ASSESSMENT OF STATUS AND CHALLENGES OF CLINICAL CHEMISTRY AUTOMATION UTILIZATION IN PUBLIC HOSPITAL LABORATORIES OF SELECTED ZONES OF OROMIA REGION, ETHIOPIA

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Assessment of Status and Challenges of Clinical Chemistry Automation Utilization in Public Hospital Laboratories of Selected Zones of Oromia Region, Ethiopia

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ABSTRACT

***Background**: Clinical laboratory automation has been widely implemented in every modern laboratory with different automation level. Though automation has many advantages, still many challenges affect its utilization in clinical laboratories of developing countries which in turn limited the capacity of health institutions to deliver adequate health care. So identifying challenges relating to clinical chemistry automation utilization faced by laboratories is important to work on and resolve those obstacles.*

***Objective**: To assess status and challenges of clinical chemistry automation utilization in public hospital laboratories of selected zones of Oromia region, Ethiopia from January 28 to March 15, 2019.*

***Method**: This study was conducted in 15 public hospitals found in Southwest Shoa, Jimma, Ilubabor and Buno-Bedele zones. Cross-sectional study using both quantitative and qualitative research approach was conducted from January 28 to March 15, 2019. A total of 68 key informants were included purposively for in-depth interview. In addition, 93 laboratory personnels who were working in the clinical chemistry section were included in the study. Data were collected by in-depth interview guides, questionnaires and checklists. The quantitative data were analyzed by simple descriptive statistics using SPSS version 23 whereas qualitative data were analyzed thematically.*

***Results**: In the assessed hospitals, almost all non-analytical activities of clinical chemistry tests were not automated. There were 14 different brands and models of clinical chemistry analyzers. More than two-thirds of analyzers found in the studied hospitals were out-of-service during the study period. In other way, only 14 (15.1%) of the laboratory personnels had received user training of clinical chemistry analyzers. Majority of the laboratories were suffered from clinical chemistry reagents shortage. There were also inappropriate procurement process of the analyzers, misuse and underuse of clinical chemistry tests in the studied hospitals, which affect the clinical chemistry automation utilization.*

***Conclusion and recommendations**: Clinical chemistry automation was not utilized appropriately due to a series of barriers in the study areas. Barriers hindering automation utilization should be acted up on by the facilities and other stakeholders.*

***Keywords**: Automation; automation utilization; clinical chemistry analyzers; Ethiopia*

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ABBREVIATIONS

CLS:	Clinical Laboratory Science
ESA:	Ethiopian Standard Agency
EPHI:	Ethiopian Public Health Institute
EPSA:	Ethiopian Pharmaceuticals Supply Agency
ETB:	Ethiopian Birr
FMoH:	Federal Ministry of Health
IDI:	In-depth Interview
NGO:	Non-Governmental Organization
ORHB :	Oromia Regional Health Bureau
PI:	Principal Investigator
SPSS:	Statistical Package for Social Science
TLA:	Total Laboratory Automation
WHO:	World Health Organization

OPERATIONAL DEFINITION

Automation: Process by which clinical chemistry analyzers perform many tests procedures with the least involvement of an analyst

Automation utilization: Effective use of clinical chemistry analyzers with minimal out-of-service

Challenges: Barriers that make clinical chemistry laboratories under utilize analyzers such as reagent shortage, lack of user training, frequent out of service of analyzers, inappropriate selection and procurement process of analyzers.

Laboratory personnels: Laboratory technicians and technologists working in clinical chemistry section

Public hospital: Hospitals financed and administered by government for the service of the community

User training: Training of laboratory personnels on clinical chemistry analyzer(s) found in their hospital

CHAPTER 1: INTRODUCTION

1.1. Background

Clinical laboratory services have a great influence on clinical decisions and 60-70% of the most important decisions on admission, discharge, and medication are based on laboratory results. Due to this overwhelming dependence of clinical decision on laboratory reporting, clinical laboratories have to improve their services (1). Improvements in the clinical laboratory workflow and the timeliness and accuracy of results reporting will not only benefit the laboratory but can also translate into increased clinician and patient satisfaction with laboratory services (2). The key to the improvement of laboratory services is the implementation of correct automation technology (3).

International Union of Pure and Applied Chemistry (IUPAC) define automation as the use of combinations of mechanical and instrumental devices to replace or supplement human (4). Other literature define automation as the process whereby an analytical instrument performs many tests with only minimal involvement of an analyst (5). Automation may range from automating only a few steps of the analytical process to total laboratory automation (TLA), depending on the needs and resources of each laboratory (6). An automated system should include as many steps as possible in the total testing process. However, most current systems only automate the actual testing procedure which starts with the application of a patient sample to the system and ends with the generation of test results (7).

Clinical laboratory automation has been widely implemented in every modern laboratory with different automation level. On the basis of the benefits of automation, the laboratories have changed manual, error-prone laboratory processes to automated ones with minimal operator intervention, resulting in increased productivity, decreased turnaround time (TAT), improvements in specimen handling, improved laboratory safety, enables use of minute amount of sample and minimizes errors (2,8).

Before the advent of automation, a single clinical chemistry assay passing through many procedures performed manually by laboratory personnels. These are sample preparation and identification, reagent preparation, manual metering and addition of sample and reagents into a reaction vessel, mixing and incubation in the reaction vessel, optical measurement of the mixture in a separate cuvette and calculation and recording of the results (9).

The era of automation of clinical chemistry started with the introduction of the Autoanalyzer 1 (Technicon Instruments Corporation, USA), which could assay blood urea nitrogen at the rate of 20 samples per hour using continuous flow analysis. It was the first practical and completely automated system described by Skeggs in 1956 (10). A few years later, a different approach appeared with the production of the Robot Chemist that used discrete analysis with conventional cuvettes and automatic pipetting and mixing, essentially automating many manual steps performed by medical laboratory personnel (11).

During successive generations of fully automated stand-alone analysers, a dichotomy emerged: mainstream clinical chemistry systems using colorimetry/spectrophotometry and immunoassay systems that used a variety of other analytical techniques. Later on, clinical chemistry and immunoassay analysers were merged as 'integrated' systems, combining immunoassay with spectrophotometric and potentiometric assays (12). Stand alone workstations or integrated workstations of immunoassay/chemistry are now available from several vendors: Roche, Siemens, Beckman-Coulter, Abbott, and some others that meet the needs of mid and high-volume laboratories (13).

Further automation was developed for pre-analytical procedures and post-analytical procedures. All phases of testing were ultimately combined in TLA through which all modules involved are physically linked by some kind of track system, moving samples through the process from beginning to end. In TLA, a complete integration has occurred which includes a complex of robotics, computers, liquid handling, and numerous other analytical and non-analytical technologies. Total laboratory systems offer substantial enhancements in throughput, allowing laboratories to increase capacity several folds without adding space or personnel; because instruments for chemistry, immunoassay,

hematology, coagulation, drug screening and other tests can be included. However, such large systems require substantial financial investment and planning (14).

Information technology is a critical element of any automation solution. Introduction of computers as information systems and as the interface for instruments after the late 1970s were significant as this allowed uploading of results into the laboratory information system. The use of automated analyzers with the ability to incorporate different software provides a comprehensive package for improving clinical effectiveness and outcomes when managed by laboratory personnels (15).

Clinical chemistry analyzers can be fully or semi-automated, large floor or benchtop models, open or closed systems (16). A fully automated analyzer is one that yields printed test results and requires nothing more of the technician than presentation the sample, controls and calibrators to the instrument while semi automated analyzer is one which requires the technicians to make some measurements, for example, the volume of sample and reagent to be added. Both types requires the technician to load reagents and samples (17). Closed systems are those analysers which use manufacturer-specific reagents only. Closed systems may be advantageous due to the use of specific reagents that are validated by the manufacturer to assure accuracy and reproducibility of test results. Open systems are those analysers that use reagents from other manufacturers (18).

Introducing an element of standardization for healthcare technology will help to limit the wide variety of makes and models of equipment acquired by the health facilities. By concentrating on a smaller range for each equipment type, technical, procedural, and training skills will increase whereas costs and logistical requirements of the facilities will decrease (19). It also allows for cost saving on equipment and reagent procurement; allows the establishment of an efficient and responsive service and maintenance infrastructure; limits overreliance on single platforms and vulnerability to supply bottlenecks, and permit instruments and reagents to be shared during breakdowns or stock shortages (20).

Selection of chemistry analyzer will depend on the test menu of the analyzer and its throughput. Other factors include sample handling, degree of automation, data management, footprint, and whether the machine can handle micro volume samples (21).

1.2. Statement of the problem

The utilization of automation in clinical laboratories of developing countries is greatly affected by many factors such as medical equipment malfunction and absence of their maintenance, shortage of laboratory consumables, inadequate logistical support, absence of governmental standards for laboratory testing and equipment, poor laboratory infrastructure and shortage of well-trained laboratory staff (22,23).

Lack of functioning medical equipment is generally regarded as a major contributor to poor automation utilization. In low income countries as much as half of the equipment in medical institutions is inoperable and not in use; where as some estimation is ranging up to 96% (24). In 16 developing countries from the Americas, Africa, and South East Asia, on average, about 38.3% of hospital medical equipment was out of service(25). Poor medical equipment handling and utilization, frequent power surges, the ages of the equipment, lack of operator training, lack of preventive maintenance, lack of spare parts, lack of maintenance capacity, and minimal knowledge regarding sophisticated equipment are factors that contribute to equipment breakdowns (26).

Some studies showed that the large diversity of analyzers is another major challenge of automation utilization in clinical laboratories. According to a study conducted within public laboratories in 15 Africa and Caribbean countries, there were 37 different manufacturers and more than 130 platforms of clinical chemistry due to lack of standardization. This leads to unnecessary technology diversity, with multiple test platforms and sometimes multiple sources for reagents and consumables for each test platform (27). Other study conducted in Tanzania in 2002 identified there were 6 Cobas Integra, 2 AxSYM, 33 fully, 82 Screen Master and 1 other type of clinical chemistry analyzers (20).

Medical equipment users should be familiar with medical and technical matters. However, usually, user's knowledge is always limited and user can not study deeply on technical matter because specialty is different and it is too complicated to users. In general, 70 – 80% of equipment trouble is caused by misuse or misunderstanding of equipment (28). According to WHO, vendors are obliged to train laboratory personnel in the calibration, operation, basic preventive maintenance and repair of particularly analysers. High quality training results in

improved equipment operation and less frequent breakdown (18). The traditional one-time training by the manufacturer as a condition of purchase is insufficient, particularly in view of the high turnover of personnel in developing countries and there is need to train new staff frequently (29).

The cost involved in purchasing medical devices can present a major obstacle to their use in developing countries. The cost of capital, however, is only the tip of the proverbial iceberg, with many recurrent costs hidden underneath, such as service contracts, spare parts, consumables and training (29).

In Africa, some institutions do not have generators and so they resort to physically switching off the analysers in order to minimize the damage during the upsurge when the power comes back. There are also instances when electrical power has been reported to be unavailable for periods, too long to be sustained by generators. Besides the effects on the analysers, the prolonged power cuts have a major effect on the stability of reagents that require refrigeration (30).

A study conducted in Tanzania showed that 2 chemistry analyzers experienced a cumulative 10 malfunctions requiring engineer technical support. Two (20%) malfunctions affected the laboratory's ability to test analytes, requiring samples to undergo either freezer archiving or shipment to a backup testing facility. The median (range) time elapsed until a service contracted engineer arrived on site for instrument repair was six (1-29) days, and the median (range) time elapsed until malfunctions were resolved was nine (1-136) days (31).

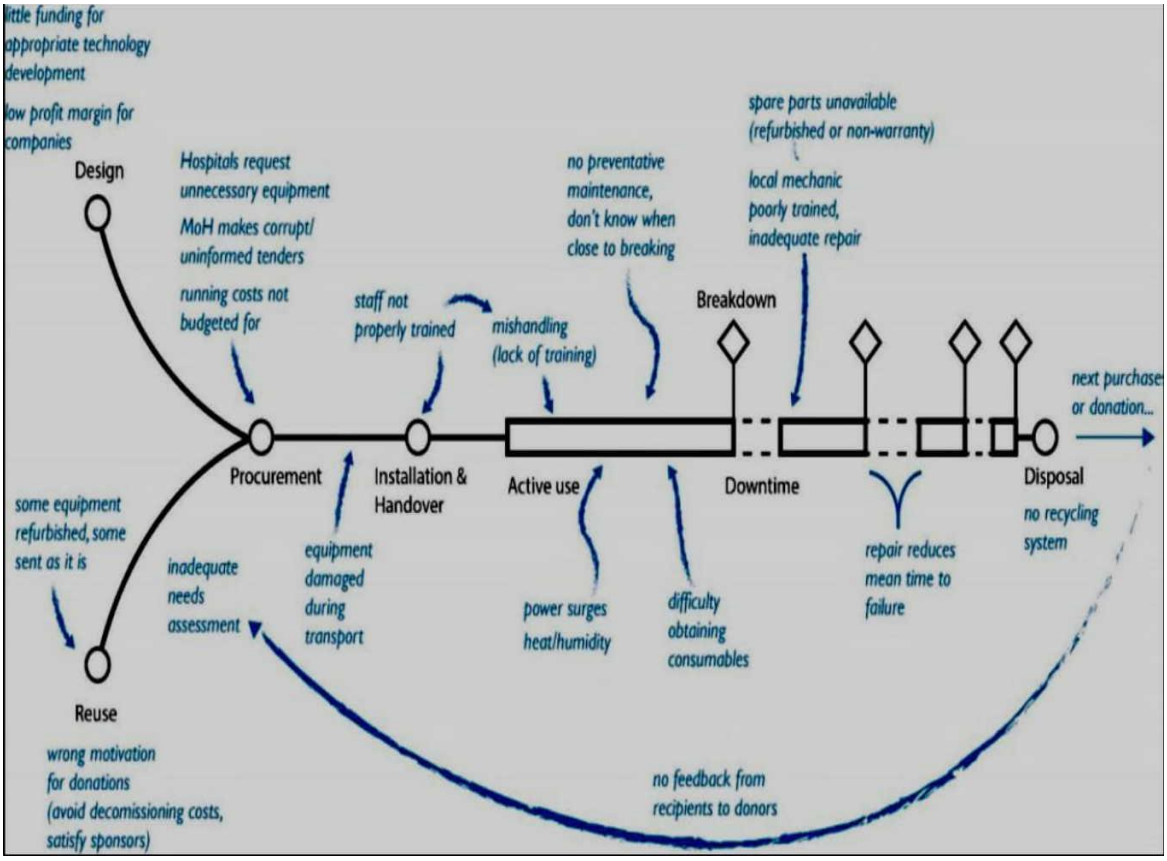


Figure 1: Life cycle of medical device in Africa [source: Designing a product-service for repair & maintenance of medical imaging equipment in Africa, 2016 p.4]

