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Assessment of FunctionalityStatus of Medical Laboratory Equipmentand Factors affecting their functionalityamong Public Hospitals in Addis Ababa.

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This is to certify that the thesis prepared by Negussu Abebe, entitled**:** **Assessment of Functionality Status of Medical Laboratory Equipment and Factors affecting their functionality among Public Hospitals in Addis Ababa**and submitted in partial fulfillment of the requirements for Master of Science degree in Clinical Laboratory Sciences (Clinical Laboratory Management and Quality Assurance) complies with the regulations of the University and meets the accepted standards with respect to originality and quality.

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ACRONYMS

AAU- Addis Ababa University

ART- Antiretroviral Therapy

EPHI- Ethiopian Public Health Institute

EPSA-Ethiopian Pharmaceutical Supply Agency

IPLS- Integrated Pharmaceuticals Logistics System

PFSA- Pharmaceuticals Fund and supply Agency

RHB – Regional Health Bureau

SCMS – Supply Chain Management System

SPSS- Statistical Packages for Social Science

WHO- World Health Organization

Operational definition of terms

Competence: Ability of a person to do the job well, indicated by education, training and work experience.

Functionality: The ability of a medical device to achieve its intended purpose as stated by the manufacturer. Performance may include both clinical and technical aspects. This is a measure of actual operation compared to full-utilization operation.

Preventive Maintenance: It is an action to eliminate the cause of a potential non-conformity. The care and servicing by personnel for the purpose of maintaining equipment and facilities in satisfactory operating condition by providing for systematic inspection, detection, and correction of incipient failures either before they occur or before they develop into major defects, including tests, measurements, adjustments, and parts replacement, performed specifically to prevent faults from occurring.

Medical equipment: Requiring calibration, maintenance, repair, user training, and decommissioning – activities usually managed by clinical engineers. Medical equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used either alone or in combination with any accessory, consumable, or other piece of medical equipment/equipment. Medical equipment excludes implantable, disposable or single-use medical equipment

Maintenance Contracts: It is the legal agreement normally conducted between two parties wherein the latter agrees to render the maintenance service annually to the formal in the exchange of a nominal amount. It ensures that the latter promises to provide maintenance services to the former all throughout the year on a regular basis. It includes service charges only. When charges include spare parts also it is termed as Comprehensive Maintenance Contract.

Work load: the amount of work that a machine, employee or group of employees can be or is expected to perform

Obsolescence: A minimum of two years of manufacturer's sales and technical support should be available. This support should include repair parts; accessories (either reusable or disposable); and troubleshooting, repair, and maintenance assistance. Obsolete equipment or equipment for which replacement parts are unavailable should be shipped only if they are designated for parts only.

Abstract:

Strengthening the health system of developing countries requires a well-functioning laboratory. In this regard, properly functioning medical laboratory equipment is one of the critical components. However, there is a great concern that the laboratory equipment maintenance is a critical bottleneck for strengthening health systems in sub-Saharan Africa.

BACKGROUND:

OBJECTIVE: To assessfunctionality status of Medical Laboratory Equipment and reasons for their malfunction among Public Health Hospitals in Addis Ababa, 2018.

METHODS: Facility basedcross-sectional study design was employed at14public hospitals in Addis Ababa from September to November, 2018.A convenient sampling method was used to include 14 public hospitals in Addis Ababa. Quantitative data collection tool with pretested interviewer administered questionnaire and checklist was used to collect pertinent data on equipment management system. Data were entered and analyzed by using SPSS version 20.0 (SPSS Inc., Chicago, IL, USA). The results were presented by using tables and graphs. Frequencies for all variables were counted and cross tabulated using percentages.

Result:A total of 115 medical laboratory equipment were assessed in this study from 14 public hospitals in Addis Ababa. Almost one-third 33% (38) of laboratory equipment were chemistry machines with different model and country of origin. The overall functionality status of medical laboratory equipment was 58.3% (67/115). Unavailability of spare parts is the primary reason for malfunction of medical laboratory equipment among public hospitals in Addis Ababa. Lack of spare parts accounts about 39.6% (19/48) ofthe non-functionality of medical laboratory equipment during the study period followed by installation problem 14.6% (7/48) and unavailability of reagents 12.5% (6/48).

Conclusion: This study has shown that a large proportion of medical laboratory equipment were non-functional among public hospitals in Addis Ababa. The study also has shown that the main reason for non-functionality of medical laboratory equipment was lack of spare parts followed by installation problem. Based on our findings, we recommend laboratories should follow manufacturer instructions to install laboratory equipment, capability building the biomedical engineers, avail necessary spare parts and reagent to utilize the most out of them.

1. Introduction

1.1 Background of the study

Medical devices are assets that directly affect human lives in medical industry. They are considerable investments and in many cases have high maintenance costs. A well-planned and managed maintenance program keeps medical equipment in a health-care institution reliable, safe and available for diagnostic procedures, therapy, treatments and monitoring of patients. Medical devices in particular are crucial in the prevention, diagnosis, and treatment of illness and disease, as well as patient rehabilitation[1].Laboratory medical equipment functionality status and managementis a strategic function and makes a positive contribution to business growth and organization success. It also involves a constant balancing act between the competing pressures of time, cost and quality [2].

