichuk I, Karaman O, Natrus L. Key success factors for the implementation of quality management systems in developing countries. Afr J Lab Med. 2023;12(1):2058.

43. Davies J, Abimiku A, Alobo M, Mullan Z, Nugent R, Schneidman M, et al. Sustainable clinical laboratory capacity for health in Africa. Lancet Glob Health. 2017;5(3):e248–9.

44. Rusanganwa V, Nzabahimana I, Evander M. Quality and resilience of clinical laboratories in Rwanda: a need for sustainable strategies. Glob Health Action. 2024;17(1):2358633.

45. Beyanga M, Gerwing-Adima L, Jackson K, Majaliwa B, Shimba H, Ezekiel S, et al. Implementation of the laboratory quality management system (ISO 15189): Experience from Bugando Medical Centre Clinical Laboratory - Mwanza, Tanzania. Afr J Lab Med. 2018;7(1):657.

46. Zeh CE, Inzaule SC, Magero VO, Thomas TK, Laserson KF, Hart CE, et al. Field experience in implementing ISO 15189 in Kisumu, Kenya. Am J Clin Pathol. 2010;134(3):410–8.

47. Shedura VJ, Malindisa KK, Nanyanga SJ. Implementation of laboratory quality management system: A cornerstone for enhanced patient safety and clinical outcomes in Tanzania. J Interv Epidemiol Public Health. 2025;8(4):84.

48. Tembo D, Kaphika JS, Ahmadu A, Alufandika L, Kalilangwe V, Kukacha C, et al. 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 Res. 2026;11:144.

49. Co O, B van der P, M M, T M, S D, T D, et al. Examining 7 years of implementing quality management systems in medical laboratories in sub-Saharan Africa. Trop Med Int Health TM IH. 2023;28(2).

50. Khadambi -Morokane H., Bhowan K, Ayuk S. An overview of medical diagnostic laboratories in South Africa that meet the international standard of accreditation: ISO 15189. J Med Lab Sci Technol South Afr. 2021;3(1):27–34.

51. Addis TL, Birhanu BS, Italemahu TZ. Factors affecting climate change governance in Addis Ababa City, Ethiopia. Sustainability. 2023;15(4):3235.

52. Authority AAF and D. Addis Ababa Food and Drug Authority. 2011. Available from: https://aafda.gov.et/

Annex 1. Research participant information sheet.

Title of the research: The Implementation of ISO 15189:2022 in Private and Government Hospital and Dignostic Laboratories in Addis Ababa, Ethiopia.

Please read and listen carefully to the general information of this study. If you have any questions or unclear ideas, you can ask freely. Thank you for all your cooperation and participation.

Background – this research is being done for partial fulfillment of a master's degree in Addis Ababa University, College of Health Science, Department of Medical Laboratory, in the laboratory management and quality assurance specialty track.

The new modified ISO 15189:2022 standard provides a framework for quality and competency in medical laboratories with special focus on sample management, risk management, point of care, and patient safety. However, given its importance to minimize error and patient safety, the implementation of this new standard faces different and countless challenges, commonly in developing countries with resource, technical, human, and other perspectives. It is also promoting the accreditation for the delivery of reliable results for patient management or the generation of reliable data for critical public health interventions.

So, this study gather information on the main challenges and risk factors to implement this new ISO.

Purpose: The main purpose of this research is to assess the major challenges and factors associated with the implementation of ISO 15189: 2022 in private and public hospital and diagnostic laboratories in Addis Ababa. On the other hand, to collect your views and experiences regarding the implementation of ISO 15189:2022.

Risk and benefit: There is no benefit or incentive for your participation in this study, and also no known harm, social discrimination, physiological trauma, or economic loss to the participant. I assure you that your response to the interview and written data was kept confidential and private. Your name is not listed on your response, rather using code, and your participation is voluntary. You can stop or cancel all your responses at any time.