In Ethiopia, there are similar challenges as other developing countries which affect utilization of automation in clinical laboratories. It is estimated that only about 61 % of medical equipment found in Ethiopian public hospitals and other health facilities were functional (25). There was also a problem of big diversity of clinical chemistry analyzers. Even though there are standard lists of laboratory equipment at each level of hospitals in Ethiopia, they are not satisfactory to limit brand and model diversity of clinical chemistry analyzers (32–34). There were 10 different platforms of clinical chemistry analyzers in Jimma zone health facilities (35). Laboratory infrastructure is also poor for which about 48% of the existing public hospital laboratories need renovations to reach acceptable standards (36). In addition, frequent or prolonged electric power disruption greatly affects health service provision (37). Thus, the aim of this study was to assess the status and challenges of clinical chemistry automation utilization in public hospitals found in Southwest Shoa, Jimma, Ilubabor and Buno Bedele zones of Oromia region, Ethiopia.

1.3. Significance of the Study

The modern practice of clinical chemistry relies ever more heavily on automation. No discipline in laboratory medicine uses more technologies than clinical chemistry (5,38). So identifying the different challenges relating to clinical chemistry automation utilization faced by laboratories is important to work on and resolve those obstacles. The findings will be so informative and to be used by the laboratories and other stakeholders helping them to take necessary measures to improve the automation utilization. As per my knowledge, there is no adequate published study that shows the status of clinical chemistry automation and challenges affect its utilization in Ethiopia, particularly in the study area. To fill this gap this assessment has been done. Thus, this study will provide baseline information for other researchers to conduct large scale survey on the issue.

CHAPTER 2: LITERATURE REVIEW

Since the pioneering work of Skeggs in developing continuous flow systems, automated analyzers have become standard in almost all laboratories. It is difficult to imagine a modern clinical laboratory without automation (39).

In CAP Today's 2008 annual survey of the automation vendors, it was estimated that there were more than 2000 clinical laboratories worldwide with total or subtotal automation supporting pre-analytic activities and/or post-analytic activities interfaces to chemistry and immunochemistry analyzers (40). By the year 2005, about 525 (32%) laboratories in the United States had some form of automation, 17% of which was TLA (6).

The John T. Mather memorial hospital in the city of New York had achieved dramatic process improvements as a result of installing automation in 2000. This community hospital reduced TAT for 7 tests of drugs of abuse panel by 79%; reduced the number of process steps by 50%; decreased labeling errors by 20%; decreased cost-per-test by 17%; increased testing volume by 113%; and increased revenue by 152% since 1996 (41).

According to WHO report, more than 50% of the laboratory and other medical equipment in resource-poor settings is not in-service. The lack of working equipment has a devastating effect on healthcare in resource-poor settings. Certainly one of the most common causes for a piece of medical equipment being out-of-service is the lack of consumables (42).

A study conducted in the Dominica Republic showed 28% of all reagents of the laboratory were out of stock at the time of the study, primarily for their high procurement cost (43). Other study conducted in Bangladesh identified that spareparts availability of old equipment is also a great challenge since they are unavailable after a certain period due to rapid technological development and changing modalities (44).

From the equipment problems reported, about one-third arise from operator problems, one-third arise from minor, easy-to-solve technical problems and only one-third require more serious fault-finding procedures and special knowledge of the equipment. So, at least two

thirds of the problems could be corrected by properly trained equipment users. Hence, at most, there is one-third of the problems which require specially trained maintenance personnel (45).

A study conducted in Addis Ababa indicated that none of 123 laboratory personnel in public hospitals were trained on equipment maintenance. Routine preventive maintenance of laboratory equipment were performed in 9 (69.2 %) visited health facilities and only 6 (46.2 %) of the laboratories had equipment services agreement (37).

A cross-sectional study conducted in Jimma zone identified that while medical devices are installed, training may be given for one person but this person may leave for different reasons, so another person without training may take over the responsibility to operate the machine which also affects the function of the device (46)**.** Other study conducted in this zone indicated that in 20 health facilities with clinical chemistry service there were 10 different platforms of clinical chemistry analyzers (35).

2.1. Conceptual framework

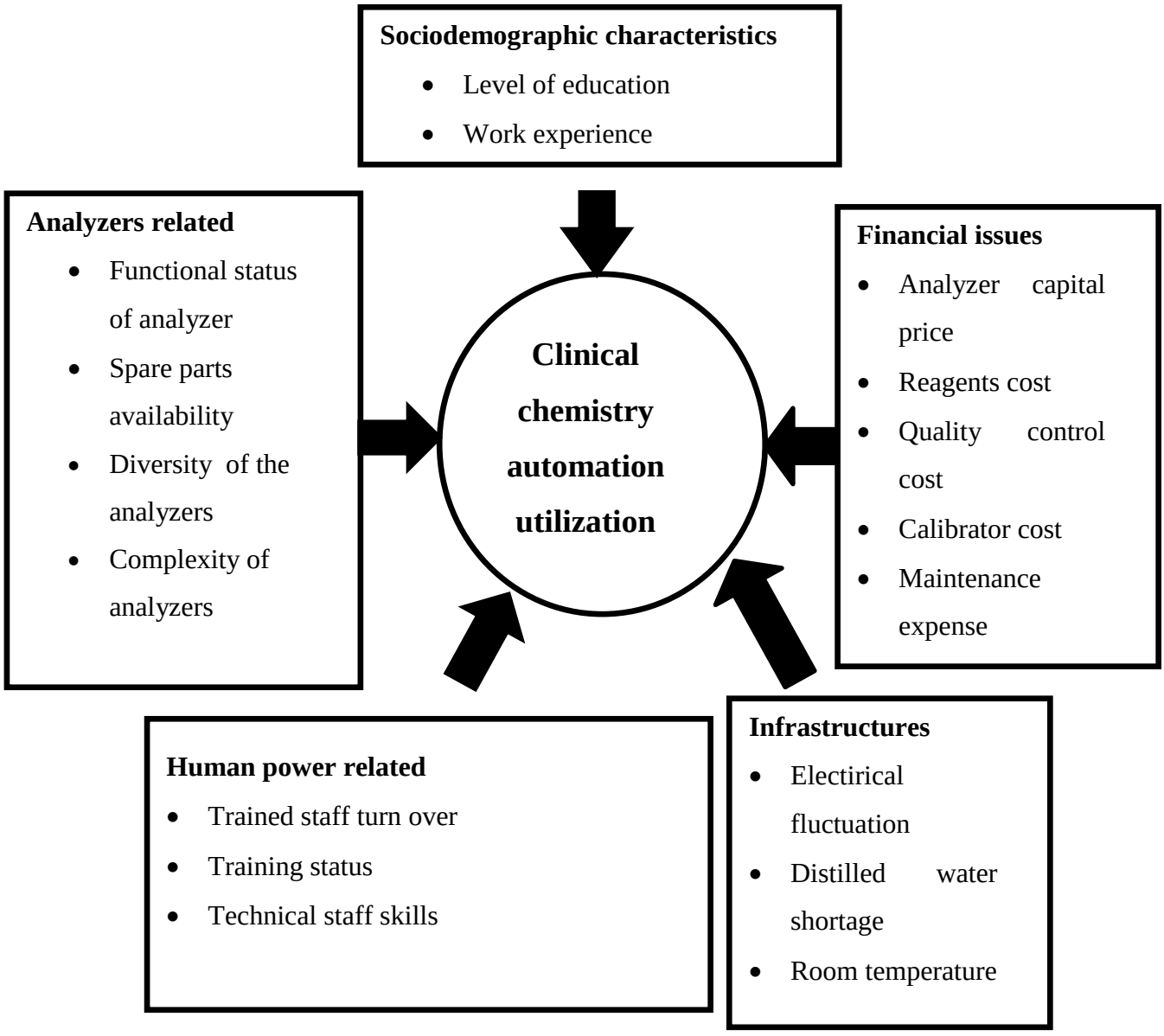


Figure 2: Conceptual framework of challenges of clinical chemistry automation utilization (developed by principal investigator)

CHAPTER 3: OBJECTIVE

3.1. General objective

- To assess status and challenges of clinical chemistry automation utilization in public hospital laboratories of selected zones of Oromia region, Ethiopia, from January 28 to March 15, 2019.

3.2. Specific objectives

- To determine the status of clinical chemistry automation in public hospital laboratories of selected zones of Oromia region, Ethiopia, from January 28 to March 15, 2019.
- To identify the main challenges of clinical chemistry automation utilization in public hospital laboratories of selected zones of Oromia region, Ethiopia, from January 28 to March 15, 2019.

CHAPTER 4: METHODS AND MATERIALS

4.1. Study Area and Period

The study was conducted in all 15 public hospitals found in Southwest Shoa, Jimma, Ilubabor and Buno-Bedele zones of Oromia region, Ethiopia. Oromia region is one of the 9 regions of Ethiopia having 20 administrative zones. According to the information obtained from Oromia Regional Health Bureau (ORHB), the region had 79 functional public hospitals during the study period.

Jimma, the capital of Jimma zone, is located at 352 Km southwest of Addis Ababa. According to the data obtained from Jimma zone health department, in this zone there were 514 health posts, 118 health centers and 7 public hospitals. The public hospitals are Jimma Medical Center, Shenen Gibe general hospital, Agaro general hospital, Limu Genet general hospital, Seka Chekorsa primary hospital, Omo Neda primary hospital and Satema primary hospital.

Woliso, the capital town of the Southwest Shoa zone, is located at 114 Km far from Addis Ababa. According to the Southwest shoa zone health department, the zone had 268 health posts, 55 health centers and 4 public hospitals. The public hospitals are Leman primary hospital, Bantu primary hospital, Tulubolo general hospital and Ameya primary hospital.

Mettu town, the capital of Ilubabor zone, is located 600 km far from Addis Ababa, Ethiopia. According to the Ilubabor zone health department, the zone has 14 woredas and 289 kebeles with a total population of 958,058. During the study period, there were 273 health posts, 39 health centers and 2 public hospitals. The public hospitals were Metu Karl hospital and Darimu primary hospital.

Buno Bedele zone is found at 480 km from Addis Ababa. There were 2 functional public hospitals Bedele general hospital and Didessa primary hospital. The study was conducted from January 28 to March 15, 2019.

4.2. Study Design

Cross-sectional study design was utilized by employing both quantitative and qualitative research approach.

4.3. Population

4.3.1. Source population

All public hospitals found in Southwest Shoa, Jimma, Ilubabor and Buno Bedelle zones of Oromia region, all laboratory personnels who were working in clinical chemistry section of those hospitals and all clinical directors, laboratory heads, finance heads, laboratory quality officers and pharmaceutical storekeepers of the hospitals were source population of the study.

4.3.2. Study population

All public hospitals found in Southwest Shoa, Jimma, Ilubabor and Buno Bedelle zones of Oromia region, laboratory personnels who were working in clinical chemistry sections, clinical directors, laboratory heads, finance heads, laboratory quality officers and pharmaceutical storekeepers of the hospitals who available during the study period were study population.

4.3.3. Sample size determination and sampling technique

From 20 zones of Oromia region, 4 zones were selected conveniently. The reason behind the selection of these zones was due to their proximity to Jimma University, where the principal investigator (PI) is situated, to reduce the travel cost. All 15 public hospital laboratories found in Jimma zone (n=7), Ilubabor zone (n=2), Southwest Shoa zone (n=4) and Buno-Bedele zone (n=2) were included in the study.

For in-depth interview (IDI) the following study participants in selected hospitals were purposively included due to their knowledge for the subject matter of this study

- Clinical directors (n_1=12)

- Laboratory heads (n_2=13)
- Laboratory quality officers (n_3=15)
- Finance heads (n_4=13)
- Pharmaceutical storekeepers (n_5=15)
    - $N = n_1+n_2+n_3+n_4+n_5=12+13+15+13+15=68$

      Therefore, a total of 68 study participants were involved.

A total of 93 laboratory personnels who were working in the clinical chemistry section and available during the study period were also included in the study.

4.4. Measurements

4.4.1. Variables

Dependent variable

- Clinical chemistry automation utilization

Independent variables

- **Sociodemographics**
    - Sex
    - Age
    - Educational level
    - Professional work experience
- **Personnel related**
    - Trained staff turn-over
    - Staff training status in automation
    - Management commitment
    - Technical staff commitment
    - Technical staff skill
- **Financial issues**
    - Cost of quality control materials
    - Cost of calibrators

- Cost of reagents
- Analyzer maintenance expenses
- Analyzer capital price

- **Analyzers related**
  - Analyzer availability
  - Analyzer functionality status
  - Spare part availability
  - Complexity of analyzers
  - Diversity of analyzers
- **Consumables related**
  - Reagent availability
  - Calibrator availability
  - Quality control material availability
- **Infrastructure**
  - Distilled water shortage
  - Electrical fluctuation
  - Room temperature controller availability
- **Organization related**
  - Level of hospital

4.4.2. Data collection tools and procedures

The self-administered questionnaires, check-lists and IDI guides were used as data collection tools. These were prepared after reviewing relevant literatures from websites, books and articles as well as by asking experts to include all the possible variables that address the objective of the study.