The increasing demand throughout the world for more and better health care greatly expands therole of technology and medical equipment in the delivery of health services[3]. The significanceof the consequences that may arise from the use of defective equipment, including injury or death and subsequent malpractice litigation, makes it incumbent upon both manufacturers and users of medical equipment to ensure that high quality equipment is properly manufactured and maintained for safe, effective and reliable operation in a clinical environment[3]. In addition, selection of the best available equipment often saves time and money as a result of a lower frequency of breakdowns and smaller expenditures for spare parts, service and maintenance [4].

Health service planners, hospital administrators, medical technologists, physicians and other health care professionals need to understand the forces that control health care delivery systems. Because technology and medical equipment plays such a significant role in health care services, it is vital to understand the role of technology management in order to be able to communicate effectively about it to health policymakers. There is not only a need for appropriate equipment; suitable infrastructural arrangements are also required in order to make the role of technology more competitive and clinically efficacious. The functional status of laboratory equipmentdirectly contributes to improved patient health outcomes[4].The process yields a better productivity which means a state of efficiency or the rate and quality of output based on the rate and quality of input [5].As it relates to health facilities' equipment's management, higher

productivity can mean safer and more reliable equipment, less service cost, less equipment downtime, more revenue and more effective use of human resource. The medical equipment management professionals ensure that equipment used in the patients caresisoperational, safe, properly configured to meet the mission of the medical treatment facility and continue tofunction effectively in a good working condition[6].

The process ensuresthat the safest, most efficient and effective devices are purchased. Human factors engineering is frequentlybeing cited as an important method to reduce medical error and adverse events and to increase patientsafety, when it is applied to the design and evaluation of medical devices [7].The medical equipment life cycle includes the tendering and commissioning of new equipment inconjunction with the end users, the training and education of all devices for staff on their operation andapplication, performing the necessary preventive maintenance, conducting repairs and finally devicedisposal, at which point the life cycle begins again [6].

Access to accurate, safe and appropriate diagnostics and reliable laboratory services is paramount for diagnosis and disease management, surveillance and securing a safe blood supply. However, testing results are only of value to those making clinical decisions if the test results reported are timely and correct[8].Standardizing the type of platform for laboratory equipment in chemistry, hematology ,CD4 and other related machines across different laboratory levels offers many benefits, including cost reduction due to bulk procurement, ease of service due to a limited variety of platforms, higher manufacturer investment in service and distribution capability in-country, ease of staff training due to common user interface on the systems, minimal additional training needed when staff members move from laboratory to laboratory and better standardization of reference ranges and test results, thus better continuity of care for patients who transfer from health centers to district facilities[9].Thus, the functionality of equipment plays a pivotal role.

1.2 Statement of the problem

Developing countries account for about $5 billion (or 7%) of the $ 71 billion spent each year on medical equipment world-wide. Nevertheless, developing countries are under heavy pressure to acquire healthcare technologies: externally from technology providers and donor agencies, and internally from rising healthcare expectations of their populations [10, 11].In Kenya, a lot of medical laboratory equipment becomes non-functional because of lack of appropriate budget allocation, lack of awareness, lack of technical competency, documentation, inadequate testing and measuring equipment [13].

Many health service provider organizations have a general inventory for their facilities kept by the store manager. This covers everything found in each unit. A record of the contents of each room is kept on a bin card, and a paper copy is held in the stores. However, the details contained within this inventory are generally insufficient to enable equipment or maintenance plans to be made. Also, the data is not easily updated or manipulated on a computerand reported to the responsible body.For this reason, a separate record unit is required, which is known as the equipment inventory and management. This covers technical details and is restricted to items of equipment Life book which means, those items which require maintenance throughout their lives [4].

Ethiopia does not have an equipment inventory and management system which is accessible for the Ethiopian Public Health Institute (EPHI) and regional Health Bureaus (RHB) maintenance team as well as for the procurement agency. EPHI has database of antiretroviral therapy (ART) laboratory monitoring machines which is not updated and hence the institute's maintenance team is not aware of the type and number of machines which are found currently in more than 350 ART laboratory monitoring sites. The absence of the inventory management hinders the institute from appropriate planning for maintenance including holding appropriate stock of spare parts. The Ethiopian Pharmaceutical Supply Agency (EPSA, former PFSA) also lacks the right information on the same, which highly affects provision of reagents and consumables required for the service [9].

Hence, this study was assessed the functionality statusof medical laboratory equipment likes CD4, clinical chemistry, hematology,PCRand Gene-Xpert and main factors affecting their functionality status among public hospitals in Addis Ababa.

1.3 Significance of the study

Although a huge amount of resources is spent for procurement of laboratory equipment, significant amount of the Equipment is not used to the best of the country's capacity because of non-functionality of the equipmentand capacity of the human resources working at health facilities.

