

Determinants of Quality Laboratory Service Provision among Government Comprehensive Specialized Hospitals in Northwest Ethiopia

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Abstract

Introduction: Clinical laboratory services are essential for accurate diagnosis and effective disease management. However, many developing countries operate poorly with persistent technical and administrative barriers. The results create challenges misdiagnosis, inappropriate clinical decisions, increased patient morbidity, and unnecessary healthcare costs. Despite the expansion of comprehensive specialized hospitals in Ethiopia, evidence on the specific technical and administrative determinants of quality laboratory services are limited. This study aimed to identify key determinants affecting the quality of laboratory services in government comprehensive specialized hospitals in Northwest Ethiopia.

Methods: An institution-based cross-sectional study was conducted from May to July 2023 in comprehensive specialized hospitals in Northwest Ethiopia. Data were collected using a pre-tested self-administered questionnaire and observation checklist. Quantitative data were analyzed using descriptive statistics and multivariable logistic regression in STATA version 14.1, with statistical significance set at $p < 0.05$. A standardized checklist was used to assess technical determinants (workflow organization, equipment reliability and maintenance, service continuity, and power stability) and administrative determinants (quality management, adherence to standard operating procedures, documentation, turnaround time, quality assurance, inventory control, feedback mechanisms, and staff training).

Results: Among 306 laboratory professionals from five comprehensive specialized hospitals, the overall quality of laboratory services was 51.6% (95% CI: 46.01–57.22). Higher quality was independently associated with effective physician communication (AOR = 2.91), access to continuing professional education (AOR = 2.67), refresher training (AOR = 3.99), adequate laboratory equipment (AOR = 3.50), and sufficient staffing (AOR = 3.75). Observation of thirty laboratory rooms revealed major technical and administrative gaps, including inadequate equipment, poor maintenance, limited training, weak documentation, and inconsistent standard procedures.

Conclusion: Laboratory services in government comprehensive specialized hospitals were suboptimal, with gaps in laboratory–physician communication, staff training, equipment,

57 and staffing, potentially causing misdiagnosis, suboptimal clinical decisions, increased
58 patient morbidity, and unnecessary healthcare costs.

59

60 **Keywords:** Clinical laboratory, quality management system, determinants, Ethiopia

Introduction

High-quality laboratory services are essential in improving diagnoses [1, 2], accurate disease prevention and control [3-5], and significant in disease management [6, 7]. It also impacts public health disease surveillance and the development of policies [8, 9]. Quality services are expressed in terms of accuracy, reliability, and meeting the requirements of established standards [10] and guidelines [10, 11]. Accurate and reliable laboratory results enhance clinical decision-making, providing approximately 60%–90% of the essential evidence on which clinicians base their judgments [7, 11–14]. However, in many low-income countries, diagnoses and clinical interventions are frequently made using poor-quality laboratory results, undermining the credibility and effectiveness of healthcare services [15].

Well-designed laboratory systems that ensure accurate, reliable, and timely test results are essential [16]. Key elements include hiring competent staff and implementing robust internal quality control (IQC) measures, which are often overlooked [17, 18]. Healthcare institutions' failure to implement IQC can lead to significant accuracy and reliability issues [4].

The International Organization for Standardization (ISO) 15189 addresses the aspects of standards and guidelines [19, 20] using the audit, monitoring [21, 22], assessment, and evaluation processes [16, 23] for improved quality service [21]. The quality control measures emphasize root cause analysis and feedback for potential improvements [22]. The technology-assisted clinical decision entails a meticulous understanding of the merits and demerits of the [24-26]. Hence, planning better quality laboratory services must focus on implementing integrated laboratory information systems (LIM) supporting referral and reporting functionalities [27, 28].

The quality of laboratory services is influenced by a combination of technical capabilities, quality management systems, and staff motivational factors [1]. Ensuring adequate resources and implementing robust quality assurance systems are essential for providing high-quality services [29]. Nowadays, competition is the positive driver for more improved quality services [30]. Whereas, in less developed countries it is restricted in bigger cities where intermediate or peripheral levels suffer from limited resources, poor management, and lack of skilled or qualified personnel [31]. This compromises diagnosis and interventions impacting quality patient care [11, 32]. The result may be delayed due to either poor or inadequate communication with serious or suboptimal consequences [33,

34]. The mere timely analysis could not ensure the quality of results unless proper reporting systems are established and maintained.

The determinants of poor decision-making are inaccurate results [35, 36] and disorganized laboratory workflow [37]. Management support, employee commitment, and resources affect the quality of services [38, 39]. Developing countries suffer a mismatch between quality and the increased needs of customers [40]. Poor quality services increase costs [2, 11] and the spread of infectious diseases due to poverty and inadequate infrastructure [2, 3, 11, 32, 40]. Physicians using inaccurate results wrongly make management decisions [41]. Common challenges affecting the quality of laboratory services in sub-Saharan Africa include shortages of supplies, negative staff attitudes, unorganized workflows, and power interruptions [1, 11, 38]. Poor quality results increase healthcare costs, drug side effect sufferings [11], and patient risks [42]. The competence of staff and the suitability of work conditions also impact service quality [40]. Additionally, low salaries, high staff turnover, lack of motivation, and limited career development opportunities can contribute to poor-quality results [43, 44].

Delayed laboratory results can prolong diagnosis and management, leading to increased costs and workload [45]. Despite efforts to drive continuous quality improvement, medical organizations often struggle to integrate core approaches to success [46]. In Ethiopia, laboratory services have received limited attention and are under-resourced [43, 47], with poor-quality results accounting for up to 61.2% of clinical laboratory services and contributing to approximately 43% of treatment delays and 61% of longer hospital stays [3, 11, 48]. Low staff capacity, limited technology adoption, ineffective communication, and inadequate funding have been identified as key factors influencing patient satisfaction and perceptions of laboratory service quality [49]. Therefore, understanding the quality of laboratory services in Ethiopia is essential for designing targeted interventions and ensuring the delivery of standardized, high-quality care.

Methods

An institution-based cross-sectional study was conducted from May to July 2023 in government comprehensive specialized hospitals in northwest Ethiopia. The study was conducted in the Amhara Regional State of Ethiopia. The region comprises 4,293 public health facilities, including 12 general hospitals, 8 referral hospitals, 61 primary hospitals, 868 health centers, and 3,342 health posts. According to regional estimates, the total population of the Amhara Region is approximately 22,536,999 [50, 51].

