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REVIEW

Medical Laboratories Quality Management and Challenges in Ethiopia: A Systematic Review

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Background: Although based on a single system, each laboratory should have their own quality management system, in Ethiopia, quality management systems in medical laboratories were introduced in 2009 with the aim of improving the quality of services.

Objective: This review was designed to evaluate the status of quality management practice and challenges among medical laboratories in Ethiopia.

Methods: A systematic qualitative review of the literature was made by searching the international electronic bibliographic database of PubMed (NML), web of science (TS), google scholar, African journals online (AJOL) and Cochrane Library.

Results: Thirty-six full-text articles, which were published between 2010 and 2022, were included in this review. In this review, 33 of 36 (91.7%) studies showed that status of quality management practice in Ethiopian medical laboratories was limited. As a result, the quality of medical laboratories was inadequate. The main challenges were problems associated with laboratory professionals (35/36=97.2%), inadequate support from management bodies (21/36=58.3%), limited on-job training access (8 /36=22.2%) and high workload (5/36=13.8%).

Conclusion: The status of quality management practice among medical laboratories in Ethiopia is limited. The main quality compromising factors were problems associated with laboratory professionals, inadequate support from management bodies, high workload, and limited on-job training access. Therefore, all responsible stakeholders should focus on ensuring Quality Management Systems and the system should be applied in all Medical laboratories. Only this will ensure the improvement of quality within medical laboratories across Ethiopia.

Keywords: quality, medical laboratory, quality management system, implementation, challenges

Introduction

Quality in medical diagnostics defined as the reliability, accuracy, and timeliness of laboratory test results.[1] In medical laboratory practice, quality needs to be viewed as "systems thinking", which is used in other business practices. Systemic thinking is a comprehensive analytical approach to understand how different elements interact within a system or structure for monitoring of quality in medical laboratories. Therefore, to ensure efficiency, effectiveness and accuracy of services provided to the customer, a quality system that monitors these areas is required.[2]

Inadequate quality of medical laboratory services results in producing wrong information, unnecessary expenditures, suffering and misery in human lives.[3] For example, over-treatment of antibiotics for inappropriate clinical conditions leads to the development of drug-resistant microorganisms.[4]

Quality laboratory testing greatly affect the affordability and quality of patient care. Any errors or defects within a medical laboratory influences patient care and can also incur added costs.[5] As a result, nowadays, quality is given a priority in many health care system.[6]

Quality laboratory services need the practice of a quality management which focuses on applying twelve quality essentials; personnel, organization, purchasing and inventory, equipment, process control, documents and records,

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information management, occurrence management, assessment, facility and safety, process improvement, and customer services.[1] Laboratory quality management is a continuous improvement process that measures processes from a client satisfaction point-of-view.[7] Implementing total quality management in a healthcare laboratory need to incorporate quality planning and quality improvement with laboratory quality assurance to provide full quality management system.[8]

In Ethiopia, quality management system in medical laboratories was implemented since 2009 for the aim of improving quality of services. National Laboratory Strategic Plan was set in 2010 to strengthen laboratory quality systems and laboratory accreditation. As a result, the so called Strengthening Laboratory Management Toward Accreditation (SLMTA) programme was launched in 45 medical laboratories.[9] This review was designed to evaluate the status of quality management practice and challenges facing medical laboratories in Ethiopia.

Methods and Materials

Study Design and Setting

Systematic qualitative literature review was made in accordance with Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guideline[10] to evaluate the quality management practice status and challenges among medical laboratories in Ethiopia.

Search Strategy

Comprehensive updated published studies from 2010 to 2022 were identified by searching from the international electronic bibliographic database of PubMed (NML), web of science (TS), google scholar, African journals online (AJOL) and Cochrane Library using EndNote X7 application software. Both primary studies and review articles were manually searched with several keywords like "quality", "medical laboratory", "quality management system", "implementation", and 'challenges 'in different combinations. The database searches were performed in the English language without research design restriction in June 2022.

Selection Criteria

We included studies that addressed the practice of the quality management, service quality, and challenges facing medical laboratories in Ethiopia. Studies were considered eligible if they were published in the English language with the full-text format at peer-reviewed journals and conducted in Ethiopian settings. Based on these criteria, the selection of studies was performed independently by the two authors (BM and HB). Differences were resolved by discussion and consensus. Studies potentially eligible for inclusion in the review were initially screened by title abstract review and/or title and then critical reviewing of full-text studies was made. Finally, from the 650 identified studies, 36 published full-text articles were considered for the synthesis of this review (Figure 1).

Data Extraction and Analysis

Data extraction form was prepared in Excel sheet by including first author's name, publication year, objective of the study, study setting, study group, and results (Table 1). An analysis of full-text articles was conducted to identify substantial information relevant to the quality management practice status, service quality, and challenges among medical laboratories in Ethiopia.

Results

This systematic review was conducted on published studies, which were conducted in different health facilities of Addis Ababa, South region, Amhara region, Oromia region, and Tigray region of Ethiopia. Thirty-six studies published between 2010 and 2022 were included in this review. The findings of this review were sorted into two main categories, namely service quality and challenges among medical laboratories.

