



**June, 2014**

**Addis Ababa, Ethiopia**

**ADDIS ABABA UNIVERSITY  
SCHOOL OF GRADUATE STUDIES**

**DEPARTMENT OF CLINICAL LABORATORY  
SCIENCES**

**Assessment of Biosafety practices in selected Public Hospital  
laboratories, East, South-West, and West Shoa Zones of Oromia  
Region, Ethiopia**

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**A thesis submitted to the School of Graduate Studies of Addis Ababa  
University in partial fulfillment of the requirements for the Degree of Masters**

**in Clinical Laboratory Sciences (Clinical Laboratory Management and Quality assurance)**

ADDIS ABABA UNIVERSITY SCHOOL OF GRADUATE STUDIES

Assessment of Biosafety practices in selected Public Hospital laboratories, East, South-West, and West Shoa Zones of Oromia Region, Ethiopia

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## ACRONYMS AND ABREVAITIONS

- AIDS           Acquired Immuno-Deficiency Syndrome
- ANOVA        Analysis of Variance
- BSC            Biosafety Cabinets
- BSL            Biosafety Level
- CDC           Centers for Disease Control and Prevention
- CLSI           Clinical and Laboratory Standards Institute
- EPHI           Ethiopian Public Health Institute
- EHNRI         Ethiopian Health and Nutrition Research Institute
- FMOH          Federal Ministry Of Health
- HCW           Health Care Workers
- HIV            Human Immunodeficiency Virus
- ISO            International Organization for Standardization
- OHB            Oromia Health Bureau
- MSDS          Material Safety data Sheet
- PEPFAR        President Emergency program for AIDS Relief
- PPE            Personal Protective Equipment
- QMS            Quality management System
- SOP            Standard Operating Procedures
- SARS          Severe Acute respiratory Syndrome
- TOT            Training Of Trainer

## Acknowledgement

First of all I would like to acknowledge Addis Ababa university school of laboratory sciences for providing the opportunity to undertake this study for students' academic achievements. My second wish to acknowledge regarding this study is, Oromia Regional Health bureau, in particular participated facilities (Adama, Bishoftu, Tulubolo, Ambo and St. Luke hospital laboratories) for their unreserved support and enthusiasm towards the collection of data from respective lab personnel to my study. I am very much indebted also to appreciate my advisor Dr. Aster Tsegaye, she has been extremely diligent to support her students though she has very tight schedule. She was involved on this paper from inception such as topic selection and proposal writing through follow up and progress monitoring till the final result interpretation and thesis write up. I am also very much grateful for the study participants who have been volunteered to give their opinion and data collectors who have shown high level professionalism and discipline during data collection. Last but not least, I would like to appreciate my wife Bethelihem Woldeamanuel, she considered my study as a pave for my professional career development way and kindly handled all family issues without any grievances. Though she has been overburdened with many family and social issues, she was never complained even for fraction of seconds.

**Background:** Persons working in clinical diagnostic laboratories are exposed to many risks. The most hazardous agent in the laboratory is a microorganism that is frequently associated with laboratory infections and can be transmitted in variety of routes, especially by aerosols. Moreover, hospital and diagnostic laboratories are a challenging environment for the surrounding community. The more the laboratorians become aware of and adhere to recommended, science-based safety precautions, the lower the risk for laboratory acquired infections. The behavior patterns and attitude of individuals towards safety programs influence their involvement in laboratory accidents that put themselves and fellow workers at risk. Assessing laboratory biosafety practices will help the laboratories to identify factors that hindered laboratory personnel from practicing good laboratory biosafety measures and to determine the existing situation of the assessed laboratories so that laboratory managers can plan towards implementation of biosafety practices and hence safe working laboratory area will be created.

**Objective:**The aim of this study was to assess biosafety practices among laboratory personnel working in selected public hospitals in the East, West and S/West Shoa zones of Oromia region.

**Methods:** Institution based cross-sectional study was conducted between December 2013 and May 2014. The study was conducted among 45 studied laboratory personnel working in 5 selected public hospital laboratories located in East, West and S/West Shoa (Adama, Bishoftu, Tulubolo, Ambo and St. Luke hospital laboratory). Data was collected between April and May 2014 using structured questionnaire. The analysis was done by SPSS version 16 statistical software using one-way ANOVA. P-values less than 0.05 were considered as statistically significant.

**Result:** Out of 45 participants greater than 37 (84%) of studied personnel were within the age range of 18-44 years. Of which the majority 23 (64%) of the studied laboratory personnel's age were aggregated within the age distribution category of 25-34. Male to female ratio of the studied participants were 3:1 with a count of male participant 34 (75.6%), and females accounted

11 (24.4%). Regarding the level of education, 23 (51.1%) of them had finished undergraduate study on medical laboratory sciences (Bachelor of sciences) and the rest 21(46.7%) were diploma holders in laboratory science. The duration of work experience in laboratory service of the studied laboratory showed that greater than 33(75%) of the group had a work experience of greater than 5years. This survey shown that the grand mean of the studied laboratory personnel for the overall biosafety practices was found to be  $36.44 \pm 7.635$  with a mean score range of 52%-80%. Laboratory personnel B exceptionally scored the highest mean score of all 42.7(80%) and fall in upper moderate level which is close to high level. The mean score for laboratory D and E had shown similar results which are a mean value of 38.6 (70%)and they are closed to be labeled as moderate. The rest two laboratories (A and C) found to be low level with laboratory A scored the least mean value of all 29.7 (50%), while laboratory C scored a mean value of 34.5.

**Conclusion:** The overall biosafety practice of the studied hospital laboratories average score is  $36.44 \pm 7.63$  from a total score value of 55. The percent range for all studied labs is 52%-80%. Laboratory B exceptionally scored the highest mean of all with a score of 80% as a result it is in the upper moderate level category.

# 1. INTRODUCTION

## 1.1. Background and statement of the problem

Persons working in clinical diagnostic laboratories are exposed to many risks. Working in the human as well as animal diagnostic laboratory is a challenging environment. The more the laboratorians become aware of and adhere to recommended, science-based safety precautions, the lower the risk for laboratory acquired infections as stated in the US recommended biosafety guideline (1)

According to Sewell's reviewed article on laboratory associated infections and biosafety, the most hazardous agent in the laboratory is a microorganism that is frequently associated with laboratory infections and can be transmitted in variety of routes, especially by aerosols (2). In addition, a Knowledge, Attitude and practice (KAP) study conducted in India revealed that numerous laboratory procedures and equipment are considered as a potential aerosol sources for health care workers unless standard infection control measures are implemented (3).

A study conducted on health care workers about the transfer of microorganisms from Personal Protective Equipment (PPE) by Casanova et al., (4) has shown that laboratory personnel are one of the risk groups among health care workers for occupational hazards. They are exposed to variety of occupational health hazards including infectious materials, blood and other body fluids from patients including pus, urine, stool, sputum, secretion or equipment contaminated with agents in the laboratory environment.

In addition the behavior patterns and attitude of individuals towards safety programs influence their involvement in laboratory accidents that put themselves and fellow workers at risk. Personnel behavior towards laboratory safety plays vital role in the control and prevention of infections. For example carelessness, poor technique in the handling of infectious materials, needle sting or infectious aerosol exposures are the cause of laboratory acquired infections. Caring for patients with communicable diseases places health care workers including laboratorians at risk. Laboratory personnel in

hospitals generally are faced with many hazards at work and his/her health and safety may be severely jeopardized unless adequate preventive protective measures are taken. Biosafety is a concept that promotes safe laboratory practices, procedures and proper use of containment equipment and facilities by laboratory workers. A lot of accidents occur in the laboratory due to lack of proper knowledge regarding laboratory measures, indifferent attitude and improper implementation of safe laboratory practices as a study in Pakistan describes (5).

Biosafety is an important issue in laboratory settings worldwide especially in developing countries where standard operating procedures (SOPs) are either lacking or not followed properly (6). Like in many developing countries biosafety is a burning issue, which needs due attention in the health laboratory system of Ethiopia.

As the Ethiopian Public Health Institute (EPHI), previously called Ethiopian Health and Nutrition Research Institute (EHNRI) has been mandated by Federal Ministry of Health (FMOH) to strengthen the Laboratory system of the country, EPHI had designed a strategy and developed national master plan for public health laboratories in 2009. One of the 17 strategic objectives was, “to expand and strengthen the national laboratory quality system” which slightly touches both safety and quality issues (7). Based on this, both basic and training of trainers (TOT) on Quality Management System (QMS) have been provided several times by EPHI in collaboration with CDC-E to laboratory professionals working in public health facilities and instructors from laboratory schools. QMS training has biosafety components as one element of the 12 QMS essentials. In 2012 and 2013, EPHI and CDC have also provided two rounds of specific biosafety TOT trainings to laboratory professionals working in public health laboratories. (EPHI unpublished report)

Health and Safety Guidelines for Public Health Laboratories in Ethiopia (8), has also been developed and distributed to public health facilities by EPHI. The guideline gives direction to laboratories how to prevent and control laboratory accidents including laboratory acquired infections and safety procedures for corrective and planning actions.

Interim report from supportive site visit being conducted by CDC-E since June 2012 at PEPFAR supported health facilities revealed that, although some facilities are trying to implement safety practices in their respective facilities, majority of them have not yet met the standards (has scored very low) in biosafety section of the assessment checklist. (CDC unpublished Rep). In addition to that, different reports including WHO/AFRO accreditation assessment conducted by EPHI indicates that majority of public laboratories were not practicing good laboratory biosafety measures (unpublished report from national laboratory review meeting).

