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Assessment of Histopathology Services in Ethiopia

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This is to certify that the thesis prepared by Giorgis Okbazgi entitled:

"Assessment of Histopathology Services in Ethiopia" and submitted in fulfillment of the requirements for the degree of Master of Science in Clinical Laboratory Science (Laboratory Management and Quality Assurance Specialty Track) complies with the regulations of the University and meets the accepted standards with respect to originality and quality.

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Chairperson of the Department of Graduate program Coordinator

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Abbreviations

AFGH	Armed Force General Hospital
AGHMC	Adama General Hospital and Medical College
AHRI	Armaeur Hansen Research Institute
ALERT	All African Leprosy, Tuberculosis rehabilitation and Training Centre
AML	Arsho Medical Laboratory
AUH	Ayder University Hospital
CLIA	Clinical Laboratory Improvement Amendment
DRERC	Department Research Ethics Review Committee
EFMHACA	Ethiopian Food, Medicine, Healthcare Administration & Control Authority
EPHI	Ethiopia Public Health Institute
FMoH	Federal Ministry of Health
FNAC	Fine Needle Aspiration Cytology
GCMS	Gondar College of Medical Sciences
GGH	Gambi General Hospital
GUH	Gondar University Hospital
HIV	Human Immunodeficiency Virus
HUH	Hawassa University Hospital
ICL	International Clinical Laboratories
IHC	Immunohistochemistry
IP	Innovative Partnership

JCI	Joint Commission International
JIHS	Jimma Institute OF Health Science
JU	Jimma University
JUSH	Jimma University Specialized Hospital
KGH	Kadisco General Hospital
NCD	Non-Communicable Disease
NGO	Non-Governmental Organization
Pap	Papanicolau
PI	Principal Investigator
PSC	Patient Sample Collection
SNNPR	South Nation Nationalities People Region
SOP	Standard Operation Procedure
St. Paul	Saint Paul
TASH	Tikur Anbessa Specialized University Hospital
TAT	Turnaround Time
USA	United States of America
WHO	World Health organization

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Operational definition

1- **Benign:**- It describes an abnormal (non-malignant) growth that is stable, treatable and generally not life-threatening.
2- **Biopsy**:-A surgical procedure in which a small piece of tissue is removed from a patient for laboratory investigation.
3- Block/Slide storage cabinet
4- **Cryostat:**- A machine uses to reduce the histopathology laboratory biopsy procedure to 20 minutes and mostly it uses at Operation theatre for quick diagnosis.
5- **Cytotechnologist:- A**n allied health professional who works with a pathologist to detect changes in body cells that may be important in early diagnosis of cancer and other diseases. The cytotechnologist prepares cellular samples and examines them under a microscope to evaluate for abnormalities in structure
6- **Cytotechnology**:- the study of human cells, especially to detect signs of cancer
7- **Dehydration**: - occurs when the body or biopsy loses more fluid than it takes in.
8- Embedding machine
9- **Embedding:-**fixation of tissue in a firm medium, in order to keep it intact during cutting of thin sections for pathological examination.
10- **Fixation**:- is the process of keeping the tissue or cells as life state as possible by the use of fixative solution. The use of a fixative is to preserve histological or cytological specimens.
11- **Gross examination:-** Macroscopic, as in gross pathology; the study of tissue changes without magnification by a microscope.
12- **Histopathology laboratory**:- a laboratory that renders diagnostic service based on the examination of tissues and cells from a patient obtained by biopsy, surgical resection, Fine Needle Aspiration Cytology (FNAC) or body fluid specimen. The laboratory must be under the supervision of certified anatomic pathologist.
13- **Histopathology**:- a branch of pathology concerned with the tissue changes characteristic of disease.
14- **Histotechnician**:- Specializing in the preparation of body tissue specimens for fixation, dehydration, embedding, sectioning, decalcification, and routine and special staining.

15- **Histotechnologist**;- performs all the functions of the histotechnician as well as identifying tissue structures, cell components, and their staining characteristics. Histotechnologists may serve as supervisors or educators.

16- **Immunohistochemistry (IHC):-** Demonstration of specific antigens in tissues by the use of markers that are either fluorescent dyes or enzymes.

17- **Impregnation**:- The process of diffusing or permeating with another substance, as in metallic impregnation of tissue components with silver nitrate or ammoniacal silver

18- **Malignant:-** a cancer which tending to become progressively worse and to result in death; having the properties of anaplasia, invasiveness, and metastasis.