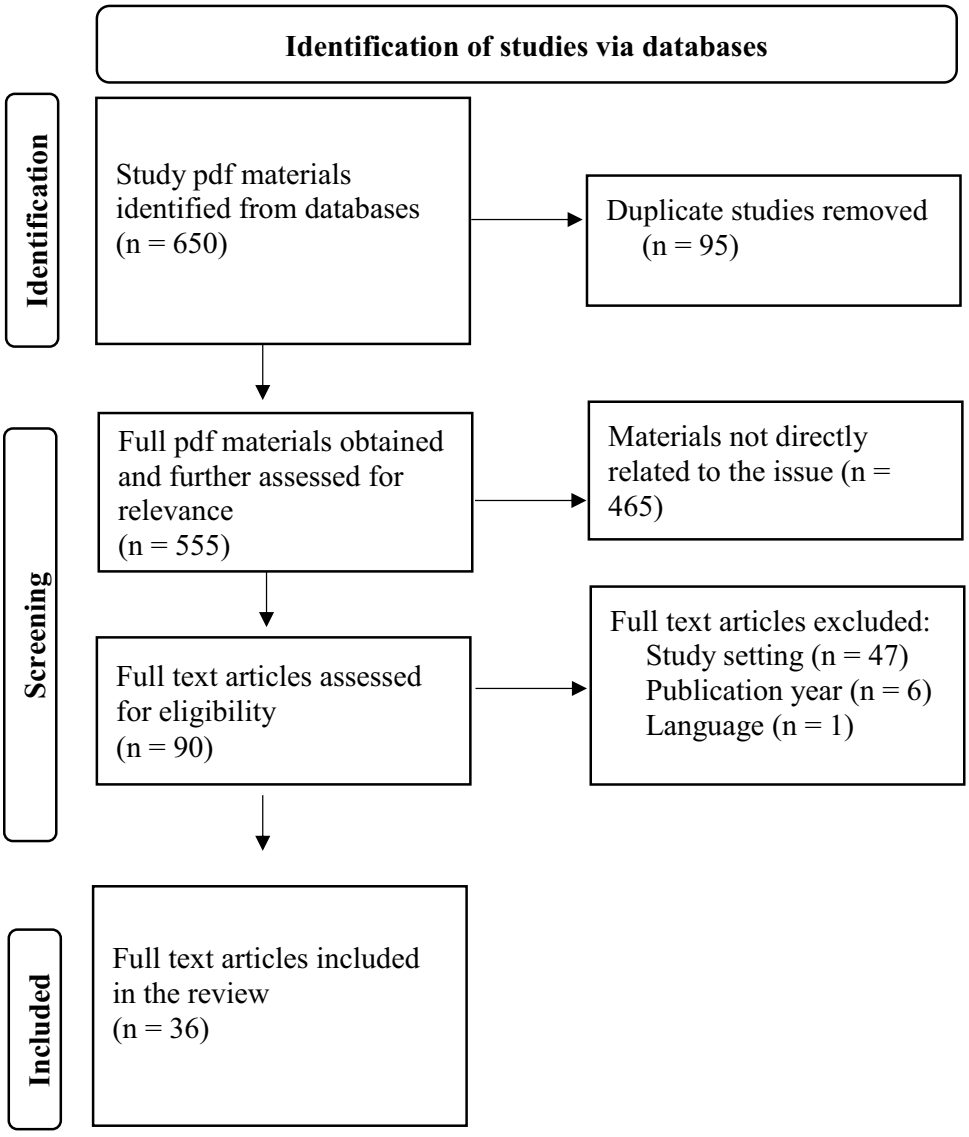

Figure 1 Flow diagram of article selection process.

Service Quality of Medical Laboratories

Even though all laboratory professionals (n=184) were informed about quality management, only about 138 (79%) were engaged in practicing it. These laboratories also had poor or very poor performance in a quality management system with five quality indicators; control of documents, control of records, setting policies and preparation of manuals, setting of processes, procedures, and communication.[11] Similarly, medical laboratories statuses towards the AFRO-WHO accreditation showed that only a laboratory from 30 laboratories achieved 156 (62%) scores, which is the minimum score required for WHO accreditation.[12] In addition, from laboratories of health center enrolled (n=89), 71 (79.8%) achieved zero stars, only 6 (6.7%) achieved star one, 9 (10.1%) achieved star two, and only 3 (3.4%) achieved star three.[13] However, from those laboratories which were implementing the system (n=45), 42 (93%) laboratories showed overall service improvements.[14] For example, a laboratory improved from the baseline score (78 points) in 2012 by achieving 198 scores (3 stars) in 2013 and 249 scores (5 stars) in 2014.[15] In addition, as one tool of quality management, SLMTA implementation increased the status of 20 laboratories from 29 laboratories from star zero to star one and above.[16] Most quality officers and managers of laboratories viewed the SLMTA program as being the most important step in the improvement process of service quality. Nevertheless, from the analysis of 17 CEOs of the hospital, only 10 (59%)

Table 1 Data Summary for Medical Laboratories Quality Management and Challenges in Ethiopia

Authors/ Publication Year/ Reference/	Objective of the Study	Study Setting	Study Design	Study Group	Summary of Findings
Girma et al, 2021[11]	To assess Laboratory Quality Management System and Quality Indicators Implementation Status as Perceived by Laboratory Professionals in Preparation for the Accreditation Process	Selected government hospitals, Ethiopia	Cross sectional study	Laboratory/ laboratory professionals	All respondents were informed about the laboratory's experience in the quality management system implementation; of those, only 138 of 175 (79%) engaged in the implementation process. From 12 selected quality indicators studied in this research, the 5 indicators with either poor or very poor performance outcome were: control of documents 136 (77.7%), control of records 123 (70.3%), development of manuals and policies 122 (69.7%), development of process and procedures 120 (68.6%), and internal communication 114 (65.1%).
Mesfin et al, 2015[12]	To determine the status of medical laboratories towards of AFRO-WHO accreditation process	Addis Ababa	Descriptive cross sectional study	Laboratories/ laboratory professionals	Out of 30 laboratory facilities 1 private laboratory scored 156 (62%) points, which is the minimum required point for WHO accreditation and the least score was 32 (12.8%) points from government laboratory. The average score for government laboratories was 78.2 (31.2%) points. Of these, 6 laboratories were under accreditation process with 106.2 (42.5%) average score, while the private laboratories had 71.2 (28.5%) average score. Of 213 respondents 197 (92.5%) professionals had a knowledge on quality system essentials whereas 155 (72.8%) respondents on accreditation.
Mulleta et al, 2021[13]	To assess the impact of laboratory quality management system implementation on improving quality laboratory service	Oromia region	Institution based cross sectional study	Health center laboratories / laboratory professionals	From the total of 89 enrolled health center laboratories, 71 (79.8%) scored between 0–105 and achieved zero stars, 6 (6.7%) scored 106–124 points and achieved star one, 9 (10.1%) scored 125–143 points, and achieved star two. Only 3 (3.4%) scored 144–162 points and achieved star three.
Hiwotu et al, 2016[14]	To evaluate the implementation of the programme, the findings from the evaluation process and key challenges	Selected laboratories in Ethiopia	Institution based cross sectional study	Laboratories	Improvements, ranging from < 1 to 51 percentage points, were noted in 42 laboratories. The average scores at the baseline and exit audits were 40% and 58% for cohort I ($p < 0.01$); and 42% and 53% for cohort II ($p < 0.01$), respectively. Poor awareness, lack of harmonisation with other facility activities and the absence of a quality manual were challenges identified

(*Continued*)

Table 1 (Continued).