ISO 15189 documents state, “the laboratory shall be designed for the efficiency of its operation, to optimize the comfort of its occupants, and to minimize the risk of injury and occupational illness. Patients, employees, and visitors shall be protected from recognized hazards” (9). In supplement with this CLSI guideline states, “To meet governmental and accreditation requirements, ‘the lab need to have well defined process of training to all staff on infection control, emergency preparedness, universal precautions, personal protective equipment, chemical and disposable of hazardous wastes (10)

Laboratory acquired infections can be reduced and/or even eliminated by implementing good laboratory practice with appropriate laboratory design, administrative and standard procedures. Published reports on biosafety practices in Ethiopia is lacking. Consequently, few studies conducted on laboratory biosafety practices in some Asian and other developing countries of having similar resource settings and reviewed for this study.

Assessing laboratory biosafety practices will help the laboratories to identify factors that hindered laboratories from practicing good laboratory biosafety measures and to determine the existing situation of the assessed laboratories so that laboratory managers can plan towards implementation of biosafety practices, and hence safe working laboratory area will be created.

## **1.2. Significance of the study**

This study was done primarily to benefit participated facilities with the recommendations and findings provided by the study. It also aimed to be an asset for those who are program people, and are in need of implementing biosafety practices in their respective laboratories as well for those who have an interest to conduct a study on the areas of biosafety issues and seeking baseline data for their research. In order to ensure biosafety practices, there is a direct need to develop SOPs (standard Operating Procedures) and to encourage use of personal protective equipment (PEP) while handling clinical specimens.

Institutional biosafety support is also helpful to control, maintain and record nosocomial infection accidents, to encourage proper use of protective equipment, proper specimen collection and processing and infective waste disposal. Regular training on biosafety principles and self-hygiene for laboratory workers is needed along with the appointment of a biosafety officer to oversee the proposed work activities, procedures, equipment, personnel, storage, material transfer and transport and proper disposal of biological materials (11).

Developing and validating an algorithm for removing PPE that prevents contamination of the skin and clothes of health care workers are keys to interrupting nosocomial transmission of infectious agents. CDC experiment demonstrates that the current CDC algorithm is insufficient to protect health care workers from contamination during PPE removal; however, options that might prevent such contamination do exist (3). For these, the laboratory personnel work practice and behavior towards usage of PPE should be assessed.

Quantitative risk assessment of laboratory accidents can provide data that can aid the design of containment laboratories and the response to laboratory accidents as evidenced by study (12). As this assessment has included almost all laboratory biosafety practices, including personnel, facility design, work flow, safety policy and manual, SOP and availability of safety materials, the significance of the study for the biosafety community is found to be unquestionable. Therefore; assessment of biosafety practices in a facility

laboratory, using a descriptive cross-sectional study design is an ideal method for improvement.

## 2. LITERATURE REVIEW

Biosafety is a concept that promotes safe laboratory practices, procedures and proper use of containment equipment and facilities by laboratory workers (11) CDC defined biosafety in the guideline (13) as development and implementation of administrative policies, work practices, facility design, and safety equipment to prevent transmission of biologic agents to workers, other persons and the environment.

According to the study on safety in the clinical microbiology laboratory, management of the risk associated with working with infectious agents is accomplished by administrative efforts, implementation of standard laboratory practices and safety equipment engineering, and facility design as well as employee health programs. The facility administration has a legal responsibility to provide a safe work site for its employees by establishing a comprehensive safety program consisting of written policies, record keeping of exposures and infections, and employee training that provides laboratory workers with understanding of the proper safety and infection control practices (14).

Another study conducted by Casanova (4) also emphasizes the importance of safety management by describing the basic approach to the management of risk associated with blood-borne pathogens and other infectious agents is to practice universal precaution, which presuppose that all blood, body fluid and other specimen collected from patients are potentially infectious and are handled by using appropriate personal protective equipment (PPE) and techniques designed to minimize the exposure of the health care workers (HCW).

Globally there are several reports on occupationally acquired microbial infections. For example, in occupationally acquired HIV infections reported to CDC through 1992 has shown that the highest rate of infection was seen in laboratory technicians 25 (24.8%) cases, nurses 26 (25.7%) cases, and physician 13 (12.8%) cases, while paramedical, dentist, health aid, house keeper and morgue personnel accounted 7 (6.9%), 6 (5.9%), 6 (5.9%), 6 (5.9%), and 3 (3.0%), respectively (15).

The magnitude of lack of biosafety practice as described in 2004 was evident from nine cases of

severe acute respiratory syndrome (SARS) which occurred in Beijing, China. “Two index cases were identified as graduate students at the University of Virology who worked in a BSL-2 laboratory with samples that were inactivated and then removed from the biosafety level-3 (BSL-3) SARS laboratory. Unfortunately, the virus inactivation procedures for SAR Co-V were not verified and were later proven to be insufficient. The mother of one student was fatally infected. The nurse who cared for both the infected student and the student’s mother also became infected and transmitted SARS Co-V to five other patients. This is the only reported instance of tertiary transmissions from laboratory associated infections. A subsequent analysis of stored serum samples identified two previous cases among the BSL-2 laboratory staff; the illnesses were self-limiting cases that were not diagnosed as SARS at the time the students were ill” (16).

In addition to the nurse infected with SARS in Beijing, three additional transmissions to medical personnel have occurred because of treating staff infected in the laboratory. One pathologist was fatally infected while conducting an autopsy of a scientist who died of a laboratory-acquired Marburg infection and the other two were cases of laboratory-acquired Brucella infections in clinical laboratory technicians who were infected when culturing blood from infected clinical laboratory technicians. Byers(16) reviewed articles of Alibek et al., 1999 and Chusid et al., 1993. Eight cases of *B. pertussis* in adults occurred in staff who did not directly work with the organism but had access to common laboratory spaces where the *B. pertussis* was manipulated; there was one secondary case of transmission to a family member (17).

The laboratory –acquired infections reported by Pike were due primarily to bacteria, viruses and reckettsiae. The recognition that the primary route of transmission of many of these agents was by aerosols led to the development and use of laminar flow biological safety cabinets. Pike tabulated the most sources of infections from published literature and survey data through 1976. Laboratory accidents were the second greatest source of infections; nearly 70% were associated with needle sticks (25%), splashes and spills (27%), and cuts from sharp objects (60%) as Sewell (2) reviewed Pikes’s report (17).

Reports have shown that from laboratory acquired infections, bacterial infection predominated with 1,669 (42.5%) being reported, followed by viral infection 1,049 (26.7%),

reckettsialinfections 573 (14.6%), fungal infection 353 (9.0%), chlamydial infection 128 (3.3%), parasitic infection 115 (2.9%) and unspecified infection 34 (0.9%). The highest mortality rate (7.8%) was associated with chlamydial infection (18).

Proficiency test samples, stock cultures, and quality control samples are not usually identified as a source of infections. However, these materials have been identified as a common source of infection over the years, especially infections associated with the handling of salmonella and Shigella(2).

Factors, which contribute individuals' exposure to nosocomial infections, include working in environments with pathogens which is a potential hazard for scientists and health care workers. Carelessness and poor technique in the handling of infectious materials were the cause of laboratory acquired infectious (19). In the standard guideline, the safety equipment included biological safety cabinets (BSC) to remove or minimize exposure to hazardous biological materials or aerosols generated by many microbiological procedures (17). Unrecognized release of aerosols during centrifugation may be responsible for the laboratory acquired infection without an identifiable source. The usual cause of a release of a microorganism by a standard laboratory centrifuge is a broken or leaking centrifuge tube. This type of accidents can be prevented by proper use of the centrifuge (4).

A study in Pakistan revealed that 46.2% of the laboratory technicians did not use any kind of personal protective equipment, and almost 39.5% of the respondents recapped used syringes regularly while 10.7% recapped occasionally. To avoid the reuse of syringes, Pakistani authorities recommend that they be cut before discarding; however, only about 36% of the respondents do this prior to discarding used syringes directly into municipal dustbins. In addition, about 65.2% of the respondents declare that there is no separate discarder for sharps so they throw these too into municipal dustbins. Although mouth pipetting is considered obsolete, 38% of the technicians continue to do so for various purposes. Additionally, standard operating procedures were not available in 73.9% of the laboratories and accident records were not maintained in 83.4%. No formal biosafety training had been provided to 85% of the respondents (6).

On the other hand, a study conducted in Turkey (20) revealed that 91.3% and 87.4% of the participants used gloves and laboratory Coats respectively. A KAP study conducted in India on biomedical waste management shows paramedical staff including laboratory staff have relatively less understanding on the subject, but has high attitude and more practical habits which may be because of strict instruction by authorities and fear for punitive action (4).

Another study in Sudan also has shown that the standard biosafety precautions adopted by diagnostic laboratories in Khartoum was very low. Further, the laboratory personnel awareness towards biosafety principles implementation was very low too (21) as cited by Ali (22). Two studies conducted in Pakistan showed that only 38.2-51.5% posted biohazard sign at the entrance of a laboratory when infectious specimens were present. This should be improved by strengthening a standard precaution which can prevent transmission of micro-organisms. Concerning facility design, less than 45.5% had an eye wash station in the laboratory (17).