Five comprehensive specialized hospitals were included in this study: Debre-Markos Comprehensive Specialized Hospital, Tibebe-Gihon Comprehensive Specialized Hospital, Felege-Hiwot Comprehensive Specialized Hospital, Debre-Tabor Comprehensive Specialized Hospital, and the University of Gondar Comprehensive Specialized Hospital. All laboratory professionals working in these five hospitals participated in the study. A total of 306 laboratory professionals were employed across the five hospitals, with the following distribution: Gondar (93), Felege-Hiwot (75), Tibebe-Gihon (48), Debre-Tabor (60), and Debre-Markos (30).

Operational definitions

Good quality service delivery: Performance score $\geq$ mean indicates good quality service delivery.

Poor-quality service: Performance score $<$ the mean refers to substandard or poor-quality service. In this study, respondents were asked to select the quality of laboratory service provision on a 2-point scale: 1 for “Yes” and 2 for “No.” The questionnaire used to assess quality laboratory practices consisted of 31 items.

Quality services score: The quality services score was calculated by adding the scores of each item and then determining the mean score to assess the overall quality of service in the laboratory [1].

Data collection tools and procedure

Self-administered questionnaire and observational checklist were used to collect the data. The questionnaire covered sociodemographic information, laboratory management

activities, quality practices, determinants influencing quality laboratory services, and associated quality factors. Five BSc nurses trained in data collection administered the pre-tested questionnaire to participants. Volunteer laboratory professionals working for at least six months were informed of the research objective (no direct incentive), the advantages and disadvantages of participation, and then given the pre-tested, self-administered questionnaire. All laboratory professionals politely requested their voluntary responses after clarifying the purpose of the study and their freedom. The voluntary laboratory professionals signed consent forms, and data were collected. Furthermore, institutional secondary data were collected and used for this research.

Data quality control

Data collection was conducted by five trained BSc nurses. A pre-test of the questionnaire was conducted on 5% of the study participants at the Woldia Comprehensive Specialized Hospital before collecting the actual data. The pre-test results were used to assess the validity and reliability of the data collection tool. The revised questionnaire was then distributed to the trained data collectors who subsequently administered it to the study participants. The principal investigator supervised the process to ensure complete data collection. Model fitness was assessed using the Hosmer–Lemeshow goodness-of-fit test. The test statistic (H) was 8.44 with a corresponding p-value of 0.08, indicating that the model adequately fit the data. In addition, multicollinearity was evaluated using the Variance Inflation Factor (VIF), with a mean VIF value of 1.64, suggesting no significant multicollinearity among the independent variables.

Data analysis and interpretation

The collected data were coded and entered into EpiData version 4.6 software. Subsequently, the data were exported to STATA version 14.1 for further analysis. Both descriptive statistics (such as frequencies and percentages) and inferential statistics were employed in the analysis. Initially, binary logistic regression analysis was conducted to identify candidate variables for multivariable logistic regression analysis. Variables with a p-value of ≤ 0.25 from the binary logistic regression were included in the multivariable regression analysis. The significance of their associations was confirmed using multivariable logistic regression, with a significance level set at $p < 0.05$. Variables with a p-value of < 0.05 in the final model were considered statistically significant. The study findings were presented in the form of texts, graphs, and tables, as appropriate.

Moreover, the data collected using observational checklist was used to systematically record detailed notes from thirty observed laboratory rooms. The collected data were coded and recoded based on the themes of technical and administrative determinants and alignment with study objectives was checked each time. Then data were subjected to thematic analysis using a systematic coding approach. A subsequent forward and backward review process was applied to refine codes, develop themes, and ensure consistency, enabling the identification and explanation of key technical and administrative determinants.

Results

Socio-demographic characteristics of study participants

Three hundred and six clinical laboratory professionals participated in the study. Among them, 179 (58.5%) were males and their interquartile age was (33 - 39 years). More than half of them have a first degree. Two hundred of the participants 146 (48%) were working in the main laboratories. Fifty-eight percent of the participants had more than 11 years of experience (Table 1).

Table 1 Socio-demographic characteristics of laboratory professionals working among comprehensive specialized hospital laboratories in Northwest Ethiopia

Variables	Categories	Frequency (n)	Percentage (%)
Age	20-30	48	15.7
	31-40	207	67.7
	41-50	46	15.0
	51-60	5	1.6
Sex	Male	179	58.5
	Female	127	41.5

Educational status	Master and above	70	22.9
	First degree	161	52.6
	Diploma	75	24.5
Service year	1-2	32	10.5
	3-5	40	13.2
	6-8	34	11.1
	9-11	22	7.2
	>11	178	58.2
Responsibility	Department head	25	8.2
	Quality officer	6	2.0
	Safety officer	5	1.6
	Technical staff	270	88.2
Laboratory discipline	Hematology	37	12.1
	Microbiology	43	14.1
	Clinical chemistry	31	10.1
	Immunology	34	11.1
	Blood bank	15	4.9
	Main laboratory/others	146	47.7

219

220 Laboratory quality management activities

221 Over half of the participants reported the absence of adequate quality equipment in the
222 laboratory. About 62% did not survey patient satisfaction, and 180 participants reported a
223 high workload. Nearly fifty-five percent of the laboratory staffs reported the absence of
224 system for the employee recognition (Table 2).

225 **Table 2** Laboratory quality management activities reported by laboratory professionals working in
226 comprehensive specialized hospitals in Northwest Ethiopia

Variables	Category	Frequency (n)	Percentage (%)
Knowledge of laboratory QSEs	Yes	236	77.1
	No	70	22.9
Laboratory communication with the physician	Yes	199	65.0
	No	107	35.0
Laboratory communication with upper management	Yes	154	50.3
	No	152	49.7
Laboratory communication among laboratory staff	Yes	264	86.3
	No	42	13.7
System for employee recognition	Yes	138	45.1
	No	168	54.9
Opportunity attending CPED	Yes	135	44.1
	No	171	55.9

Attending laboratory refreshing training	Yes	149	48.7
	No	157	51.3
Job description for the assigned task	Yes	162	52.9
	No	144	47.1
Adequate staff for laboratory service	Yes	187	61.1
	No	119	38.9
Availability of adequate quality supplies and reagent	Yes	131	42.8
	No	175	57.2
Available adequate quality equipment in the laboratory	Yes	141	46.1
	No	165	53.9
Conduct patient satisfaction survey	Yes	117	38.2
	No	189	61.8
Available quality manual in the laboratory	Yes	225	73.5
	No	81	26.5
Laboratory workload	High	180	58.8
	Faire	126	41.2

227

228 **Quality laboratory practices**

229 This study revealed that the majority of the study participants (77%, 236/306) reported
230 engaging in quality improvement activities. Over two-thirds (66.7%, 204/306) of
231 participants reported performing internal quality control (IQC) to ensure accurate results
232 for each test batch, while nearly the same proportion (60.8%, 186/306) met turnaround
233 times (TAT) for lab results. However, significant challenges were identified. Over 60% of
234 respondents (60.8%, 186/306) indicated inadequate laboratory supplies and reagents, and
235 an even greater proportion (68.6%, 210/306) reported insufficient laboratory budgets.
236 Additionally, more than half (50.7%, 155/306) of laboratory professionals did not perform
237 quality control procedures regularly (Table 3). Majority of the respondents 166 (54.2%)
238 responded their experience as an electronic manual hybrid form of laboratory data and
239 result management methods. Whereas, the remaining respondents reported the mere
240 manual data recording method.

