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# The Current Laboratory Quality Managements Practice in Ethiopian Public Hospitals from July 2012 up to March 2013

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**Abstract:** Background: Accurate clinical laboratory testing service is key component clinical service to diagnosis disease, follow up and treatment patient care. The levels of quality management's practice in Ethiopia were not adequately assessed. Therefore, this study was aimed to determine the quality of clinical laboratory managements practice and associated factors in across the country. Method: this study was used cross-sectional study design with quantitative approach using minimum standard set out by the ministry. No need of sampling technique and sample size determination rather all public hospital laboratories who conducted the report through DHIS2 were included in the study. Data was collected by quality officer of hospital itself. SPSS version 20 was used for data entry, data cleaning and data analysis was used to determine distribution and comparing the mean was also used to see significance difference across the reporting time, level of hospitals and regions. Result: Highest mean score of laboratory quality management practice 232 (92%) was seen in related to establishing system for document and record managements. The practice in related laboratory information managements was 220 (87%) and laboratory supply supplies managements system 218 (87%) and incident handling system 211 (84%). Lowest mean score 101 (40%) were observed in the standard related to cold chain managements system for blood and blood product until used by the prescriber. There is no significance difference between mean score of laboratory quality managements practice across the time, level of hospitals and region but better implementation score laboratory quality managements practice were observed in specialized compressive as compared to general and primary hospitals. Conclusion: In considering all the questioners were a minimum standard set out by the ministry, none of the standard was addressed 100%. However, better implementation were seen on standard related to establishes system for records and documents management, laboratory information and supplies management systems, and incident handling and reporting system. Low internal quality control (IQC) and EQA) and have no availing back up equipment. Half of public hospitals laboratories were not fully engaged in mobilization of blood donation in community awareness programmed. More than half of the public hospitals laboratories had no appropriate cold chain management system for blood product and blood until used by prescribers. Better implementation of LQM was seen in specialized compressive hospital as compared to general and primary hospitals.

**Keywords:** Clinical Laboratory, Quality Management, Practice, Ethiopia

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## 1. Introduction

Clinical laboratories are healthcare facilities providing a wide range of laboratory procedures which aid the physicians in carrying out the diagnosis, treatment, follow up, prevention and surveillance [1-6]. Quality of clinical laboratory can be defined as accuracy, reliability and

timeliness of reported test results. The laboratory results must be as accurate as possible, all aspects of the laboratory operations must be reliable, and reporting must be timely in order to be useful in a clinical or healthcare setting [7]. To attain this goal, several issues and problems are needed to be identified.

As indicated by different journal and report the identified problem were human and financial resources, training and

supervision, planning and budgeting, quality assurance, logistics and supply, biosafety and equipment management and others related problem [7-9]. This large and huge complex problem requires many processes and procedures to improve working capacity. Therefore, the quality management system model, which looks at the entire system, is very important to address the problem and to improve performance clinical laboratory [10].

In order to have a functioning quality management system, the structure and management of the laboratory must be organized so that quality policies can be established and implemented. There must be a strong supporting organizational structure—management commitment is crucial—and there must be a mechanism for implementation and monitoring. The laboratory needs to be organized around a formal quality management system that supports consistent procedures [11].

The management team and quality unit play an integral role in a quality-driven culture, along with structures for monitoring ongoing quality and the staff member's is most important asset to a laboratory. Training, motivation, and engagement are key parts of the quality management system. Every piece of equipment used in the laboratory must be maintained to operate safely. Properly managing the supply chain is critical to ensure that raw inputs and other supplies are consistently high-quality with no interruption. Inventory activities should verify that materials and supplies are stored in a way that protects integrity [12, 13].