In Pakistan ignorance among laboratory technicians is mainly due to lack of awareness and the scarcity of biosafety training programs regarding the proper handling of clinical samples and instruments (23). In addition to the potential spreading of infections to others, these workers are constantly exposed to opportunistic pathogens or potentially pathogenic organisms since thousands of healthcare workers in developing nations, including Pakistan, suffer accidental needle sticks every day (24). Since improving laboratory workers' knowledge of and capabilities for safe-handling of dangerous infectious agents and highly virulent pathogens is so important, biosafety issues within the BSL-2 laboratories are an important concern as stated by Nasim (6).

A study in Nigeria conducted by Ejilemele AA and Ojule AC showed that cross deficiencies were found in the knowledge, attitude and practice of laboratory safety by laboratory staff in areas of use of personal protective, specimen collection and processing, centrifuge related hazards, infective hazards waste disposal and provision and use of first aid kits. Issues pertaining to laboratory safety are not yet given adequate attention by both employers and employees in developing countries in this year of resurgence of disease such as HIV/AIDS and hepatitis B and C, is emphasized (25).

### 3. HYPOTHESIS

The biosafety practice among laboratory professionals of selected public hospital laboratories located in East, S-West and West Shoa zones of Oromia region is below moderate level.

$H_0: X \leq GX \pm SD$

$H_1: X > GX \pm SD$

**N.B.**  $H_0$ ; the mean score (X) of the laboratory activity in relation to biosafety is less than or equal to the grand mean score (GX) plus/minus standard deviation (SD).

And  $H_1$ : the mean score (X) of the laboratory activity in relation to biosafety is greater than or equal to the grand mean score (GX) plus/minus standard deviation (SD).

### 4. OBJECTIVES

#### **General Objective:**

- To assess biosafety practices of selected public hospital laboratories located in East, South west and West Shoa zones of Oromia Region, 2014.

#### **Specific objective:**

- To assess biosafety practices among laboratory personnel of five selected public hospitals in East, South-West and West Shoa zones of Oromia region, 2014.
- To compare the biosafety practices by facility in the five selected public hospitals laboratories in the East, South-West and West Shoa zones of Oromia region, 2014.

## **5. METHODOLOGY**

According to the Ethiopian health and health related indicators report of 2004EC /2012 GC/, a total of 125 public hospitals (all types) are available, of which 41 of them are located in Oromia region. The report indicates, a total of 1,264 laboratory personnel (470 laboratory technologists and 794 laboratory technicians) are working in public hospital laboratories in Oromia region. (25)

There are forty-one public hospitals in Oromia region, of which eleven of them are situated in the North, South, East, and Western part of Shoa in the Oromia region, surrounding the capital “Addis Ababa”.

### **5.1. Study Design**

Institution based cross-sectional study was conducted between April and May 2014 to assess the situation of biosafety practices among five laboratories’ personnel working in selected public hospital laboratories of Oromia region.

### **5.2. Study Area**

The study was conducted in East, west and South-west shoa zones of Oromia region. Namely, Adama, Bishoftu, Woliso, Tulubolo and Ambo. Adama and Bishoftu hospitals are located to the eastern part of the country at about 100 and 47km, respectively from Addis Ababa. Woliso and Tulubolo hospitals are located to the South-West of the capital city with a distance of about 115 and 77km respectively from it. Ambo hospital is also in the Oromia region and located to the West of the capital city in the town of Ambo, and its distance is about 125 Km away from the capital. Adama hospital is the biggest of all and is a teaching hospital. It resided in Adama town which is one of the high populous areas in the country. Bishoftu is located on the same road to the eastern part of the country from Addis Ababa, in the town of Bishoftu. St. Luke hospital (usually known and called as Woliso) is resided in Woliso town. Although St. Luke has been constructed by Catholic church as Faith Based Organization (FBO), it is currently running by both catholic church and OHB. Tulubolo hospital as the name indicates located in Tulubolo town which is around 77km from the

capital, Addis Ababa to South-West of the country.

The reasons behind the selection of the facilities were based on the student's advantages. Such as relatively accessible sites, comparatively closer sites to Addis Ababa city where the student as well as AAU resided, additionally Oromia regional health bureau is located in Addis Ababa for the research approval. Besides the existence of similar study (same year with related topic) have been undergoing within the same period of time at public hospital laboratories in Addis Ababa. There is no any other Oromia hospital within the radius of 125km from the center Addis (Oromia is the closest region to Addis). In the case of health centers, in Ethiopia health centers are categorized as the third tier level of the health service system, so that they render limited number of laboratory services (test menus) with inadequate number of laboratory personnel and equipment. It is known that going far regions and conducting a research incurs a lot of financial issues including transportation and logging. These all reasons hindered the investigator from conducting the research on more health facilities.

### **5.3. Study Period**

This study was conducted between the month of April and May 2014. This period covers data collection, data analysis and write-up of the thesis.

### **5.4. Study Population**

All volunteered laboratory personnel working in the selected public hospital laboratories were participated in this study. As laboratory personnel plays vital role towards good biosafety practices in the laboratory, this study primarily focused on this particular population, as biosafety defined promotion of safe laboratory *practices, procedures* and proper use of *containment equipment and facilities* by *laboratory workers*, (11). As well CDC defined biosafety in the guideline (13) as *development and implementation of administrative policies, work practices, facility design, and safety equipment* to prevent transmission of biologic agents to workers, other persons and the environment; the investigator believed that these are laboratory personnel activities so that they are the first and the only option to assess biosafety practices of the laboratory. As other parties' involvement (data clerk, runners, biomedical engineers and cleaners) in biosafety practices of the aforementioned activities is minimal, the study included only laboratorian

who are running routine laboratory tasks including sample collection to analysis and reporting of results. Most researchers conducted Biosafety and Waste management studies separately as these topics are assumed to be very vast and time taking to study all at once. Additionally, most researches are conducted separately.

### **5.5. Inclusion criteria**

All volunteered individuals working in the selected hospital laboratories with a laboratory work experience of more than or equal to one year of service had been included in the study.

### **5.6. Sample size determination and sampling technique**

A cross-sectional study with convenient sampling technique was used for this study. The total number of participants was relying on the number of laboratory staff members who are volunteered to participate on the study. Therefore; this study had included all the available laboratory personnel in the selected hospital laboratories irrespective of work station assignment. During the assessment period, a total of 45 laboratory personnel were working in all selected hospital laboratories.

Originally the estimated number of laboratory personnel working in five selected hospital laboratories was 67, however; due to different reasons, this number could not be reachable. Staff enrollment for long-term training and turn over are among the reasons explained by laboratory heads. The rate of non-respondent for this study was found to be zero as all participants are volunteered. This study had included 12 laboratory personnel from hospital A (Adama hospital), 11 from hospital B (Bishoftu hospital), 9 from hospital C (Ambo hospital), 4 from hospital D (Tulubolo Hospital) and 9 Laboratory personnel from hospital E (St. Luke hospital). All are district hospitals in the Oromia region and each of the hospitals' laboratory testing menus included clinical chemistry, hematology, microbiology, serology, immunology and clinical microscopy.

### **5.7.Data collection procedure and Quality assurance**

Data was collected between April 2014 and May 2014 using structured questionnaire. Only volunteered and consented participants of the study had been interviewed. Study sites also visually observed by the investigator using the same questionnaire, so that data quality could be verified easily. The questionnaire was comprised of socio demographic information, work information and biosafety practices. The biosafety practice questions cover administrative policy perception, work practice, use of protective barriers and facility design. Each of the questions had scores of equal to one point. The questions are adapted from BMBL (Biosafety in Microbiological and Biomedical Laboratories), Centers for Disease Control and Prevention (CDC) and National Institute of Health (NIH) (17).

Two data collectors have been recruited to collect the information from each of the study sites. One day orientation training has been provided to data collectors by the principal investigator (PI) of this study. As the collectors have understood how to conduct the interview with the developed questionnaire, there was no disciplinary and/or knowledge gap among the data collectors during the assessment. The data has been cleaned before proceeding to the analysis and both electronic and hard copies of the collected data are kept securely. During data collection, code was provided to each participated laboratories and accordingly “A” represent Adama, “B” represent Bishoftu, “C” Ambo, “D” Tulubolo and “E” Saint Luke laboratories. For the simplicity of populating symbols in a data table over long names, as well as for confidentiality reasons in some parts (result and discussion areas) of this paper, the investigator uses English alphabet letters (A-D) to distinguish respective facilities under this study.

### **5.8.Study variables**

- 1) Dependent variable:-Situation of Biosafety practices
- 2) Independent variable:-Age, Gender, level of education, work experience, marital status

## 5.9. Operational Definitions

**Biosafety Perception:**-the level of laboratory personnel's insight, awareness, understanding including attitude towards laboratory biosafety activities or issues

**Biosafety practice:**-the laboratory personnel's routine activities or exercises while dealing with sample collection, analysis and retention and personnel's tendency towards the use of PEP including its consistency availability.