Self administered questionnaires: the data from laboratory personnels who work in clinical chemistry section were collected using self-admistered semi-structured questionnaires (Annex II). First, the participants were communicated to get their consent. Once their consent was known, the prepared questionnaires were distributed to each participant by the PI. The questionnaires were collected on spot by thanking the respondents.

Checklists: this part was divided into two sections.

i. **Section A**: used to collect data concerning the hospital, hospital laboratory and hospital laboratory clinical chemistry section (Annex IIIA).
ii. **Section B:** this section was filled for all clinical chemistry analyzers found in selected hospitals (both in-service and out-of- service) separately (Annex IIIB).

In-depth interview guides: using the in-depth interview guides (Annex IV), in-depth interviews were conducted with clinical directors, laboratory heads, finance heads, laboratory quality officers and pharmaceutical storekeepers of the selected hospitals by PI. The verbatim of IDI participant were written on note and assisted with tape recorder after consent was obtained to do so. The jotted note and the audio recorded verbatim were transcribed and translated at daily base during data collection time.

4.5. Data processing and analysis

The quantitative data were entered and cleaned using epidata 3.1 and exported to SPSS version 23 (IBM, USA) for analysis. Descriptive statistics (percentage and frequency) were computed and results were presented using tables and graphs. The qualitative portions of the study from open-ended questions and IDI were thematized to major themes after analyzing each response in different categorization and codes. Finally the data match each other were extracted and written by narrating the finding.

4.6. Data quality assurance

Data collection tools were reviewed and appropriate modification made accordingly before actual data collection. During data collection, filled questionnaires were checked for completeness and validity. After data collection, quantitative data was entered to EPI-Data 3.1 and cleaned before exported to SPSS version 23. The transcribed and translated data obtained from indepth interviews were read and checked against the recorded audio for accuracy of verbatim and transcripts. Data were stored in a password- protected computer to protect alteration and backup was saved by removable disk and personal email.

4.7. Ethical consideration

Ethical clearance (annex V) has been obtained from Institutional Review Board (IRB) of Jimma University, Institute of Health. Soft copy of ethically reviewed research protocol along with copy of ethical clearance had been submitted to ORHB; consequently the support letter (annex VI) has also been obtained. Finally, the support letter from ORHB has been presented to each of the study hospitals management. Participants were given consent after read information sheet. Data confidentiality was maintained by keeping all electronic files in password-protected computer and hard copies locked. Questionnaires and checklists were allocated a unique number code and therefore the identities of participants and facilities were not revealed. The collected data not used for other than this study.

4.8. Plan for utilization and dissemination of result

After the findings of this thesis approved by Jimma University, it will be submitted to the School of Medical Laboratory Sciences, Faculty of Health Sciences, Institute of Health, Jimma University, ORHB, studied hospitals and other concerned bodies. Also, the findings will be presented on ORHB review meeting and professional conferences. Finally, the manuscript will be submitted to a reputable scientific journal for publication.

4.9. Limitation of the study

The study did not include biomedical engineers/technicians who do have the potential to identify other challenges in clinical chemistry automation utilization.

CHAPTER 5: RESULTS

5.1. Description of hospitals

From hospitals included in the study, majority of them, 8 (53.3%) were primary hospitals. In other way, 8 (53.3%) of hospitals had less than 5 years of service. Regarding clinical chemistry section status, in 10 (66.7%) hospitals clinical chemistry services had been given with hematology/immunohematology services in one section whereas in only 2 (13.3%) hospitals where it had separated section [**Table 1**].

Table 1: Description of public hospitals in selected zones of Oromia region, Ethiopia, 2019 (N=15)

Variables		Level of hospital			Total N (%)
		Primary (n=8)	General (n=5)	Specialized (n=2)	
Clinical chemistry section status	Separate	0	0	2	2 (13.3)
	With hematology	7	3	0	10 (66.7)
	With hematology and serology	1	2	0	3 (20.0)
Years of service	<5	8	0	0	8 (53.3)
	5-10	0	1	0	1 (6.7)
	> 10	0	4	2	6 (40.0)

5.2. Background characteristics of study participants

From 104 eligible laboratory personnels working in clinical chemistry section, 93 were respondents of this study a response rate 89.4%. From 75 initially proposed as study participants for IDI, 68 (90.7%) of them were participated in the study.

As shown in **Table 2**, from laboratory personnels working in clinical chemistry section and participated in the study 76(81.7%) of them were males. Most of the respondents were within 25-29 age group 46 (49.5%), BSc holders 70 (75.2%) and had greater than 5 years of working experience 41(44.1%).

Table 2: Background characteristics of laboratory personnels working in clinical chemistry section of public hospitals in selected zones of Oromia region, Ethiopia, 2019 (N=93)

Variable		Number (%)
Sex	Male	76 (81.7)
	Female	17 (18.3)
Age group (in years)	20-24	10 (10.8)
	25-29	46 (49.5)
	30-34	24 (25.8)
	35-39	7 (7.5)
	Missing	6 (6.9)
Educational level	MSc	2 (2.2)
	BSc	70 (75.2)
	Diploma	21 (22.6)
Professional work experience (in years)	<2	32 (34.4)
	2-5	20 (21.5)
	>5	41 (44.1)

5.3. Status of clinical chemistry automation

As indicated in Figure 3, in all 15 (100.0%) assessed hospitals the non-analytical activities of clinical chemistry tests such as transportation of specimen, decapping and recapping of specimen tube, sorting, aliquoting, archival storage and disposal of the leftover specimen were done manually by laboratory personnels.

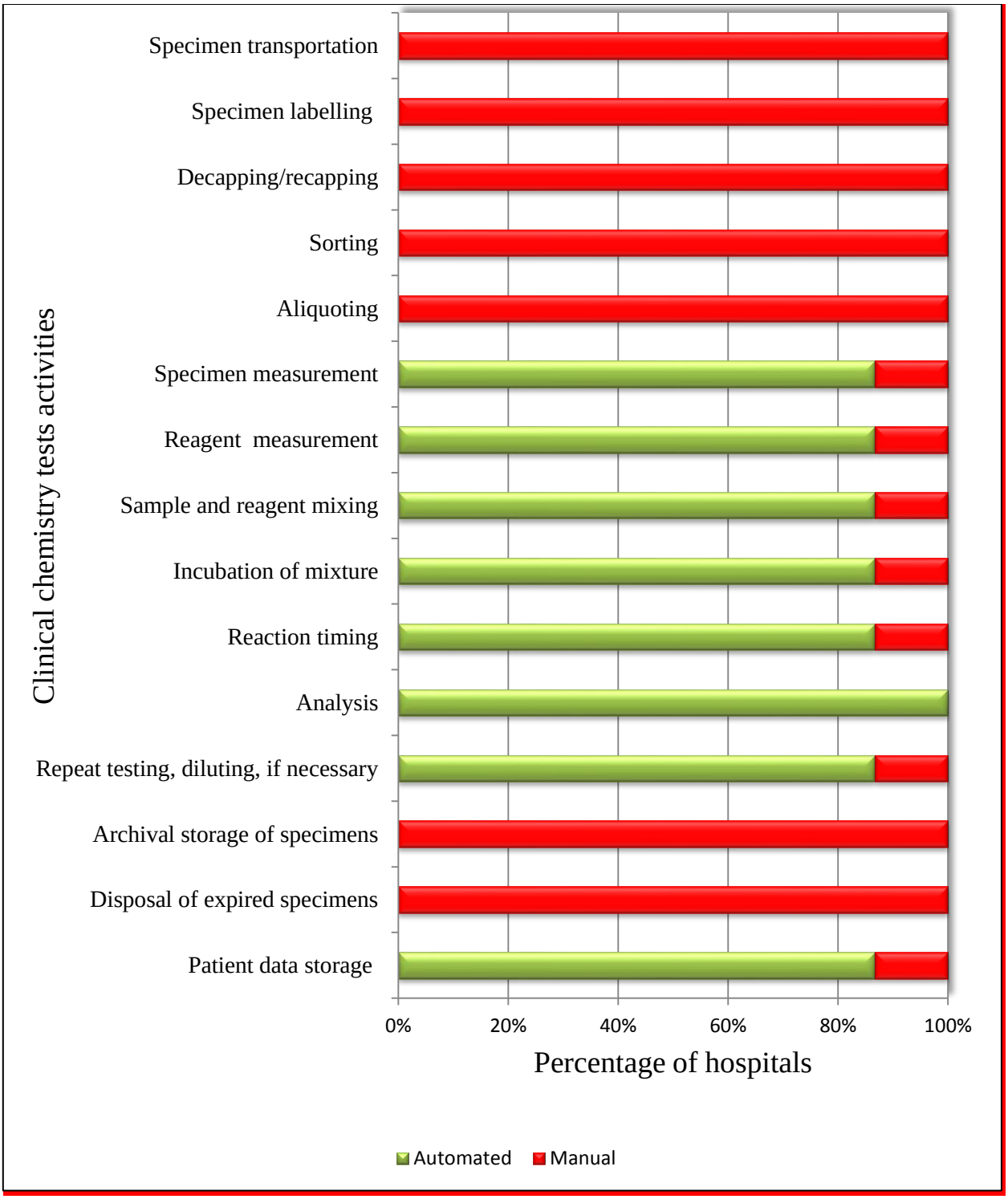


Figure 3: Status of automation of clinical chemistry tests activities in public hospitals laboratories of selected zones of Oromia region, Ethiopia, 2019 (N=15)

5.4. Perception based challenges of clinical chemistry automation utilization

Out of 93 respondents majority of them, 28 (30.1%), perceived that the utilization of clinical chemistry automation in laboratories affected by high capital price of analyzers moderately. About 36 (38.7%) of study participants perceived that high maintenance expenses of analyzers affect automation utilization in large degree. On the other hand, 28 (30.1%) of respondents perceived high cost of reagents affect it moderately. Majority of study participants, 27 (29.0%), perceived high cost of calibrator affect the utilization in large degree while 36 (38.7%) had perception that cost of quality controls affect it in large degree.

In other way, complexity of clinical chemistry analyzers perceived by 27 (29.0%) of respondents as it affect clinical chemistry automation utilization in very large degree. About 38(40.9%) of study participants responded, the diversity of analyzers affect clinical chemistry automation utilization in large degree. Slightly more than one-third of respondents perceived unavailability of spare parts affects clinical chemistry automation utilization at large degree.

Regarding electicity fluctuation, 29 (31.2%) of respondents believed that electricity fluctuation affect clinical chemistry automation utilization at very large degree. In other way, about 38 (40.9%) of the study subjects believed that technical staff commitment affect clinical chemistry automation utilization in large degree while 25 (26.9%) of them responded as management commitment affect it in very large degree [**Table 3**].

Table 3: Perception based challenges of clinical chemistry automation utilization of public hospitals of selected zones of Oromia region, Ethiopia, 2019 (N=93)

Variables	Number(%) of responses indicating the extent of challenges					
	Do not know	Not at all	Very small degree	Moderate degree	Large degree	Very large degree
Capital price of analyzer	5 (5.4)	3 (3.2)	12 (12.9)	28 (30.1)	20 (21.5)	25 (26.9)
Cost of analyzer maintenance	4 (4.3)	5 (5.4)	10 (10.8)	17 (18.3)	36 (38.7)	21 (22.6)
Cost of reagents	0 (0.0)	8 (8.6)	10 (10.8)	28 (30.1)	25 (26.9)	22 (23.7)
Cost of quality controls	8 (8.6)	5 (5.4)	8 (8.6)	10 (10.8)	36 (38.7)	28 (30.1)
Cost of calibrator	3 (3.2)	7 (7.5)	19 (20.4)	14 (15.1)	27 (29.0)	23 (24.7)
Availability of spare parts	4 (4.3)	7 (7.5)	6 (6.5)	11 (11.8)	33 (35.5)	32 (34.4)
Electricity fluctuation	9 (9.7)	13(14.0)	11 (11.8)	20 (21.5)	11 (11.8)	29 (31.2)
Trained staff turnover	10 (10.8)	6 (6.5)	11 (11.8)	22 (23.7)	13 (14.0)	31 (33.3)
Complexity of the analyzer	5 (5.4)	7 (7.5)	21 (22.6)	21 (22.6)	12 (12.9)	27 (29.0)
Technical staff commitment	1 (1.1)	9 (9.7)	9 (9.7)	16 (17.2)	38 (40.9)	20 (21.5)
Management commitment	0 (0.0)	4 (4.3)	21 (22.6)	21 (22.6)	22 (23.7)	25 (26.9)
Diversity of analyzers	0 (0.0)	4 (4.3)	5 (5.4)	9 (9.7)	38 (40.9)	37 (39.8)

5.5. Description of clinical chemistry analyzers

From 31 clinical chemistry analyzers, 25 (80.8%), 25 (80.8%) and 23 (74.2%) were chemistry analyzers, fully-automated analyzers and open reagent system analyzers respectively. Regarding warranty condition, about 26 (83.9%) analyzers warranty was expired. In other way, all analyzers were new when received/purchased [**Table 4**].