241 **Table 3** Quality laboratory service provision among comprehensive specialized hospital
242 laboratories in Northwest Ethiopia

Variables	Response	
	Yes Frequency	No Frequency

	N (%)	N (%)
Adherence to the SOP	233 (76.1)	73 (23.9)
Equipment calibration and maintenance	185 (60.5)	121 (39.5)
Utilization of personnel protective equipment	240 (78.4)	66 (21.6)
Applying Lab safety practice	240 (78.4)	66 (21.6)
Standard test request and report format	257 (84.0)	49(16.0)
Provision of uninterrupted diagnostic service for all requested test	119 (38.9)	187 (61.1)
Perform Lab quality improvement activities	236 (77.1)	70 (22.9)
Laboratory result report within TAT	186 (60.8)	120 (39.2)
Customer service management	186 (60.8)	120 (39.2)
Achieve acceptable PT/EQA results	177 (57.8)	129 (42.2)
Lab result verification	184 (60.1)	122 (39.9)
Assuring the accuracy and completion of all tests	224 (73.2)	82 (26.8)
Perform IQC to verify the accuracy results on each batch	204 (66.7)	102 (33.3)
Document and review IQC before the release of the result	228 (74.5)	78 (25.5)
Improvement measures and follow-ups to fill gaps	231 (75.5)	75 (24.5)
Setting biological reference range for each test	272 (88.9)	34 (11.1)
Lab developed and monitors TAT	246 (80.4)	60 (19.6)
Date and time of specimen collection, receipt of specimen, and release of report	217 (70.9)	89 (29.1)
Periodically evaluate turnaround time	161 (52.6)	145 (47.4)
Laboratories provide quality Lab service	187 (61.1)	119 (38.9)
Availability of Lab guideline	237 (77.5)	69 (22.6)
Availability of Lab policies and procedures	267 (87.3)	39 (12.8)
Availability of quality control measures	263 (86.0)	43 (14.1)
External quality assessment programs	251 (82.0)	55 (18.0)
Adequate laboratory infrastructure	169 (55.2)	137 (44.8)
Adequate laboratory supplies and reagents	120 (39.2)	186 (60.8)
Adequate laboratory budget	96 (31.4)	210 (68.6)
Quality control performed regularly in Lab	151 (49.4)	155 (49.4)
Lab data and results are stored securely	260 (85.0)	46 (15.0)

243 Keys: EQA = External Quality Assessment; IQC = Internal Quality Control; Lab = Laboratory; PT =
244 Proficiency Test; SOP = Standard Operating Procedures; TAT = turnaround time

245

246 **Quality laboratory service provision related to technical and administrative**

247 Technical determinants refer to the factors that influence the design, development, and
248 implementation of a technical solution or system. These determinants include failure to
249 ensure the accuracy of tests, lack of documentation and review of IQC data before
250 releasing results, and a shortage of internal control reagents. Other technical determinants

251 include a lack of refresher training, high workload, poor equipment quality, and skill gaps
252 (Table 4).

253 **Table 4.** Factors affecting laboratory performance as reported by laboratory professionals
254 in comprehensive specialized hospitals in northwest Ethiopia

Variables (n)	Lack of refreshing training	High workload	Poor equipment quality	Skill gap
Equipment preventive maintenance not performed (95)	29(30.5)	23(24.5%)	30(31.6%)	13(13.7%)
Interrupted diagnostic service (32)	10(31.25%)	8(25%)	10(31.25%)	4(12.5%)
Non-adherence to standard operating procedures (57)	-	37(64.9%)	-	20(35.1%)
Lack of customer service management (31)	17(54.8%)	14(45.2%)	-	-
Laboratory results not reported within turnaround time (105)	-	37(35.2%)	48(45.7%)	20(19.1%)
Lack of laboratory result verification (105)	-	68(64.8%)	-	37(35.2%)
Absence of IQC activities conducted (80)	24(30%)	20(25.0%)	25(31.2%)	11(13.8%)
Failure to ensure accuracy and completion of all tests (59)	18(30.5%)	14(23.7%)	19(32.2%)	8(13.6%)
Failure to document and review IQC before release of results (66)	20(30.3%)	16(24.3)	21(31.8%)	9(13.6%)
Non-application of laboratory safety practices (41)	28(68.3%)	-	-	13(31.7%)
Inadequate laboratory data and results security (16)	11(68.8%)	-	-	5(31.2%)

255

256 The technical determinants influence the quality of laboratory service provision. The most
257 impactful determinant was high workload, followed by poor equipment quality, lack of
258 refresher training, and skill gaps, which affected the quality of laboratory service provision
259 at 36%, 33%, and 22%, respectively (Figure 1).