Parallel to this, Process control encompasses quality control processes for testing, including: sample collection, handling, method verification and process validation. The laboratory produces many forms of information, including quality control test results, maintenance reports, and other data. This data needs to be managed in a way that ensures all information is accurate, secure, confidential, and accessible to individuals with the right privileges, such as lab managers. Documents need to be available at the point of work, maintained, accurate, and secure. One of the most essential lab documents is standard operating procedures (SOPs) to create a standard for each process [14].

Similarly, a quality management system support continuous process improvement of laboratory processes on the gap identified at the time of internal and external audit. Customer service is the goal of a laboratory. The laboratory needs to understand the customers and their needs and use customer feedback for improvement. A laboratory's quality managements system should support operations that consistently high-quality laboratory service meeting customer need. Laboratories need a comprehensive set of procedures and standards to ensure a safe, secure, and clean environment. This includes physically securing the lab, containment procedures for hazards, worker safety [15].

This stud was used questioners found in Ethiopian hospital service transformation guideline (EHSTG) laboratory chapter. It has 14 minimum standards for all level of hospitals [16]. The content of this standard was assess organizational plan, human and financial resources,

supervision and training, logistics and supply, budgeting and planning, biosafety, quality assurance, equipment management information managements, document and records laboratory and extra. The levels of quality management's practice in Ethiopia were not adequately assessed. Therefore, this study was aimed to determine the quality of clinical laboratory managements practice and associated factors in across the country.

## 2. Methodology

This study used a quantitative approach with cross-sectional study design to determine the level laboratory service quality and identify factors associated. Ethiopia had registered 355 registered public hospitals in DHIS2. Among those 241 (68%) were reported through DHIS2. All public hospital laboratories who conducted report through DHIS2 were included in the study. These participants' public hospitals were coming from all regions (Oromyia, Amhara, SNNPR, Sidama, Addis Ababa City Administration, Somali, Afar, Benishangule, Gambella, Dire Dawa, and Harari) except Tigray region. All level of hospitals (Primary, General and Comprehensive specialized) were participated and the assessment tools was prepared by the ministry of health, used to assess all levels of public hospitals.

### 2.1. Sample Size Determination and Sampling Technique

All hospitals registered in DHIS2 and conducted reports through DHIS2 were included in the study and no sampling technique and sampling size determination.

### 2.2. Data Collection

The study used hospital self-assessment reports that, reported in DHIS2 starting from July 1, 2020 –to June 30, 2021, G. C with the National Assessment Handbook developed by the Ministry of Health (MoH). The tools were used to assess Laboratory quality management practices in all types of public hospitals laboratory in every quarter of a year and reported through DHIS2. This study used four consecutive quarters. The data from DHIS2 were checked for completeness, accuracy, clarity, and consistency.

Level of quality management's practices was calculated against the assessment handbook that had fourteen standards with a total of 59 verification points. Each clause was weighted as "met" (with value 1) when the hospital had fulfilled the verification point to the expected standard or "unmet" (weighted value 0) when the hospital had not fulfilled the verification point to the expected standard. Finally, level of leadership, management and governance practices was determined as percentage.

### 2.3. Data Analysis

Data entry, coding, cleaning, and data analysis were done by using SPSS version 20 software. Data were checked and cleaned by running frequencies, sorting, and listing variables for consistency. Descriptive analysis, cross tabulation, box

plot analyses was used to see the presence significance difference of quality of laboratory service over a time and across type of hospitals. P value less than 0.05 was

considered as significant difference, by comparing mean score using with the level of hospital, region and across the time.

$$\text{Level of Laboratory Management Practice} = \frac{\text{Total Number of Met Standard}}{\text{Total Number of Met + Unmet Standard}} \times 100$$

**2.4. Ethics**

Since this study used secondary data, there was no need of asking for ethical clearance; but principal investigator presented a formal written request letter to Policy plan, monitoring and evaluation directorate at the Federal Ministry of Health (FMoH-Clinical Service Directorate) and obtained a written permission through formal Letter. The data collected from DHIS2 was kept in a safe place and used for the purpose of the study only. The assessment findings were reported to regional health bureaus and the Ministry.