19- **Microtome:-** An instrument for making sections of biologic tissue for examination under the microscope.

20- **Mounting**:- to prepare (a sample) for examination by a microscope, as by covering the slide by coverslip. The chemical uses known as DPX (Di-N-Butyle Phthalate in Xylene).

21- **Oven:-** A chamber or enclosed compartment for heating the slide to remove (melt) the paraffin from the slide after sectioning.

22- **Pap smear:-** A screening test, especially for cervical cancer, in which a smear of cells exfoliated or scraped from the cervix or vagina is treated with Papanicolaou stain and examined under a microscope for pathological changes, also called Papanicolaou smear, Papanicolaou test, Pap test.

23- **Pathologist:-**A physician specialized in the study of disease. A pathologist usually specializes in autopsy or in clinical or surgical pathology.

24- **Sectioning (Microtomy):-**preparation of sections from fixed and embedded blocks of tissue by thin shaving with a microtome.

25- **Solid cancer**:- Solid tumor Oncology A malignancy that forms a discrete tumor mass–e.g., cancer of brain, breast, prostate, colorectum, kidney; sarcoma; melanoma, in contrast to lymphoproliferative malignancies–example, leukemia, which may diffusely infiltrate a tissue without forming a mass.

26- **Staining**:-artificial coloration of a substance to facilitate examination of tissues, microorganisms, or other cells under the microscope

27- **Tissue Processing Machine**:- The machine uses to process animal and human tissues automatically. It uses chemicals like Formaline, alcohol, Xylene and Paraffin.

28- **Workload**:- The amount of work assigned to or expected from a worker in a specified time period.

29- **Turnaround Time (TAT):-** The interval between the ordering of a clinical laboratory test or other diagnostic procedure and the reporting of results.

Abstract

Background: The scarcity of having histopathology laboratory in the nation will cause the difficulty to diagnose as well as follow up cancer diseases. Besides, the scarcity of professionals also contributes for the lack of the service in developing countries like Ethiopia. Laboratory technicians who do not have proper training and experience are active in the current histopathology laboratories in these countries.

Objective: To assess the histopathology laboratory practices in Ethiopia.

Method: Cross sectional study-design, and convenient sampling method were used. Data were collected by using pretested observational checklist. The Principal Investigator (PI) collected the data in April 2015 at all histopathology laboratories in Ethiopia, which practice investigation of both biopsy and cytology, Fine Needle Aspiration Cytology (FNAC) and have set up of histopathology laboratory. The number of histopathology specimen per year computed the data by the number of pathologists and laboratory personnel in that laboratory. Data was entered and analyzed using Microsoft Excel 2010 software.

Result: There were 11 histopathology laboratories who set up with equipment except Afar and Somali region where no histopathology laboratories were available. The available laboratories process and diagnose biopsy as well as FNAC. About 55% of laboratories in the country owned cryostat. All laboratories own microtome, 82% of the laboratories use automatic tissue processing and embedding machine whereas the rest use manually. All facilities use manual mounting and staining method, and 36.4% owned automatic staining machine. Grossing equipment and slide warmer table or oven is available at all facilities, whereas slide and block storage cabinet is available in 54.5% of the laboratories.

The number of pathologists range between one and eight where AFGH, AGHMC, GGH have one. AHRI, KGH, GUH, ASUH, HUH, and JUSH have two. EPHI /St. Paul have four, and TASH has eight pathologists: thus the highest number of biopsies per pathologist per year was received by EPHI/St. Paul (1144), GGH (1008), and TASH (813). The highest FNAC per pathologist per year was practiced by GGH (4800), ASUH (1488), AFGH (1365), HUH (1200), and GUH (1196). The overall average numbers of biopsies and FNAC per pathologist per year were 715 and 901 respectively. Whereas the respective average numbers for histopathology

laboratory personnel per year were 508 and 640. The lowest turnaround time (TAT) of 1 week for biopsy samples analysis was achieved by KGH and AFGH while three teaching hospitals had longer TAT of 30 days. (JUSH, HUH, ASUH)

Conclusion: There is a scarcity of a histopathology laboratory set up as well as of pathologists and laboratory personnel. The available histopathology laboratories are not adequate and their distribution is concerned in Addis Ababa and major cities: besides; there is no histopathology laboratory in two regions of the country (Afar and Somali regions).

Recommendation: The Federal Ministry of Health (FMoH) must give attention to the regular distribution of histopathology laboratory service to avoid unnecessary traveling to find the simplest technique FNAC by the population. Moreover, establishing a sample referral network could help address the unmet gap as cancer is on the rise. It also recommended the training of pathologists as well as histotechnologists and establishment of new histopathology laboratories at non-available areas of the country.