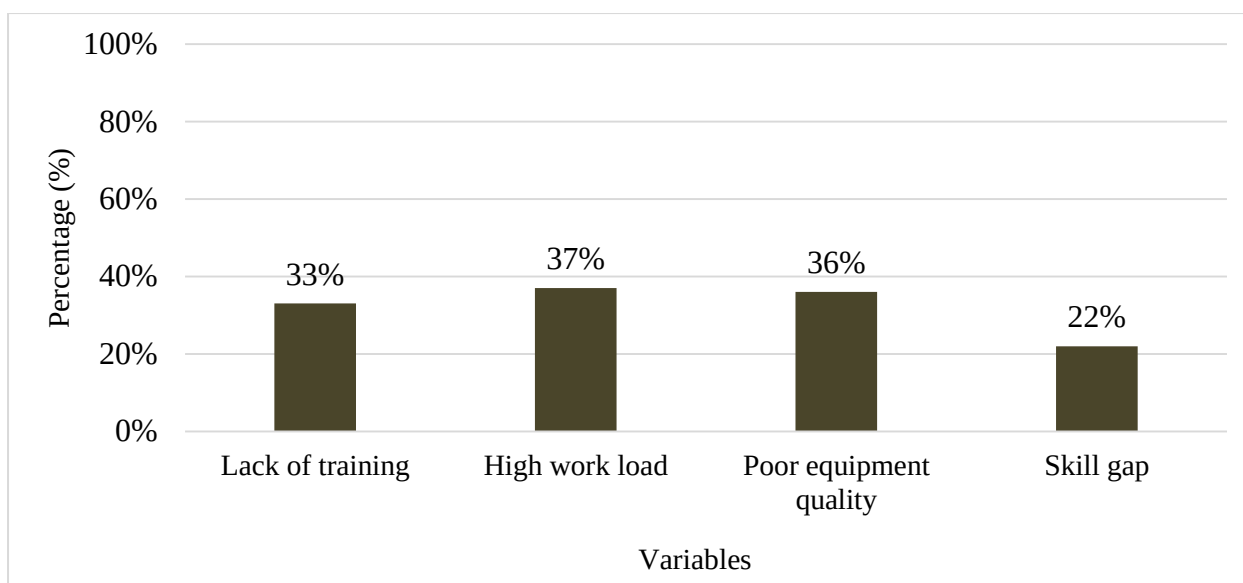


Figure 1 Technical determinant of quality clinical laboratory service provisions among comprehensive specialized hospitals in Northwest Ethiopia

Laboratory administration plays a crucial role in ensuring quality service. Its duties include explaining policies, procedures, and standards for compliance, along with the consequences of non-compliance. Additionally, the administration responds to reported issues and implements corrective actions to prevent recurrence. However, administrative shortcomings can negatively impact service quality. This study identified several factors affecting quality, including a lack of resources, low staff motivation, insufficient staffing levels, and inadequate management support (Table 5).

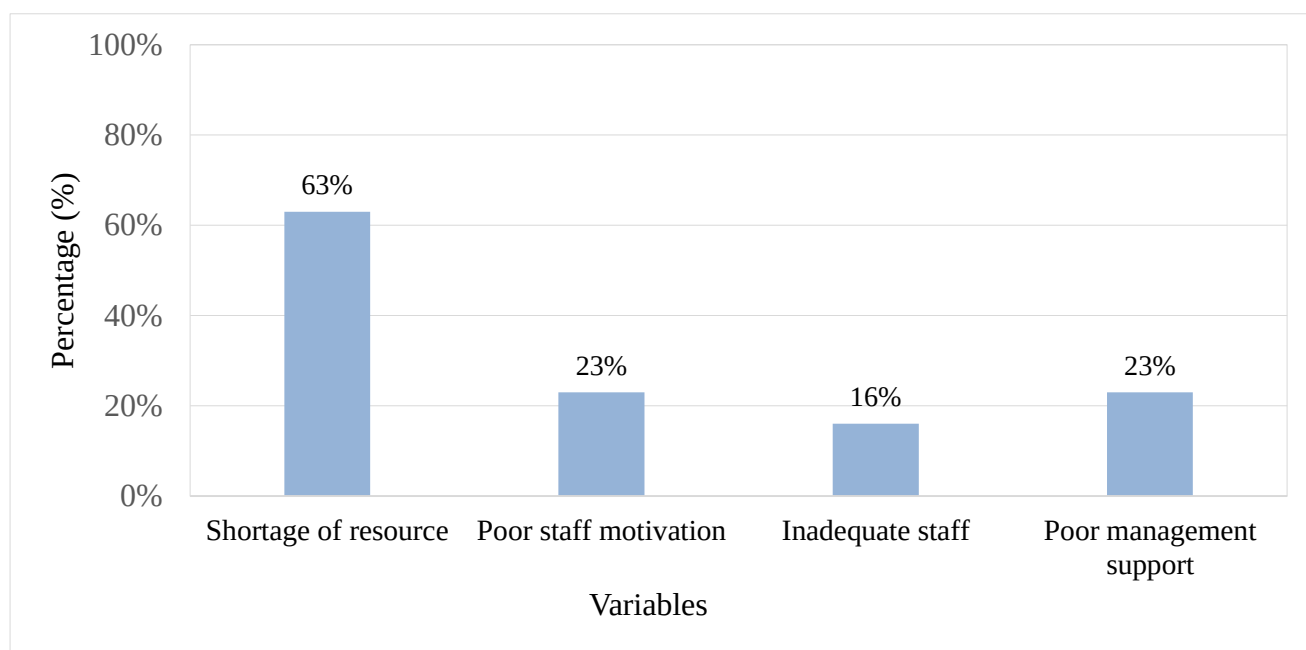
Table 5 Administrative determinants of quality laboratory practice reported by laboratory professionals working among comprehensive specialized in Northwest Ethiopia

Variables (n)	Shortage of resource	Poor staff motivation	Inadequate laboratory staff	Poor management support
Standard operating procedure non-adherence (16)	8(50%)	3(19%)	2(12%)	3(19%)
Lack of equipment preventive maintenance (26)	13(51%)	5(19%)	4(15%)	4(15%)
Absence of personnel protective equipment utilization (40)	30(75%)	-	-	10(25%)
Failure to apply laboratory safety practices (25)	13(38%)	5(25%)	3(12%)	5(20%)
Absence of standard test request and reporting format (33)	25(76%)	-	-	8(24%)
Lack of customer service management (90)	46(51%)	17(19%)	12(13%)	15(17%)

Inadequate laboratory infrastructure (116)	59(51%)	22(19%)	15(13%)	20(17%)
Insufficient laboratory budget (198)	148(75%)	-	-	50(25%)
Lack of periodic evaluation for turnaround time compliance (67)	-	26(39%)	18(27%)	23(34%)
Disrupted diagnostic service (155)	116(75%)	-	-	39(25%)
Delayed laboratory result verification (17)	-	10(59%)	7(41%)	-
Failure to report laboratory results within turnaround time (15)	-	9(60%)	6(40%)	-

273

274 These factors, termed “administrative determinants,” include poor human resource
275 management, insufficient resource allocation, weak management commitment, an
276 inefficient communication system, and the absence of a quality management system.
277 Particularly, the study found resource shortages to be the most influential determinant.
278 Staff motivation, management support, and insufficient staffing levels followed in
279 significance, ultimately impacting the quality of laboratory services (Figure 2).