Authors/ Publication Year/ Reference/	Objective of the Study	Study Setting	Study Design	Study Group	Summary of Findings
Getahun et al, 2019[15]	To share the experiences, benefits and challenges of the laboratory journey towards accreditation	Addis ketema health center, Addis Ababa	Retrospective review of laboratory records	A laboratory	The laboratory journey towards accreditation began with a baseline assessment in 2012. The baseline score was 78 points (0 stars). After mentorship support, the laboratory improved to 198 points (3 stars) in 2013 and 249 points (5 stars) in 2014. The laboratory scaled up to International Organization for Standardization 15,189 requirements and received limited-scope accreditation for tuberculosis sputum microscopy and hematology tests in 2015. After adopting and implementing the standards, steady improvement was observed in the reliability of the laboratory services.
Sisay et al, 2015[16]	To assess the outcome of SLMTA on laboratory quality management system	Addis Ababa	Institution based cross sectional study	Medical laboratories / laboratory professionals	Before SLMTA implementation, all laboratories (29) were in star zero level. After implementation of SLMTA, the final assessment indicated that 3 laboratories became 3 star 6 laboratories were at 2 star, 11 were at 1 star and the rest 9 were at zero star.
Lulie et al, 2016[17]	To assess laboratory professionals' and hospital chief executive officers' (CEOs) perceptions and attitudes toward the SLMTA programme	Selected health facilities of Ethiopia	Cross sectional descriptive study	Laboratory professionals and hospital executive officers	All of the participants agreed that the programme had brought substantial improvements to the quality of laboratory services, All 17 hospital CEOs agreed that the programme was resource-demanding and focused more on documentation than on actual laboratory testing. Eight (47%) believed that SLMTA was of insufficient value in their facilities given the significant amount of precious human resources consumed.
Shiferaw et al, 2015[18]	To assess the quality of sputum smear microscopy performance	Western Amhara	Cross sectional study	Laboratories	Among 201 laboratories enrolled in this study, 47 (23.4%) laboratories had major errors. Forty one (20.4%) laboratories had a total of 67 false negative and 29 (14.4%) laboratories had a total of 68 false positive results.
Mekonen et al, 2018[19]	To evaluate the technical quality and the findings of sputum smear microscopy for acid fast bacilli (AFB)	Hararge Zone	cross sectional study	Laboratories	Of the total 55 health center laboratories which had been assessed during the study period, 20 (36.4%) had major technical errors; 13 (23.6%) had 15 false negative results and 17 (30.9%) had 22 false positive results. False negative AFB findings were significantly associated with lack of Internal Quality Control (IQC) measures and poor staining procedures

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Table 1 (Continued).

Authors/ Publication Year/ Reference/	Objective of the Study	Study Setting	Study Design	Study Group	Summary of Findings
Desalegn et al, 2018[20]	To review misdiagnosis of pulmonary TB and associated factors in peripheral laboratories	Addis Ababa	Retrospective review of EQA records	Government and private laboratories	Of 1033 positive slides reported by peripheral laboratories, 25 (2.4%) were false positive. Out of 8783 smear negative slides reported by peripheral laboratories, 35 (0.4%) were false negative. Of 135 peripheral labo ratories, 93 (68.9%) read negative and positive slides correctly
Weldemhret et al, 2020[21]	To determine blinded rechecking of sputum smear microscopy performance in public health facilities	Tigray region	Retrospective cross sectional study	Laboratories	In average, the perfor mances of sputum smear quality were 61%, 68%, 64%, 66%, 62% and 75% for specimen quality, staining quality, smear size, smear thickness, smear evenness and smear cleanliness respectively.
Tadesse et al, 2018[22]	To determine the magnitude of pre-analytical, analytical and post-analytical laboratory errors in hematology tests	Paul's Hospital Millennium Medical College, Addis Ababa	cross sectional study	Laboratory test requests with specimens	Overall 742 (28.5%) hematology laboratory errors were detected, of which 560 (75.5%) were pre-analytic, 14 (2%) analytical, 168 (22.6%) post-analytical errors.
Teka and Kibatu, 2012[23]	To assess the accuracy and precision of clinical chemistry laboratories in western region of Amhara national regional state of Ethiopia in testing liver and kidney functions.	Western Amhara	Institution based cross sectional study	Laboratories	None of the study subject laboratories could deliver all the six tests for estimation of both liver and renal functions simultaneously during the study period. Only 213 values from the expected 324 values were reported and about 65% of the 213 values reported fell outside of the allowable limits of errors for the chemistry tests of the control specimen used
Mengistu et al, 2015[24]	To assess the performance of laboratory professionals in detecting TB bacilli at Hawassa town health institutions.	Hawassa Town	Cross sectional study	Laboratory professionals	Among the 81 participant, 11(13.6%) correctly reported all panel slides, 70 (86.4%) missed at least one slides. A total of 29.75% (241/810) error was reported that include major errors of 2.22% (13 HFN; 5 HFP) and minor errors of 27.5% (25 LFN; 60 LFP and138 QE).
Habtamu Molla et al, 2015[25]	To determine the frequency of specimen rejection and associated factors	St. Paul's Hospital Millennium Medical College, Addis Ababa Ethiopia	Cross sectional study	Laboratory specimens	of the total 8063 specimens submitted to the laboratory, 116(1.4%) were rejected. The most frequent reason of rejection was hemolysis (27.6%), followed by clotting specimens (16.4%) and unlabelled specimens (16.4%). Significantly more rejected specimens occurred in Hematology (2.1%) and Serology (2.1%) departments

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Table 1 (Continued).