1 Introduction

1.1 Background

Cancer is a growing concern in the developing world as has been recognized by the World Health Organization (WHO). Moreover; it is estimated, there are about 1 million new cancer cases each year in Africa among them, 80% are first seen at an advanced stage. Sub Saharan Africa countries are the poorest nations in the world, while experiencing increasing cancer due to Human Immunodeficiency Virus (HIV) epidemic, growth and aging of population and adoption of 'westernized' lifestyles (1). The diagnosis and treatment of cancer is based on the report from histopathology laboratory. This laboratory received biopsies after the infected tissue are removed from the patients in operation theatre by the surgeon. This laboratory helps the surgeon in planning for therapeutic decision for early malignant and all benign lesions (2-5).

In the histopathology laboratory, organ and tissue specimens received from the surgical and autopsy departments. After the initial physical examination, different techniques are applied. These include tissue processing by different chemicals (alcohol, xylene, paraffin), embedding with paraffin block, sectioning with microtome, and staining with hematoxylin and eosin (routine stains). When these procedures are, completed pathologist interprets the slides by studying the slides under microscope. There is also a procedure for storage of slides and blocks, retention of biopsies and disposal (disposal of diagnosed biopsies, blocks, and stained slides) (6-8).

Moreover; Fine needle Aspiration Cytology (FNAC) is a procedure of collecting cytology samples from palpaple tumor by the help of needle and syringe. It is a simple, reliable, safe and highly accurate preoperative method for diagnosis of both benign and malignant lesions quite accurately, thus reducing unnecessary surgeries. It has become an accepted technique for palpable and radiographically detected lesions at a wide variety of body sites. Little information exists regarding the degree of utilization of the technique in the general medical community (9, 10).

An accurate histopathology result is depending up on the quality of good sectioning. Report from South Korea in 2009 indicated that, the regulations in South Korea require that departments of pathology have a structured and active program of quality assurance and quality improvement with the goals of enhancing patient safety, minimizing error, ensuring timely delivery of reports and monitoring physician competence. Like other medical laboratories, histopathology laboratory also has the pre-analytical, analytical and post-analytical part. The pre-analytical phase of the laboratory includes the tissue processing and sectioning. Interpretation of slides and making diagnosis considered as analytical phase. The post-analytical phase involves the generation and transmission of the histopathology report, storage/disposal of samples, slides and blocks and proper retention of test results (4, 11, 12).

Workload is among the factors affecting quality of services. If someone is working under extreme pressure to complete a given amount of work at a time, there could be an error in laboratory diagnosis. Even though there were only a few data relating error and gynecology cytology workload, the Clinical Laboratory Improvement Amendment (CLIA'88) of 1988 has set guidelines and strictly regulates workload of cytologists, presumably to limit error rates. Similarly, several organizations have made their own recommendations on workload limits in surgical pathology and cytology specimens (4,13).

For patients with cancer throughout the region, scarcity of histopathology services has often been an obstacle toward receiving appropriate diagnosis and treatment. Pathologists' availability in the region is typically less than one per million populations versus more than 60 per million populations in the United States of America (USA), for example (1).

In developing African nations, if there is availability of histopathology services it is below acceptable standards. This is mainly because diagnostic pathology services lag behind the development of clinical resources and lag behind in the availability of upgrading. Besides regional and remote small hospitals have poor access to histopathology expertise and services. Referral systems are often inadequate and further complicated by difficult, slow and costly transport to or from hospitals (6,14).

Lack of infrastructure and training are another problem confronting the provision of histopathology laboratory in developing countries. Moreover, in Sub-Saharan African countries there is scarcity of pathologists; for instance, in the West African Sub-region is facing many problems in training of pathologists and delivery of histopathology services in the hospitals (6, 14). Besides consultation between pathologists and their colleagues in many developing countries are difficult to arrange and organize. However, the consultation has great importance for not only minimize the errors but also increase the whole spectrum of daily reporting system (4, 13).

In Ethiopia the practice of cytopathology and FNAC started sometime after the establishment of the pathology department in Addis Ababa in 1965. However; the service is only given in 11 cities in the country with at least one pathologist; these cities are Addis Ababa, Nazareth, Dessie, Gondar, Dilla, Hawassa, Mekelle/Adwa, Bahir Dar, Jimma, Harar, and Dire Dawa (9, 10, 15).