280

281 **Figure 2** Administrative determinants of quality laboratory service provisions among
282 comprehensive specialized hospital laboratories in northwest Ethiopia

283 **Factors associated with quality laboratory service provision**

284 Study participants lacking knowledge of quality system essentials were 4.28 times more
285 likely to experience poor-quality laboratory service than those with adequate knowledge

(95% CI: 2.31-7.91, $p < 0.001$). Inadequate communication between the laboratory and other healthcare providers was also strongly linked to poor laboratory service quality, with participants without such communication being 4.93 times more likely to experience it (95% CI: 2.91-8.35, $p < 0.001$). Participants unable to engage in continuous professional education and development (CPED) were 6.40 times more likely to experience poor-quality laboratory service compared to those involved (95% CI: 3.88-10.58, $p < 0.001$). Similarly, a lack of quality laboratory equipment was significantly associated with poor-quality service, demonstrating a 6.76 times higher likelihood (95% CI: 4.09-11.17, $p < 0.001$). Insufficient laboratory staffing emerged as a significant predictor of poor-quality service, with a 6.25 times higher chance (95% CI: 3.70-10.54, $p < 0.001$). Other contributing factors included poor communication among laboratory professionals, the absence of patient satisfaction surveys (Table 6).

Table 6 Factors associated with quality laboratory service provision among comprehensive specialized hospital laboratory professionals in Northwest Ethiopia

Variables	Response	Quality service Good	Poor	COR (95%CI)	AOR (95%CI)	p-value
Knowledge of laboratory QSEs	Yes	132	104	1	1	
	No	16	54	4.28(2.31- 7.91)	2.15(0 .85- 5.43)	0.11
Laboratory communication with the physician	Yes	122	77	1	1	
	No	26	81	4.93(2.91- 8.35)	2.91(1.28- 6.59)	0.01*
Laboratory communication with upper management	Yes	98	56	1	1	
	No	50	102	3.57(2.22- 5.72)	0.80 (0.35-1.82)	0.59
Opportunity attending CPED	Yes	98	37	1	1	
	No	50	121	6.40(3.88- 10.58)	2.67(1.29 - 5.52)	0.01*
Attending laboratory refreshing training	Yes	106	43	1	1	
	No	42	115	6.74(4.09- 11.13)	3.99(2.03- 7.85)	0.01*
Job description for the assigned task	Yes	101	61	1	1	
	No	47	97	3.41(2.13- 5.47)	1.10(0 .55- 2.21)	0.79
Availability of adequate quality supplies and reagents	Yes	78	53	1	1	
	No	70	105	2.20(1.39- 3.50)	1.04(0.49 - 2.19)	0.91
Available adequate quality equipment in the laboratory	Yes	102	39	1	1	
	No	46	119	6.76(4.09- 11.17)	3.50(1.81- 6.80)	0.001*
Adequate staff for	Yes	121	66	1	1	

laboratory service	No	27	92	6.25(3.70- 10.54)	3.75(1.95-7.20)	0.01*
Quality manual	Yes	12	100	1	1	
	No	23	58	3.15(1.82- 5.46)	1.17(0.53- 2.61)	0.69
Patient satisfaction survey	Yes	70	47	1	1	
	No	78	111	2.12(1.33-3.39)	1.18(0.57- 2.45)	0.65
Communication between laboratory professional	Yes	136	128	1	1	
	No	12	30	2.65(1.30- 5.41)	0.85(0.29-2.53)	0.78
Employ recognition	Yes	83	55	1	1	
	No	65	103	2.39(1.51- 3.79)	0.59(.28- 1.24)	0.16

300

301 **Facility observation results**

302 Facility observations indicated that workloads across all thirty laboratory rooms were
303 generally well organized. Most laboratories (97%) demonstrated organized work processes
304 supported by quality policies and effective record control systems, while 93% had defined
305 and monitored turnaround times. Internal quality control practices were common, with
306 76.7% of laboratories regularly reviewing quality control documentation.

307 Preventive equipment maintenance in accordance with standard operating procedures was
308 observed in 63.3% of laboratories. Nearly all laboratories (97%) demonstrated compliance
309 quality assurance practices through the availability of standard operating procedures and
310 clear specimen rejection criteria. In contrast, customer service and feedback systems were
311 limited, with only one-third of laboratories having formal complaint and feedback
312 mechanisms, although 96% maintained an overall quality policy.

313 Most laboratories (83%) participated in external quality assurance programs, and 97%
314 implemented improvement measures with follow-up actions based on quality indicator
315 monitoring. Despite these efforts, notable logistical challenges were identified: only 20%
316 had adequate laboratory equipment, and just 3.3% maintained uninterrupted testing
317 services due to equipment failures in the past year. Electricity interruptions were less
318 frequent, with 63% of laboratories sustaining uninterrupted services. Inventory
319 management practices were limited, with 20% defining minimum and maximum stock
320 levels, 8% conducting routine stock counts with documentation, and 37% having adequate
321 storage space.

322 Analysis of thirty laboratory rooms identified key technical and administrative
323 determinants affecting performance. Technically, frequent issues included insufficient

equipment, irregular maintenance, and disorganized workspaces. Administratively, gaps were observed in staff training, documentation, and compliance with standard procedures. These findings highlight the critical interplay between technical and administrative factors in influencing laboratory efficiency and quality.

Discussion

The provision of quality laboratory services is crucial for accurate diagnoses, effective disease prevention, timely interventions, and improved patient outcomes [6]. Conversely, poor-quality services can lead to potential misdiagnosis, false negative results, and serious consequences, such as complications and increased patient stress. The overall quality laboratory service score of our study was 51.6% [95% CI: 46.0-57.2]), which is similar to the 47.5% score reported in a study conducted in Hawassa [52]. On the other hand, the finding is higher than the study conducted in Addis Ababa 35.2% [11]. On the contrary, the current finding was lower than the study done in Gondar (61.2%) [3]. The discrepancy in the quality of laboratory service scores across different studies can be attributed to several factors that influence the provision and evaluation of these services. Geographical and institutional disparities, including variations in resource allocation, infrastructure, and adherence to standards, significantly impact service delivery and evaluation. Differences in quality indicators, data collection methods, and scoring systems can lead to varying results

across studies, making direct comparisons difficult. In addition, changes in technology, policies, and resource use over time can affect laboratory performance and should be considered when interpreting quality scores.

About 56% of the study participants believed the lack of opportunities to attend CPED which is lower than the findings from Awi Zone (77%) [53] and Nigeria (87%) [54]. For the disparity in the findings, geographical, socioeconomic, and healthcare infrastructure variations across these regions could significantly influence the availability and accessibility of CPED programs. Additionally, differences in study methodologies, sample sizes, and participant characteristics might contribute to the observed discrepancy. Furthermore, the specific focus of CPED opportunities within each study could vary, leading to different levels of reported insufficiency. In the current study, participants who did not attend CPED training are 2.7 times more likely to provide poor-quality service. This shows the significance of ongoing education and professional development opportunities in improving and maintaining better quality services. The finding agrees with the previous studies done in Addis Ababa and Gondar [3, 11]. The lack of access to participate in the CPED program can negatively affect the laboratory's overall service quality and hinder the employees' competence, performance, and career growth, ultimately reducing the overall quality of service delivery [55].