Authors/ Publication Year/ Reference/	Objective of the Study	Study Setting	Study Design	Study Group	Summary of Findings
Shiferaw et al, 2018[26]	To assess the magnitude, trend and reasons of rejection among referred specimens through referral network to the Amhara Public Health Institute (APHI) for laboratory testing.	APHI	Retrospective cross sectional study	Laboratory specimens	A total of 42,923 specimens were received at APHI reference laboratories. Of which, 221 (0.5%) specimens were rejected. CD4, HIV viral load, genexpert and EID specimens' rejection rates were 0.7%, 0.6%, 0.3% and 0.2%, respectively.
Gebreyes et al, 2020[27]	To evaluate the laboratory performance and associated factors towards achieving TAT in clinical chemistry and hematology tests	Armed Force Comprehensive Specialized Hospital, Addis Ababa	Hospital based cross sectional study	Test results	From the expected below 90 minutes TAT set for clinical chemistry tests, only one sixth achieved the target time, 41/253 (16.2%), whereas from the established less than 60 minutes TAT for hematology test, only one fourth, 37/169 (21.9%), met the target
Shiferaw and Yismaw, 2019[28]	To assess the TAT of laboratory results done in the reference laboratories of the Amhara Public Health Institute	Amhara Public health institute	Retrospective cross sectional study	Patient sample results	A total of 34,233 patients samples were tested during the study period. Monthly average TAT ranged from 38.6 to 51.3 days for tuberculosis (TB) culture, 5.3 to 42.4 days for exposed infant diagnosis (EID) for HIV, 8.4 to 26 days for HIV 1 viral load, and 1.9 to 3.5 days for TB genexpert tests. Compared with the standard, 76.5% of the viral load, 68.1% of the EID for HIV and 53.8% of the TB genexpert tests had delayed TAT.
Desalegn et al, 2017[29]	To assess the quality of focused antenatal care laboratory services provided at public health facilities	Addis Ababa	Institution based cross sectional study	Pregnant mothers	Of 422 pregnant mothers involved in this study, 56.9% (240/422) satisfied with FANC laboratory services.
Abebe et al, 2022[30]	To assess the level of patients' satisfaction and associated factors with clinical laboratory services provided at public health facilities.	East amhara	Facility based cross sectional study	Laboratories / patient	Overall, majority of the respondents (73.5%) were found to be satisfied. Patients were more likely to be satisfied in health centers (75.2%) than in hospitals (68.6%).
Hailu et al, 2020[31]	To assess satisfaction level of physicians with laboratory services at public hospitals	Selected public hospitals in Ethiopia	Institutional based cross-sectional study	physicians	Overall, from 327 physicians, 55% of physicians were satisfied with the clinical laboratory services.
Abebe et al, 2022[32]	To assess clinicians' satisfaction with laboratory services delivered at public hospitals and health centres.	East amhara	Facility based cross sectional study	Clinicians (doctors, health officers and nurses)	Most clinicians reported the absence of a laboratory handbook (75.1% out of 224 clinicians). More than one-third claimed to receive test results out of the expected TAT (34.4%), quality/ reliability of test results inconsistent (35.3%), and backup/specimen referral system unavailable (42.5%) or backup test results unreliable (38.3%). The overall percentage of satisfied clinicians with laboratory services was 72.8%.

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Table 1 (Continued).

Authors/ Publication Year/ Reference/	Objective of the Study	Study Setting	Study Design	Study Group	Summary of Findings
Deress et al, 2020[33]	To provide an estimated pooled satisfaction level of clinical laboratory customers with laboratory services	Ethiopian laboratories	Systematic review and meta analysis	Customers	The analysis of 18 Full text articles showed that the level of clinical laboratory service satisfaction among Ethiopian laboratories ranged from 48–91%. The pooled estimate was 66%.
Bogale and Baye, 2021[34]	To assess the effect of customer satisfaction as a quality indicator in medical laboratory services of the national reference laboratory to generate evidence based information for some programmatic initiatives.	EPHI	Facility based survey	Customers (clinicians, laboratory professionals andpatients)	42 clinicians and 37 laboratory professionals were considered. Clinician's satisfaction was 85.7% and 91.9%, while patient's satisfaction was 95.0% and 88.4%, and laboratory professional's satisfaction was 75.7% and 80.6% in the first and second round survey respectively.
Assemahegn, 2014[35]	To assess the quality of tuberculosis laboratory services in selected public and private health facilities in Western Amhara	Western Amhara	Institution based cross sectional study	Health facilities / laboratory professionals / patients	Almost all, 38 from 47 private laboratory technicians reported as they did not get regular supportive supervision and feedback from governmental health offices. More than half, 80 (67.0%) laboratory personnel from public and private reported the presence of unfair distribution of reagents, trainings, reporting formats, registration books, manuals, equipments and incentives among health institutions. Only 27 (45.0%) TB laboratories run quality control smears while performing routine tests.
Dabaro, 2017[36]	To investigate the factors affecting tuberculosis case detection in Kersa District, south west Ethiopia.	Kersa district/ Jimma zone	Institution based cross sectional study	Health centeres/ health workers/ patients	4 health centeres, 18 health workers, and 384 patients were considered for the study. Significant number, 135 (35.2%) of tuberculosis suspects were not requested for microscopic examination of sputum smear, the laboratory results 21 (8.4%) of requested patients were not recorded in both patient folders and laboratory registers. Only 10 (4.4%) of those examined and recorded were smearing positive.
Getachew et al, 2019[37]	To assess the coverage and quality of selected clinical chemistry tests among medical laboratories of health facilities	Jimma zone	cross sectional study	Laboratories	Out of the total participated health facilities (86), only 20 (23%) were givingclinical chemistry service. The main reason for these laboratories not to undertake the clinical chemistry test service was lack of financial efficiency to employ lab personnel and to purchase machine and reagents which accounts 63/66 (95%).

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Table 1 (Continued).