Addressing the problems will enable the government to use scarce resources efficiently in addition to improving health care of clients and increasing client satisfaction. Moreover, the improvement of the functionality statusof laboratory equipmentwillreduce the waiting time of clients to get their test result and health care providers perform their duty effectively and efficiently.

Therefore, this study will fill the gap whether the available medical laboratory equipment is functional or not to perform the diagnosis, treatment and prevention of health Problemswhenever needed and to recommend some ways to improve their functionality status at public hospitals.

2. Literature review

2.1. Magnitude of the problem

Strengthening the health system of developing countries requires a well-functioning laboratory. In this regard, properly functioning medical laboratory equipment is one of the critical components. However, there is a great concern that the laboratory equipment maintenance is a critical bottleneck for strengthening health systems in sub-Saharan Africa [13]. Despite this, there are very limited published studies assessing the functional status of medical laboratory equipment and associated factors. This review will try to assess available studies and general issues related to equipment management.

Health care technology management which isan accountable, systematic approach to ensuring that cost-effective, efficacious, safe, and appropriate equipment is available to meet the demands of quality care is at its infancy stage in developing countries. In most hospitals in industrialized countries, the importance oftechnology management, especially equipment maintenance, is well recognized as an integralpart of hospital management [13].

Equipment asset management encompasses the traditional duties of a clinical engineering department. This includes involvement in equipment acquisition and other life-cycle issues, supplying equipment information and training, monitoring and evaluating equipment, and documenting equipment [14-16].

It also includes using equipment management information systems to provide a more complete analysis of specific financial and clinical indicators, as well as for compliance with the regulatory and accreditation requirements [14]. Viewed from this perspective, technology management is actually the practice of integrating technology strategy with the health service strategy of the hospital, in the most efficient and cost-effective way [17, 18]. It is an accepted norm in developed countries that technology forms an integral part of health policy and planning. In many hospitals in these countries, medical equipment maintenance and management have become the responsibility of the clinical/medical engineering department [14, 19]. In contrast, in many developing, emerging economies, like South Africa, medical equipment still remains a major problem in the delivery of health services [17, 18].

A study conducted on tertiary hospitals in South East Nigeria observed that healthcare facilities maintenance centered mainly on structure, equipment and machinery used by healthcare institutions while the cleaning of wards, offices and general areas as well as the supply of clean linen and disposal of waste bins were carried out by the facility management unit. The maintenance units of tertiary hospitals were responsible for maintaining the structural aspects of healthcare buildings, equipment and plants and machinery. This reduces the responsibility of the maintenance unit but by no means reduces the complexity of their duty [20].

According to an assessmentcarried out in Ethiopia, the total performance rate of the machines was 65% i.e., 35% of the machines werenot functional at the time of the visit. The highest performance rates were100% for DNA PCR machines, 96% for viral load machines and 80% for CD4 machines. Chemistry and hematology machines have lowest performance rates. Chemistry machines have 59% and the hematology machines have 62% performance rates. Based on the study of Optimizing Ethiopia's Laboratory referral network conducted in 2013, the percentage of non-functional machines of CD4, Hematology and Chemistry machines were 20%, 38% and 41% respectively [9].

A study conducted on Monitoring machines and commodities management in ART Laboratory Monitoring Sites of Ethiopia observed that the significant challenges in management of ART laboratory monitoring machines, in the areas of staffing capacity, inventory management, equipment variation, and inventory management/maintenance management. Even though the majority of the sites have sufficient number of staff, there are huge technical gaps to operate the machines and manage the maintenance and commodities[9].

2.2. Factors associated with non-functionality of medical laboratory equipment

The maintenance management of laboratory machines is poor. The poor management of the machines is manifested by non-functioning equipment, absence of scheduled preventive and service maintenances, and absence or shortage of spare parts. In general, the major causes for failure of the machines are operation of machines by untrained laboratory professionals, electric power interruption, and failure to calibrate machines periodically. There are training gaps in the

operation of various types of machines,Integrated Pharmaceuticals Logistics System(IPLS) and logistics chain management (LCM). Trainings are vital to run the machines effectively, hence to decrease frequent machine failure. Properly trained staff also has a positive impact on performance on proper management of ART laboratory monitoring reagents and supplies at health facility [9].

The major reason for the malfunction of chemistry machines were absence of reagents, shortage of laboratory professionals, capacity limitations, no training was given, absence of standardization of the machines. In addition to this, the major reasons for the malfunction of hematology machines were reagent stock out, shortage of trained man power, and not willing to perform tests. In this regard, except PCR DNA machines, other laboratory equipment become non-functional due to installation [9].

In a Regional Medical Equipment Maintenance Workshops in Uganda, it was reported that inadequate spare parts for faulty medical equipment, was pointed out as a factor fornot addressing all the equipment repair needs within the regions. In addition to this, absence of Biomedical engineering technicians/Biomedical engineers in the government staffing structure for regional workshops and knowledge and skills gaps with regional workshop staffs is the leading challenges [21].