Turnaround time (TAT) is among many areas of concern in laboratory services. The total TAT for laboratory assays includes the entire interval from ordering of the test to the clinicians' awareness of the result. TAT is one of indicators of quality, effectiveness, and obvious measures of the service in the clinical laboratory. The solution to the uncertainty for the presence or extent of malignancy by the clinicians to a biopsy requires decision by a pathologist. Therefore, the clinicians and their patients expect not only accurate, but also rapid surgical pathology reports. Additional pressures for short TAT in surgical pathology come from economic issues that involve striving to reduce the lengths of hospital stays and to finalize bills shortly after discharge (16 - 19).

1.2 Statement of the problem

Deaths due to cancer became higher generally in Africa and specifically in sub Saharan African countries like Ethiopia. Especially the problem is amplified in women in whom uterine cervix and breast cancer are common. In developing countries, women are an essential part of the population. If a woman is unwell or dies, it will result in break-up of the family or her daughter may be forced to shoulder family responsibility and be forced to stop education. Unavailability or scarcity of this service in the nation causes unnecessary death and complications due to non-diagnosed or delayed diagnosis of benign or malignant cases. The shortage of histopathology service in Ethiopia with its insufficiency of resource in terms of its infrastructure and professionals made it difficult to prevent, diagnosis and treatment of cancer. It also forced to transport the specimen from the collection site to an accessible laboratory by using different transportation methods; which has its own difficulty of being, slow and costly.

1.3 Significance of the study

Histopathology laboratory service helps to detect cancer tissues and cells from a biopsy and cytology samples. The availability of this service is crucial for the diagnosis, treatment and follows up of the prognosis as well as to prevent further complication. Most of cancer diseases can be diagnosed and treated, if they can be detected early. However; the scarcity of histopathology laboratory service and critical shortage of professionals worsen the disease. Assessment of health facilities will help to identify gaps and suggest appropriate solutions.

Hypothesis: The histopathology facility and respective services are not up to the demand of the National Health Service.

2 Literature review

In developed countries, pathology service and pathology staffing is relatively adequate (10). Extreme Shortage of pathologists is the main problem for cancer diagnosis in sub-Saharan African countries, for instance after establishment of the Sudan National Health Laboratory, in 1903 the histopathology report was sent by telegraph to all Sudanese states until 1978. In addition, the problem continues with only 51 pathologists for 35 million populations (6).

The story is the same in other sub-Saharan African countries, where shortage of pathologists is a great problem for implementing the histopathology laboratory. Research from West Africa in 2009 indicated that in Uganda there were 18 practicing pathologists for a population of 28 million, and Tanzania 15 pathologists serving 38 million people. The situation is similar in West Africa as well. According to 2009 report, Sierra-Leone had only 3 pathologists for five million people and Ghana about 20 pathologists for 22 million (14).

Fine Needle Aspiration Cytology (FNAC) practice helps as preventive in screening procedure and diagnostic in pre-operative decision. It is also a reasonably sensitive, specific and accurate initial diagnostic test for pre-operative evaluation of patients such as with thyroid swellings. The clinicians should be encouraged to use the procedure, as it is minimally invasive and easily performed in an outpatient setting (3).

As research in 2011 showed that, in Vietnam FNAC is widely practiced and the service is increasing rapidly. FNAC is believed to have met its debut in the 1980s or earlier in Malaysia. But it is now a regular service in government hospitals, and university pathology departments for weekly outpatient, inpatient services and breast clinics (20). It is also reported that the service is given in South Africa in larger state hospitals, medical schools and private facilities. In Nigeria FNAC practice is increasing rapidly and the population is served with this easy, reliable, test for screening and therapeutic decision. In Uganda, for example, during the first five months of 2010, histopathology laboratory performed about 500 Papanicolau test and 30 FNAC (21, 22).

While the demand for the service is growing in developing countries, both infrastructure and human resource are still challenging. Some countries are trying to overcome this through different projects. According to the 2011 report from Afghanistan, the pathology laboratory was set up by a volunteer American pathologist in 2005 with assistance from worldwide labs, a Non-

Governmental Organization (NGO) that works to assist NGO hospital laboratories. The laboratory has fairly standard equipment including ventilated mounting station. A top end Olympus microscope was fitted with digital camera allowing consultation by internet with a panel of American pathologists as well as Canadian pathologists (23).