Table 4: Description of clinical chemistry analyzers by the level of hospitals in public hospitals of selected zones of Oromia region, Ethiopia, 2019 (N=31)

Variables		Number of analyzers by level of hospital			Total N (%)
		Primary	General	Specialized	
Analyzer type	Chemistry	9	11	5	25 (80.8)
	Immunoassay	0	0	2	2 (6.4)
	Integrated chemistry /immunoassay	0	0	2	2 (6.4)
	Electrolyte analyzer	0	0	2	2 (6.4)
Automation grade	Semi-automated	3	3	0	6 (19.2)
	Fully automated	6	8	11	25 (80.8)
Reagent form	Open system	9	11	3	23 (74.2)
	Closed system	0	0	8	8 (25.8)
Warranty condition	Within period	4	1	0	5 (16.1)
	Expired	5	10	11	26 (83.9)
Condition when received /purchased	New	9	11	11	31 (100.0)
	Reconditioned	0	0	0	0 (0.0)

5.6. Challenges of clinical chemistry automation utilization

From the entire information gathered by different data collection tools, 7 main challenges were identified that hinder the utilization of clinical chemistry automation in the assessed hospitals.

5.6.1. Diversity of analyzers platform

There were 14 different brands and models of clinical chemistry analyzers in the assessed hospitals. Among 31, most of them (22.6%) were Dirui CS-T240 (Dirui Industrial Co., Ltd, China) followed by Biosystem A25 (BioSystems SA, Spain) [**Table 5**].

Table 5: Types and number of clinical chemistry analyzers in public hospitals of selected zones of Oromia region, Ethiopia, 2019 (N=31)

Name of analyzer	Number (%)
Dirui CS-T240 (Dirui Industrial Co., Ltd, China)	7 (22.6)
Biosystem A25 (BioSystems SA, Spain)	4 (12.9)
Biosystem BTS 350 (BioSystems SA, Spain)	3 (9.7)
Mindray BS 200E (Mindray Bio-Medical Electronics Co., Ltd, China)	3 (9.7)
ABX Pentra 400 (Horiba ABX, France)	2 (6.5)
HumaStar 200 (Human GmbH, Germany)	2 (6.5)
COBAS Integra 400 Plus (Roche Diagnostics)	2 (6.5)
VIDAS ® (BioMérieux SA, France)	2 (6.5)
Humalyte plus 3 (Human GmbH, Germany)	1 (3.2)
Opt Lion (OPTI Medical Systems, Inc., Georgia, USA)	1 (3.2)
SBA 733 plus (Sunostik Medical Technology Co.,Ltd ,China)	1 (3.2)
Photometer 5010 V5+ (Robert Riele GmbH & Co KG, Germany)	1 (3.2)
Vegasys	1 (3.2)
3000 Evolution	1 (3.2)

In-depth interview with key informants also clearly identified that diversity of clinical chemistry analyzers was one of the main challenges in laboratories. Laboratory head of one hospital gave his opinion as follows

> "*Currently there are many types of clinical chemistry analyzers in our country [Ethiopia]. Clinical chemistry analyzers you find in this hospital and other hospitals are different. Even though someone is an expert on one model of clinical chemistry analyzer, he/she may not on others. This also creates difficulty in procuring spare parts and consumables and also in providing training for operators. I suggest that standardization of clinical chemistry analyzers including other sophisticated laboratory analyzers should be done at national or regional level which will be renewed with a specific period of time with the technology development. The old*

analyzers also should be retired to decrease the diversity." (Laboratory head 14, personal communication, 12 March 2019)

Quality officer of one hospital gave his opinion as follows:

> *"It is known that different brands and models of clinical chemistry analyzers are found in different laboratories. This makes difficulty to get support such as reagents during stock out and other consumables from neighbor hospitals. So, it is better to limit clinical chemistry analyzers to 2 or 3 brands and models*."(Quality officer 7, personal communication, 20 February 2019)

5.6.2. Malfunction of analyzers

During the study period, from assessed hospitals, only 7 (46.7%) of them had been giving the clinical chemistry tests service using analyzers. The rest 8 (53.3%) hospitals had been giving only blood glucose test service using glucometers.

About 14 (45%) clinical chemistry analyzers were non-functional whereas 7 (23%) of them were functional but not in use; totally 21 (68%) analyzers were out-of-service during the study period. The causes of non-functionality were installation problem (n=4), hardware malfunction (n=9), calibration and quality control failure (n=1) whereas the causes for functional but not in use of analyzers were reagent shortage (n=5) and lack of user training (n=2). In one hospital three analyzers have been kept without being installed for more than 6 years because of vendor engineer unavailability.

The reasons for why curative maintenance were not done for non-functional analyzers were due to delayed responses to repair requests (n=7) and unavailable spare parts (n=6) whereas the curative maintenance of one analyzer was on progress during the study period.

Only vendors of 8 (25.8%) analyzers are available for technical support in a reasonable period of time on request. The rest were delayed for a long period of time.

The key informant indicated the problem as follows;

"The vendor engineers delay our request for maintenance of the analyzer. There is a time we wait for them for up to 4 months. The reason they give for delay is that there is a few service engineers for many analyzers throughout the country. Many time we get technical support for minor troubleshoot from the vendor engineer by contacting them through phone." (Laboratory head 13, personal communication, 7 March 2019)

As explained by many interviwees, curative maintenance of clinical chemistry analyzers were also challenging in the assessed hospitals due to its expensiveness. The key informants identified it in detail as follows;

*"Curative maintenance fee asked by vendor representative engineers is not affordable. A few months ago, the engineer asked 25,000 ETB in cash in addition to air flight ticket fee and hotel expenses to change the cuvette of the analyzer. They are also not interested to show the curative maintenance procedures to onsite biomedical engineers and to us [laboratory personnels]." (*Quality office 10, personal communication, 28 February 2019)

"*Curative maintainance of clinical chemistry machine is one of our head ache. We take it to Addis Ababa for maintenance. To check whether it is repairable or not, they ask more than 20,000 ETB in addition to the reagent cost. If the spare part is needed to replace, more expense up to 50,000 ETB is needed."* (Finance head 14, personal communication, 12 March 2019)

5.6.3. Reagents shortage

This study showed that 7 (46.7%), 8 (53.3%), 9 (60.0%) and 5 (33.3%) hospitals had stock-out at the time of visit for quality control (normal), quality control (pathological), calibrator and assay reagents respectively.

As most key informants agreed and observed by the PI of this study, the challenges related to reagent shortages were the main reason for most test interruptions which predominantly hinder proper utilization of automated clinical chemistry analyzers. Although various factors contribute to the challenges related to clinical chemistry reagents, majority of them suggested the problem was related to the country's supply chain system.

Laboratory heads of hospitals gave similar opinions on clinical chemistry reagents shortage;

> *"Stock-out of clinical chemistry reagents happens more frequently than other reagents in this hospital. Since we receive nearly expired reagents from Ethiopian Pharmaceuticals Supply Agency (EPSA), stock-out occurs within a short period of time after procurement. Totally the analyzer had given service for not more than four months in two years due to frequent reagent shortage occurrences."(*Laboratory head 9, personal communication, 22 February 2019*)*

> *"Currently we are giving the service of four clinical chemistry tests: creatinine, urea, aspartate aminotransferase (AST) and alanine aminotransferase (ALT) only. Both the vendor of the analyzer and EPSA supply only the most frequently ordered reagents. For example, we have ordered HbA1c many times but we could not get it." (*Laboratory head 7, personal communication, 20 February 2019*)*

> *"Even though our hospital analyzer is an open system, there are difficulties to adapt to reagents from other manufacturers. It failed calibration for reagents from many other manufacturers."(*Laboratory head 10, personal communication, 28 February 2019)

There were 3 open system analyzers which did not accept other manufacturer's reagents in the studied hospitals. As a result, all of them were out of service due to reagent shortage during the study period. As clearly indicated by key informants this was done intentionally by vendors for the benefit they get from the sale of reagents.

Others opinion on the challenges related to clinical chemistry reagents in in-depth interviews were also supported the idea of laboratory heads

> *"The hospital has started service 2 years ago. Most necessary supplies of this analyzer not found in the market at the same time. If we get calibrator, we may not get quality control; if we get quality control, we may not get assay reagents such as creatinine, urea, AST, ALT and so on. Sometimes we perform tests for a long period of time without calibration and quality control. Also, we use control from one manufacturer with reagents from other manufacturer. Currently our analyzer is out of service for*

anti-bacterial detergent. No other types of analyzers from different manufacturer use this kind of reagent. The analyzer is open system; that is we can procure and use reagents from other manufacturers. However, this detergent is specific to this brand of analyzers. Therefore, its availability is limited in the analyzer vendor even though we can purchase other of its reagents from EPSA or other vendors" (Quality officer 2, personal communication, 31 January 2019)

"*The vendor of the chemistry analyzer is the sole source of the analyzer reagents. Currently, we could not procure the reagents without bid since the vendor was unable to give the approval document that indicates it is the sole source of the reagents. The current finance law does not permit procurement of greater than 1,500 ETB without bid unless the vendor is sole source with approval document."(*Finance head 10, personal communication, 28 February 2019*)*

5.6.4. Lack of training and skill gap

In the hospitals covered by the survey, only 14 (15.1%) of the laboratory personnels had received user training from which 12 of them were trained by the vendor representatives whereas the left were trained by ORHB. The trained individuals were also concentrated on few hospitals only. As clearly indicated by respondents, the users training duration were from 1-2 days which vary from vendor to vendor. In addition, the interviwees showed that the training was not satisfactory and mostly procedural orientation only. In other way, 49 (52.7%) and 74 (79.6%) of study subjects responded they could not perform quality control and calibration without supervision respectively [**Table 6**].

Table 6: Training and skills related to clinical chemistry automation utilization of study participants in public hospitals of selected zones of Oromia region, Ethiopia, 2019 (N=93)

Variable			Number (%)
Taking training on clinical chemistry analyzer in the hospital	yes		14 (15.1)
	No		79 (84.9)
Knowledge of clinical chemistry tests principle	Yes		29 (31.2)
	Partly		37 (39.8)
	No		27 (29.0)
Activities the laboratory personnel can perform independently	Running test	Yes	88 (94.6)
		No	5 (5.4)
	Calibration	Yes	19 (20.4)
		No	74 (79.6)
	Quality control running and monitoring	Yes	44 (47.3)
		No	49 (52.7)
	Preventive maintenance	Yes	25 (26.9)
		No	68 (73.1)
	Troubleshooting minor problems	Yes	18 (19.4)
		No	75 (80.6)

The in-depth interview conducted also showed that there was gap in in-service training of laboratory personnels on clinical chemistry analyzers.

> "*The training given by the vendor representative engineer was not satisfactory. The engineer showed us only operation procedures of a limited number of tests for a day. Even though the analyzer has the capacity to analyze the serum electrolytes, we could not perform by this analyzer because of skill gap. Clinical chemistry analyzer is sophisticated equipment which cannot be operated properly by one day training.* " (Quality officer 3, personal communication, 4 February 2019)

> *"During the installation of the analyzer the vendor engineer had given training for two laboratory personnels but both left the hospital. No re-training was given for other workers currently working in clinical chemistry section." (*Quality officer 4, personal communication, 7 February 2019*)*

> "*Most of training in clinical laboratory in this country is funded by NGOs. Unfortunately clinical chemistry is not their focus area. This negatively affects it*."(Laboratory head 10, personal communication, 28 February 2019)

One key informant also gave his opinion regarding the skill gap of laboratory personnels due to preservice education training inadequacy as follows:

> "*Education given in our universities focus on theories. Practical training is very limited and based on obsolete analyzers. Many of the newly hired laboratory personnels even do not know the term quality control and calibration. This indicates how much the quality of education is poor. This negatively affects the automation utilization in health facilities. I suggest that universities and colleges should focus on the practical aspect of learning and teaching process to produce competent laboratory staffs."* (Laboratory head 4, personal communication, 7 February 2019)

The entire assessed hospitals have one or more than one biomedical engineers and/or biomedical technicians. However, many key informants suggest that they should take advanced maintenance training.

One key informant explained it as follows;

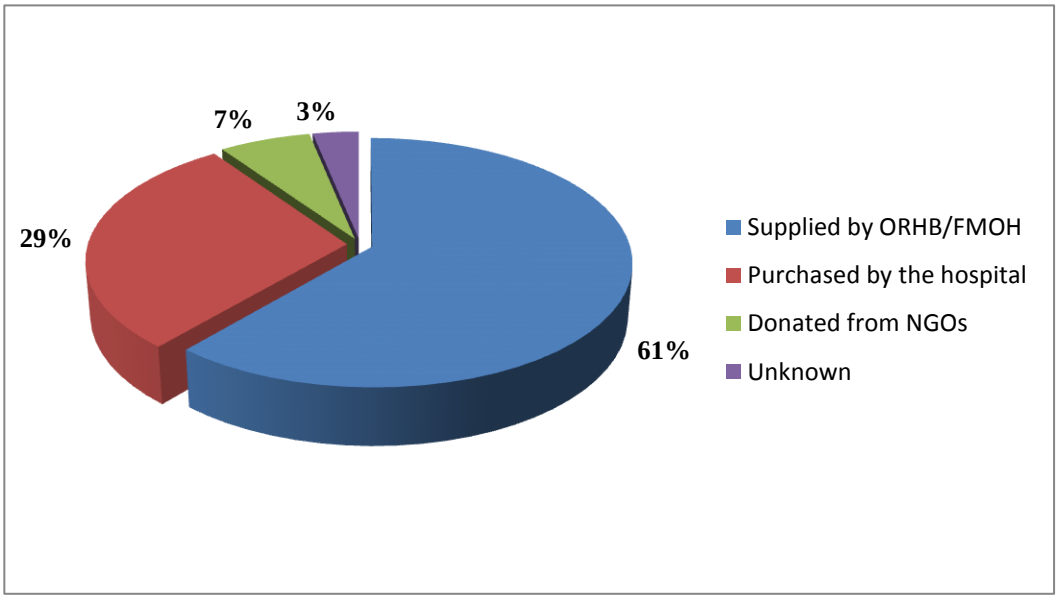
> *"The biomedical engineer and technician in our hospital are not familiar with our clinical chemistry analyzer because they did not get training on it. I think they have to take advanced training on maintenance of clinical chemistry analyzers."* (Quality officer 10, personal communication, 28 February 2019)

5.6.5. Inappropriate selection and procurement process of analyzers

As indicated by **Figure 4**, 9 (29%) of clinical chemistry analyzers in the studied hospitals were purchased by the hospitals themselves.