2.3. Study framework

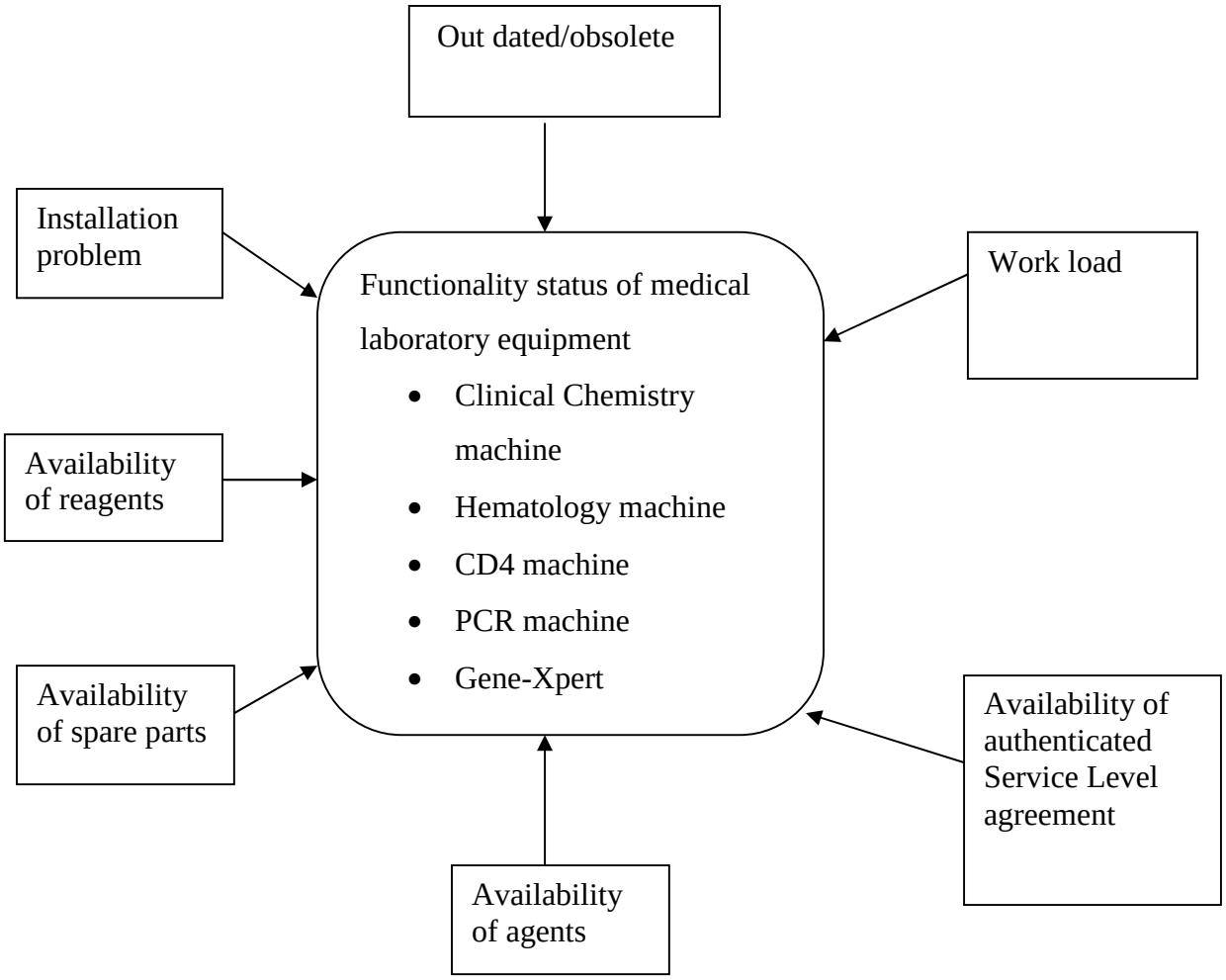

Figure 1: Conceptual framework to assess the functionality status of medical laboratory equipment among public hospitals in Addis Ababa, 2018.

3. Objective

3.1. General objective

- The main objective of this study is to assess functionality status of Medical Laboratory Equipment and factors affecting their functionality among Public Health Hospitals in Addis Ababa, 2018.

3.2. Specific objectives

- To assess the functionality status ofselected medical laboratory equipment in 14 public Hospitals of Addis Ababa
- To identify the factors affecting the utilization of the medical laboratory equipment.

4. Materials and Methods

4.1. Study area and period

The study was conducted in Addis Ababa;the capital city of Ethiopia.Addis Ababa is administratively divided into ten sub-cities and 116 districts (the smallest administrative unit in Addis Ababa*)*. It is located on a well-watered plateau surrounded by hills and mountains, in the geographic center of the country.The projected figures for July, 2015 from Central Statistics Agency of Ethiopia, Addis Ababa has estimated total population of 3,273,000 [22]. An estimated area of Addis Ababa is 526.99 square kilometers; this region has an estimated density of 5,535.8 people per square kilometer [22].Addis Ababa has about 14Public Hospitals and more than95 Health Centers.Of them, six are administered under Addis Ababa City Administration Health Bureau while four are administrated under the Federal Ministry of Health and one is a teaching referral hospital under Addis Ababa University. Three of them are uniformed service hospitals. The study was conducted fromSeptemberto November, 2018 in all the 14 public Hospitals.