Project assisted experience showing improvement of histopathology laboratories also exist in Africa. For example, a report in 2010 indicated that a new histopathology laboratory was established in Uganda with western standards and machineries. The most critical issues were technicians' training made inside the laboratory, the written protocols approved by the pathologist to ensure the continuity and a quality control system introduced in sample preparation and diagnosis, thus resulting in the improvement of both teaching and service (22).

On the other hand, there are still countries suffering not only from shortage but from distribution of the limited number of their trained pathologists. Researches in 2010 from the Sudan showed that there are 51 pathologists in Sudan, among them 40 (78.4%) are working in the capital, Khartoum (6).

The problem of histopathology service is manifold in Ethiopia, given the relative lack of resource in most parts of the country. Most of the pathologists reside in the capital, Addis Ababa or other urban areas, whereas most of the population lives in rural areas (15).

The initial goal of the pathology department in Tikur Anbessa Specialized hospital was teaching medical students, conducting research and performing clinical diagnostic services when established in 1965. And the department diversified and expanded its teaching program in 1981, and then it began a graduate training program. Despite this effort, the annual intake of trainees is very low, and there is a severe shortage of pathologists in the country. There are approximately 30 pathologists for a country with a 90 million inhabitants. The Addis Ababa University, School of Medicine, Pathology Laboratory, which is the largest histopathology laboratory in the country, receives an estimated 10,000 biopsy specimens annually. It is also the only institution currently offering a pathology residency program as well as oncology service including chemotherapy and radiotherapy (24).

Laboratory TATs clearly are important in anatomic pathology and in clinical pathology. Clinicians depend on fast TATs to achieve early diagnosis and treatment of their patients and to achieve early patient discharge and minimize hospital in-patient staying services. For better or worse, TATs also influence the perception of the laboratory in the community of health care providers (19). Therefore at the summit of African pathologists, 2013 set on the improvement of TATs which centered its objective on shortening of TATs to a small biopsy 3 days and large biopsy 5 days (25).

3 Objectives

3.1 General Objective

The general objective of the study is to assess the status of histopathology service in Ethiopia.

3.2 Specific Objective

- To assess the availability of basic histopathology laboratory equipment.
- To assess the proportion of FNAC/biopsy per year per pathologist.
- To assess the proportion of FNAC/biopsy per year per laboratory personnel.
- To assess the TAT of each histopathology laboratory

4 Materials and Methods

4.1 Study design

A cross sectional study was conducted to assess the histopathology laboratory facility in Ethiopia. Checklist was prepared to assess the availability of basic histopathology equipment and the proportion of pathologist and laboratory personnel / proportion of biopsy/FNAC performed per year.

4.2 Study Period

The study period was April 2015.

4.3 Study Area

The study was carried out in all government and private owned histopathology laboratories in Ethiopia. They are; Tikur AnbessaSpecialized University Hospital, (TASH) (Also commonly known as Black Lion Hospital), Armaeur Hansen Research Institute (AHRI), Armed Force General Hospital (AFGH), and Ethiopian Public Health Institution (EPHI) from Addis Ababa. Jimma University Specialized Hospital (JUSH) (Jimma), Gondar University Hospital (GUH) (Gondar), Hawassa University Hospital (HUH) (Hawassa), Ayder Specialized University Hospital (ASUH) (Mekelle). Also included in the study were privately owned independent laboratories such as; Arsho Medical Laboratory P.L.C , and International Clinical Laboratories (ICL) (Addis Ababa); private owned Hospitals such as; Kadisco General Hospital (KGH) (Addis

Ababa), Adama General Hospital and Medical College (AGHMC) (Nazareth), Gambi General Hopital (GGH) (Bahrdar)

TikurAnbessa (Black Lion) Specialized Hospital is located in Addis Ababa at Lideta sub-city opposite to Immigration office Ethiopia. It is the teaching hospital of the Addis Ababa University and the largest referral hospital in the country. It is currently the only hospital in Ethiopia that provides an oncology service (cancer treatment includes surgery, chemotherapy, and radiotherapy). It receives 10,000 biopsy specimens annually (24, 26).

All African Leprosy and Tuberculosis rehabilitation and Training centre (ALERT) is a medical facility on the edge of Addis Ababa, located at Kolfe Keranyo sub city. It is situated at about 7km of the city of Addis Ababa, southwest on the way to Jimma road. It's originating from the previous surroundings of Zenebework Memorial Hospital back in 1965, founded by the Ministry of Health, Addis Ababa University, The Leprosy International, American Leprosy Mission and the Society for rehabilitation of the disabled. It has also pathological unit (27, 28). The histopathology laboratory is owned by Armaeur Hansen Research Institute (AHRI), which is part of the research and training arm of ALERT.