**3. Result**

Total number of public hospitals who were registered in DHIS2 was 355, among this 219 were primary hospital, 103 were general hospitals, and 34 were specialized compressive hospitals. From the total public hospitals 241 (68%) were participated in this study.

Large number of participant hospitals coming from Amhara regional state health bureau was 77 (32%). followed by Oromyia regional Health Bureau was 74 (31%). The third

highest number of hospital coming from SNNPR was 47 (19.5%) and hospitals from Sidama regional health bureau was 15 (6.2%), More than 90% of participant hospital was coming from the above four big region.

Hospitals participated from Somali regional health bureau was 6 (2.4%), followed by Addis Ababa city administration health bureau was 10 (4.2%), number participant hospitals from afar regional health bureau was 5 (2.1%), and Binishangul Gunuze 2 (0.8%), from Dirdwa city administration 1 (0.4%), and Gambella health bureau 2 (0.8%), Finally, the number of hospitals from Harari regional health bureau was 2 (0.8%), whereas no participant hospitals from Tigray regional health bureau.

From total public hospital was 219 (61.7%) was Primary Hospitals, 102 (28.7%) General Hospitals, and 34 (9.9%) was Compressive Specialized Hospitals. Among this the participant public hospitals was 145 (60.2%) was Primary Hospitals, 69 (28.6%) General Hospitals, and 27 (11.6%) was Compressive Specialized Hospitals.

Less than 8% of participant’s hospitals were coming from five different regional state which was Somali, Afar, Gambella, harari regional health bureau, and Dirdawa city administration.

*Table 1. Socio demography characteristic of public hospitals in Ethiopia from xx 2013.*

Variable	Total number of public hospitals in Ethiopia across the region and Its percentage from total	Total number of participant public hospitals in the study across the region and Its percentage from total
Region		
Oromyia RHB	109 (31.0%)	74 (31.0%)
Amhara RHB	88 (32.0%)	77 (32.0%)
SNNPR	57 (19.5%)	47 (19.5%)
Sidama	17 (6.2%)	15 (6.2%)
Addis Ababa HB	15 (4.2%)	10 (4.2%)
Somali	9 (2.4%)	6 (2.4%)
Afar RHB	6 (2.1%)	5 (2.1%)
Benishangul RHB	6 (2.1%)	2 (0.8%)
Gambella RHB	4 (0.8%)	2 (0.8%)
Harari RHB	3 (0.6%)	2 (0.8%)
Dirdawa RHB	2 (0.4%)	1 (0.4%)
Tigray	39 (11%)	0 (0%)
Total	355 (100%)	241 (100%)
2. Level of Hospitals		
Primary Hospitals	219 (61.7%)	145 (60.2%)
General Hospitals	102 (28.7%)	69 (28.6%)
Compressive Specialized	34 (9.6%)	27 (11.6%)
Total	355 (100%)	241 (100%)

The overall mean score of laboratory quality management practice across the country public hospital laboratory was 62%, 65%, and 67% in the first, second, and third consecutive quarter of 2013. The highest score of laboratory practice was seen in Harari regional health bureau. Mean score of harari region was 75%, 75%, and 79% in the first, second, and third consecutive quarter of 2013. However, it has only two hospitals was included in this study which mean

low reporting rate as compared to the other regions. The second highest score of laboratory quality management practice was observed in Addis Ababa City Administration (67%, 67%, and 72%) consecutive quarter in 2013.

Similarly, the mean score of laboratory quality management practice in SNNPR were 66%, 72%, and 71% in three quarter of 2013 year and in Sidama regional health were 66%, 72%, and 71%. In the same way, laboratory practice of public

hospitals in afar regional Health Bureau was 54%, 55%, and 67% in the three consecutive quarters of 2013.