4.2. Study design

Facility based cross-sectional study design was employedfor this particular study.

4.3. Study Population

All Publichospitals medical laboratory equipment in Addis Ababa citywas considered as study population. These are TikurAnbessa, St Peter, St Paul's, ALERT, Amanuel, RasDesta, Yekatit 12,MinelikII, Zewditu Memorial, Ghandi Memorial, Tirunesh Beijing, Armed Forces, Federal Police and Federal Prison Hospitals medical laboratory equipment.

4.4. Inclusion and exclusion criteria

4.4.1. Inclusivecriteria

Criteria	Category	Subgroup	Number value
Function	Diagnostic	Life save care monitoring	3
		additional physiological monitoring and diagnosis	2
	Analytical	Analytical laboratory	4
		Laboratory accessory	3
		Computer & related	2
	Miscellaneous	Patient related & other	1
Maintenance requirement		Extensive	3
		Average	2
		Minimal	1
National program need(HIV & TB)		High	3
		Medium	2
		Low	1

*Adopted from WHO

4.4.2. Exclusion criteria

Medical laboratory equipment that hasbelow 65 % score was excluded in this study.

4.5. Measurement

4.5.1. Variables

4.5.1.1. Outcome/Dependent variables

Functionality status of selected medical laboratory equipment (CD4 machine, Chemistry machine, Hematology machine, PCR machine and Gene-Xpert machine)

4.5.1.2. Independent/Explanatory variables

Outdated, installation, availability of spare parts, availability of reagents, availability of agents in the country, availability of trained service engineers ,work load, Preventive maintenance practice, Equipment service level agreement, presence of in facility biomedical engineers and availability of operator manuals were included.

4.6. Sample size

All of public hospitals Laboratory in Addis Ababa were included in the study.

4.7. Data Collection methods and instruments

The data was collected by using quantitative data collection tool with pretested interviewer administered questionnaire and checklist used to collect pertinent data on equipment functionality and management system at Minelik II Hospital.Face to face interview with laboratory head or the person in charge by using checklist for their functionality status and other pertinent equipment management indicators was carried out. The data was collected by four medical laboratory technologists who have experience in data collection. The data collectors weretrained intensively for two days on how to collect the data.

4.8. Data quality assurance

The collected data was checked for its completeness and consistency on daily basis. The quality of data was assured through training of data collectors and close supervision at the time of data collection.

4.9. Data analysis

Data was entered and analyzed by using SPSS version 20 (SPSS Inc., Chicago, IL, USA). The results were presented by using tables and graphs. Descriptive statistics was employed to determine frequencies for all variables and cross tabulated using percentages.

4.10. Ethical consideration

The study was ethically approved by Addis Ababa University, Department of Medical Laboratory Sciences Research and Ethics committee. Official permission was secured from Addis Ababa City Administration Health bureau and then from the head management of public hospitals. The health facilities' privacy and confidentiality was respected by using codes(A-N)

that was accessible to the investigator only. The final report of the study will be disseminated to Department of Medical LaboratoryScience and to all public hospitals in Addis Ababa. In addition to this, the result of this study will be presented in different conferencesand submitted to journals for publication.

5. Results

5.1. Distribution of medical laboratory equipment's among public hospitals in Addis Ababa, 2018.

A total of 115 medical laboratory equipment were assessed in this study from 14 public hospitals in Addis Ababa. Almost one-third 33% (38/115) of the equipment were chemistry machines with different model and country of origin. Following to chemistry machine, hematology analyzers account to the highest frequency 32% (37/115) from the total equipment assessed in this study.Only 3.5% (4/115) PCR machineswere assessed from black lion, Alert, Federal police and Armed force hospitals**(See Figure2).**