## 5.10. Data analysis

The collected data has been analyzed by descriptive and analytic statistics. In order to compare the means differences (*the difference between the average/mean/ score which is calculated from each of the laboratory personnel result with in specific facility as one group and the grand mean, which is the average score calculated from all participated laboratories*) among five groups of selected hospital laboratories, SPSS version 16 statistical software of One-way ANOVA was used. From the four categories of the study questionnaire, Biosafety policy perception had 11 questions with each of the items scoring 1 point for positive answers, Biosafety practice comprised of 22 questions and each items score 1 point for yes answers, Biosafety practice on the use of protective equipment and Facility design also had 8 and 14 questions, respectively and each items in both Questions' section had same score 1 point for positive responses. Based on the available information; the scoring for answering "yes" or "practiced" is 1 point, likewise answering "no" or "not practiced" is score 0 (no score) . The level of biosafety practice was classified by using the mean and standard deviation. The scores for all categories had been changed in to percentage. Accordingly a low level assigned for group mean (the average specific laboratory score) less than or equal to the grand mean minus grand standard deviation ( $G\bar{X}-SD$ ). Likewise the moderate level assigned, if the group mean of specific laboratory scored is between  $G\bar{X}-SD$  and  $\bar{X}+SD$ . High level is also assigned to the group mean score is fall above or more than  $G\bar{X}+SD$ . WHO/AFRO and most assessing bodies for accreditation purpose including regulatory forms use >80% as high, 70-79% moderate and <70% is as low level performance the standard classification. P value <0.05 is considered as statistically significant.

### **5.11. Result Dissemination**

Finding of the study will be submitted to Addis Ababa University, College of Health Sciences, and Department of Medical Laboratory Sciences and to the study hospitals. It will also reach to the community through peer reviewed and published journals. The study will be presented in scientific conferences and journal clubs where the opportunity allows.

After the completion of the study, based on recommendations provided from the investigator, improvement measures will be communicated to respective laboratories' biosafety practices.

## **6. ETHICAL CLEARANCE**

Ethical clearance with protocol number DRERC 079/14/MLS has been obtained from Addis Ababa University, College of Health Sciences, School of allied Health Sciences, Department of Medical Laboratory Science, Departmental Research and Ethics Review Committee (DRERC). Two copies of ethically reviewed research protocols along with the letter of clearance for ethics had been submitted to Oromia health bureau, consequently the support letter has also been obtained from OHB. Finally the approval from OHB has been presented to each of the study hospitals management. During the assessment all the study participants are consented and signed to be interviewed by the data collectors. Data confidentiality will be maintained by keeping all electronic files password protected and hard copies locked.

## 7. RESULT

Among 45 studied laboratory personnel working in the selected public hospital laboratories, more than 37 (84%) of them were within the age range of 15-44 years. Of which the majority 28 (64%) participants' age aggregated within the age distribution category of 25-34. Based on categorical method of age distribution classification only one individual from laboratory E with the age of 22 years fall on the lower interval limit of the age group. Majority of the participants were males, 34 (75.6%) while females accounted 11 (24.4%) and hence male to female ratio found to be 3:1. With regard to educational level that the study participant academic achievements, 23 (51.1%) of them are BSc degree holders on medical laboratory sciences and the rest 21 (46.7%) are laboratory technicians with diploma on medical laboratory science. While one individual from hospital laboratory B has a certificate of one year basic laboratory training. Work experience related to laboratory services, more than 75% of the group had a work experience of greater than 5 years. Of which, 8 of them had 16 and above years of work experience for on laboratory area. Details are presented in Table 2.

**Table 1:** General characteristics of the study participants from selected public hospitals located in East, South west and West Shoa zones of Oromia Region, May 2014

General Characteristics		Laboratory A (n=12) %	Laboratory B (n=11)%	Laboratory C (n=9)%	Laboratory D (n=4)%	Laboratory E (n=9)%
Age	15 - 24	0	0	0	0	1(11.1)
	25 - 34	8 (66.7)	3(27.3)	8(88.9)	4(100.0)	6(66.7)
	35 - 44	2(16.7)	3(27.3)	1(11.1)		2(22.2)
	45 - 54	2(16.7)	3(27.3)			
	55+		2(18.2)			
Gender	Male	9(75.0)	7(63.6)	7(77.8)	4(100.0)	7(77.8)
	Female	3(25.0)	4(36.4)	2(22.2)		2(22.2)
Marital status	Single	3(25.0)	3(27.3)	2(22.2)	2(50.0)	5(55.6)
	Married	9(75.0)	8(72.7)	7(77.8)	2(50.0)	4(44.4)

<b>General Characteristics</b>	<b>Laboratory A (n=12)%</b>	<b>Laboratory B (n=11)</b>	<b>Laboratory C (n=9)</b>	<b>Laboratory D (n=4)</b>	<b>Laboratory E (n=9)</b>
Education					
<=12 Certificate		1(9.1)			4 44.4
Diploma	7(58.3)	4(36.4)	4(44.4)	2(50.0)	
BSc	5(41.7)	6(54.5)	5(55.6)	2(50.0)	5(55.6)
Experience (Working years)					
1-5	1(8.3)	1(9.1)	4(44.4)	1(25.0)	4(44.4)
6-10	8(66.7)	1(9.1)	3(33.3)	3(75.0)	4(44.4)
11-15	1(8.3)	3(27.3)	2(22.2)		1(11.1)
>=16	2(16.7)	6(54.5)			

### **Overall situation of the Biosafety practices among the five selected hospital laboratories**

Data in relation to biosafety practices of the laboratory personnel working in five selected hospital laboratories are categorized in to four distinctive sections of related items and presented in four different tables. As a whole, the mean scores of biosafety practices to all studied laboratory personnel were ranged from is  $36.44 \pm 7.63$  (low to moderate level). Details are presented in the below table 2.

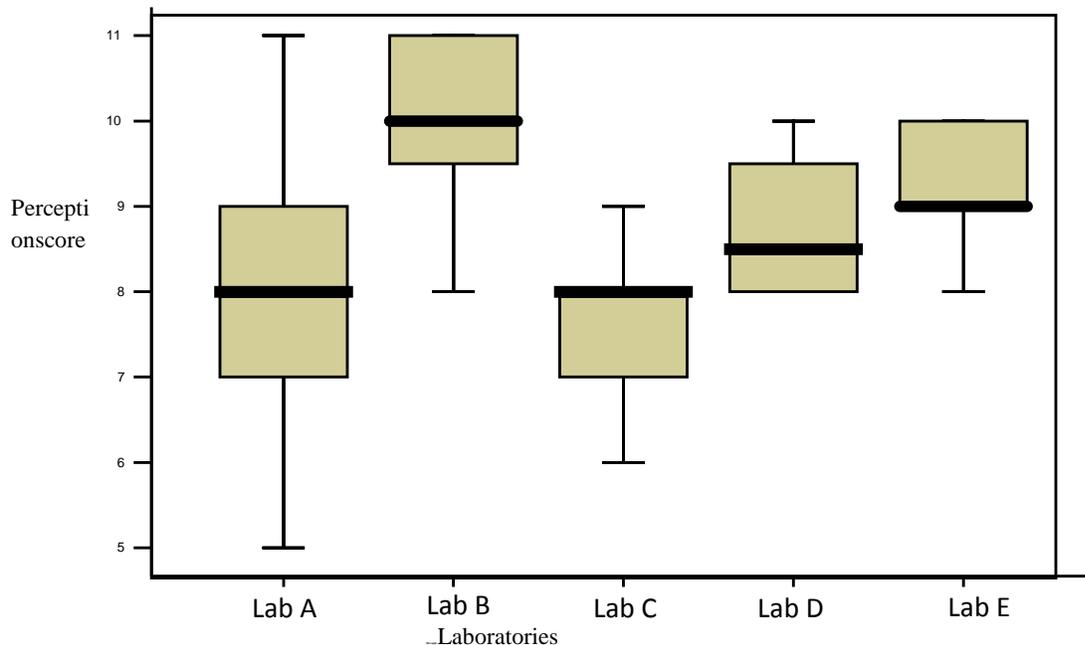
**Table 2:** Over all situation of biosafety practices' mean in all four categories of selected public hospitals located in East, South west and West Shoa zones of Oromia Region, May 2014

<b>Items</b>	<b>Laboratory "A" (n=12) X</b>	<b>Laboratory "B" (n=11) X</b>	<b>Laboratory "C" (n=9) X</b>	<b>Laboratory "D" (n=4) X</b>	<b>Laboratory "E" (n=12) X</b>
Biosafety towards policy perception (Total score 11)	8	10	8	9	9
Biosafety towards work practice (Total score 22)	11	18	15	19	17
Biosafety towards using protective barriers and safety equipment (Total score 8)	4	5	5	5	6
Biosafety towards facility design (Total score 14)	6	9	7	5	7
<b>Total score 55X</b>	<b>7.3</b>	<b>10.5</b>	<b>8.8</b>	<b>9.5</b>	<b>9.8</b>

### 7.1 Biosafety towards administrative policy perceptions

GX scores  $\pm$  Standard Deviation (SD) towards biosafety administrative policy perceptions among 5 studied hospital laboratory personnel found to be  $8.8 \pm 1.575$  (Total score 11). The within group mean score also, ranged from  $7.8 \pm 1.8$  to  $10.4 \pm 0.8$ . Laboratory personnel of hospital B scored significantly higher mean than of A and C laboratories with  $10.4 \pm 0.8$  and relatively higher score than laboratory D and E (approximately 90% of the total score) so that, it has been categorized as high level in terms of biosafety policy perception.

On the other hand, laboratory A and C had a score of  $7.8 \pm 1.9$  and  $7.7 \pm 0.9$  respectively, and categorized as a range of low to moderate level. Both Laboratory A and B personnel have received vaccination against hepatitis B virus. More than 85% of personnel from both facilities' have been vaccinated in 2014 (Personal communication with respective heads). In the case of Laboratory D and E, none of the staff, had been offered any kind of preventive vaccines from the employers. The P-value for administrative policy perception was  $P < 0.001$ . Details are presented in Table 3 and clearly depicted in Figure 1.