Fifty-one percent of the study participants reported a lack of refresher training which is similar to the study done in Awi zone (54%) [53]. However, the result is much lower than the findings from Gondar (70%) [3] and Addis Ababa (62.4%) [11]. Conversely, the current finding is significantly higher than those from Ethiopia (22.2%) [36] and Malawi (34%) [40]. Potential reasons for these discrepancies include differences in facility type, sample size, study area, and population. Such variations may be attributed to factors like specific context, resource availability, and training program implementation across study locations. The finding from the present study reported that 55% inadequate quality laboratory equipment which is similar to a finding from Addis Ababa 56% [11]. However, it is much lower than a finding from Hawassa (93%) [52]. This may be due to infrastructure, capital budget differences, and management commitment. Facilities with adequate laboratory equipment are 3.5 times more likely to provide better quality results than their absence. This was supported by studies done in Malawi, in sub-Saharan Africa, Addis Ababa, Hawassa, Afar, and Gondar Town [3, 11, 40]. The probable reasons for equipment-related inferior quality may be a failure to run quality control, releasing quality

compromised output, lack of quality controls, and failure to apply regular and periodic equipment safety measures.

Thirty-nine percent of the respondents reported availability of inadequate laboratory staff. This is lower than the study done in Hawassa (59%) [52]. The difference in the availability of adequate laboratory staff between the two studies could be attributed to several factors. Workload and staffing requirements may vary between the locations, with the current study area potentially experiencing a lower overall workload manageable by the available laboratory staff. Additionally, sample size and sampling methodology differences between the studies could influence the representativeness of the findings. The smaller percentage of respondents reporting inadequate laboratory staff in the current study might suggest better staffing levels or more efficient resource allocation compared to the Hawassa study. However, further investigation is necessary to fully comprehend the reasons behind the observed disparity in this metric between the study locations. In this study, the inadequate number of laboratory staffs were found to be 3.8 times higher in providing poor-quality service than adequately staffed. This study is supported by the studies conducted in Addis Ababa [11] and in Hawassa [52].

Thirty-five percent of laboratory professionals reported poor physician and laboratory staff communication which is more or less similar to a finding from Addis Ababa (33%) [11]. This inadequate laboratory staff versus physician communication worsened by workload negatively affects the service quality. Poor communication among laboratory professionals and physicians was found to be a 2.9 times higher likelihood of providing poor quality services. In the absence of communication and effective feedback mechanisms laboratory professionals are more likely to provide poor quality services and unable to improve quality services. This was supported by the studies done in Gondar and Addis Ababa [3, 11]. Effective communication between laboratory professionals and physicians is crucial for ensuring high-quality healthcare services. However, the study suggests that there are significant communication challenges between these two groups. One potential reason for this could be the high workloads and busy schedules, which can make it difficult for laboratory staff and physicians to regularly coordinate and share information. This worsening of communication due to workload pressures can then negatively impact the overall quality of services provided. Another factor contributing to poor communication might be a lack of established feedback mechanisms and protocols between the laboratory and clinical teams. Without clear channels for exchanging information, providing updates, and addressing issues, misunderstandings, and breakdowns in communication are more

likely to occur. This lack of structured communication can leave laboratory professionals feeling disconnected from the clinical decision-making process and unable to effectively improve service quality.

The major technical and administrative factors affecting the quality of laboratory service provision in government comprehensive specialized hospitals were the lack of refresher training and limited opportunities to attend CPED. Furthermore, poor communication among laboratory professionals and physicians contributed to compromised quality service provision. Insufficient numbers of laboratory staff also impacted the overall quality of care. Addressing administrative gaps ensures that tasks are completed efficiently, goals are met, and resources are used effectively. Individuals who did not attend technical refreshment training were 4-fold more likely to provide poor quality compared to those who attended laboratory refreshment training. The importance of ongoing training in ensuring standardized and accurate results was emphasized by the studies done in Mzuzu city, southern Ethiopia, Addis Ababa, Hawassa, and Gondar [1, 3, 40, 46]. Having the right technical determinants in place can also ensure that tasks are conducted accurately and efficiently. On the contrary, the lack of refreshment training for laboratory professionals ultimately leads to demotivation, disconnection, and inability to adopt new testing methods, further affecting the accuracy and reliability of results.

The findings indicate that both technical and administrative factors critically influence laboratory performance. Equipment shortages, maintenance lapses, and workspace disorganization, alongside gaps in training, documentation, and procedural compliance, collectively undermine efficiency and quality, underscoring the need for integrated technical and managerial interventions.

Strengths and limitations

The study combined structured observations and questionnaires across multiple hospitals, enhancing validity and regional representativeness. Rigorous thematic and statistical analyses ensured systematic identification of key technical and administrative determinants of laboratory service quality.

The cross-sectional design limits causal inference, and reliance on self-reported data may introduce bias. Observations were confined to thirty laboratory rooms in five hospitals, restricting generalizability. Patient-level outcomes were not assessed, limiting direct links between laboratory quality and clinical impact. The cross-sectional design prevents establishing causal relationships between identified determinants and laboratory service

quality. Second, the use of self-reported questionnaire data may have introduced response bias, as participants could have over- or underreported their practices. Third, the observational assessment was limited to thirty laboratory rooms in five hospitals, which may not fully reflect the diversity of laboratory practices in other public or private hospitals in the region. Finally, the study did not assess patient-level outcomes, limiting the ability to directly link laboratory service quality with clinical impact. These limitations should be considered when interpreting the findings and generalizing them to other settings.

Conclusions

The overall quality of laboratory services in government comprehensive specialized hospitals was substandard, stem from technical and administrative challenges. Key technical deficiencies included inadequate and unreliable equipment, irregular preventive maintenance, disorganized workflows, interruptions in testing services, and unstable power supply. Administrative shortcomings involved gaps in quality management systems, SOP adherence, documentation, turnaround time monitoring, internal and external quality assurance, inventory management, customer feedback mechanisms, and staff training. Low performance was particularly noted in uninterrupted testing, accurate inventory records, routine stock counts, and storage capacity.

These combined deficiencies can compromise laboratory performance, potentially resulting in misdiagnosis, suboptimal clinical decisions, increased patient morbidity, and unnecessary healthcare costs. Addressing both technical and administrative determinants through strengthened laboratory–physician collaboration, targeted capacity-building initiatives, adequate staffing, optimized resource allocation, and consistent quality management is essential to enhance laboratory service quality, reliability, and patient care outcomes.