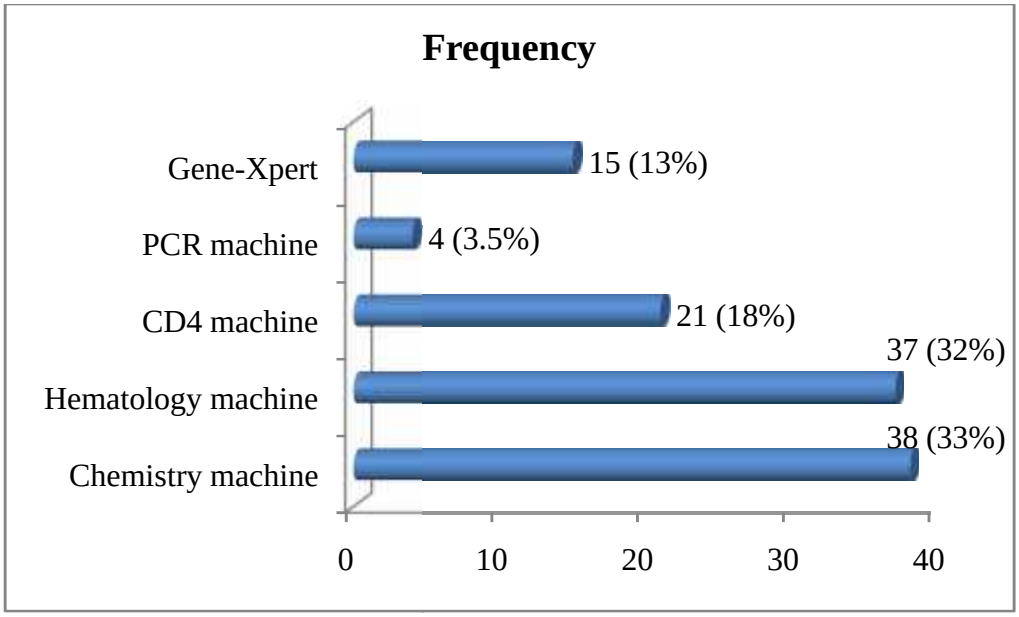

Figure 2: Distribution of selected medical laboratory equipment among public hospitals in Addis Ababa, 2018.

5.2. Overall Functionality status of medical laboratory equipment

From the total equipment assessed in this particular study from 14 public hospitals in Addis Ababa, about 41.7% (48) of them were non-functional at the time of data collection. **(SeeFigure3).**

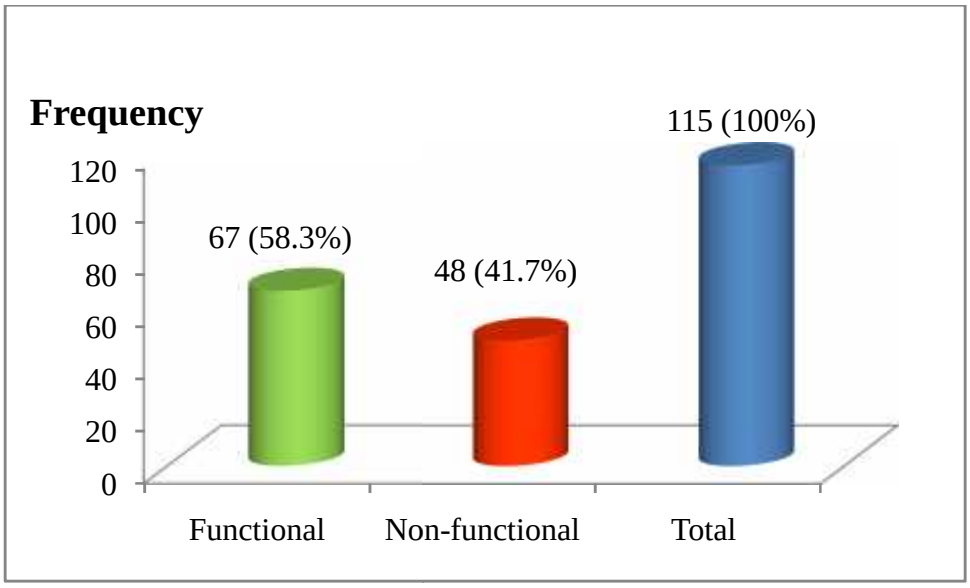

Figure 3: Functionality status of selected medical laboratory equipment among public hospitals in Addis Ababa, 2018.

5.3. Functionality status by medical laboratory equipment type among public hospitals in Addis Ababa, 2018.

The overall functionality status of medical laboratory equipment's was 58.3% (67/115). AllPCR machines 100% (4) and 80% (12) Gene-Xpert machines were functional during the study period (if two or more modules of Gene Xpert machine was functional, it was considered as functional).Less than half 44.7% (17) of chemistry machines, about 57.1% (12) of CD4 machinesand 59.5% (22) of hematology machineswere functional at the time of data collection**(See Table 1).**

Table 1: Functionality status by equipmenttype among public hospitals in Addis Ababa, 2018

Types of equipment	Total number of machines assessed	Number of functional machines	% of functional machines
Chemistry	38	17	44.7
Hematology	37	22	59.5
CD4	21	12	57.1
PCR	4	4	100.0
Gene-Xpert	15	12	80.0
Total	**115**	**67**	**58.3**

5.4. Reasons for non-functionality of medical laboratory machines

Overall and equipment specific reasons are presented in Table2. Unavailability of spare partswas the primary reasonfor malfunction of medical laboratory equipment among public hospitals in Addis Ababa.

It accounts about 39.6% (19/48) for the non-functionality of medical laboratory equipment'sduring the study period followed by installation problem 14.6% (7/48) because of they do not implement basic requirements guideline of installation and commissioning of medical equipment properly, unavailability of reagents 12.5% (6/48) andLack of trained service engineer10.4 % (5/48).Work load and unavailability of agents in the country 6.3% (3/48) for each were the least reasons for non-functionality of medical laboratory equipment among public hospitals in Addis Ababa (Table 2).