**Figure 1:** Box plot showing biosafety policy perception of laboratory personnel in selected public hospitals located in East, S\west and West Shoa zones of Oromia Region, May 2014

**Table 3:** Laboratory personnel's biosafety policy perception in selected public hospitals located in East, S\west and West Shoa zones of Oromia Region, May 2014.

Items	Laboratory A (n=12)	Laboratory B (n=11)	Laboratory C (n=9)	Laboratory D (n=4)	Laboratory E (n=9)
1) Practice of laboratory restricted when experiments on progress	8(66.7)	9(81.8)	2(22.2)	3 (75.0)	4(44.4)
2) Practice of receiving an appropriate immunization for potentially infectious pathogens	11 (91.7)	9(81.8)	3(33.3)		
3) Practice of a policy and procedure of the potential hazard and meet specific entry requirements may enter the laboratory	7 (58.3)	10(90.9)	4(44.4)	3(75.0)	9(100.0)
4) Practice of waste disposal protocol in place for laboratory personnel	5(41.7)	11(100.0)	8(88.9)	4(100.0)	9(100.0)
5) Practice of trend appropriate safety precautions and procedures	8(66.7)	11(100.0)	8(88.9)	4(100.0)	9(100.0)
6) Practice of policies for the safe handling of sharps are instituted	11(91.7)	11(100.0)	9(100.0)	4(100.0)	9(100.0)
7) Practice of a guide line for laboratory safety of laboratory personnel	10(83.3)	11(100.0)	8(88.9)	4(100.0)	9(100.0)
8) Practice of a protocol and SOP by laboratory personnel	11(90.7)	11(100)	7(77.8)	4(100)	8(88.9)
9) Assignment of biosafety officer to monitor biosafety practices in the laboratory	11(91.7)	11(100.0)	9(100.0)	4(100.0)	9(100.0)
10) Practice of providing biosafety training/orientation to newly hired laboratory personnel	2(16.7)	9(81.8)	3(33.3)		9(100.0)
11) Practice of emergency plan to prevent and control post exposures to infectious and/ hazardous events	10(83.3)	11(100.0)	8(88.9)	4(100.0)	9(100.0)
X ±SD	7.8±1.9 <sup>a</sup>	10.4±0.8 <sup>b</sup>	7.7±0.9 <sup>c</sup>	8.8±1 <sup>d</sup>	9.3±0.7 <sup>e</sup>

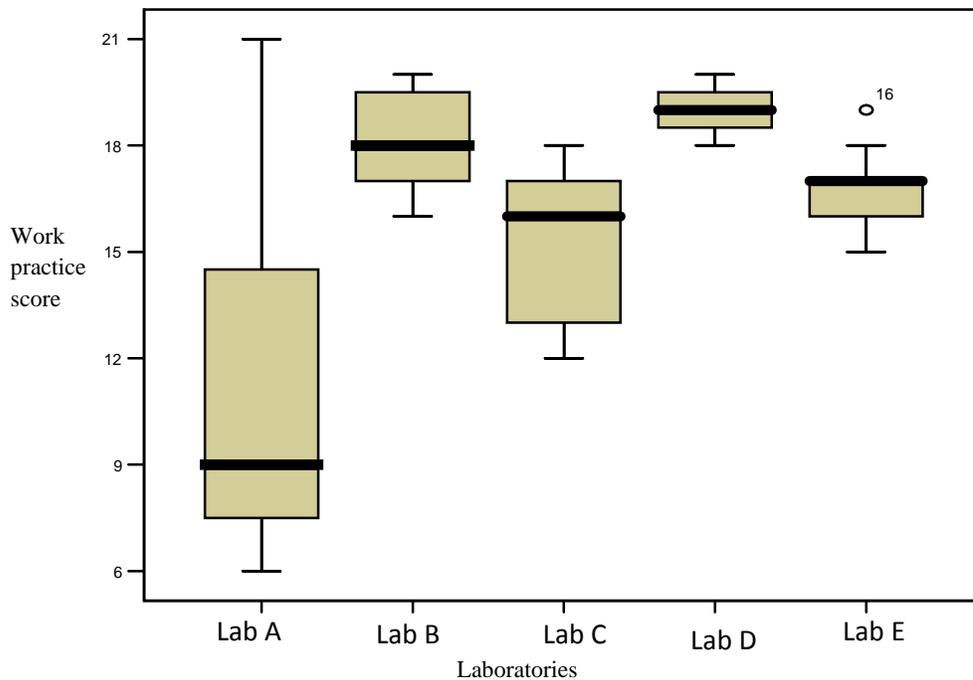
<sup>bcd</sup> Statistically significant difference by ANOVA, P<0.001

<sup>ab</sup> Significant difference by Tukey HSD, P=0.001, <sup>bc</sup> Significant difference by Tukey HSD, P=0.001

<sup>ac, ad, ae, bd, be, cd, ce& de</sup> all had no significant difference by Tukey HSD, P=0.998, P=0.703, P=0.064, P=0.358, P=0.655, P=0.596, P=0.050 & P=0.934 respectively.

## 7.2 Biosafety towards work practices

The grand mean scores for biosafety towards work practices among all studied groups of personnel were  $15.60 \pm 3.899$ . The within group mean score, also ranged from  $11.4 \pm 4.8$  to  $19 \pm 1$  (Total score 22). Laboratory personnel of hospital D scored significantly highest mean result of all. Hospital A laboratory personnel had scored significantly lower result than those of other hospital laboratories and the P-values found to be less than  $P < 0.001$  (See Table 4 and Figure 2 for detail).



**Figure 2:** Box plot representing comparison of the mean score of laboratory personnel's work practice in each of studied laboratories in selected public hospitals located in East, South west and West Shoa zones of Oromia Region, May 2014.

**Table 4:** Laboratory personnel's biosafety work practices in selected public hospitals located in East, S\west and West Shoa zones of Oromia Region, May 2014.

Items	Laboratory A (n=12)	Laboratory B (n=11)	Laboratory C (n=9)	Laboratory D (n=4)	Laboratory E (n=9)
1) Do not eat and drink in the work areas	6(50.0)	10(90.9)	6(66.7)	4(100.0)	7(77.8)
2) Are biohazard signs posted at the entrance of laboratory?	11(91.7)	11(100.0)	9(100.0)	3(75.0)	7(77.8)
3) Do you keep your laboratory doors closed, when testing is undergoing?	4(33.3)	8(72.7)	1(11.1)	4(100.0)	3(33.3)
4) Do you have an incident report system in the laboratory?	6(50.0)	11(100.0)	6(66.7)	4(100.0)	8(88.9)
5) Do you decontaminate all cultures and waste before disposal?	2(16.7)	7(63.6)	2(22.2)	2(50.0)	5(55.6)
6) Do you have mechanical/micro pipet to replace mouth pipet and using them?	11(91.7)	10(90.9)	8(88.9)	4(100.0)	9(100.0)
7) Do you seal rotor heads and centrifuge cup regularly, while they are running?	4(33.3)	11(100.0)	7(77.8)	4(100.0)	9(100.0)
8) Remove broken glassware mechanically using appropriate techniques	5(41.7)	9(81.8)	8(88.9)	4(100.0)	9(100.0)
9) Are you using disposable needles for drawing blood specimens and discard them in appropriate waste disposal bin?	12(100.0)	11(100.0)	9(100.0)	4(100.0)	9(100.0)
10) Decontaminate used material outside of the laboratory	2(16.7)	8(72.7)	4(44.4)	4(100.0)	2(22.2)
11) Do you wash hands before leaving the laboratory?	12(100.0)	11(100.0)	9(100.0)	4(100.0)	9(100.0)
12) Do you decontaminate infectious liquid waste with appropriate chemical/physical before discharge?	4(33.3)	8(72.7)	1(11.1)	3(75.0)	9(100.0)
13) Store food outside the work area of the laboratory	3(25.0)	8(72.7)	8(88.9)	4(100.0)	5(55.6)
14) Laboratory decontaminates equipment before repair, maintenance, or removal	2(16.7)			1(25.0)	
15) Routine safety audits conduct, document to ensure laboratory containment parameters	5(41.7)	3(27.3)	4(44.4)		9(100.0)
16) Does the laboratory properly handle/manage hazardous chemicals using MSDS	4(33.3)	10(90.9)	9(100.0)	3(75.0)	
17) Do you wash hands after handing bio hazardous materials?	12(100.0)	11(100.0)	9(100.0)	4(100.0)	9(100.0)
18) Do you wash hands after removing gloves?	9(75.0)	10(90.9)	9(100.0)	4(100.0)	9(100.0)
19) Do you clean &decontaminate work surface at least after each day work?	7(58.3)	10(90.9)	7(77.8)	4(100.0)	9(100.0)
20) Does your lab perform activities carefully to minimize the creation of splashes?	9(81.8)	11(100.0)	8(88.9)	4(100.0)	9(100.0)
21) Do you place specimens in compliant with triple method packaging for transportation?	2(16.7)	11(100.0)	5(55.6)	4(100.0)	7(77.8)
22) Does the laboratory segregate infectious, noninfectious and sharps of laboratory wastes properly?	5(41.7)	10(90.9)	9(100.0)	4(100.0)	9(100.0)
X±SD	11.4±4.8 <sup>a</sup>	18.1±1.5 <sup>b</sup>	15.3±2.2 <sup>c</sup>	19±0.8 <sup>d</sup>	16.9±1.2 <sup>e</sup>