Your voluntary willingness to participate in the study is important and appreciated. I (principal investigator) put my signature below to confirm to you that I take over the responsibility for the information that you give.

Contact

Principal investigator: Melkamu Kassaw Worku: Email: melkye618@gmail.com. Tel: +251939999887

Advisor contact.

Dr. Daniel Beshah (MSc., Ph.D.)Email: danibeshah@gmail.com, Tel: +251911151317

Dr. Woinshet Hailu (MSc, Ph.D.)Email: weinshet.hailu@aau.edu.et, Tel: +251913710094.

Dr. Dimamu Reta (MD, MPH.)Email: demamu2009@gmail.com, Tel: +251967316090

Annex 2. Consent form

I have been well informed about the research that plans to address the major challenge and factors associated with the implementation of ISO 15189: 2022 in selected private and public hospital laboratories in Addis Ababa. The aim of this study was clear, brief, and well explained to me. I also know about my privacy and confidentiality granted by the PI and have enough information about my right to refuse, stop, or drop out of the study if I want. I agree to give the information voluntarily to the researchers with the capacity of my ability, idea, and knowledge on the research title. I have confirmed my consent by signature below.

Participant code: _____

Signature: _____ Date: _____

Annex 3. Data Collection clarification

I am a postgraduate student of Addis Ababa University pursuing a Master of Laboratory Quality Management and Quality Assurance. I am conducting the study on the implementation of ISO 15189:2022 in private and government hospital and diagnostic laboratories: challenges, factors, and current status in Addis Ababa, Ethiopia. I believe that this finding helps your organization and the whole country in seeking the implementation of this program, and also supports the program. If you are willing to participate in the research, be as honest as possible. Don't forget that the data collected was only for research purposes. Thank you for your willingness!!!

This questionnaire is divided into three parts. The first part includes information about yourself, the second part includes 4 sections such as organization, human, infrastructure, and resource factors, and the third part is only for the interviewed respondent. Every individual response was

kept confidential. Kindly answer your best answer and do not hesitate to ask the data collector or call on 0939999887 or melkye618@gmail.com.

Thank you!!!!

Annex 4. Questionnaires

Participant code: _____.

Closed-ended questionnaires

Part one. Socio-demographic information.

1. Sex Male Female
2. Age _____
3. Marital status
   1. Single 2. Married 3. Divorced 4. Widowed 5. Separated
4. Education level
   1. BSc 2. MSc 3. PhD 4. Diploma 5. Other (specify)_____
5. Primary working section
   1. Clinical Chemistry 2. Hematology 3. Microbiology 4. Immunohematology 5. Other (specify)_____
6. Types of institutions. 1. public hospital laboratory 2. private hospital laboratory
7. Facility type
   1. Primary hospital lab.
   2. General Hospital lab
   3. Comprehensive hospital lab
   4. Public and private diagnostic labs
8. Number of employees per organization
   1. ≤10
   2. 11-20
   3. 21-30
   4. ≥30
9. Responsible for 1. Minister of health 2. AA. City administration health bureau.
10. Work experience as a medical laboratory scientist _____
11. Position in your laboratory
    1. Technical staff 2. Quality officer 3. Laboratory manager/head 4. Laboratory consultant
12. Did You know About Medical Laboratory Quality and Competency Standard ISO 15189?
    1. Yes B. No
13. Your organization implementation status

1. Implemented 2. Withdrawal 3. Ongoing

14. Displine of your organization accridated_____

15. Have you participated in the implementation of ISO 15189 before?

    1. Yes, what kind of participation 2. No, Why?

Part two. Associated Challenges of ISO 15189:2022 Implementation

The standard Likert scale was used, with the response option designed to measure the participants' level of agreement that a specific factor is a significant challenge to their laboratories' ISO 15189:2022 implementation. Level of agreement 1- strongly disagree, 2-disagree, 3- neutral, 4-agree, 5-strongly agree.