As shown in Table 2, except for CD4 machines, lack of spare parts was the primary reason for non-functionality.Being outdated/obsolete was the primary reason for non-functionality of CD4 machines. Lack of spare parts was the main reason for non-functionality of Gene-Xpert.

The availability of authenticated Service Level agreement was not meeting the operating specifications and repair demand of the facilities.

Table 2: Reasons for non-functionality of medical laboratory equipment's among public hospitals in Addis Ababa, 2018.

Reasons for non-functionality	**Chemistry**	**Hematology**	**CD4**	**Gene-Xpert**	**Total (%)**
Outdated/obsolete	1 (5%)	0 (0%)	4 (45%)	0 (0%)	**5 (10.4%)**
Installation problem	5 (23%)	2 (13%)	0 (0%)	0 (0%)	**7 (14.6 %)**
Lack of spare parts	10 (48%)	5 (33%)	1 (11%)	3 (100%)	**19 (39.6%)**
Lack of reagents	1 (5%)	3 (20%)	2 (22%)	0 (0%)	**6 (12.5%)**
Lack of agents in the country	1 (5%)	1 (7%)	1 (11%)	0 (0%)	**3 (6.2%)**
Lack of trained service engineer	2 (9%)	3 (20%)	0 (0%)	0 (0%)	**5 (10.4%)**
Work load	1 (5%)	1 (7%)	1 (11%)	0 (0%)	**3 (6.2%)**
Total	**21 (100%)**	**15 (100%)**	**9 (100%)**	**3 (100%)**	**48 (100%)**

6. Discussion

In this study, the magnitudes of non-functionality status of medical laboratory equipment (about 41.7%) were higher among public hospitals in Addis Ababa. More specifically, more than half of chemistry machines were non-functional at the time of data collection followed by CD4 and Hematology machines, respectively. Even though they were low in number, all PCR machines were functional at the time of study. The main and primary reasons for non-functionality of medical laboratory equipment were lack of spare parts followed by installation problem across all equipment.

A study conducted in Ethiopia showed that more than two-third (65%) of medical laboratory equipment were functional at the time of visit [9]. In contrast to this study, our results showed that overall 58.3% of medical laboratory equipment were functional at the time of data collection. When we compare this study to the previous one, more than half of chemistry machines were non-functional whereas about one-third chemistry machines were non-functional in the previous study. In this study, more CD4 machines were non-functional compared to the previous study whereas low hematology machines were non-functional when we compared to the previous literature. Overall, it was lower than the above mentioned study and it might be due to time laps and ownership issues.

In this study, lack of spare parts was the primary and leading reasons for non-functionality of medical laboratory equipment's. It was contrary to a study conducted in Kenya that medical laboratory equipment become non-functional due to lack of technical competency of medical laboratory professionals [12].

This study claimed that unavailability of spare parts were the major reasons for malfunction of medical laboratory equipment among public hospitals in Addis Ababa. It was consistent with the regional medical laboratory equipment workshop report which was held in Uganda [21]. In addition to this,absence of service engineers (for Chemistry & Hematology machines) was another reason for non-functionality of medical laboratory equipment among public hospitals in Addis Ababa. It was also, consistent with regional medical laboratory equipment's workshop report in Uganda [21].

In this study, lack of spare parts and installation problems were the main reasons for non-functionality of chemistry machines among public hospitals in Addis Ababa. In contrast to this; a study conducted in other parts of Ethiopia showed that lack of reagents and shortage of

laboratory professionals were the main reasons for non-functionality of medical laboratory equipment [9]. Regarding to hematology machines, this study revealed that lack of spare parts, lack of reagents and lack of trained man power (service engineer) were the leading causes for non-functionality. In contrast to this study, lack of reagents was the primary reason for malfunction and it was comparable to the previous study conducted in Ethiopia for the following reasons for malfunction of medical laboratory equipment's [9]. Installation problem was one of the main reasons for non-functionality for almost all medical laboratory equipment [9] whereas in this study, it was the reason for non-functionality of chemistry and hematology machines.

Of note, close to a quarter (5/21) of the 21 nonfunctional chemistry machines and 2 out of the 15 nonfunctional hematology machines are out of use due to installation reasons.

7. Strength and Limitations

7.1.Strength

The study strongly believes this is very important investigation into the area of asset assessment andfactors affecting their functionality of medical laboratory equipment. It will serve as a:

- Baseline data that will be used to study equipment management system and maintenance at large scale.

7.2.Limitations

The limitations of this study relate to the difficulties in accessing relevant and reliable data. This is because:

- The majority of health facilities surveyed didn't establish standardized equipment management data including preventive & curative maintenance, calibration, decontamination …etc. Due to this a number of pertinent checklist questions weren't answered adequately.
- Lack of similar assessment and findings to compare and contrast this finding.

8. Conclusion and Recommendation

8.1. Conclusion

All PCR machines were functional during the study period.

A large proportion of medical laboratory equipment's were non-functional among public hospitals in Addis Ababa due to lack of spare parts followed by installation problem.