In the same way, the mean score of laboratory practice in Amhara regional health bureau were 62%, 64%, and 66% in three quarter of 2013 year. Followed by the mean score of laboratory practice in Oromyia regional health bureau were 63%, 64%, and 65% in three quarter of 2013 year. Likewise, laboratory practice of public hospitals in Benishangul Gumuze Regional Health Bureau was 48%, 50%, and 64% in the three consecutive quarters of 2013.

The least mean score of laboratory practice was observed in Somali Regional Health Bureau and Dire-dawa City Administration were (54%, 57%, and 61%) and (50%, 50%, and 50%) in three quarter of 2013 year.

On the other hand, laboratory quality management practices in primary hospitals were 58%, 62%, and 66%. And the mean of laboratory quality management practices in general public hospitals were 70%, 72%, and 71%. Whereas, the score of compressive specialized public hospital laboratory quality management practices was 65%, 69%, and 73% in three consecutive quarters of 2013.

To sum up, laboratory practice in compressive specialized hospitals much better than general hospitals laboratory and laboratory practice of general hospital laboratory also much better than the mean score of primary hospitals laboratory practice. But mean composite score of laboratory quality management practices have no significance difference across time of report, level of hospitals and regions.

*Table 2. Mean score of laboratory practice in Ethiopian public hospitals.*

Variable	Mean Q1 2013	Mean Q2 2013	Mean Q3 2013
Region			
Harari RHB	75%	75%	79%
Addis Ababa RHB	67%	67%	72%
SNNPR RHB	66%	72%	71%
Sidama	70%	65%	70%
Afar RHB	54%	55%	67%
Amhara RHB	62%	64%	66%
Oromyia RHB	63%	64%	65%
Benishangul RHB	48%	50%	64%
Gambella RHB	57%	46%	64%
Somali	54%	57%	61%
Dirdawa RHB	50%	50%	50%
Tigray	54%	-	-
Total	62%	65%	67%
Level of Hospitals			
Primary Hospitals	58%	62%	66%
General Hospitals	70%	72%	71%
Compressive Specialized	65%	69%	73%
Total	62%	65%	67%

Among all standard or requirements the highest score was observed in the standard related to have system for documents and records managements that are controlled, reviewed, maintained and approved at work place to ensure the quality laboratory services. In this regard: among the total participant hospital laboratory in the study, 232 (92%) were meet the standard. This implies that, 92% of public hospital laboratory had system and practice in generation of record and document, identification, endorsement, usage, control and removal procedure. Equally it explain the presence of quality and safety manual, guideline for sample management, Clinician handbooks, Technical and Managerial standard operating procedures, Formats, Job aids at work place.

The second highest score 220 (87%) was observed in the standard related to establish system laboratory information management. The standard revels that hospitals have written procedure for laboratory information managements system that prevent patient's data loss, ensure confidentiality, security, timeliness, accuracy, accessibility, and patient information privacy. Similarly, the third highest score 218 (87%) was observed in the standard related to establishing system laboratory supplies. To get full score hospital laboratory had ensure an effective supply chain management

system had in place to choice, estimate, transport, store, dispense and retain records of all reagents and supplies. Moreover, laboratory should have functional inventory system and practices including bin cards are utilization.

Every public hospital laboratory expected to establishes system incident managements and reporting. It's confirmed by observing occurrence or incidence record and its action plan for improvements. Among all 211 (84%) of public hospitals was have system and practice in related to incident handling and reporting system. The other standard was explain about that every laboratory has and implements proper equipment's management system including the ways of involvement health professionals on consultation selection, requirement, installation, standardization, maintenance and removal to ensure the provision of accurate, reliable and timely testing service. In this regard 209 (82%) hospital laboratories were meeting the standard. Likewise, the 180 (71%) public hospital laboratory has system to monitor the effectiveness patient satisfaction.