As explained by interviwees included in the study, during procurement of these analyzers detail technical and performance review were not done. Only the capital price and automation grade of the analyzer considered. There was also no formal pre-purchase consultation system

in hospitals as clearly identified in in-depth interview conducted with clinical directors and laboratory heads.



ORHB- Oromia Regional Health Bureau, FMOH- Federal Ministry of Health, NGOs- Non Governmental Organizations

Figure 4: Source of clinical chemistry analyzers in public hospitals of selected zones of Oromia region, Ethiopia, 2019 (N=31)

Laboratory heads indicated the challenge as follows

> "*There are also no criteria for procurement of analyzers at our hospital level. We ask laboratory personnel we know from other hospitals for best analyzer. There is no formal pre-purchase consultation system with experts. In addition, we have no information whether consultants in this area available or not.*" (Laboratory head 7, personal communication, 20 February 2019*)*

> *"Four years ago, I had purchased semi-automated clinical chemistry analyzer by 178,000 ETB. The sales person tried to install it but now it is non-functional because of an incomplete installation at that time."* (Laboratory head 14, personal communication, 12 March 2019)

Quality officer of one hospital stated as follows

"The clinical chemistry analyzer we purchased is an open system. But it does not work with reagents from other manufacturers. The analyzer also not stable; frequent breakdown occurs. I think this is the result of inappropriate selection and procurement, which is not based on pre defined criteria. Before procurement, we searched for information on the internet and ordered the analyzer for procurement. Detail review and comparison with other brand and model was not done." (Quality officer 10, personal communication, 28 February 2019)

5.6.6. Under Use/Misuse of Clinical Chemistry Tests

As shown in **Table 7**, 7 (46.6%) hospitals had being performed less than 5 clinical chemistry tests per day in average. In other way, 9 (60.0%) of hospitals had performed only 1 to 5 clinical chemistry parameters during the study period.

Table 7: Clinical chemistry tests service in public hospitals of selected zones of Oromia region, Ethiopia, 2019 (N=15)

Variables		Level of Hospital			Total N (%)
		Primary N (%)	General N (%)	Specialized N (%)	
Number of tests performed per day (average)	< 5	6 (40.0)	1 (6.7)	0 (0.0)	7 (46.7)
	5-25	1 (6.7)	2 (13.3)	1 (6.7)	4 (26.7)
	> 25	1 (6.7)	2 (13.3)	1 (6.7)	4 (26.7)
Types of parameters available	1-4	5 (33.3)	4 (26.7)	0 (0.0)	9 (60.0)
	5-10	3 (20.0)	0 (0.0)	1 (6.7)	4 (26.7)
	> 10	0 (0.0)	1 (6.7)	1 (6.7)	2 (13.3)

One hospital laboratory personnel indicated that there was misuse of clinical chemistry tests by physicians; they have been requesting all test lists on the request paper which leads to unnecessary expenditures in a hospital already plagued by consumables shortages. This also increases the load of the analyzer which in turn causes the frequent breakdown of the analyzer. In other way, the laboratory personnels of some hospitals especially of primary hospitals explained that physicians did not request clinical chemistry tests because of lack of awareness. In addition, one laboratory head gave his opinion as follows

> "*Clinical chemistry tests requested rarely. We perform only 1 or 2 clinical chemistry tests per week by the analyzer. This causes expiration of analyzer consumables without service.*" (Laboratory head 2, personal communication, 31 January 2019)

5.6.7. Poor laboratory infrastructure

In the studied hospital laboratories, there were also challenges of infrastructures which had affected proper utilization of clinical chemistry automation. Power fluctuation, distilled water shortage and uncontrolled room temperature were among the identified.

All the assessed hospital laboratories had electric power supply and functional generator for power back up. But, there was complain of power fluctuation in most hospitals as explained by most key informants.

There was no control system of temperature in clinical chemistry section except one. Quality officer of one hospital stated it as follows

> ”*Clinical chemistry and hematology section has no temperature controlling system. In addition sun light is entering the section directly in afternoon. The analyzer always shows error relating with high temperature. This is highly affecting our analysis.”(*Quality officer 2, personal communication, 31 January 2019*)*

All laboratories used distilled water for clinical chemistry analyzers; but there was shortage. The hospitals vary by their source of distilled water. Only 2 (13.0%) of them had functional distiller to fulfill water consumption. About 3 (20.0%) hospital laboratories were using car battery water by purchasing from shops while 4 (27.0%) were used bottled water which was prepared for human consumption. The other 6 (40.0%) hospitals were used distilled water procured from EPSA.

The laboratory head of one hospital said

“The hospital has 2 fully automated clinical chemistry analyzers. One analyzer became out of service because it consumes high volume of distilled water i.e. up to 6 liters per hour. It is unaffordable to purchase distilled water for this analyzer since the distiller we have produces not more than one liter per day.” (Laboratory head 10, personal communication, 28 February 2019)

CHAPTER 6: DISCUSSION

This study revealed that almost all non-analytical activities of clinical chemistry tests in assessed hospital laboratories were not automated. This is due to the absence of the pre-and post automation workstations. The laboratories focus on automating analytical (testing) processes. However, a large percentage of laboratory errors occur in the pre- and post-analytical phases, with fewer mistakes occurring during the analytical step (1). Nowadays, many low-to-medium sized laboratories have been using stand-alone pre-analytical automation systems commonly to automate specimen-processing steps which is capable of specimen identification, labeling, decapping/recapping, centrifugation, and sorting to different analyzer racks in laboratory (8). Therefore, it is more effective to consider the entire process for automation especially in specialized hospitals that process high number of clinical chemistry tests daily.

This study revealed that all the 5 assessed general hospitals had no automated immunoassay analyzer for immunoassay tests service. This contradicts the minimum standard requirement for general hospitals set by ESA. The standard [ES 3614: 2012] stressed that hormonal assay analyzer shall be required as a minimum in general hospitals (33). This might be due to poor resource allocation for laboratory services.

Clinical chemistry analyzer brands and models diversity was the major challenge which affected the utilization of automation in the studied hospitals. There were 14 different types of clinical chemistry analyzers each with different software and operating procedures. This challenge is occurred due to lack of proper analyzers standardization at national level. As it was explained by interviewees, this creates difficulties in procuring reagents and spare parts and providing training for users and biomedical engineers. A survey conducted in the Dominican Republic in 26 clinical laboratories showed that there were 37 types of clinical chemistry and special clinical chemistry auto analysis equipment (43). Another study conducted in 15 African and Caribbean countries support this study where there were about 37 different manufacturers and more than 130 platforms of clinical chemistry (27). A study conducted in 20 health facilities with clinical chemistry services in Jimma zone indicated that there were 10 different brands and models of clinical chemistry analyzers (35). Even though

there are standard lists of laboratory equipment at each level of hospitals in Ethiopia (32–34), they are not satisfactory to limit brand and model diversity of clinical chemistry analyzers.

Clinical chemistry analyzers functionality status (non-function and not in use) was also another major challenge for automation utilization in the study area. During the study period, 21 (68%) of clinical chemistry analyzers were out of service due to an installation problem, hardware malfunction, calibration and quality control failure, reagent shortage and lack of user training. It is high when compared with a study conducted in Jimma zone revealed 33.3% of clinical chemistry analyzers were out of service (46) and other study showed that about 39% of medical equipment found in Ethiopian public hospitals and other facilities was out of service at any one time (25). This might be due to the sample size variability. But it is comparable with WHO which estimated that up to 70% of laboratory and medical equipment in resource poor settings is out of service due to mismanagement of the technology acquisition process, lack of user-training and lack of effective technical support (47).

This study showed the majority of the laboratories were suffered from reagent shortages. This has been shown by 7 (46.7%), 8 (53.3%), 9 (60.0%) and 5 (33.3%) hospitals had stock outs for quality control (normal), quality control (pathological), calibrator and assay reagents respectively. Challenges related to laboratory supplies were also reported by the study done in Jimma zone (46) in Addis Ababa (48) and in sub Saharan Africa (22).

According to Ethiopian hospital reform implementation guidelines, laboratory equipment should only be used by appropriately trained staff (26). WHO also recommends the vendor should be obliged to train laboratory personnel in the calibration, operation, (basic preventive maintenance and repair) of analysers (18). However in this study, 79 (84.9%) of the clinical chemistry analyzers operators had not received user training. Due to lack of training from study subjects only 19 (20.4%), 44 (47.3%) and 25 (26.9%) of them responded they could perform independently calibration, quality control running and monitoring and preventive maintenance respectively. Similar challenge also reported in several studies done in Ethiopia (46,49) and in Malawi (50).

There were biomedical engineers and/or technicians in all assessed hospitals. However, as elaborated by key informants most of them need advanced maintenance training. Several

studies showed that there was often a gap between biomedical technicians knowledge and the level of technology (25), thus even minor equipment failures go unattended. Due to this, facilities are forced to call the manufacturer for basic problems. To solve this problem, biomedical engineers also need maintenance and service training (51).

The finding of this study showed that there was weak curative maintenance of clinical chemistry analyzers throughout the studied hospitals. During the study period, there were 14 (45.2%) analyzers which need curative maintenance. Similar challenges were reported by studies done in Jimma zone (46) and in Tanzania (31). The in-depth interview also showed that analyzers maintenance fees were unaffordable and not fair. WHO recommends that trained staffs have to carry out regular preventive maintenance as recommended by the manufacturers. Laboratories also need a curative maintenance contract with manufacturers, their representatives, or well-trained biomedical instrument technicians (18).

This study revealed that many clinical chemistry analyzers selected, procured centrally and supplied by FMOH or ORHB for the hospitals. But, about 29% of analyzers were selected and procured by the facilities. As many key informants explained, the process had problems. The selection criteria used were only automation grade (semi-automated/fully-automated) and the cost of the analyzer. However, according to WHO procurement guideline selection criteria should include detail review of equipment quality specifications and product specifications (18).

There was also problem of underuse of clinical chemistry tests as about 46.6% the hospitals had performed less than 5 tests per day and 66.7% of them had 1 to 5 parameters only. These resulted in expiration of the reagents. There were also electric interruption and distilled water shortage in the studied hospitals.

CHAPTER 7: CONCLUSION AND RECOMMENDATIONS

7.1. Conclusion

In assessed hospital laboratories, only analytical phase procedures of clinical chemistry were automated. There were 14 different brands and models of clinical chemistry analyzers. More than two-thirds of analyzers found in the studied hospitals were out-of-service during the study period. In other way, only 14 (15.1%) of the laboratory personnels had received user training of clinical chemistry analyzers. Majority of the laboratories were suffered from clinical chemistry reagents shortage. There were also inappropriate procurement process of the analyzers, misuse and underuse of clinical chemistry tests in the studied hospitals, which affect the clinical chemistry automation utilization. Due to these barriers, clinical chemistry automation in the studied hospitals was not utilized appropriately.

7.2. Recommendations

The following recommendations were made for FMoH, EPSA, ORHB, EPHI, higher institutions and assessed hospitals to take corrective action for the improved utilization of clinical chemistry automation.

Federal Ministry of Health:

- FMoH has to standardize the clinical chemistry analyzers by limiting to a small range of platforms and update it within a certain period of time to walk with the advancement of technologies. But, caution must be taken not to create a monopoly of vendor which may result in difficulty of pricing and delay in installation, service and maintenance request due to human resource contraints on the part of the vendors. If there were cessation of production by the manufacturer the supply chain system may also be disturbed.
- The Ministry has to create adequate pool of technicians that are specialized in the maintenance of clinical chemistry automation and other high value and sophisticated medical equipment.
- The ministry has to establish national maintenance and training center for clinical chemistry analyzers and other sophisticated equipment.

Ethiopian Public Health Institute:

- The institute in conjuction with manufacturers has to prepare capacity building materials such as demonstration videos of installation, preventive and curative maintenance, operation procedures of clinical chemistry analyzers in the country and make accessible through its official website.
- The institute in conjuction with manufacturer or manufacturer's representative should give in-service (offsite or onsite) user training for laboratory personnels and maintenance training for biomedical eingineers/technicians.

Ethiopian Pharmaceuticals Supply Agency:

- Should work strongly for the sustainable supply chain system of the country
- Should update its procurement lists by considering the analyzers in the country and their consumables

Oromia Regional Health Bureau:

- The bureau in conjuction with manufacturers or universities should offer inservice training, to the users of all new clinical chemistry analyzers. There should be constant re-training in time of staff turnover and refresher training.

- Travel by well-trained engineers to provide diagnosis where laboratories have some equipment that requires maintenance beyond the capability of onsite biomedical engineers/technicians.

Studied hospitals:

- Before procurement of clinical chemistry as well as other sophisticated medical equipment, detail technical review should be done.
- Addressing maintenance issues, reagent shortages and capacity building of laboratory personnels and biomedical engineers/technicians on time are also recommended.
- Should facilitate experience sharing of laboratory personnels and biomedical engineers/technicians from other more performing hospital.