Table 4 has the following p-value results by ANOVA and Tukeys multiple comparison tools

<sup>abcde</sup>Statistically significant difference by ANOVA,  $P < 0.001$

<sup>ab</sup>Significant difference by Tukey HSD,  $P < 0.001$ ,      <sup>ac</sup>Significant difference by Tukey HSD,  $P = 0.035$

<sup>ad</sup> statistically significant difference by Tukey HSD  $P = 0.001$  ,      <sup>ae</sup>Significant difference by Tukey HSD,  $P = 0.001$

<sup>bc</sup>No significant difference by Tukey HSD,  $P = 0.212$ ,      <sup>bd</sup>No significant difference by Tukey HSD,  $P = 0.984$

<sup>be</sup>No significant difference by Tukey HSD  $P = 0.892$ ,      <sup>cd</sup>No significant difference by Tukey HSD,  $P = 0.225$

<sup>ce</sup>No significant difference by Tukey HSD,  $P = 0.750$ ,      <sup>de</sup>No significant difference by Tukey HSD,  $P = 0.754$

### **7.3 biosafety towards using protective barriers and safety equipment**

The grand mean scores of biosafety towards using protective barriers and safety equipment among all studied hospital laboratory personnel was  $5.04 \pm 1.364$ . There wereranging from  $4.4 \pm 2.2$  to  $5.8 \pm 0.8$  (Total score 8).Laboratory personnel of hospital E had relatively higher mean score than those of other hospital laboratory personnel, however; this was not statistically significant ( $P = 0.263$ ). The mean scores for hospitals A, B, C, D, and E were,  $4.4 \pm 2.2$ ,  $5.1 \pm 0.7$ ,  $5.0 \pm 1.1$ ,  $5.3 \pm 0.5$ , and  $5.8 \pm 0.7$  respectively. (Detail shown in Table 5).

The observed mean score of  $5 \pm 1$  by these laboratories when two questions related to the presence of Biosafety cabinets (BSC) for laboratory procedures of potentially infectious agents and practices of regular BSC maintenance service for BSC were excluded, demonstrated high level of biosafety practice on the category of protective barriers. This indicates that there is no significant difference among the studied laboratory personnel in terms of using protective barriers, which is again encouraging and needs to be sustained.

**Table 5:** Biosafety practice towards use of protective barriers of the studied laboratory personnel of selected public hospitals located in East, S\west and West Shoa zones of Oromia Region, May 2014.

Items	Laboratory A (n=12)	Laboratory B ( n=11)	Laboratory C (n=9)	Laboratory D (n=4)	LaboratoryE (n=9)
1) Use safe protective barriers for splashing or spraying of infectious micro-organisms done outside the BSC like apron, goggle etc...	5(41.7)	7(63.6)	5(55.6)	3(75.0)	8(88.9)
2) Maintain the BSC properly and certified annually (if applicable)	1(8.3)				
3) Use the BSC regularly for potential procedures with creating infectious aerosols	9(75.0)	3(27.3)			9(100.0)
4) Use PPE regularly for potential procedures creating infectious aerosols	7(58.3)	11(100.0)	8(88.9)	3(75.0)	8(88.9)
5) Do not use disposable gloves for touching clean surface and materials (pen, door handle, telephone etc...)	8(66.7)	6(54.5)	9(100.0)	4(100.0)	5(55.6)
6) Remove protective clothes before leaving for non-laboratory areas	4(33.3)	7(63.6)	7(77.8)	3(75.0)	7(77.8)
7) Wear protective coats /gowns for working in the laboratory at all times	7(58.3)	11(100.0)	8(88.9)	4(100.0)	9(100.0)
8) Wear gloves when hands may contact potentially infectious materials, contaminated surfaces etc.	12(100.0)	11(100.0)	8(88.9)	4(100.0)	6(66.7)
X± SD	4.4±2.2*	5.1± 0.7*	5.0± 1.1*	5.3±0.5*	5.8±0.7*

\*No significant difference by ANOVA, P=0.263

#### **7.4 Biosafety practice towards facility design**

The observed biosafety of facility design mean scores in this study were low ranging between the  $5.3 \pm 1.7$  and  $9.2 \pm 1.9$  (of Total score 14). Laboratory personnel of hospital B had relatively higher scores than laboratory personnel of hospital C and E with a mean score of  $9.2 \pm 1.9$ , whereas hospital B personnel scored significantly higher result of mean than those of hospital laboratory personnel A & D. The difference reached at a statistically significant level for A and D as compared to B p-values ( $P=0.026$  and  $P=0.044$ , respectively). The respective mean square values for biosafety practices towards facility design (like presence of eye wash, emergency shower, fire extinguisher, BSL-2 facility, separate sink for hand wash, ets) were  $6.0 \pm 3.4a$ ,  $9.2 \pm 1.9b$ ,  $6.6 \pm 1.0c$ ,  $5.3 \pm 1.7d$ ,  $6.7 \pm 0.7e$ . Details are presented in Table 6.

**Table 6:** Biosafety practice towards facility design of the studied laboratory Personnel of selected public hospitals located in East, S\west and West Shoa zones of Oromia Region, May 2014

Item	Laboratory A (n=12)	Laboratory B (n=11)	Laboratory C (n=9)	Laboratory D (n=4)	Laboratory E (n=9)
1) Is there an eye wash station readily available in the room?	11(91.7)	11(100.0)	1(11.1)	-	4(44.4)
2) Laboratory facilities in biosafety level 2-4. Do you have laboratory away public traffic areas?	1(8.3)	4(36.4)	1(11.1)	-	-
3) Are biological safety cabinets located away from doors & windows that can be opened from heavily traveled lab areas? If applicable	8(66.7)	6(54.5)	1(11.1)	-	2(22.2)
4) Facility for eating, drinking and for rest provided outside the lab area	1(8.3)	10(90.9)	-	-	-
5) Is there a facility to store outer garments outside the lab area?	7(58.3)	9(81.8)	9(100.0)	3(75.0)	9(100.0)
6) Do you have opening the exhaust fans to reduce the microbial count in air? If applicable	2(16.7)	2(18.2)	-	1(25.0)	-
7) Do you have the spaces between benches and cabinets accessible for cleaning?	6(50.0)	8(72.7)	6(66.7)	3(75.0)	5(55.6)
8) Is the design suitable so that it can be easily cleaned, and optimal to conduct laboratory work?	6(50.0)	9(81.8)	6(66.7)	3(75.0)	9(100.0)
9) Do chairs and other furniture used in laboratory work have non fabric materials that can be easily decontaminated?	2(16.7)	10(90.9)	9(100.0)	-	9(100.0)
10) Is illumination/the brightness of the room/ adequate for all activities?	10(83.3)	11(100.0)	9(100.0)	4(100.0)	9(100.0)
11) Do you have a sink for hand washing in each laboratory room?	8(66.7)	10(90.9)	8(88.9)	3(75.0)	4(44.4)
12) Emergency shower available & accessible	2(16.7)	-	-	-	-
13) Fire extinguisher available & serviced	7(63.6)	10(90.9)	9(100.0)	4(100.0)	9(100.0)
14) Windows are screened with arthropods-proof material,	1(8.3)	1(9.1)	-	-	-
X±SD	6.0±3.4 <sup>a</sup>	9.2±1.9 <sup>b</sup>	6.6±1.0 <sup>c</sup>	5.3±1.7 <sup>d</sup>	6.7±0.7 <sup>e</sup>

<sup>abcde</sup> Statistically significant difference by ANOVA, P=0.015, <sup>ab</sup> statistically significant difference by Tukey HSD, P=0.026, <sup>bd</sup> significant difference by Tukey HSD, P=0.044 <sup>ac, ad, ae, bd, be, cd, ce& de</sup> all had no significant difference by Tukey HSD

## 8. DISCUSSION

In this study over all the biosafety practices of the studied laboratories ranged between low to moderate level with different findings in each studied facilities. Detailed categorized results are discussed and presented below in related sections of biosafety practices.

### 8.1. Laboratory personnel biosafety policy perception

One of the questions in this category was about practice of receiving an appropriate immunization against potentially infectious pathogen that could potentially be present in the laboratory. Although laboratory D and E had mean score of  $8.8 \pm 1$  and  $9.3 \pm 0.7$  respectively, and categorized in moderate level, both had never started to offer the required preventative vaccines for potential infections, in contrary to recommendations (8, 27).

Eleven points including immunization, assignment of safety officer, provision of training, use of SOPs, manuals, and guidelines, practice of an emergency plan to prevent and control post exposures and infections.etc were addressed under biosafety policy to assess the perception of the laboratory personnel regarding their implementation.

The national safety manual recommend, laboratory personnel should be provided with appropriate immunizations or tests for agents that are handled or potentially present in the laboratory (e.g. TB skin test, Hepatitis B vaccine)(8). ISO also warned that, laboratory staff should be offered appropriate vaccinations--particularly Hepatitis B. Staff may decline to receive the vaccination, but should sign a declination form to be held in the staff member's personnel file (27). A study conducted in Sudan at Khartoum state diagnostic laboratories by Elduma, A.H and *et al.* (20) revealed that only 19 (10%) laboratories had hepatitis B vaccination program.