Recommendations

- The government, stakeholders, and hospital management should allocate adequate funding and resources to improve laboratory facilities, equipment, and supplies.
- Hospitals should establish clear and timely communication channels between laboratory staff and physicians should be established to optimize patient care.

- Opportunities for CPED and regular refresher training should be provided to enhance laboratory staff competencies.
- The government and key stakeholders should collaborate to identify factors influencing laboratory service quality and implement targeted interventions.
- Healthcare organizations should allocate resources and implement strategies to enhance the overall quality of laboratory services.
- A comprehensive study encompassing both government and private general hospitals should be conducted to gain a deeper understanding of laboratory service delivery and quality across different healthcare settings.

Abbreviations

AOR: Adjusted Odds Ratio

COR: Crude Odd Ratio

CPED: Continuing Professional Education and Development

IQC: Internal Quality Control

QA: Quality Assurance

QSEs: Quality System Essentials

SOP: Standard Operating Procedure

TAT: Turnaround Time

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Author contributions

TN: conceptualization, investigation, writing—original draft, methodology, validation, data curation, project administration, formal analysis, supervision. TD: conceptualization, methodology, data analysis, writing—review and editing, supervision,

resources. BM: investigation, writing–review and editing, methodology, formal analysis. KA: conceptualization, methodology, writing–review and editing, supervision.

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Availability of data and materials

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

Declarations

Ethical approval and consent to participate

An ethical clearance letter with an “Ethics Approval Number: SBMLS/504” was obtained from the Research and Ethics Review Committee of the School of Biomedical and Laboratory Sciences, College of Medicine and Health Sciences, University of Gondar. Before commencing the data collection process, the School of Biomedical and Laboratory Sciences wrote a support letter to the hospitals. Then, subsequent permission was obtained from the hospital manager and respective heads. Additionally, A brief explanation of the voluntary ness of the participation or the freedom to withdraw, as the purpose and benefits of the study was given before they decided to sign informed consent. The confidentiality of participants' personal private information was maintained by removing personal identifiers and analysis was done anonymously.

Concept for publication

Note application.

Competing interest

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

References

1. Mengesha MB: The clinical laboratory service: medical practitioners’ satisfaction in Southern Ethiopia. *American Journal of Clinical Pathology* 2015, 144:895-901.
2. 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, 1:343.

3. Biadgo B, Zakir A, Malede T, Getachew E, Girma M: Assessment of Quality of Medical Laboratory Services Provision and Associated Factors in Public Health Facilities at Gondar Town, Amhara Regional State, Northwest Ethiopia. *Clinical Laboratory* 2019, 65.
4. Shumbej T, Menu S, Gebru T, Girum T, Bekele F, Solomon A, 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. *Tropical Diseases, Travel Medicine and Vaccines* 2020, 6:1-7.
5. The American Clinical Laboratory Association: Value of Clinical Labs: The Power of Knowing.
6. Jain R, Rao B: Medical diagnostic laboratories provisioning of services in India. *CHRISMED Journal of Health and Research* 2015, 2:19-21.
7. Genet AC, Andualem T: A Cross-Sectional Study to Assess Capacity of Health Facility Laboratories in Zone One of Afar Regional State, Ethiopia. *Journal of Tropical Medicine* 2018.
8. Hailu HA, Desale A, Yalew A, Asrat H, Kebede S, Dejene D, et al: Patients' satisfaction with clinical laboratory services in public hospitals in Ethiopia. *BMC Health Services Research* 2020, 20:1-9.
9. Kachuwaire O, Zakaryan A, Manjengwa J, Davtyan Z, Châtard J, Orelle A, et al: Quality management system implementation in human and animal laboratories. *One Health* 2021;13:100278 2021, 13.
10. Clinical Laboratory services for physicians *JAMA* 2021, 326:1498- 1499.
11. 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, 28:205.
12. Abebe DD, Temesgen MM, Abozin AT: Clinicians' satisfaction with laboratory services and associated factors at public health facilities in Northeast Ethiopia. *BMC Health Services Research* 2023, 23:1-9.
13. Alebachew S, Adane K, Worede A, Abebe M, Damite S, Melak T, et al: Quality Assessment in the Laboratory: Errors in the Total Testing Process in the Clinical Chemistry Laboratory at University of Gondar Hospital, Northwest Ethiopia. 2019.
14. Zuhair MM: Improving Quality in a Cytopathology Laboratory. *Global Journal of Health Science* 2020, 12:121.
15. 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. *Clinical Laboratory* 2020, 86.
16. 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. *Pathology and Laboratory Medicine International* 2021:7-19.
17. Rebezov M, Chuprakova A, Tretyak L, Nesterenko A, Zaitseva T, Trofimova I, et al: Improvement of Laboratory Services When using Sample Preparation in Microwave System. *International Journal of Current Research and Review* 2020, 12:29-33.

18. Mbah HA: Phlebotomy and quality in the African laboratory: opinion paper. *African Journal of Laboratory Medicine* 2014, 3:1-4.
19. Connor NE, Islam MS, Arvay ML, Baqui AH, Zaidi AK, Soofi SB, et al: Methods employed in monitoring and evaluating field and laboratory systems in the ANISA study: ensuring quality. *The Pediatric Infectious Disease Journal* 2016, 35:539-544.
20. World Health Organization: Module for assessing and strengthening the quality of viral load testing data within HIV programmes and patient monitoring systems: implementation tool. 2020.
21. International Organization for standardization: Medical laboratories: requirements for quality and competence. 2012.
22. Markiewicz A, Patrick I: Developing monitoring and evaluation frameworks: Sage Publications. *Sage Publications* 2015.
23. Mokobela KO, Moatshe MT, Modukanele M: Accelerating the spread of laboratory quality improvement efforts in Botswana. *African Journal of Laboratory Medicine* 2016, 5:1-6.
24. Homolka S, Zallet J, Albert H, Witt AK, Kranzer K: Introduction of quality management in a National Reference Laboratory in Germany. *PloS One* 2019, 14.
25. Plebani M: Quality in laboratory medicine and the Journal: walking together. *Clinical Chemistry and Laboratory Medicine (CCLM)* 2023, 61:713-720.
26. Plebani M: Clinical laboratory: bigger is not always better. *Diagnosis* 2018, 5:41-46.
27. Kebede Y, Fonjungo PN, Tibesso G, Shrivastava R, Nkengasong JN, Kenyon T, et al: Improved specimen-referral system and increased access to quality laboratory services in Ethiopia: the role of the public-private partnership. *The Journal of Infectious Diseases* 2016, 213:559-564.
28. Abera B: Measuring Patient Satisfaction with Quality of Laboratory Services in Bele Primary Hospital, Southern Nations Nationalities and People Region, Ethiopia. Hawassa University, 2018.
29. Alemnji G, Zeh C, Yao K, Fonjungo P: Strengthening national health laboratories in sub-Saharan Africa: a decade of remarkable progress. *Tropical Medicine & International Health* 2014, 19:450-450.
30. Ramessur V, Hurreeram DK, Maistry K: Service quality framework for clinical laboratories. *International Journal of Health Care Quality Assurance* 2015, 28:367-381.
31. Zhang HL, Omondi MW, Musyoka AM, Afwamba IA, Swai RP, Karia FP, et al: Challenges of maintaining good clinical laboratory practices in low-resource settings: a health program evaluation framework case study from East Africa. *American Journal of Clinical Pathology* 2016, 146:199-206.
32. Abera RG, Abota BA, Legese MH, Negesso AE: Patient satisfaction with clinical laboratory services at Tikur Anbessa specialized hospital, Addis Ababa, Ethiopia. *Patient Preference and Adherence* 2017, 1181-1188:1721.
33. Elhoseeny T, Mohammad E: Quality of the clinical laboratory department in a specialized hospital in Alexandria. *Eastern Mediterranean Health Journal* 2013, 19:81-87.
34. Wilson ML, Fleming KA, Kuti MA, Looi LM, Lago N, Ru K: Access to pathology and laboratory medicine services: a crucial gap. *The Lancet* 2018, 391:1927-1938.