The hospital laboratory could be organized and designed at least for bio safety level 2 or above and work atmosphere is kept cleaned at all times. Among all participant hospital 177 (70%) were had adequate work space and work stations, floor

and easily cleanable walls, availability of safety equipment and supplies like first aid kit, fire extinguisher, and eye wash, PPE, emergency shower etc. presence of orientation to staff in relevant safety awareness and restricted access.

Regarding to monitoring whole process starting from pre analytical or sample collection to post analytical phase or reporting of result including external quality assurance (EQA) and Internal Quality Control (IQC) were practiced 162 (64%) public hospital laboratories. They have system to review and approved the result before releasing independently. Whereas, from the total participants hospitals 160 (64%) had availing back up laboratory equipment or back up laboratory facility to address on time customer expectation.

All public hospitals laboratory expected to have suitable storage and stock management systems for blood. However, only 156 (62%) hospitals laboratories have appropriate storage and good stock management systems. Whereas, 141 (56%) hospital laboratory blood bank conduct report to the hospital management and patient safety information to corresponding regional blood banks. Likewise, 123 (49%) public hospital laboratory blood banks were participated in community mobilization in community awareness program so as to have adequate blood donor and donation.

In the implementation process of EHSTG laboratory from all (14) standard chapter least score, 101 (40%) had suitable cold chain system for blood until used by prescribers.

**Table 3.** The frequency of meet and its percentage of each standard or requirement from the total public hospitals involved in this study.

No	Standard	Frequency & its Percentage that meet the requirements
1	The hospital laboratory management has established system for management of documents and records.	232 (92%)
2	The hospital has established laboratory management information system	220 (87%)
3	The hospital has a laboratory supplies management system	218 (87%)
4	The hospital laboratory has established incident handling and reporting system which includes errors or near errors (also called near misses)	211 (84%)
5	The hospital laboratory has and implements a proper management system for its equipment that includes the calibration, maintenance and inventory to ensure the provision of accurate, reliable and timely test results	209 (82%)
6	The hospital laboratory has established system to monitor the effectiveness of its customer service programmed	180 (71%)
7	The hospital laboratory should be designed and organized at least for bio safety level 2 or above and work environment is clean and well maintained at all times	177 (70%)
8	The hospital laboratory shall implement a process control system that monitors the processes from pre analytical to post analytical phases of testing, including an established internal quality control (IQC) and EQA	162 (64%)
9	The laboratory design a backup laboratory service through availing back up laboratory equipment or backup laboratory facility	160 (64%)
10	The laboratory has appropriate storage and stock management systems for blood and blood products received from blood	156 (62%)
11	The hospital laboratory blood bank shall report blood administration and patient safety information to respective regional blood banks	141 (56%)
12	Laboratory collaboration regional blood bank engaged in the mobilization of blood donation strategy like community awareness programs	123 (49%)
13	The laboratory blood bank service has appropriate cold chain system for blood and blood products until used by prescribers.	101 (40%)
	Overall	169 (67%)

## 4. Discussion

The mean quality score of laboratory service against minimum standard set out by Ethiopian Hospitals Service Transformation Guideline (EHSTG) was 62%, 65%, and 67%. Every public hospital laboratory expected to implement to 100%. Even though the implementation score was improved from time to time, the hospitals expected to fulfill the minimum standard set out by the ministry.

Highest mean score implementations of laboratory quality management practice were observed in Harari. It had low in reporting rate only one hospital was involved in the study. The region that had better implementation score with good reporting rate was seen Addis Ababa, SNNPR and Sidama regional health bureau. Even if, the laboratory quality managements practice were better as compared to the other regions, it's below expected by 20-30 percent from the minimum standard set out by the ministry. This might be because of less attention given by top managements.