All participated laboratories have assigned an officer who oversees biosafety issues and orient new employees about the facility biosafety practices. As biosafety officers have been assigned very recently in all studied facilities to safeguard biosafety issues, except laboratory E the rest have not yet provided biosafety trainings/orientation to their respective staff. According to World Health Organization (WHO), biosafety manual to safe laboratory practice (26), a safety-conscious staff, well informed about the recognition and control of laboratory hazards, is key to

the prevention of laboratory acquired infections, incidents and accidents. As WHO biosafety manual recommends; integration of continuous in-service training in safety measures is essential. Training in safety measures should be an integral part of new employees' introduction to the laboratory. Employees should be introduced to the code of practice and to local guidelines, including safety or operations manual. The biosafety officer can assist in training and with the development of training aids and documentation (26).

More than 85% of the studied laboratory personnel perceive as well as practiced emergency plan to prevent and control post exposures and infections. SOPs had also been posted to be followed for HIV infection that might be occurred incidentally to laboratory personnel while performing laboratory procedures. Laboratories obliged to ISO clauses that state laboratory must have a procedure for follow-up of possible and known percutaneous, mucus membrane, or abraded skin exposure to HIV, HBV, or HCV. The procedure should include clinical and serological evaluation and appropriate prophylaxis (27). In this regards, the finding is in the present study regarding emergency plan is encouraging and needs to be sustainably implemented.

## **8.2. Biosafety towards laboratory work practices among studied hospital laboratories**

A big difference was observed regarding biosafety issues related to laboratory work practices (common safety issues in the laboratory like not eating drinking in the lab, biohazard signs, decontamination, hand washing, waste disposal, etc) amongst the five studied laboratory personnel. Between laboratory A and the rest four laboratory personnel (A-B, A-C, A-D and A-E), there were significant differences so that further calculated and compared by multiple comparison calculation using SPSS, Tukey HSD tool, which demonstrated a statistically significant difference between laboratory A personnel and the rest. This indicates that the level of biosafety practices among the studied personnel varies significantly.

As part of good laboratory practice to protect the community from acquiring hospital acquired infections coming from poor management of wastes, decontamination of infectious or contaminated liquids with chemicals or by autoclaving before discharge into the sanitary sewer has been clearly stated in the national safety manual. Laboratory equipment and work surfaces should also be cleaned using effective disinfectant on a routine basis and after spills and

splashes. In addition, any laboratory equipment which needs maintenance by biomedical or service engineers should also be decontaminated according to local regulations before being sent for repair (8).

### **8.3. Biosafety practice towards use of protective barriers of the studied laboratory**

In the present study under the assessment of biosafety practices towards protective barriers, result showed that, laboratory C and D had no Biosafety cabinets (BSC). Bear in mind that public hospitals be it district, primary or referral, they all considered as BSL-2 or above as they deal with aerosol pathogens such as Tb including MDR. This suggests laboratory activities including aerosol creating activities are being performed on the open bench, which is against recommendations (26).

A study conducted by Ejilemele et al, in University of Port Harcourt teaching hospital, Nigeria showed that gross deficiencies were seen in knowledge, attitude and practice of laboratory safety by laboratory staff in areas of use of PPE (24). Moderate -risk agents, that are present in the community and associated with human disease of varying severity, can be treated safely in a laboratory activities conducted on the open bench. This is possible, provided the potential for producing splashes or aerosols is low, consistent and appropriate use of PPE is in place and accompanied by good microbiological techniques (8, 16). Among the above mentioned three laboratories (A, B, and E) all laboratory's biosafety cabinet was not maintained regularly, however; during the site assessment, it was possible to notice that laboratory personnel were using with little or no knowledge of service maintenance, as if they were being protected from potential aerosols created by laboratory activities. Whereas, ISO 15190 states, biosafety cabinet should be used for to prevent aerosol exposure to contagious specimens or organisms. For proper functioning and full protection, biosafety cabinets require periodic maintenance and should be serviced accordingly (27).

The national safety manual declares that, respect the use of laboratory coats, gloves, and masks and face shields. Certification and recertification of equipment are required at regular intervals according to the manufacturer's instructions (8). Although, the result in the general use of PPE was encouraging, still in laboratory A there was relatively low level of acceptance about using

protective barriers. Lack of goggles and masks rose as the major gap to protect themselves from aerosols by all studied facility personnel.

#### **8.4. Biosafety practice towards facility design of the studied laboratory personnel**

The grand mean score of facility design was  $6.96 \pm 2.44$ . According to the national biosafety manual (8) which had been developed and distributed across in country laboratories by EPHI, provision of sufficient space for safe conduct of laboratory work and for cleaning and maintenance, availability of a sink for hand washing in each room and adequate illumination of light are a requirement for BSL-2 laboratories. Hepatitis B virus, HIV, the salmonellae, and *Toxoplasma* spp. are representative of microorganisms assigned to this containment level. BSL-2 is appropriate when work is done with any human-derived blood, body fluids, tissues, or primary human cell lines where the presence of an infectious agent may be unknown and practicing by referring specific required precautions (16).

Except laboratory A and B, all had no or insufficient and inappropriate eye wash station. Which means in laboratory C there is an eye wash station only in ART laboratory the rest sections have no any. In the case of laboratory D the eye station is placed in the core lab but it was not appropriate site as well there is no water flush collection vessel or container in place. Interestingly all had maintenance serviced fire extinguisher in respective facilities. According to ISO15190 clause 19.7 (27) appropriate fire extinguisher should be available and periodically serviced for the institution of safety in the laboratory. As compared to a study conducted in Pakistan medical research council, Karachi, fire extinguisher was not available in 76.7% of public hospital labs. (6) Another study conducted in Khartoum state, national public health laboratory Sudan, by Elduma, A.H and *et al.* (20) shown that only 20.5% of diagnostic laboratories had fire extinguisher. Emergency shower, windows screened with arthropods-proof material, separate and appropriate facility for laboratory staff eating, drinking and resting are not instituted almost in all of the studied laboratories. Eye wash stations also were not available in most of studied laboratories.

Of interest, there was no mouth pipetting in any of the studied facilities. Even the youngest personnel did not know whether this experience was used to be practiced by laboratory personnel in the world before. Biohazard signs had been posted in each of the facilities. To the contrary all, laboratories never decontaminate equipment before repair, maintenance, or removal and there is no regular or not at all safety audits to ensure laboratory containment parameters. Majority of the laboratory personnel except laboratory C did not properly handle/manage hazardous chemicals using MSDS. Taken together, although encouraging perceptions and practices were noted for some of the biosafety elements, there is still a need to ensure biosafety measures are in place in the studied facilities.

## 9. CONCLUSION

As the assessment result indicates that the overall biosafety practice of the studied hospital laboratories average score is  $36.44 \pm 7.63$  from a total score value of 55, with the score range of 52%-80%. Laboratory B exceptionally scored the mean score of 80% and fall in the upper moderate level which will fall to highest level with little improvement. The mean score for laboratory D and E were similar in result which close to 70% to be labeled as moderate. The rest found to be low level with laboratory A scored half of the percentages.

Strikingly, personal protective equipment excluding gown and glove are not being supplied by any agency (These includes goggles, masks and covering aprons) across the studied laboratories. Eye wash station, emergency shower, furniture of non-fabric materials and adequate space for laboratory procedures were also areas where immediate remedial actions is required.

Although all studied laboratories are public hospitals and administered by Oromia regional health bureau, there was a difference in provision of vaccines among laboratories located in the same region.

Although all studied laboratories are assigned biosafety officers, the roles and responsibilities has not been clearly defined and communicated to the staff. As a result there were differences in attitude and practices among biosafety officers. In the level of biosafety practice is differs one another so that training with appropriate monitoring might be considered to bring the laboratory personnel practice to the same level.

## 10. RECOMMENDATIONS

Based on the assessment result, the investigator would like to recommend the following points along with appropriate and responsible bodies to address specific issues. Some can be managed to keep the standard by the laboratory itself and others are beyond the laboratory control so that they will go to either hospital management or regional lab or even at large national level laboratory programs.

- Hospital management need to sit down together with laboratory representatives /Safety officers/ and discuss about the assessment result particularly the areas where specific laboratory could not be in compliance with the ISO standards or low scored biosafety sections.
- Immunization of laboratorians for hepatitis B and C, and *N. meningitides* is very important and should be offered by employers /hospitals/ to all potentially acquiring laboratory individuals.
- Oromia regional laboratory should organize and provide appropriate biosafety trainings to hospital laboratory personnel. Priority should be given to safety officers as they have the responsibility to monitor and ensure laboratory biosafety issues. However; all laboratory personnel should receive at least any biosafety training. The training need to include the risk of working with infectious agents and appropriate use of safety equipment and should also be reinforced annually. Appropriate orientation should also be provided to new employees on biosafety issues before introducing them any laboratory activities.
- Regions can request technical and material support from MoH mandated national laboratory technical hand called Regional Capacity Building Directorate at EPHI for the gaps that are beyond the region's capacity such as experienced biosafety trainers as well as for procurement of big protective barrier equipment or BSC along with service maintenance packages. BSCs which are available in the assessed hospitals but not yet installed and/or serviced can also be addressed via EPHI if the lab can communicate them.
- Hospital infection prevention and control committee (it has been established in each hospital) should involve laboratory safety officer as part of the committee member and work together on cross cutting biosafety issues.

- Adequate and appropriate Personal protective equipment should also be provided laboratory personnel working with infectious agents.
- Each laboratory should provide job descriptions to the assigned biosafety officers with clearly defined roles and responsibilities
- There should be institutional biosafety support to control maintain and record nosocomial infection and accidents in each laboratories.