Authors/ Publication Year/ Reference/	Objective of the Study	Study Setting	Study Design	Study Group	Summary of Findings
Mesfin et al, 2017[38]	To assess factors affecting the quality of laboratory service at private and public health institutions	Addis Ababa	Cross sectional study	Public and private laboratories / laboratory professionals	187 of 213 (87.8%) of the laboratory professionals were not satisfied with their salary and 178 of 213 (83.6%) respondents indicated that there was no system for staff recognition, and 133 of 213 (62.4%) of the laboratory professionals did not attend any task specific training and 128 of 213 (60.1%) continuing education program. A total of 150 (70.4%) of the laboratory professionals had high workload while 125 (58.7%) of the respondents indicated a shortage of human resources in their laboratories.
Abebaw et al, 2022[39]	To assess the quality assurance practices in the tuberculosis diagnostic health facilities of Ethiopia	Selected health facilities of Ethiopia	cross sectional study	Diagnostic laboratories	From a total of 34 Xpert® MTB/RIF testing laboratories, 50% run Internal Quality Control (IQC) for Acid-Fast Bacillus (AFB) Microscopy and 67.6% had lot-to-lot verification of staining reagents. All 9 TB-culture laboratories included in the study ran negative control (start and end IQC) during TB-culture sample processing and performed lot-to-lot verification for Mycobacteria Growth Indicator Tube (MGIT) in 88.9% of TB-culture laboratories.
Weldu et al, 2017[40]	To assess the utilization of standard operating procedures for acid-fast bacilli (AFB) smear microscopy	Mekelie city, Tigray region	Facility based cross sectional study	Laboratories	Of the 18 laboratory facilities, only seven (38.9%) had a legible AFB registration book. Most laboratories, 16 (88.9%) and 17 (94.4%), respectively, did not run positive and negative controls after new batch reagent preparation
Fenta and Ali, 2020[41]	To determine factors affecting the quality of laboratory results through the entire process	Hawassa University hospital	Cross sectional study	Patients / clinicians / laboratory professionals	From a total of 40 laboratory professionals 18 (45%) did not attend any work-related refreshment training, 19 (47.5%) of them believed that their laboratories did not produce quality laboratory results for their patients. according to the laboratory professionals, the major factors affecting the quality of laboratory results in this study were the shortage of supplies and reagents (95%), poor management support (72.5%), high workload 35 (87.5%), missing of laboratory results 28 (70%) and lack of equipment 37 (92.5%). From clinical service provider, 173 (74.90%), and 199 (86.1%) responded as the laboratory test result is not trustful and the laboratory service is not efficient repectively.

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Table 1 (Continued).

Authors/ Publication Year/ Reference/	Objective of the Study	Study Setting	Study Design	Study Group	Summary of Findings
Hailegiorgis et al, 2010[42]	To assess laboratory malaria diagnostic capacity in health facilities in five administrative zones of Oromia Regional State, Ethiopia	Oromia region	Institution based cross sectional study	health facilities	Of 69 facilities surveyed, 53 provided both comprehensive malaria laboratory diagnosis and outpatient treatment services, five provided malaria microscopy services (referring elsewhere for treatment), and 11 primary care health posts provided rapid diagnostic testing and outpatient malaria treatment. Of the 58 facilities providing laboratory services,24% of the 159 laboratory staff had received malaria microscopy training in the year prior to this survey. None of the surveyed laboratory facilities had formal quality assurance / quality control protocols for either microscopy or RDTs
Desale et al, 2013[43]	To assess the status of laboratory logistics management information system for HIV/ AIDS and TB laboratory commodities at selected public health facilities in Addis Ababa	Addis Ababa	Cross sectional descriptive study	Health facilities / laboratory professionals / pharmacy professionals	From a total of 114 professionals involved in laboratory commodity management, 71 (62.3%) were trained in logistics management information system (integrated pharmaceutical logistics system or Ethiopian laboratory logistics system). Of these, 67 (58.8%) were pharmacy professions and 4 (3.5%) were laboratory professionals.
Shumbej et al, 2020[44]	To assess essential in-vitro laboratory service provision in accordance with the WHO standards in Guragae Zone primary health care unit level, South Ethiopia	Guragae Zone, south Ethiopia	Institution based cross sectional study	Health facilities	Of the surveyed facilities, all PHCU had at least one electric binocular microscope, glucometer, centrifuge, and refrigerator. Otherwise, all surveyed facilities had limited major laboratory equipment and consumables.
Dellie et al, 2019[45]	To assess intentions to leave workplace and associated factors among laboratory professionals working at public hospitals	Amhara region	Institution based cross sectional study	Laboratory professionals	Over all 336 laboratory professionals were considered for this study. The overall intention to leave hospitals among laboratory professionals in the study was 65.5%, whereas 179 of 336 (53.3%) of the LPs had intentions to leave their jobs.

understood the requirements, the importance and the outcomes of the SLMTA program, while the others seven CEOs (41%) were uncertain.[17]

In this review, the service quality of medical laboratories was assessed with five quality indicators; namely frequency of laboratory errors, proficiency test performance, specimen rejection rate, turnaround time, and customer satisfaction.

Frequency of Laboratory Errors

In frequency of laboratory errors, six papers[18–23] were looked at specific major technical laboratory errors. Shiferaw et al,[18] showed that 47 of 201 (23.4%) laboratories in the study had major false positive and false negative errors in diagnosing tuberculosis. Similarly, Mekonen et al[19] showed that 20 of 55 (36.4%) health center laboratories had false positive and false negative results in diagnosing tuberculosis. In addition, Desalegn et al[20]

demonstrated that only 96 of 135 (68.9%) peripheral laboratories read positive and negative AFB slides correctly. Measuring with some indicators like smear size, specimen quality, smear thickness, smear evenness and smear cleanliness, Weldemhret et al[21] showed that the performance of sputum smear quality were 68%, 61, 64%, 62 and 66% respectively. On the other hand, Tadesse et al study[22] showed that 742 of 2606 (28.5%) hematology laboratory specimens in the study had different technical errors. One study conducted, Teka and Kibatu[23] showed that 65% of the 213-control measurement values were outside of the allowable errors limits in clinical chemistry laboratory.

Proficiency Test Performance

In proficiency test performance, one paper was looked at for evaluating the performance of laboratory professionals in tuberculosis microscopy. Mengistu et al[24] showed that only 11 of 81 (13.6%) laboratory professionals reported all positive and negative tuberculosis smear panel slides correctly. The others 70 of 81 (86.4%) laboratory professionals reported at least one false positive or false negative result in tuberculosis microscopy.