On the contrary, worsen implementations of laboratory quality management practice were observed in DireDawa, Somali, Gambella and Benishangule regional health bureau whereas, the reporting rate and number of hospital involved from DireDawa, Somali, Gambella and Benishangule were low in number which implies low reporting rate. Laboratory quality managements practice implementation score were low both as compared to the other regions and minimum standard set out by the ministry. Implementation result was reduced by (35-50%) from expected. This might be because of low commitment top managements of the hospitals and regions. The SNNPR regions, Oromyia and Amhara regional health bureau had many participated hospitals. It had medium implementation score of score of laboratory quality management's practice. This might be because of low commitment difference by the top managements of both hospitals and regional health bureau.

Little improvement in the implementations of laboratory quality management practice was observed compressive specialized hospitals as compared to general and primary

hospitals. All level of hospitals was not meeting the minimum standard fully. This might be because of low attention given by top management of both hospital chief executive office and medical director.

Among all variable the highest score was observed in the practice of establishing system for documents and records management, system for laboratory information management, and system for laboratory supplies management. Approximately, the observed score was reduced by 20% from expected standard. The next highest score was seen in the process of establishing system and practice for incident handling and reporting mechanism. This might be because of repeatability of the work relatively low.

The implementation quality score of hospital laboratory in related to assuring system and practice to monitor the effectiveness of its customer service satisfaction, and should be designed and organized at least for bio safety level 2 or above were 70%. Quality score was reduced by 30% to implement fully. This might be because of poor attention given by both laboratory manager and hospital chief executive officer. Equal point was observed in both internal quality control (IQC) and external quality assurance (EQA), and in related to availing a backup laboratory service by availing back up laboratory equipment or backup laboratory facility. This might be because the absence of mandatory low to do internal quality control in daily basis.

The other variable, explained about every public hospital laboratories may have system of equipment management and 209 (82%) public hospital laboratory had system for Equipment management. It includes participation respected professionals on consultation, specification, selection, installation, calibration, maintenance and disposal and inventory to ensure reliable, accurate and timely results. This might be because of poor attention given by both laboratory manager and hospital chief executive officer.

The least score was observed in the practice of managing cold chain that was used for receiving blood and blood product from the blood bank and transport to the hospital laboratory. This might be because of no orientation on how to use and managing blood bank. The next least score was observed in mobilization of community to get potential voluntary donor and poor reporting mechanism to respected regional health bureau and others respected body. This also might be because of poor commitment and low engagement of top management or administrative structure of blood bank in the health system.

## 5. Conclusion

Most public hospital laboratory had establishes system for documents and records management, laboratory information management, laboratory supplies management system, and incident handling and reporting system. But the standard we used was minimum standard to implement fully (100%). Similarly, more than 82% public hospital laboratories has and implements a proper management system for its equipment that includes the calibration, maintenance and inventory to

ensure the provision of accurate, reliable and timely test results. Whereas, more than 36% were not public hospital laboratory implement a process control system that monitors the processes from sample collection to reporting of testing result, including internal quality control (IQC) and EQA) and have no availing back up medical laboratory equipment or backup laboratory facility.

More than 38% public hospital had not system to ensure proper stock managements and appropriate storage for blood and its product and 44% of public health laboratory were not conduct report to blood administration and respective regional blood banks. Half of public hospitals laboratories were not fully engaged in mobilization of blood donation in community awareness programmed. More than half of the public hospitals laboratories had no system appropriate cold chain managements for blood and its products until used by prescribers.

## 6. Recommendation

To FMOH and RHB: Federal ministry of health have great role in evaluating the effectiveness of quality management practice across the country. Identify and prioritize the problem that actually present in hospital laboratory and then find appropriate change idea to bring efficient and effective laboratory service. In addition to this, continues follow up and capacity building would be given to assure the access and quality health laboratory service.

To Hospital and Laboratory: The principle of supplies management system would be practical in main and mini store to encounter the absence of laboratory tests. Daily internal quality control should be in place to assure correctness of the testing service that comes from reagents, equipment's or laboratory professionals.

To other researchers: Finally, we encourage other researchers to study the subject so as to explore more detail.

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