## **11. LIMITATION OF THE STUDY**

Due to the investigator's financial constraint, the numbers of facilities where participants (laboratory personnel) working in is limited to five hospitals; consequently the studied participants could be small. As well, so as to include hospital laboratories located in Addis Ababa administrative region, there was an issue of conflict of interest among students of same department. Existence of similar study (same year with related topic) have been undergoing within the same period of time at public hospital laboratories in Addis Ababa. Besides the There is no any other Oromia hospital with in the radius of 125km from the center Addis (Oromia is the closest region than others to Addis).

Biosafety information gap among facilities and even individual laboratory personnel level working in the same facility was one of the challenges which could varies the interview time among participants. For example during the interview, in some cases the process were too much prolonged for explanation of terms and statements in the questionnaire and took more than the predicted or expected time, also individual's opinion might be influenced. Some laboratorians were anxiety about the negative answers as they wrongly conceived that the study might disclose sensitive issues so that they were trying to deny the real scenarios.

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### **13. ANNEXURES**

#### **ANNEX. 1: Principal investigator assurance form**

##### **ASSURANCE OF PRINCIPAL INVESTIGATOR**

I the undersigned agree to accept all responsibilities for the scientific and ethical conduct of the research project. I will provide timely progress report to my advisor and seek the necessary advice and approval from my primary advisors in the course of the research. I will communicate timely to my advisors all stakeholders involved in the study including any source of funding for this research.

Name of the student: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

##### **Approval of the primary Advisor**

Name of the primary advisor: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

## ANNEX 2: Consent form

Code number \_\_\_\_\_

Name of the Health facility \_\_\_\_\_

I have been informed about the study which is aimed at assessing Current situation of Biosafety Practices in selected hospital laboratories in East, West and South-West Shoa zones of Oromia region. For this study true and direct information is needed to fill the questionnaire and a document observation will be performed. The aims of the study were explained to me.

I am also informed that all the information contained within the questionnaire is to be kept confidential. Moreover, I have been well informed of my right to keep hold of information, decline to cooperate and make myself withdraw from the study.

It is therefore with full understanding of the situation that I gave the informed consent voluntarily to the researcher to use the information gathered from me for the study. In addition, I have had the opportunity to ask questions about it and received clarification to my satisfaction. I have also been informed that the benefit of participation is to improve the biosafety practice of laboratories and hence laboratory acquired infections and accidents will be reduced.

Participant's Signature \_\_\_\_\_

Name of Interviewer \_\_\_\_\_ Signature \_\_\_\_\_ Date \_\_\_\_\_

### **Please direct any questions or problems you may encounter during this study to:**

Name: Derese Tefera

Mobile: +251-91-167-61-63

Email: [derese\\_tf@yahoo.com](mailto:derese_tf@yahoo.com)

For further information please contact AAU, Department of Medical Laboratory sciences

Name: Dr. Aster Tsegaye

Mobile: +251-91-1 696085

Email: [tsegayeaster@yahoo.com](mailto:tsegayeaster@yahoo.com)

### **ANNEX 3: Questionnaire**

#### **Interview Questionnaire for the assessment of biosafety practices in selected hospital laboratories, located in East, West and South-West Shoa zones of Oromia region.**

The aim of this assessment is to undertake individual's Master thesis as a partial fulfillment for MSc degree requirements by Addis Ababa University. The proposal for this study has been passed through all necessary requirements as deemed for any study to be conducted on individuals' opinion and confidentiality issues including organizations conflict of interest required by departmental research and ethics review committee. The PI has full autonomy to undertake this study and also responsible for all the issues which may be raised by the study related to participants information and confidentiality breakage. All the selected hospitals will benefit from the study as the result along with recommendations will be provided them. As it is a KAP study and does not involve human subject as experimental study, it will not harm any participants of this study.

The objective of the study is to assess the biosafety practice of public hospital laboratories in East, West and South-West Shoa zones of Oromia region. The under interviewed laboratory personnel gave the informed consent voluntarily to the researcher to use the information gathered from him/her for the study. In addition, the interviewee have had the opportunity to ask questions about it and received clarification to his/her satisfaction. The interviewee has also been informed as the benefit of participation is to improve the biosafety practice of laboratories and hence laboratory acquired infections and accidents will be reduced, Participants of this study will not have issues related to justice.

Date of interview \_\_\_\_\_

## Section I

### Socio-demographic Characteristics of the study Laboratory personnel

Check the box under the answers where participants provided for each of the question

1. Name (code) \_\_\_\_\_
2. Age \_\_\_\_\_
3. Gender                      Male                                      Female
4. Marital Status  
                    Single                      Married                                      Divorced                                      Widowed
5. Educational Level  
                    12<sup>th</sup> completion                      Certificate                      Diploma                      BSc                      MSc & above
6. Experience (duration of working years)  
                    1-5                                      6-10                                      11-15                                      16

## Section II

### Biosafety policy perception among study hospital laboratory personnel

What is your perception towards laboratory biosafety policy of the following items?

1. Practice of laboratory limited or restricted when experiments on progress  
Yes                                      No
2. Practice of receiving an appropriate immunization against potentially infectious pathogen present in the laboratory  
Yes,                      , please specify-----                      Not
3. Practice of a policy and procedure of the potential hazards and meet specific entry requirements may enter the lab  
Yes                                      No
4. Practice of waste disposal protocol in place of laboratory personnel  
Yes                                      No



5. Do you decontaminate all cultures, stocks and waste before disposal such as autoclaving?

Yes                      No

6. Do you have mechanical/micro pipet to replace mouth pipet and using them?

Yes                      No

7. Do you seal rotor heads and centrifuge cup regularly, while they are running?

Yes                      No

8. Remove broken glassware from the floor mechanically using appropriate techniques (using broom/brush and card board)

Yes                      No

9. Are you using disposable needles for drawing blood specimens and discard them in appropriate waste disposal bin?

Yes                      No

10. Decontaminate used material outside of the laboratory

Yes                      No

11. Do you wash hands before leaving the laboratory?

Yes                      No

12. Do you decontaminate infectious liquid waste with appropriate chemical/physical before discharge to the sewer?

Yes                      No

13. Store food outside the work area of the laboratory

Yes                      No

14. Laboratory decontaminates equipment before repair, maintenance, or removal

Yes                      No

15. Routine safety audits conduct, document to ensure laboratory containment parameters

Yes                      No

16. Does the laboratory properly handle/manage hazardous chemicals using MSDS

Yes                      No

17. Do you wash hands after handling bio hazardous materials?

Yes                      No

18. Do you wash hands after removing gloves?

Yes                      No

19. Do you clean and decontaminate work surface at least after the completion of each day work?              Yes                      No

20. Does your lab perform laboratory activities carefully to minimize the creation of splashes?              Yes                      No

21. Do you place culture and specimens in compliant with triple packaging method during transportation?              Yes                      No

22. Does the laboratory segregate infectious, noninfectious and sharps of laboratory wastes properly?

Yes                      No

## Section IV

### Biosafety practices towards use of protective barrier of the study laboratory personnel

1. Use safe protective barriers for splashing or spraying of infectious micro-organisms done outside the biological safety cabinet (BSC) like apron, goggle etc...

Yes                      No

2. Maintain the BSC properly and certified annually (if applicable)

Yes                      No                      Not applicable (Do Not have BSC)

3. Use the BSC regularly for potential procedures with creating infectious aerosols

Yes                      No                      Not applicable (Do Not have BSC)

4. Use PPE regularly for potential procedures creating infectious aerosols (glove, lab coat & goggle) if no for any tick on “No” box

Yes                      No

5. Use disposable gloves for touching clean surface and materials (pen, door handle, telephone etc...) and do not wear outside the laboratory

Yes                      No

6. Remove protective clothes before leaving for non-laboratory areas

Yes                      No

7. Wear protective coats /gowns for working in the laboratory at all times

Yes                      No

8. Wear gloves when hands may contact potentially infectious materials, contaminated surfaces or equipment

Yes                      No

## **Section V**

### **Biosafety practices towards facility design for the laboratory personnel**

1. Is there an eye wash station readily available in the room?

Yes                      No

2. Laboratory facilities in biosafety level 2-4. Do you have laboratory away public traffic areas? (Appropriate BSC placement)

Yes                      No

3. Are biological safety cabinets located away from doors, from windows that can be opened from heavily traveled lab areas? If applicable

Yes                      No

4. Facility for eating, drinking and for rest provided outside the lab area

Yes                      No

5. Is there a facility to store outer garments /street clothes/ outside the laboratory area?

Yes                      No

6. Do you have opening the exhaust fans to reduce the microbial count in air? If applicable

Yes No

7. Do you have the spaces between benches and cabinets accessible for cleaning?

Yes No

8. Is the design suitable so that it can be easily cleaned, and optimal to conduct laboratory work?

Yes No

9. Do chairs and other furniture used in laboratory work have non fabric materials that can be easily decontaminated?

Yes No

10. Is illumination/the brightness of the room/ adequate for all activities?

Yes No

11. Do you have a sink for hand washing in each laboratory room?

Yes No

12. Emergency shower available and accessible

Yes No

13. Fire extinguisher available and serviced

Yes No

14. Windows are screened with arthropods-proof material, when they are opened

Yes No

## DECLARATION

I undersigned, declare that is my original work and has never been presented for the degree in this or any other university and all the source material used for this thesis is duly acknowledge.

Name of the Student: Derese Tefera

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Approval of the primary Advisor

Name of the primary Advisor: Aster Tsegaye (MSc, PhD)

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