Catagory	Variable/Domain	Level of agreement				
		1	2	3	4	5
HRF	Your laboratory provides deliberate adequate on-the-job training.					
	Your laboratory has competent staff to implement quality standards.					
	High workload is a significant barrier to your implementation					
	Your organization has an adequate staff motivation and recognition program.					
	Your laboratory conducted a formal staff competency assessment					
	Staff turnover hurts the implementation process of your laboratory.					
	Staff turnover hurts the maintenance of implementation in your laboratory.					
	Shortage of staff compromises daily quality services					
	Your laboratory has adequate CPD/training					
FRF	Your organization allocates sufficient budget to ISO implementation					
	Budget constraints delay implementation process of your laboratory.					
	The cost of EQA is a barrier to your laboratory.					
	Adequate organizational support for training of staff on ISO.					
ITF	Your lab has adequate lab facilities to implement ISO.					
	Your laboratory has functional and modern equipment that supports implementation.					
	Your laboratory consistent calibrate and maintains laboratory equipment.					
	An easily accessible maintenance expert is available.					
	An Effective LIMS is reliable and available to support implementation					
	Reagents and consumables are available consistently in your laboratory.					

	Equipment breakdown and reagent supply are major hindrances to your quality services.					
	Management of POCT devices is associated with QA in your lab					
OF	Your laboratory management is committed to implementing and maintaining.					
	Your Organization's administration facilitates implementation.					
	Your organizations communication between staff and management is highly effective.					
	Your organization's culture towards quality improvement activity.					
QMF	Risk management practices are integrated into the daily laboratory operations.					
	Point-of-Care Testing (POCT) is aligned with your ISO 15189:2022 requirements implementation.					
	Patient safety is prioritized in accordance with ISO 15189:2022.					
	Continuous improvement and corrective action systems are in place and functional.					
	Operating and following the quality procedure is challenged.					
	Your laboratory documented risk management plan according to updated ISO 15189:2022.					
	The effectiveness of risk identification, assessment, and control for patient safety is high.					
	Consistently used policy, SOP, and documentation are updated and practiced daily.					
	The frequency and thoroughness of internal audits or reviews as part of the QMS are highly effective.					
	External Quality Assessment (EQA) conducted regularly at scheduled					
	The process of method validation or verification is straightforward.					
EXF	Your health authorities have adequately supported the implementation process.					
	Your organization has effective international partner collaboration.					
	The regulatory authority facilitates your implementation activity.					
	Your organization gained consistent mentorship or support.					

Open-ended questions (only for the interviewed participant)

1. Describe your laboratory's journey in implementing the ISO 15189:2022 standard. What stage would you say your laboratory is currently at?

2. What are the biggest challenges your laboratory faces in implementing ISO 15189:2022?
3. How has your laboratory changed its approach to identifying and managing risk (both laboratory and patient-related) since implementing this new standard? What are the biggest challenges in changing to a proactive risk-based approach?
4. What challenges does your laboratory face in strictly adhering to the ISO 15189:2022 requirements regarding HRF, IRF, ITF, OF, QMF, and EXF, especially given local contexts or institutional pressures?
5. What strategies could help improve that challenge?
6. What strategies could help your laboratory achieve accreditation successfully?

Declaration

This is to certify that the thesis prepared by Melkamu Kassaw, entitled: implementation of ISO 15189:2022 standard among private and government hospitals and diagnostic laboratories in Addis Ababa, Ethiopia, and submitted in Partial fulfilment of the requirements for the Degree of Master of Science in Clinical Laboratory Sciences (Clinical Laboratory Management and Quality Assurance specialty track) complies with the regulations of the University and meets the accepted standards with respect to originality and quality.

Principal Investigator: Melkamu Kassaw Signature _____ Date _____

Advisors:

Dr. Daniel Beshah (MSc, Ph.D.) signature_____ Date _____

Dr. Woinshet Hailu (MSc, Ph.D.) signature_____ Date _____

Dr. Dimamu Reta (MD, MPH) signature_____ Date _____