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ANNEXES

Annex I: Informed Consent Form

Part I: Participant Information Sheet

Greetings! My name is Rebuma Belete. I am doing a research on "**Assessment of challenges of clinical chemistry automation utilization in public hospital laboratories of selected zones of Oromia region, Ethiopia**" in partial fulfillment of the requirement of Master of Science degree in Clinical Laboratory Science specialty in Clinical Chemistry at Jimma University.

Procedure and duration

I would like to inform you that we would have interview concerning this study. Before we go to interview, I ask you to read carefully about the purpose and general condition of the study and tell me whether you agree or disagree to participate in this study. The data collection will take about 25-30 minutes.

Aim of the study

The purpose of this study is to assess the major challenges related with automation in clinical chemistry section and set the possible future solutions for the identified challenges.

Benefits for participants

Study participants will not have any financial incentives or other inducements from participating on this study.

Risks for participant

The proposed research will not have any known harm, social discrimination, physiological trauma and economical loss on study participants.

Confidentiality

I assure that all the information you provide during the interview and data collection process will be kept confidential by using codes instead of names. Your participation in this research is entirely voluntary. Your willingness to participate in this study is essential and highly appreciated.

Assurance of principal investigator

I put my signature below to confirm you that I take over the responsibility for the information that you give.

Rebuma Belete (PI): Signature: _____Date: _____

Contact address

If you have any questions about this study, feel free to ask now or anytime by contacting:

PI: Rebuma Belete (BSc) (Mob. +251922843016 Email:rebuma.belete2016@gmail.com)

Advisors: Waqtola Cheneke (MSc) (Mob. +251917804412, Email:waqtolachalt@yahoo.com)

Aklilu Getachew (Msc) (mob. +251911743331,E- mail: akeachew@yahoo.com)

Part II: Certificate of Consent

I have read the foregoing information. I have had the opportunity to ask questions about it and any questions I have been asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study.

Name of Participant_____ Signature of Participant _____ Date _____

Statement by the person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

Signature of person taking the consent _____Date _____

NB: *A copy of this informed consent should be provided to the participant.*

ANNEX I: INFORMED CONSENT FORM- AFAAN OROMOO VERSION

Kutaa I: odeeffannoo hirmaattotaa

Nagaa! Maqaan koo Obboo Rabbumaa Ballaxaa jedhama. Qorannoo waa'ee" sakatta'iinsa rakkoolee awutoomeeshinii fi waantota isaan walqabatan kutaa laaboraatorii Kilinikaal keemistirii hoospitaalota mootummaa godinoota naannoo Oromiyaa filataman keessatti, Itiyoophiyaa" jedhu digrii maastarii saayinsii kilinikaal laaboratorii ispeeshaalitii kilinikaal keemistiriin yuuniversiitii Jimmaatti guuttachuuf hojjatan jira.

Adeemsa fi yeroo fudhatu

Hamma qorannoo kanaaf anii fi ati gaafii fi deebii waliin gochuuf jirra.Osoo gara gaafii fi deebiitti hin deemin dura, sababa fi haala walii gala qorannoo kanaa dubbisiiti hirmaachuufi hirmaachuu dhiisuu kee natti himi.Ragaa guuruun daqiiqaa 25 -30 fudhachuu danda'a.

Kaayyoo qorannichaa

Kaayyoon qorannoo kanaa rakkoolee hojiirra oolmaa awutoomeeshinii fi waantota isaan walqabatan kutaa laaboraatorii Kilinikaal keemistirii hoospitaalota mootummaa godinoota naannoo Oromiyaa filataman keessatti, Itiyoophiyaa keessatti mul'atan sakatta'uu fi rakkoolee adda bahaniif furmaata gara fuulduraa kaa'uu dha.

Faayidaa hirmaattotaa

Hirmaattota qorannoo kanaaf onnachiistuun mallaqaa ykn waa biroon kennamu hin jiru..

Miidhaa hirmaattotaa

Qorannoon yaadame miidhaa, qoqqobbii hawaasummaa fi hubaatii diinagdee hirmaattota qorannichaa irraan hin gahu.

Iccitii

Odeeffannoo ati yeroo gaafii fi deebii kennitu hundi iccitiidhan koodii fayyadamuun kan kan qabamu ta'uu siif mirkaneessun barbaada. Hirmaannaan kee qorannoo kanaaf guutummaan guututti fedhii irratti kan hundaa'e dha. Hirmaannan qorannoo kana irratti gootu barbaachisaa fi kan si galateeffachiisu dha.

Mirkaneessa qorataa olaanaa

Odeeffannoo ati kennitu hunda isaa irratti ittigaafatamummaa fudhachuuf mallattoo kootinin mirkaneessa.

Rabbumaa Ballaxaa (qorataa olaanaa): mallattoo: _____guyyaa: _____

Teessoo

Waa'ee qorannoo kanaa gaafii yoo qabaatte hammas ta'ee yeroo barbaadde teessoo kanaan gaafachuu dandeessa:

Qorataa olaanaa: Rabbumaa Ballaxaa (Mob. +251922843016 Email:rebuma.belete2016@gmail.com)

Gorsitoota: Waaqtola Cannaqaa (Bsc, MSc) (Mob. +251917804412, Email:waqtolachalt@yahoo.com)

Akliilu Getachew (Bsc, Msc) (mob. +251911743331, E- mail: akeachew@yahoo.com)

Kutaa II: waraqaa waliigaltee

Odeeffannoo hunda dubbiseera.Carraan gaafii gaafachuu fi gaafiin gaafadheef deebiin quubsaan naaf laatameera.Fedhii kootiin qorannicha irratti hirmaachufi waliigaleera.

Maqaa hirmaataa_____

Mallattoo hirmaataa _____

Guyyaa _____

Yaada nama waliigaltee guuchisiisee

Ani uunkaa odeeffannoo hirmaataa/ttuu kanin dubbisee fi hirmaataan/ttun hunda isaa kan galeef ta'uu mirkaneeffadheera:

Maqaa _____

Mallattoo _____

Guyyaa _____

Hub: garagalchi waliigaltee kanaa hirmaataa/ttuf kennamuu qaba.

ANNEX I: INFORMED CONSENT FORM- AMHARIC VERSION

ክፍል 1፡የተሳተፍዎች መረጃ

ሰላም! ስሜ አቶ ረቡማ በለጠ እባላለሁ፡፡ በአዉቶሜሽን አተገባበር ችግሮችና የተገነኙ ነገሮች በመንግስት ሆስፒታሎች ላቦራቶሪ በክልንካል ኬምስትሪ ክፍል በኦሮምያ ክልል በተመረጡ ዞኖች ለማስተር ድግሪ ማሞያ በክልንካል ላቦራቶሪ ሳይንስ በክልንካል ኬምስትሪ ስፔሻሊቲ በጅማ ዩኒቨርሲቲ ለምሰረ ጥናት መረጃ እየሰበሰብኩኝ ነዉ::

አከሄድና የሚወስደዉ ጊዜ

አሁን ቃለ መጠይቅ ልናረግ ነዉ:: ወደ ቃለ መጠይቁ ሳናልፍ ስለቃለመጠይቁ ሁኔታ አንብበዉና ማሳተፊና አለመሳተፍ ንንገረኝ/ንገሪኝ :: መረጃ መሰብሰብ ከ25-30 ደቂቃ ልወስድ ይችላል::

የጥናቱ አላማ

የጥናቱ አላማ በአዉቶሜሽን አተገባበር ላይ የሚታዩ ችግሮችና የተገነኙ ነገሮች በኦሮምያ ክልል በተመረጡ ዞኖች ዉስጥ በሚገኙ በመንግስት ሆስፒታሎች ላቦራቶሪ በክልንካል ኬምስትሪ ክፍል አሰሳ በማድረግ ለመለየትና መፍትሄ ማስቀመጥ ነዉ::

የተሳታፊዮች ጥቅም

በጥናቱ ለይ በመሳተፎ የሚደረግ የገንዘብ ክፍያ ወይም ሌላ ማበረታቻ የለም::

የተሳታፊዮች ጉዳት

የታሰበዉ ጥናት በተሳታፊዮች ላይ የሚያደርሰዉ ጉዳት ማህበራዊና ኢኮኖሚያዊ ችግር የለም::

የመረጃ ምስጥራዊነት

በቃለ መጠይቁ ጊዜ የምትሰጠዉ መረጃ በምስጥር በኮድ የሚቀመጥ መሆኑን አረጋግጣለሁ:: የእርሶ ተሳትፎ ሙሉ በሙሉ በፍላጎት ላይ የተመሰረታ ነዉ:: ነገር ግን የእርሶ ተሳትፎ በጣም አስፈላጊና የምበረታታ ነዉ::

የጥናቱ መሪ ማረጋገጫ

እርሶ በሚትሰጡት መረጃ ላይ ተጠያቅነት ለመዉሰድ በፍርማዬ አረጋግጣለሁ::

ረቡማ በለጠ (የጥናቱ መሪ): ፍርማ: _____ቀን: _____

አድራሻ

ስለ ጥናቱ ጥያቄ ካሎት አሁንም ሆነ ሌላ ጊዜ በዚህ አድራሻ መጠየቅ ይችላሉ

ረቡማ በለጠ (የጥናቱ መሪ)(ስልክ. +251922843016 ኢሜይል: rebuma.belete2016@gmail.com)

አማካርዎች፡ ዋቅቶላ ጨነቃ (ስልክ፡ +251917804412, ኢሜይል: waqtolachalt@yahoo.com)

አክሊሉ ጌታቸዉ (ስልክ፡ +251911743331, ኢሜይል: akeachew@yahoo.com)

ክፍል II: የዉል ምስክር ወረቀት

ሁሉንም መረጃ አንብቤሃለሁ:: ጥየቄ ለመጠየቅ ዕድል ተሰቶኝ በቂ መልስ ተሰቶኛል፡፡ በፍላጎቴ በጥናቱ ላይ ለማሳተፍ ተስማምቼሃለሁ::

የጥናቱ ተሳታፊ ስም_____

ፍርማ _____

ቀን _____

ዉል ሰጪ ሀሳብ

ተሳታፍዉ አንብቦ የተረዳ መሆኑን አለጋግጩሃለሁ::

ስም _____

ፍርማ _____

ቀን _____

ማሳሰብያ: የዉል ግልባጭ ለተሳታፍዉ መሰጠት አለበት ::

Annex II: Self administered questionnaire for laboratory personnel working in clinical chemistry section

Hospital code _____ (to be completed by the researcher)

Questionnaire identification number _____

Date of interview: _______________

I: Socio-demographic information		
No	Questions	Options
101	Sex	1. Male 2. Female
102	Age	_____ years
103	Educational level	1. MSC 2. BSC 3. Diploma 4. Certificate
104	Work experience	_____years
105	How long have you worked at this hospital?	-------years-------months
106	How long have you worked at clinical chemistry section?	-------years-------months
II: Skills of workers related to automated clinical chemistry analyzer		
201	Have you taken training on clinical chemistry analyzer?	1. Yes 2. No
202	If "yes" to question no. 201, who gave you the training/orientation?	1. vendor representative 2. hospital expertise 3. other/specify----------
203	Which activities do you do independently?	1. Running the test 2. Analyzer calibration

		3. Preventive maintenance 4. Quality control running 5. Troubleshoot minor analyzer problem
204	Do you know the principle of the tests analyzed by the clinical chemistry analyzer?	1. Yes 2. Partly 3. No
205	If 'No' to question no. 204, what is the reason behind?	

Section C: perception of workers on challenges affected utilization of clinical chemistry automation

a)Please indicate by encircling in the appropriate column (with the guidance of the key below)

0 = Don't Know 1 = Not at all 2=Very small degree

3 = Moderate degree 4 = Large degree 5 =Very large degree

	Factors affect automation	Extent of effect					
301	Capital price of the analyzer	0	1	2	3	4	5
302	Cost of analyzer maintenance	0	1	2	3	4	5
303	Cost of reagents	0	1	2	3	4	5
304	Cost of calibrators	0	1	2	3	4	5
305	Cost of quality controls	0	1	2	3	4	5
306	Availability of spareparts	0	1	2	3	4	5
307	Electricity fluctuation	0	1	2	3	4	5
308	Trained staff turnover	0	1	2	3	4	5
309	Technical staff commitment	0	1	2	3	4	5
310	Management commitment	0	1	2	3	4	5
311	Complexity of the analyzer	0	1	2	3	4	5
312	diversity of analyzers	0	1	2	3	4	5

(b) What other critical challenges are facing utilization of clinical chemistry analyzers?

ANNEX II: Self administered questionnaire for laboratory personnel working in clinical chemistry section - Afaan Oromoo Version

Koodii hospitaalaa _____ (gaggeessaa qorataan guutamuu qaba)

Lakk waraqaa gaafii fi deebii _____

Guyyaa gaafii fi deebii: _______________

lakk	Gaafilee	filannoo
101	Saala	1. dhiira 2. dhalaa
102	Umrii	_____ waggaan
103	Haala barumsaa	1. MSc fi isaa ol 2. BSc 3. Diplomaa 4. seertifikeeta
104	Muxannoo hojii	----------waggaan
105	Hospitaala kana keessa hammam hojjatte?	Waggaa _____ji'a_____
106	Kutaa laaboraatorii kilinikaal keemistirii kana keessa hoo hammam hojjatte?	Waggaa _____ji'a_____
kutaa B: dandeettiiwwan maashina kilinikaal keemistiriin walqabatan		
201	Hanga hammaatti leenjii/ orenteeshinii maashina kilinikaal keemistirii waliin wal qabatu fudhattee beekta?	1. Eeyyee 2. Lakki
202	Gaafii lakk. 201 eyyee yoo ta'e, leenjicha eenyutu siif kenne?	1. Bakka bu'aa dhiyeessaa maashinaa 2. Hojjataa hospitaala muuxannoo qabu 3. Kan biraa /ibsi----------
203	Kanneen keessaa kami kophaa kee	1. Qorannoo hojjachuu

	hojjachuu dandeessaa?	2. Maashina kalibirati gochuu 3. Maashinaaf suphaa ittisaa gochuu 4. 'quality control' hojjachu 5. Rakkoo xixiqqaa furuu
204	Qorannoowwan maashinaan hojjataman akkamin akka hojjataman (principle) beektaa?	1. Eeyyee 2. Walakkaa 3. Lakki
205	Deebiin "Lakk 204" kee lakki yoo ta.e, sababni isaa maalii?	