Specimen Rejection Rate

In specimen rejection, two articles were looked at for evaluating service quality of medical laboratories. Habtamu Molla et al[25] showed that 116 of 8063 (1.4%) laboratory specimens were rejected due to different technical errors. Similarly, Shiferaw et al[26] noted that 221 of 42,923 (0.5%) laboratory samples were rejected.

Turnaround Time (TAT)

In turnaround time, two articles were looked at to evaluate service quality of medical laboratories. Gebreyes et al[27] showed that only 41 of 253 (16.2%) clinical chemistry test results were released within the target TAT. Shiferaw and Yismaw[28] also showed that 68.1% of the EID for HIV, 53.8% of the TB genexpert tests and 76.5% of the viral load had delayed turnaround time compared with the standard.

Customer Satisfaction

In customer satisfaction, five articles were looked at to evaluate service quality of medical laboratories. Studies showed that different customers of laboratories had different level of satisfaction. For example, Desalegn et al[29] noted that 240 of 422 (56.9%) pregnant mothers were satisfied with Focused Antenatal Care (FANC) laboratory service. A study conducted on satisfaction level of patients (n=502), 73.5% of patients were found to be satisfied.[30] In another national survey analysis, the satisfaction level of physicians (medical doctors) in medical laboratory services was 55%.[31] In one study, the clinician's (medical doctors, nurses and health officers) satisfaction level with clinical laboratory services was 72.8%.[32] However, the pooled client satisfaction level with medical laboratory services was 66%.[33]

Quality Challenges

In this review, the quality challenges were demonstrated in three categories, which includes problems associated with laboratory professionals, inadequate support from management bodies and others.

Problems Associated with Laboratory Professionals

The main problems were improper provision of information,[30,33,34] lack of commitment,[11,12,17,22,35,36] poor professional skill,[15,18,19,21,23,24,32,37,38] poor communication,[31–33,35] poor internal quality control practice[19,23,29,35,36,39,40] and inadequate utilization of laboratory documents.[13,14,31,32,35,40,41]

Inadequate Support from Management Bodies

In this category, quality challenges were limited budget allocation for laboratory,[15–17,35,37,38,41] poor laboratory infrastructure,[11,13,16,30,42] limited supply of reagents and equipment's,[16,18,20,23,28,29,36,41–44] poor recognition and rewards for laboratory professionals.[45]

Others

The other quality challenges were limited on job training access[9,14,17,26,35,36,41,43] and high workload.[27,28,38,41,42]

Discussion

Practicing quality management is possible in medical laboratories of resource-limited countries.[46] However, it was found to be weak implementation status.[47] Our systematic review of 36 studies on implementation of quality management system showed that even though there was good beginning in most medical laboratories, still QMS was not achieved as expected in each laboratory.[11–17]

Practicing the system of quality management facilitated the attainment of target quality indicators, and led to high client satisfaction.[48] An interrupted practice of quality systems may cause a services quality decline and hence poor accreditation achievement.[49] According to this review, service quality among Ethiopian medical laboratories was limited. This fact was shown with different quality indicators like frequency of laboratory errors, proficiency test performance, specimen rejection rate, turnaround time and customer satisfaction level. The error rate in medical laboratory diagnostics is about 0.3% according to accurate and recent information retrieved from scientific literature.[50] However, the error rate in most medical laboratories of Ethiopia was higher than 0.3%.[18–23] Even though the variety of proficiency testing was limited, AFB proficiency test performance in most Ethiopian medical laboratories was good when we compared to the standard passing score.[51] As a standard, specimen rejection rate in medical laboratories should be below 0.3%.[52] When we evaluated the service quality of medical laboratories with the standard specimen rejection rate, most Ethiopian medical laboratories had poor quality services.[25,26] In addition, this review noted that most laboratory tests had delayed TAT.[27] As good performance laboratory indicator, at least 90% of the tests need to be released within the target turnaround time.[28] Customer satisfaction also considered as laboratory service quality indicator and serves as an important improvement process tool using benchmark satisfaction level of 80% and above.[53] The overall customer satisfaction level in most Ethiopian medical laboratories was below this benchmark satisfaction level.[29–33]

Accessing quality laboratory services is a challenge in low-resource countries.[54] According to this review, the main challenges of laboratory service were problems associated with laboratory professionals,[11,13,15,19] inadequate support from management bodies,[11,15,16,45] high workload[27] and limited on job training access.[9] A similar study in Nigerian medical laboratories showed that poor infrastructure, financial limitations, insufficient capacity building, lack of consumables and equipment's, and motivated and dedicated laboratory personnel have been the main service quality challenges.[55] Another study at hospitals and institutions of Sri Lanka showed that the main challenges of quality services were lack of knowledge on ISO standards and limited training access for laboratory professionals.[56]

Conclusion

The status of quality management practice among medical laboratories in Ethiopia is limited. The main quality compromising factors were problems associated with laboratory professionals, inadequate support from management bodies, high workload, and limited on-job training access. Therefore, all responsible stakeholders should focus on ensuring Quality Management Systems and the system should be applied in all Medical laboratories. Only this will ensure the improvement of quality within medical laboratories across Ethiopia.

Recommendation

This review strongly recommends that regional health bureaus, Ethiopian public health institute, Ethiopian Ministry of Health, and other stakeholders should focus on strengthening and implementation of quality management among medical laboratories to ensure the overall quality of healthcare system.

Disclosure

The authors report no conflicts of interest in this work.