35. Plebani M, Astion ML, Barth JH, Chen W, de Oliveira Galoro CA, Escuer MI, et al: Harmonization of quality indicators in laboratory medicine: A preliminary consensus. *Clinical Chemistry and Laboratory Medicine (CCLM)* 2014, 52:951-958.
36. Mesganaw B, Fenta A, Hibstu Z, Belew H, Misganaw K, Belayneh M: Medical Laboratories Quality Management and Challenges in Ethiopia: A Systematic Review. *Pathology and Laboratory Medicine International* 2023:13-26.
37. Sciacovelli L, Lippi G, Sumarac Z, West J, del Pino Castro IG, Vieira KF, et al: Quality indicators in laboratory medicine: the status of the progress of IFCC Working Group “Laboratory Errors and Patient Safety” project. *Clinical Chemistry and Laboratory Medicine (CCLM)* 2017, 55:348-357.
38. Mbah H, Negedu-Momoh OR, Adedokun O, Ikani PA, Balogun O, Sanwo O, et al: Implementing and measuring the level of laboratory service integration in a program setting in Nigeria. *PloS One* 2014, 9.
39. Abebe DD, Temesgen MM, Abozin AT, Zeleke AE, Hassen SL, Gebremichael HB: Patients’ satisfaction and quality of clinical laboratory services provision at public health facilities in northeast Ethiopia. *medRxiv* 2022, 25:22269238.
40. Chidzay RW: Accessing barriers to medical laboratory diagnostic services delivery in Mzusu city. *In J Biomed Sci* 2012, 15:32-56.
41. Jones KJ, Crowe J, Allen JA, Skinner AM, High R, Kennel V, et al: The impact of post-fall huddles on repeat fall rates and perceptions of safety culture: a quasi-experimental evaluation of a patient safety demonstration project. *BMC Health Services Research* 2019, 19:1-14.
42. Petrose LG, Fisher AM, Douglas GP, Terry MA, Muula A, Chawani MS, et al: Assessing perceived challenges to laboratory testing at a Malawian referral hospital. *The American Journal of Tropical Medicine and Hygiene* 94, 94:1426.
43. Osaro E, Chima N: Challenges of a negative work load and implications on morale, productivity and quality of service delivered in NHS laboratories in England. *Asian Pacific Journal of Tropical Biomedicine* 2014, 4:421-429.
44. Ishengoma DS, Kamugisha ML, Rutta AS, Kagaruki GB, Kilale AM, Kahwa A, et al: Performance of health laboratories in provision of HIV diagnostic and supportive services in selected districts of Tanzania. *BMC Health Services Research* 2017, 17.
45. Shiferaw MB, Yismaw G: Magnitude of delayed turnaround time of laboratory results in Amhara Public Health Institute, Bahir Dar, Ethiopia. *BMC Health Services Research* 2019, 19:1-6.
46. 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. *The Pan African Medical Journal* 2015, 20.
47. Kagaruki GB, Kamugisha ML, Kilale AM, Kamugisha E, Rutta AS, Baraka V, et al: Supply chain management of laboratory supportive services and its potential implications on the quality of HIV diagnostic services in Tanzania. *Tanzania Journal of Health Research* 2018, 20.

48. Ialongo C, Porzio O, Giambini I, Bernardini S: Total automation for the core laboratory: improving the turnaround time helps to reduce the volume of ordered STAT tests. *Journal of Laboratory Automation* 2016, 21:451-456.
49. Sinishaw MA, Gebregergs GB, Shiferaw MB: Longer lead time of tuberculosis laboratory commodities in Amhara region, Ethiopia. *Asian Pacific Journal of Tropical Disease* 2016, 6:269-271.
50. Chanyalew MA, Yitayal M, Atnafu A, Tilahun B: Assessment of data demand for informed-decisions among health facility and department heads in public health facilities of Amhara Region, northwest Ethiopia. *Health Research Policy and Systems* 2023, 21:1-9.
51. Ezezew M, Yehualaw A, Demsie DG: Assessment of availability and challenges of WHO recommended priority life-saving medicines for under five-year children in primary public health facilities of Amhara region. *BMC Pediatrics* 2023, 23:395.
52. 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. *Journal of Multidisciplinary Healthcare* 2020:809-821.
53. Bogale A, Ali J, Tsegaye A, Hassen F: Health Professionals Perception and Satisfaction on Quality of Laboratory Malaria Diagnostic Service; the Case Awi Zone, North Ethiopia. *Am J Med Public Health* 2020, 1.
54. Kaoje AU, Mohammed U, Mohammed Y, Ibrahim U, Alhassan S, Obi A, et al: Quality of medical laboratory services in a tertiary health institution in Sokoto, Nigeria. *International Journal of Medical Laboratory* 2017, 4:246-250.
55. Goulet F, Hudon E, Gagnon R, Gauvin E, Lemire F, Arsenault I: Effects of continuing professional development on clinical performance: results of a study involving family practitioners in Quebec. *Can Fam Physician* 2013, 59:518-825.