Kutaa C: sababoota hojiirra oolmaa awutoomeshinii kilinikaal keemistirii jijjiiran

a)filannoowwan deebii ta'etti maruun hamma sadarkaa inni miidhuu agarsiisa: -

0 = hin beeku 1 = hin miidhu 2= baay'ee xiqqaa

3 =hamma giddugaleessaa 4 = guddaa 5 =Baay'ee guddaa

301	Gatiin bittaa maashinaa olaanaa ta'uu	0	1	2	3	4	5
302	Gatiin suphaa maashinaa ol aanaa ta'uu	0	1	2	3	4	5
303	Gatiin ri'ajentoota olaana ta'uu	0	1	2	3	4	5
304	Gatiin kalibireetarii olaanaa ta'uu	0	1	2	3	4	5
305	Gatiin 'quality control' olaanaa ta'uu	0	1	2	3	4	5
306	Meeshaaleen jijjiirraa argamuu dhabuu	0	1	2	3	4	5
307	Rakkoo ibsaa addaan ciccituu	0	1	2	3	4	5
308	Humni namaa leenji'e gadi lakkisuu	0	1	2	3	4	5
309	Of keenninsa ogeessotaa	0	1	2	3	4	5
310	Of kenniinsa gaggeessitoota	0	1	2	3	4	5
311	Walxaxiinsa maashinaa	0	1	2	3	4	5
312	Waltina maashinaa dhabamuu	0	1	2	3	4	5

(b) Rakkooleen haala hojiirra oolmaa awutoomeeshinii kilinikaal keemistirii keessatti miidhan kan biroo maal fa'aa dha?

(c) Akka ilaalcha keetti tarkaanfileen bulchiinsanis ta'ee qaama biro dhimmi isaa ilaallatuun rakkoolee armaan olii kana ittiin hir'isuun danda'ama jettu maal fa'aadha?

Hirmaannaa keessaniif galatoomaa!

ANNEX II: Self administered questionnaire for laboratory personnel working in clinical chemistry section - Amharic Version

የሆስፒታል ኮድ _____

መለያ ቁጥር _____

የቃለ መጠይቁ ቀን: _____

ክፍል ሐ፡ የግል ሁኔታ		
No	ጥያቄዎች	አማራጭ
101	*ፆታ*	1. ወንድ 2. ሴት
102	*ዕድሜ*	_____ *ዓመት ነው*
103	የትምህርት ደረጃ	ı. ከ MSC እና ከዛ በላይ 2. BSC 3. ዲፕሎማ 4. የምስክር ወረቀት
104	የስራ ልምድ	----------
105	በዚህ ድርጅት / ሆስፒታል ምን ያህል ጊዜ ሠርተዋል?	----------ዓመታት ------- ወራት
106	ክሊኒካል ኬሚስትሪ ዩኒት ውስጥ ምን ያህል ጊዜ ሠርተዋል?	----------ዓመታት ------- ወራት
ክፍል ለ: ኬሚስትሪ ጥናቶች ጋር የተዛመዱ ክህሎቶች		
201	በክሊኒካል ኬሚስትሪ ምርመራ ስልጠና ወስደዋል?	1. አዎ 2. አይ የለም
202	ጥያቄ 201 አዎ ከሆነ, ስልጠና የሚሰጥዎ ማን ነው?	1. የሻጭ ተወካይ 2. የሆስፒታል ችሎታ ያለሁ 3. ሌላ ----------
203	በግል ዬትኛዉነ ስራ ይሰራሉ?	1. ሙከራውን ማካሄድ 2. ካልብሬት ማድረግ 3. የመከላከያ ጥገና ማድረግ

		4. ጥራት ቁጥጥር መስራት 5. ትናንሽ ብልሺቶችን ማስተካከል					
204	በክሊኒካል ኬሚስትሪ ትንታኔ የሚሰራውን ምርመራ መርሆዎች ያውቃሉ?	1. አዎ 2. በከፊል 3. አይ					
205	ለ 204 አይ ከሆና ምክንያቱ ምንድነዉ						
ክፍል ሐ: ራስ-ነክ ክሊኒካል ኬሚስትሪ ትንታኔን የሚያንፀባርቁ ሁኔታዎች ሀ) በተገቢው አምድ እባክዎን ያሳዩ. የነጻ ቴክኒካል ኬሚስትሪ ትንበያዎች ተግባራዊነት በሚከተሉት ምክንያቶች ተፅዕኖ ተደርጓል. 0 = የማታውቀው 1 = በፍጹም አይደለም. 2 = በጣም ትንሽ ዲግሪ 3 = ዝቅተኛ ዲግሪ 4 = ከፍተኛ ዲግሪ 5 = በጣም ትልቅ							
301	የመግዛት ከፍተኛ ወጪ	0	1	2	3	4	5
302	ከፍተኛ ጥገና ወጪ	0	1	2	3	4	5
303	የሪኤጀንት ከፍተኛ ወጪ	0	1	2	3	4	5
304	ካልብሬተር ከፍተኛ ወጪ	0	1	2	3	4	5
305	የጥራት ቁጥጥር ከፍተኛ ወጪ	0	1	2	3	4	5
306	መለዋወጫዎች አለመገኘት	0	1	2	3	4	5
307	የኤሌክትሪ ክኃይል መለዋወጥ	0	1	2	3	4	5
308	የሰለጠነ የሰውኃይል ሽግግር	0	1	2	3	4	5
309	የቴክንክ ሰራተኛ ቁርጠኝነት	0	1	2	3	4	5
310	የሥራ አመራር ቁርጠኝነት	0	1	2	3	4	5
311	የማሽኑ ውስብስብነት	0	1	2	3	4	5
312	የማሽኑ ስታንደርድ አለመኖር	0	1	2	3	4	5

(ለ) በክልንካል ኬሚስትሪ አዉቶምሽን አተገባበር የሚጎዱ ሌሎች ወሳኝ ችግሮች የትኞቹ ናቸው??

(ሐ)እነዚን ችግሮች መጠን ለመቀነስ በአስተዳደሩ ወይም በሌሎች አካላትም እርምጃዎች መውሰድ እንደሚገባቸው በርስዎ አመለካከት ይግለጹ----------

Annex III: Checklist

Hospital code: _____

Questionnaire identification number: _____

Date of interview: _______________

SECTION A. General information of facility laboratory **(Encircle to the correct option/s or write the correct response)**			
No	Questions		Options
A101	Level of hospital		1. Primary 2. General 3. Specialized
A102	Distance of the hospital from:	Zone capital	_____km
		Region capital	_____km
A103	Is the clinical chemistry section functional?		1. Yes 2. No
A104	If no what is the reason behind?		1. The hospital has not started all laboratory service 2. No analyzers 3. Analyzers not installed 4. No staffs trained on analyzers 5. Other/specify_____
A105	Is the clinical chemistry section separated from other sections?		1. Yes 2. No
A106	If "No" to Question A105, with which service(s) it sectioned in one room?		1._____ 2. _____
A107	How many clinical chemistry analyzers available in your hospital? (both in-service		_____

	and out of service)	
A108	How many clinical chemistry analyzers on service currently?	_____
A109	How many laboratory personnels are currently working in this hospital?	1. MSC and above_____ 2. BSC _____ 3. Diploma_____ 4. Certificate_____
A110	How many laboratory personnels are currently working in clinical chemistry section?	1. MSC and above_____ 2. BSC _____ 3. Diploma_____ 4. Certificate_____
A111	Is there biomedical engineer/technician at this hospital?	1. Yes 2. No
A112	Does the laboratory face electricity interruption?	1. Never 2. Sometimes 3. Regularly
A113	Is there generator for power back up?	1. Yes 2. No
A114	Is there budget assigned for consumable and reagent purchase for this budget year?	1. Yes 2. Not adequate 3. No
A115	Is there budget assigned for equipment maintenance for this budget year?	1. Yes 2. Not adequate 3. No
A116	How many tests performed in clinical chemistry section per day (approximate average)?	_____
A117	Which procedure is automated in your clinical chemistry section?	1. Transportation 2. labelling 3. Decapping 4. Recapping

		5. Sorting 6. Aliquoting 7. Specimen measurement 8. Reagent measurement 9. Sample and reagent mixing 10. Mixture incubation 11. Reaction timing 12. Analysis 13. Repeat testing, if necessary 14. Archival storage of specimen 15. Disposal of expired specimen 16. Data storage

Section B: Clinical Chemistry Analyzer Information ***(This section should be filled for each analyzer found in the hospital separately)*** ***Code of hospital: _____*** ***Code of analyzer: _____*** ***Checklist identification number _____*** ***Date filled: _______________***		
No	Questions	Options
Analyzer related		
B101	Name of the analyzer (brand name and model)	_____
B102	Analyzer type	1. Chemistry analyzer 2. Immunoassay analyzer 3. Integrated chemistry /immunoassay analyzer 4. Electrolyte analyzer
B103	Automation grade	1. Semi-automated 2. Fully automated
B104	Reagent form	1. Open system 2. Closed system
B105	Source of the analyzer	1. FMOH/ORHB 2. Purchased by the hospital 3. Donated from NGO 4. Other/specify
B106	Year of manufacture	_____
B107	Purchase date	_____/_____/____
B108	Installation date	____/_____/_____
B109	Throughput of the analyzer	_____tests/hr.
B110	Number of parameters of the	

	analyzer	
B111	Analyzer full test menu	
B112	Currently performed tests by the analyzer	
B113	What are reasons for not performing the tests?	
B114	Current status of analyzer	1. Functional 2. Functional but not in use 3. Non functional
B115	If the answer for question number B114 is "**functional but not in use**", what is the reason?	1. Outdated 2. Due to reagent shortage 3. No trained staff 4. Other/specify_____
B116	If the answer for question number B114 is "**non-functional**", explain the problem	
B117	If the answer for question number B114 is "**non-functional**", why curative maintenance not done?	1. There is backup analyzer 2. Unavailable maintenance engineer 3. Unavailable spare parts 4. Unavailable maintenance fund 5. delayed responses to repair requests 6. Non repairable 7. Other/specify_____
B118	Was there warranty for the analyzer from the	1. Yes 2. No

	manufacturer/vendor when purchased/received?	
B119	What type of warranty was given?	1. Lifetime 2. Time-limited
B120	If time-limited, what is the current condition of the warranty?	1. Within time 2. Expired
B121	Is a local (in-country) authorized manufacturer distributor available?	1. Yes 2. No
B122	Is there a regular on-site maintenance and calibration visit by manufacturer/vendor representative within warranty period?	1. Yes 2. No
B123	Is there a maintenance service agreement (MSA) in place for analyzer?	1. Yes 2. No
B124	Is the vendor/supplier available for technical support in a reasonable period of time?	1. Yes 2. No
B125	Responsible body to supply spare parts?	1. Manufacturer/vendor 2. External organizations 3. No supplier
B126	Are spare parts available?	1. Yes 2. No 3. Unknown
B127	Were spare parts replaced before?	1. Yes 2. No
B128	If 'YES' to question no. B127, write their name	

B129	Is routine laboratory equipment preventive maintenance performed according to schedule?	1. Yes 2. Partly 3. No
B130	Can the analyzer interfaced with laboratory information system (LIS)?	1. Yes 2. No
Analyzer consumables and accessories		
B131	Supplier of consumables(reagents, quality controls and calibrators) and other accessories (**multiple responses is possible**)	1. Manufacturer/vendor of the analyzer 2. Ethiopian Pharmaceuticals supply agency 3. Other/specify_____
B132	Are the quality control (N) materials available?	1. Yes 2. No
B133	Are the quality control (P) materials available?	1. Yes 2. No
B134	Is the calibrator available?	1. Yes 2. No
B135	If not available, list the reason?	
B136	Are the assay reagents available? (at least one reagent)	1. Yes 2. No
B137	If not available what is/are the reason/s?	
B138	Are other accessories such as cuvettes, sample cup etc. readily available?	1. Yes 2. No
Financial issues		
B139	What was the capital price of the	

	analyzer?	_____ birr
B140	Is the cost of the quality control affordable?	1. Yes 2. No
B141	Is the cost of the reagents affordable?	1. Yes 2. No
B142	Is the cost of the calibrator affordable?	1. Yes 2. No
B143	Is the cost of the cuvettes affordable?	1. Yes 2. No
B144	If spare part changed previously for the analyzer, how was its price relatively?	1. Costly 2. Affordable
B145	If curative maintenance performed with your organization expense previously, was that affordable?	1. Yes 2. No
Personnel/training related		
B146	Is the staff duly trained and authorized before first using analyzer?	1. Yes 2. Not at all
B147	If yesto Q. B146, how many staffs trained and authorized on this analyzer?	_____
B148	If yes to Q. B146, who gave operator training on analyzers?	1. Vendor representative 2. Laboratory personnel trained by manufacturer/vendor 3. Other/specify----------
B149	If not at all to Q. B146, how many staffs operate the analyzer without advance training?	_____

B150	Was there staff that received training on this analyzer and left the facility?	1. Yes 2. No
B151	If yes to Q. B150, how many staffs left the hospital?	_____
B152	Is there breakdown of the analyzer due to untrained staff?	1. Yes 2. No
B153	If yes to Q. B152, explain the occurrence	
B154	Is there service interruption to laboratory due to operating analyzer by untrained staff?	1. Yes 2. No
B155	If yes, explain it	
Infrastructure		
B156	Is the equipment maintained in a safe working condition (including electrical safety)?	1. Yes 2. No
B157	Is your laboratory prepare distilled water for clinical chemistry analyzer use?	1. Yes 2. No
B158	If no to question B157, explain the reason	

(c) What other critical challenges are facing utilization of clinical chemistry analyzers?