References

1. World Health Organization. *Laboratory Quality Management System: Handbook*. World Health Organization; 2011.

2. Berte LM, Nevalainen DE. Quality management for the laboratory. *Lab Med*. 1996;27(4):232–235. doi:10.1093/labmed/27.4.232
3. Carlson RO, Amirahmadi F, Hernandez JS. A primer on the cost of quality for improvement of laboratory and pathology specimen processes. *Am J Clin Pathol*. 2012;138(3):347–354. doi:10.1309/AJCPSMQYAF6X1HUT
4. Joint W. *CDC Conference on Health Laboratory Quality Systems*. Geneva: World Health Organization; 2008.
5. Plebani M. The detection and prevention of errors in laboratory medicine. *Ann Clin Biochem*. 2010;47(2):101–110. doi:10.1258/acb.2009.009222
6. Saurav Patra M, Mukherjee B, Das AK. Pre-analytical errors in the clinical laboratory and how to minimize them. *Int J Bioassays*. 2013;2 (3):551–553.
7. Simpson K, Kaluzny A, McLaughlin C. Total quality and the management of laboratories. *Clin Lab Manage Rev*. 1991;5(6):448–9, 52.
8. Westgard J, Barry P, Tomar R. Implementing total quality management (TQM) in health-care laboratories. *Clin Lab Manage Rev*. 1991;5(5):353–5, 8.
9. Sisay A, Gurmessa A, Liknew W. Factors affecting implementation of laboratory quality management system in *Addis Ababa* public health laboratories, *Addis Ababa, Ethiopia*. *J Trop Dis Public Health*. 2019;8:343.
10. Moher D, Shamseer L, Clarke M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Syst Rev*. 2015;4(1):1–9. doi:10.1186/2046-4053-4-1
11. Girma M, Deress T, Adane K. Laboratory Quality Management System and Quality Indicators Implementation Status as Perceived by Laboratory Professionals in Preparation for the Accreditation Process from Selected Government Hospitals of Ethiopia. *Clin Lab*. 2020;66:4. doi:10.7754/Clin.Lab.2019.190718
12. Mesfin EA, Taye B, Belay G, Ashenafi A. The status of medical laboratory towards of AFRO-WHO accreditation process in government and private health facilities in Addis Ababa, *Ethiopia*. *Pan Af Med J*. 2015;22:1. doi:10.11604/pamj.2015.22.136.7187
13. Mulleta D, Jaleta F, Banti 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. doi:10.2147/PLMI.S314656
14. Hiwotu TM, Ayana G, Mulugeta A, et al. Laboratory system strengthening and quality improvement in Ethiopia. *Af j lab med*. 2016;5(2):1–6.
15. Getahun MS, Yemanebrhane N, Desalegn DM, et al. Medical laboratory accreditation in a resource-limited district health centre laboratory, Addis Ababa, *Ethiopia*. *Af J Lab Med*. 2019;8(1):1–5.
16. Sisay A, Mindaye T, Tesfaye A, Abera E, Desale A. Assessing the outcome of Strengthening Laboratory Management Towards Accreditation (SLMTA) on laboratory quality management system in city government of Addis Ababa, *Ethiopia*. *Pan Afr Med J*. 2015;1:20.
17. Lulie AD, Hiwotu TM, Mulugeta A, et al. Perceptions and attitudes toward SLMTA amongst laboratory and hospital professionals in Ethiopia. *Af J Lab Med*. 2016;5(2):1–6.
18. Shiferaw MB, Hailu HA, Fola AA, et al. Tuberculosis laboratory diagnosis quality assurance among public health facilities in West Amhara Region, Ethiopia. *PLoS One*. 2015;10(9):e0138488. doi:10.1371/journal.pone.0138488
19. Mekonen A, Ayele Y, Berhan Y, Woldeyohannes D, Erku W, Sisay S. Factors which contributed for low quality sputum smears for the detection of acid fast bacilli (AFB) at selected health centers in Ethiopia: a quality control perspective. *PLoS One*. 2018;13(6):e0198947. doi:10.1371/journal.pone.0198947
20. Desalegn DM, Kitila KT, Balcha HM, et al. Misdiagnosis of pulmonary tuberculosis and associated factors in peripheral laboratories: a retrospective study, Addis Ababa, *Ethiopia*. *BMC Res Notes*. 2018;11(1):1–7. doi:10.1186/s13104-018-3414-6
21. Weldemhret L, Hailu A, Gebremedhn G, et al. Blinded rechecking of sputum smear microscopy performance in public health facilities in Tigray region, Northern Ethiopia: retrospective cross sectional study. *PLoS One*. 2020;15(10):e0239342. doi:10.1371/journal.pone.0239342
22. Tadesse H, Desta K, Kinde S, Hassen F, Gize A. Errors in the Hematology Laboratory at St Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia BMC Research Notes. *Int J Med*. 2018;11(1):1–5.
23. Teka A, Kibatu G. Quality of liver and kidney function tests among public medical laboratories in western region of Amhara national regional state of Ethiopia. *Ethiop J Health Sci*. 2012;22(1):19–26.
24. Mengistu H, Abebe M, Gezahegn B, Tadesse A, Yismake W, Moges D. Performance evaluation of laboratory professionals on tuberculosis microscopy at Hawassa Town, Southern Ethiopia. *Af J Microbiol Res*. 2015;9(16):1132–1138. doi:10.5897/AJMR2015.7402
25. Habtamu Molla T, Aster T, Fatuma H. *Frequency of Specimen Rejection and Associated Factors St*. Paul's Hospital Millennium Medical College, Addis Ababa Ethiopia; 2015.
26. Shiferaw MB, Yismaw G, Getachew H. Specimen rejections among referred specimens through referral network to the Amhara Public Health Institute for laboratory testing, Bahir Dar, Ethiopia. *BMC Res Notes*. 2018;11(1):1–6. doi:10.1186/s13104-018-3891-7
27. Gebreyes M, Sisay A, Tegen D, Asnake A, Wolde M. Evaluation of Laboratory Performance, Associated Factors and Staff Awareness Towards Achieving Turnaround Time in Tertiary Hospitals, Ethiopia. *Ethiop J Health Sci*. 2020;30:5. doi:10.4314/ejhs.v30i1.2
28. Shiferaw MB, Yismaw G. Magnitude of delayed turnaround time of laboratory results in Amhara Public Health Institute, Bahir Dar, Ethiopia. *BMC Health Serv Res*. 2019;19(1):1–6. doi:10.1186/s12913-019-4077-2
29. Desalegn DM, Abay S, Abebe A, et al. Quality of focused antenatal care laboratory services provided at public health facilities in Addis Ababa, Ethiopia. *Qual Prim Care*. 2017;26(3):81–89.
30. Abebe DD, Hassen SL, Temesgen MM. Patients' satisfaction and quality of clinical laboratory services provision at public health facilities in northeast Ethiopia. *medRxiv*. 2022.
31. Hailu HA, Yalew A, Desale A, et al. Physicians' satisfaction with clinical laboratory services at public hospitals in Ethiopia: a national survey. *PLoS One*. 2020;15(4):e0232178. doi:10.1371/journal.pone.0232178
32. Abebe DD, Temesgen MM, Abozin AT. Clinicians' perceived quality of laboratory services provided at public hospitals and primary health centres in northeast Ethiopia. 2022.
33. Deress T, Million Y, Belachew T, Girma M. Customer satisfaction with clinical laboratory services provided by the Ethiopian health facilities: a systematic review and meta-analysis. 2020.
34. Bogale AL, Baye AY. Customer Satisfaction Survey as Quality Indicator on Laboratory Medicine Accreditation: the Case of EPHI National HIV Molecular Reference Laboratory. 2021.
35. Asemahagn M. Assessing the quality of tuberculosis laboratory services in selected public and private health facilities in Western Amhara, Ethiopia. *J Med Diagn Meth*. 2014;3(158):2. doi:10.4172/2168-9784.1000158