8.2. Recommendation

Based on the result findings, the following points are recommended in order to improve Equipment management practice.

- The government should avail medical laboratory equipment spare parts and reagent for those program based equipment
- Installation should be performed by trained and competent personnel as per the manufacturer instructions.
- Facilities should improve maintenanceand inventory record managementfor laboratory equipment.

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Addis Ababa University

College of Health Science

School of Allied Health Science

Department of Medical Laboratory Sciences

Questionnaire for a study onAssessment of Medical Laboratory Equipment functionality status and Associated Factors among Public Health Hospitals in Addis Ababa

i. Study information sheet

My name is_____. I belong to the research team studying Medical Laboratory Equipment Management Practice and Associated Factors among Public Health Hospitals in Addis Ababa The study is being conducted by a graduate student of Medical Laboratory (NegussuAbebe) at the Department of Medical Laboratory Sciences, School of Allied Health Science in Addis Ababa University.

The objective of this study is to assess the functionality status of selected medical laboratory equipmentand factors associated with non-functionalityamong public hospitalsin Addis Ababa. I kindly ask you to participate in this study and give me genuine answers for my queries. Your participation in this study is greatly helpful in identifying problems related to functionality of medical laboratory equipment. The interview will take about 30 minutes. Your name as well as your institution name will not be written in this form and will never be used mentioned in the report either. You will not get payment because of your participation in this study and will not lose any service. All information given by you will be kept confidential and no one except the research team members will have access to the information. Your participation is completely voluntary and you are not obligated to answer any question you are not willing to respond. If you feel any discomfort with the question, it is your right to drop it at any time you want. You as well as your institution may even decide not to engage in this study from the very beginning. I hope I have clarified the purposes of the study. If you have any question you can ask me now or you may ask the principal investigator, NegussuAbebe, whose telephone is 0911395909 or email:negussuabebe@gmail.com

ii. Consent Form

I have understood the explanation of the information sheet concerning this study and I understood what will be required of me and what will happen to me if I take part in it. I also understand that any time I may withdraw from this study without giving a reason.

Are you willing to participate in this study?

1. Yes…….. Continue to the next page
2. No…… Skip to the next participant

Signature of interviewer----------

Signature of interviewee----------

Date of data collection--------/--------/----------

iii. English version Questionnaire

Addis Ababa University, College of Health Sciences, School of Allied Health Science, Department of Medical laboratory sciencesQuestionnaire toAssessment of Medical Laboratory Equipment Management Practice and Associated Factors among Public Health Hospitals in Addis Ababa, 2018.

Check list [23].

01. Questionnaire ID----------
02. Name of Hospital:----------
03. Contact person Phone number----------

S.No	**Equipment name**	**Model**	**Country of origin**	**Status 1. Functional 2. Non-functional**	Reason for malfunction 1. Out of date, 2.Uninstalled, 3. Lack of spare parts, 4. Lack of reagent, 5. No agent in the country, 6. Lack of trainedService engineer, 7. Work load	Remark
I	**Chemistry machine**					
1						
2						
3						
4						
5						
6						
7						
8						
9						
II	**Hematology machine**					
1						
2						
3						

4						
5						
6						
III	**CD4 machine**					
1						
2						
3						
4						
5						
6						
IV	**Viral load machine**					
1						
2						
3						
V	**PCR DNA machines**					
1						
2						
3						
VI	**Gene-Xpert**					
1						
2						
3						

Is current equipment inventory data available on all equipment in the laboratory?	Y	P	N	
	Tick for each item			
	Yes	No	N/A	
Name of equipment				
Manufacturer				
Condition received (new, used, reconditioned)				
Serial number				

Date of purchase				
Date of entry into service				
Is relevant equipment service information readily available in the laboratory?	Y	P	N	
	Tick for each item			
	Yes	No	N/A	
Service contract information				
Contact details for service provider				
Performance and maintenance records				
Last date of service				
Next date of service				
Current location				
Has the laboratory provided uninterrupted testing services				
the equipment manufacturer's operator manuals readily available to testing staff				
Repair orders monitored to determine if the service is completed				
stock of expendable parts present on site				
Routine preventive maintenance performed on all equipment and recorded according to SOPs				
Non-functioning equipment removed from the laboratory and storage area				

Thank you very much for your cooperation

Declaration

I, the undersigned, declare that this M.Sc. thesis is my original work, has not been presented for a degree in this or any other university and that all sources of materials used for the thesis have been duly acknowledged.

M.Sc. candidate: NegussuAbebe(B.Sc.)

Signature: _____ Date of submission: _____

This paper has been submitted with our approval as advisors.

FatumaHassen**(M.Sc, PhD candidate)**

Signature: _____

Date: _____

Place: Addis Ababa, Ethiopia.

AdinewDesale **(M.Sc)**

Signature: _____

Date: _____

Place: Addis Ababa, Ethiopia.

Aster Tsegaye (PhD)

Signature: _____

Date: _____

Place: Addis Ababa, Ethiopia.