Annex IV: IDI Guides

IDI Guide for Laboratory Head

Code of hospital: _____
Date of interview: _____

Introduction: My name is Rebuma Belete. I came from Jimma University. I am here today to interview workers and officials in your hospital to collect data for Research with the title "**Assessment of tatus and challenges of clinical chemistry automation utilization in public hospital laboratories of selected zones of Oromia region, Ethiopia**" for the partial fulfillment of Degree of MSc in CLS specialty in Clinical chemistry. All comments, both positive and negative, are welcome.

Interview guiding questions:

1. Do you think current clinical chemistry analyzers are appropriate for your laboratory?
2. Do you have planned to change current clinical chemistry analyzers? Why? What type of automated clinical chemistry analyzer do you want to have? Why?
3. Is there pre-purchase consultation system in your organization? If no, why?
4. Who participate in the selection, purchasing and receiving process of the clinical chemistry analyzers? Why they selected?
5. What are the selection criteria to purchase clinical chemistry analyzers
6. Is there training given for all the analyzer operators? If yes was it satisfactory? If no, why?
7. Are there problems encountered your hospital relates to quality control materials, calibrators and other reagents? If yes, what are they?
8. Is there hidden cost in relation with the clinical chemistry analyzer? if yes explain
9. Do you think there is corruption in relation to selection, purchasing and utilizing the clinical chemistry analyzers, spare parts, other accessories and their consumables which affect automation in clinical chemistry section
10. Are the new staffs employed in your laboratory skilled enough as expected to do with clinical chemistry automation? If no, what is the problem?
11. In your view, what will be the possible solutions for those challenges

In-depth Interview Guide for Hospital Clinical Director/Finance Head

Code of hospital: _____

Date of interview: _____

Introduction: My name is Rebuma Belete. I came from Jimma University. I am here today to interview workers and officials in your hospital to collect data for Research with the title "**Assessment of status and challenges of clinical chemistry automation utilization in public hospital laboratories of selected zones of Oromia region, Ethiopia**" for the partial fulfillment of Degree of MSc in CLS specialty in Clinical chemistry. All comments, both positive and negative, are welcome.

Interview guiding questions:

1. Is there pre-purchase consultation system in your organization?
2. If yes, who is consulted? If no, Why?
3. Who participate in the selection, purchasing and receiving process of the clinical chemistry analyzers? Why they were selected?
4. What are challenges those affect the proper implementation and utilization of automated clinical chemistry analyzers in this hospital?
5. In your view, what will be the possible solutions for those challenges?

IDI Guide for Laboratory Quality Officer

Code of hospital: _____

Date of interview: _____

Introduction: My name is Rebuma Belete. I came from Jimma University. I am here today to interview workers and officials in your hospital to collect data for Research with the title "**Assessment of status and challenges of clinical chemistry automation utilization in public hospital laboratories of selected zones of Oromia region, Ethiopia**" for the partial fulfillment of Degree of MSc in CLS specialty in Clinical chemistry. All comments, both positive and negative, are welcome.

Interview guiding questions:

1. Do you think current clinical chemistry analyzers are appropriate for your laboratory?
2. Do you have planned to change current clinical chemistry analyzers? If No, Why? If yes what type of automated clinical chemistry analyzer do you want to have? Why?
3. Are there problems encountered your clinical chemistry section relates to quality control materials, calibrators and other reagents? If yes, what are they?
4. What are other challenges those affect the proper implementation and utilization of automated clinical chemistry analyzers in this hospital?
5. In your view, what will be the possible solutions for those challenges?

IDI Guide for Pharmaceutical storekeepers

Code of hospital: _____
Date of interview: _____

Introduction: My name is Rebuma Belete. I came from Jimma University. I am here today to interview workers and officials in your hospital to collect data for Research with the title "**Assessment of status and challenges of clinical chemistry automation utilization in public hospital laboratories of selected zones of Oromia region, Ethiopia**" for the partial fulfillment of Degree of MSc in CLS specialty in Clinical chemistry. All comments, both positive and negative, are welcome.

Interview guiding questions:

1. Are there clinical chemistry analyzers and their spare parts, consumables and other accessories in this store?
2. Is there Inventory of spare parts, consumables and other accessories?
3. Are there clinical chemistry quality control materials, calibrators and other reagents with very short shelf life?
4. If yes is it affect the automation utilization? In your view, what should be done to solve this problem?
5. Do you participate in the selection and purchasing of clinical chemistry analyzers? If yes what is your contribution? If not, do you think that your absence affect the process?
6. Do you have any other comments or suggestions relating with clinical chemistry accessories?

Annex V: Copy of Ethical Clearance

JIMMA UNIVERSITY
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ቀጥር
Ref. No JHRPGD/590/2018
ቀን
Date 10/12/2018

Institutional Review Board (IRB)
Institute of Health
Jimma University
Tel: +251471120945
E-mail: zelekc.mekonnen@ju.edu.et

To: Rebuma Belete

Subject: Ethical approval of research protocol

The IRB of institute of health has reviewed your research project entitled:

"Assess challenges of automation implementation and contributing factors in clinical chemistry unit of public hospital laboratories in selected zones of Oromia region, Ethiopia"

This is to notify that this research protocol as presented to the IRB meets the ethical and scientific standards outlined in national and international guidelines. Hence, we are pleased to inform you that your protocol is ethically cleared.

We strongly recommended that any significant deviation from the methodological details indicated in the approved protocol must be communicated to the IRB before they are implemented.

With regards!

Zeleke Mekonnen (PhD)
Associate Professor, Health
Research and Postgraduate
Director

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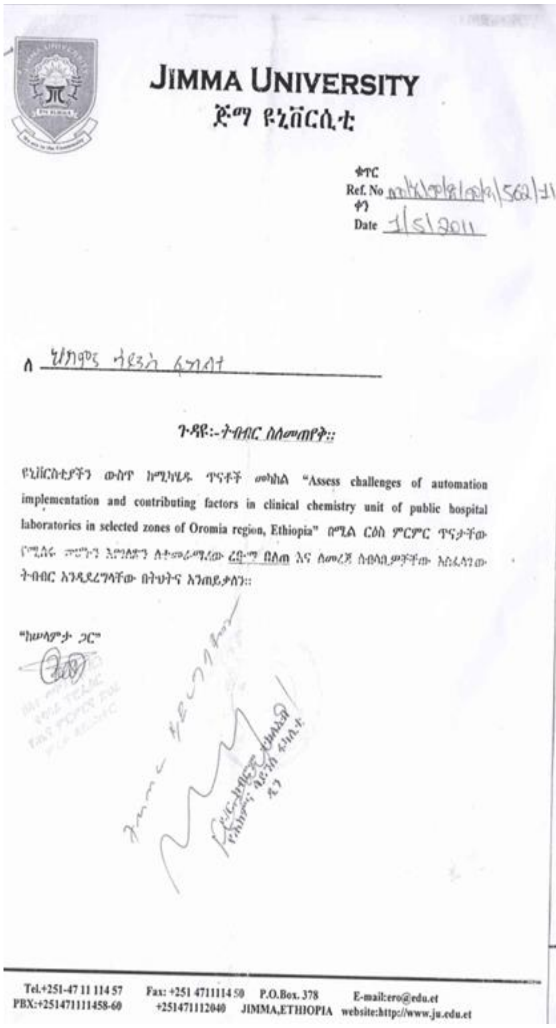
PBX:+251471111458-60 +251471112040 JIMMA,ETHIOPIA website:http://www.ju.edu.et

Annex VI: Copy of Support Letters



JIMMA UNIVERSITY
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ቁጥር
Ref. No [illegible]/562/11
ቀን
Date 1/5/2011

ለ [illegible]

ጉዳዩ:- ትብብር ስለመጠየቅ::

ዩኒቨርስቲያችን ውስጥ ከሚካሄዱ ጥናቶች መካከል "Assess challenges of automation implementation and contributing factors in clinical chemistry unit of public hospital laboratories in selected zones of Oromia region, Ethiopia" በሚል ርዕስ ምርምር ጥናታቸው [illegible] ትብብር እንዲያደርጉላቸው በትህትና እንጠይቃለን::

"ከሠላምታ ጋር"

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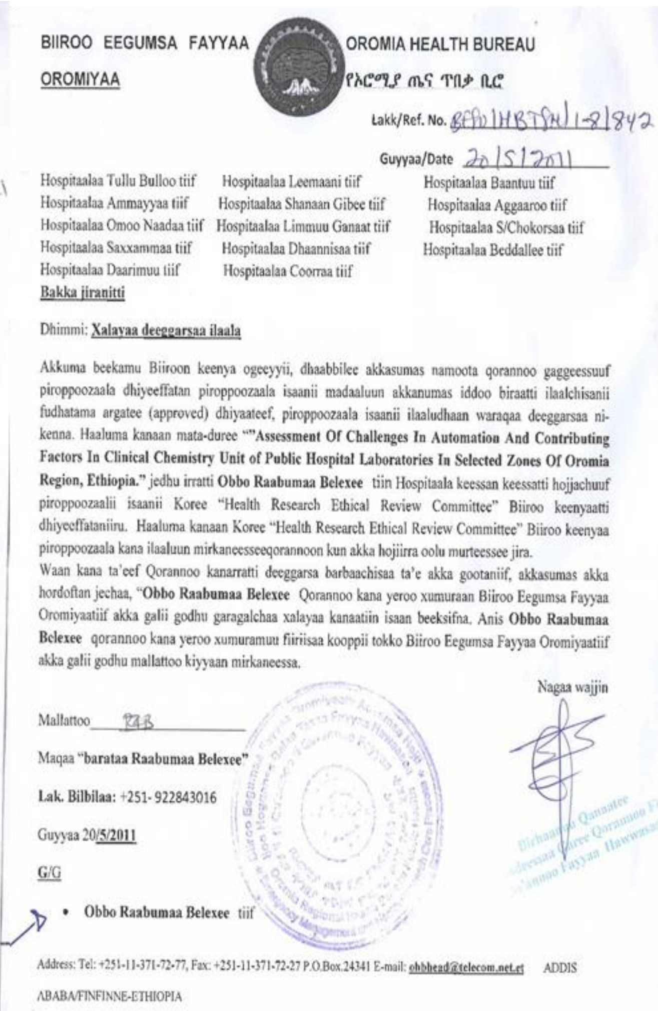

BIIROO EEGUMSA FAYYAA OROMIYAA
OROMIA HEALTH BUREAU
የኦሮሚያ ጤና ጥበቃ ቢሮ

Lakk/Ref. No. BEFO/HBTSH/1-8/842
Guyyaa/Date 20/5/2011

Hospitaalaa Tullu Bulloo tiif
Hospitaalaa Ammayyaa tiif
Hospitaalaa Omoo Naadaa tiif
Hospitaalaa Saxxammaa tiif
Hospitaalaa Daarimuu tiif
Hospitaalaa Leemaani tiif
Hospitaalaa Shanaan Gibee tiif
Hospitaalaa Limmuu Ganaat tiif
Hospitaalaa Dhaannisaa tiif
Hospitaalaa Coorraa tiif
Hospitaalaa Baantuu tiif
Hospitaalaa Aggaaroo tiif
Hospitaalaa S/Chokorsaa tiif
Hospitaalaa Beddallee tiif
Bakka jiranitti

Dhimmi: **Xalayaa deeggarsaa ilaala**

Akkuma beekamu Biiroon keenya ogeeyyii, dhaabbilee akkasumas namoota qorannoo gaggeessuuf piroppoozaala dhiyeeffatan piroppoozaala isaanii madaaluun akkanumas iddoo biraatti ilaalchisanii fudhatama argatee (approved) dhiyaateef, piroppoozaala isaanii ilaaludhaan waraqaa deeggarsaa ni-kenna. Haaluma kanaan mata-duree ""**Assessment Of Challenges In Automation And Contributing Factors In Clinical Chemistry Unit of Public Hospital Laboratories In Selected Zones Of Oromia Region, Ethiopia.**" jedhu irratti **Obbo Raabumaa Belexee** tiin Hospitaala keessan keessatti hojjachuuf piroppoozaalii isaanii Koree "Health Research Ethical Review Committee" Biiroo keenyaatti dhiyeeffataniiru. Haaluma kanaan Koree "Health Research Ethical Review Committee" Biiroo keenyaa piroppoozaala kana ilaaluun mirkaneesseeqorannoon kun akka hojiirra oolu murteessee jira.

Waan kana ta'eef Qorannoo kanarratti deeggarsa barbaachisaa ta'e akka gootaniif, akkasumas akka hordoftan jechaa, "**Obbo Raabumaa Belexee** Qorannoo kana yeroo xumuraan Biiroo Eegumsa Fayyaa Oromiyaatiif akka galii godhu garagalchaa xalayaa kanaatiin isaan beeksifna. Anis **Obbo Raabumaa Belexee** qorannoo kana yeroo xumuramuu fiiriisaa kooppii tokko Biiroo Eegumsa Fayyaa Oromiyaatiif akka galii godhu mallattoo kiyyaan mirkaneessa.

Nagaa wajjin

Mallattoo ____

Maqaa "**barataa Raabumaa Belexee**"

Lak. Bilbilaa: +251- 922843016

Guyyaa 20/**5/2011**

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- **Obbo Raabumaa Belexee** tiif

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