36. Dabaro D. Factors affecting tuberculosis case detection in Kersa district, south west Ethiopia. *J Clin Tuberculosis Other Mycobacterial Dis*. 2017;9:1–4. doi:10.1016/j.jctube.2017.08.003
37. Getachew A, Cheneke W, Asres Y, Bekele S, Kebede E. Assessment of coverage and quality of selected clinical chemistry tests among medical Laboratories of Health Facilities in Jimma zone, South West Ethiopia. *J Trop Med*. 2019;2019.
38. Mesfin EA, Taye B, Belay G, Ashenafi A, Girma V. Factors affecting quality of laboratory services in public and private health facilities in Addis Ababa, Ethiopia. *Ejifcc*. 2017;28(3):205.
39. Abebaw Y, Kebede A, Eshetu K, et al. Quality assurance practices in tuberculosis diagnostic health facilities in Ethiopia. *PLoS One*. 2022;17(6): e0269601. doi:10.1371/journal.pone.0269601
40. Weldu Y, Gebru H, Kahsay G, Teweldemedhn G, Hagos Y, Kahsay A. Standard operating procedure utilization for tuberculosis microscopy in Mekelle City, North Ethiopia. *Am J Clin Pathol*. 2017;147(1):83–88. doi:10.1093/ajcp/aqw196
41. Fenta DA, Ali MM. Factors affecting quality of laboratory result during ordering, handling, and testing of the patient's specimen at hawassa university college of medicine and health science comprehensive specialized hospital. *J Multidiscip Healthc*. 2020;13:809. doi:10.2147/JMDH.S264671
42. Hailegiorgis B, Girma S, Melaku Z, et al. Laboratory malaria diagnostic capacity in health facilities in five administrative zones of Oromia Regional State, Ethiopia. *Trop Med Int Health*. 2010;15(12):1449–1457. doi:10.1111/j.1365-3156.2010.02646.x
43. Desale A, Taye B, Belay G, Nigatu A. Assessment of laboratory logistics management information system practice for HIV/AIDS and tuberculosis laboratory commodities in selected public health facilities in Addis Ababa, Ethiopia. *Pan Af Med J*. 2013;15:1. doi:10.11604/pamj.2013.15.46.1969
44. Shumbej T, Menu S, Gebru T, et al. Essential in-vitro laboratory diagnostic services provision in accordance with the WHO standards in Guragae zone primary health care unit level, South Ethiopia. *Trop Dis Travel Med Vaccines*. 2020;6(1):1–7. doi:10.1186/s40794-020-0101-0
45. Dellie E, Andargie Biks G, Asrade G, Gebremedhin T. Intentions to leave and associated factors among laboratory professionals working at Amhara National Regional State public hospitals, Ethiopia: an institution-based cross-sectional study. *BMC Res Notes*. 2019;12(1):1–7. doi:10.1186/s13104-019-4688-z
46. Tamil Selvi M, Implementing AS. QMS and accreditation standards in medical diagnostics for quality of services. *Med Lab J*. 2019;13(1):37–41. doi:10.29252/mlj.13.1.37
47. Schroeder LF, Amukele T. Medical laboratories in sub-Saharan Africa that meet international quality standards. *Am J Clin Pathol*. 2014;141 (6):791–795. doi:10.1309/AJCPQ5KTKAGSSCFN
48. Musau S, McCarthy K, Okumu A, et al. Experience in implementing a quality management system in a tuberculosis laboratory, Kisumu, Kenya. *Int J Tuberculosis Lung Dis*. 2015;19(6):693–695. doi:10.5588/ijtld.14.0886
49. Tamil SM, Srinivas A. Evaluation of quality management systems implementation in medical diagnostic laboratories benchmarked for accreditation. *J Med Lab Diagnosis*. 2015;6(5):27–35. doi:10.5897/JMLD2015.0104
50. Carraro P, Plebani M. Errors in a stat laboratory: types and frequencies 10 years later. *Clin Chem*. 2007;53(7):1338–1342. doi:10.1373/clinchem.2007.088344
51. Aziz MA. External quality assessment for AFB smear microscopy. 2002.
52. Dale JC, Novis DA. Outpatient phlebotomy success and reasons for specimen rejection: a Q-Probes study. *Arch Pathol Lab Med*. 2002;126 (4):416–419.
53. Bharadwaj S. Customer satisfaction leads to sustainable competitive advantage: with special reference to the Lalimou eco-tourism camp in Nameri national park. *Int J Res Humanities Arts Literature*. 2018;6(7):29–38.
54. Mekonen T, de Dieu Iragena J, Albert H, Kao K, Erni D, Onyebujoh PC. Implementation of quality management systems and progress towards accreditation of National Tuberculosis Reference Laboratories in Africa. *Af J Lab Med*. 2017;6(2):1–8.
55. Nwaokorie F, Ojo E. Overview of the implementation of quality management system in Nigerian medical laboratories. *Univ Lagos J Basic Med Sci*. 2021;6:548.
56. De Silva S, Gunarathna HT, Rajakulasooriya R, Thambavita D. Assessment of knowledge and practices related to technical requirements recommended by ISO 15189: 2012 standards among medical laboratory technology staff in tertiary care hospitals and institutions in Western Province, Sri Lanka. 2021.