Armed Force General Hospital (AFGH) is located in Addis Ababa, Lideta Sub-city on Jimma road and right opposite to the Old Airport. It is formerly known as Princess Tsehai Memorial Hospital. The Armed Forces General Hospital was renamed after the 1974 revolution. Emperor Haile Selassie (I) founded the Hospital in memory of his daughter, Princess Tsehai Haile Selassie. After the coup of Emperor Hailesilassie, the military regime used it only for military (29, 30).

Ethiopian Public Health Institution (EPHI) is located in west Addis Ababa, Gulelle Sub-city at Arbegnoch Street, close to St. Paul Hospital. It was formerly called Institute de Pasteur. It is the largest referral laboratory in the country and possesses a well-equipped histopathology laboratory infrastructure, which was not active for a long period. However, training has been given at the laboratory on histopathology techniques for few laboratory personnel (31). Currently the laboratory is giving its service to the St. Paul University Hospital.

Jimma University specialized Hospital (JUSH) is located in Jimma city 350 km south west of Addis Ababa, South east of Ethiopia, established as Jimma University in 1983 G.C. with the birth of Jimma Institute of Health Science (JIHS). Jimma University (JU) was established as a public higher education institution in December 1997 in Jimma Institute of Health Sciences by splitting the health section in to two faculties- namely Faculty of Public Health, Faculty of Medical Sciences. The redesigning has also aligned Jimma University Specialized Hospital (JUSH) is managed under college of health sciences as doctors of the college while clinically teaching students are providing the hospital's medical services (32, 33).

The Gondar University Hospital is located in Gondar in the Northwestern part of Ethiopia. The college, founded in 1954, is the oldest health professional training institute in Ethiopia. At this year the medical college was established as part of the malaria epidemic that devastated the region during 1952 and 1953. In 1961, the college was placed under the direction of the Haile Selassie (I) University, now known as Addis Ababa University. The college also offered for the first time a Bachelor of Science degree in Public Health. In 1978 the institution was authorized to establish a medical school to train doctors, health officers, community nurses, and other health professionals. Since 1979 first class was enrolled in the school's medical program, since then the program has grown in both size and function. In 1994, the college was renamed as the Gondar College of Medical Sciences (GCMS), and its mission was redefined to include the basic research in health sciences and to serve as a referral health center for the region (34).

Hawassa University Hospital is the teaching hospital of Hawassa University. Hawassa is located 350km from Addis Ababa to the South of Ethiopia, on the shores of Lake Awassa in the Great Rift valley of Ethiopia. The hospital is serving as referral centre for the Southern Nations Nationalities and Peoples Region of Ethiopia (35).

Ayder University Hospital is located in Northern part of Ethiopia, Tigray Mekelle and commenced rendering its referral and non-referral services in 2008 to the 8 million populations in its catchment areas of the Tigray, Afar and South-eastern parts of the Amhara Regional States. It provides a broad range of medical services to both in and out patients of all age groups. As such, the Hospital can be designated as the most advanced medical facility, by all accounts, in the Northern part of the country and that it stands as the second largest hospital in the nation.

With the total capacity of about 500 inpatient beds in four major departments and other specialty units, the Ayder Referral Hospital is also used as a teaching hospital for the College of Health Sciences, Mekelle University (36).

International Clinical laboratories (ICL) is an independent advanced medical laboratory which opened its doors in 2004 with the great aim of providing quality laboratory service all over Ethiopia. Based on this target ICL is now expanding its service throughout Addis Ababa and the different regions (Bahirdar, Gondar, Mekelle, Hawassa, Harar, Jimma and Nazareth). With its main laboratory located in Addis Ababa, at Bulgaria square a road to Kera area, and about 8 Patient Service Centers (PSC's) and 1 Satellite Laboratory, it serves more than 240 health care centers throughout the country. As part of commitment to quality, ICL participates in international quality assurance program with American Proficiency Institutes three times a year. ICL is the first and the only laboratory in Africa accredited by Joint commission International (JCI) (37).

Adama General Hospital and Medical College (AGHMC) is located in Nazareth 100 km south of Addis Ababa, the nation's capital. It provides tertiary medical services that range from primary and intensive care to general and specialized surgeries, as well as outpatient care. Nazareth is a developing city with a population of more than 250,000 (38).

Kadisco General Hospital is located in Addis Ababa Bole sub city Gerji area; it is acquiring a slide scanner which can make digital images of laboratory slides. These digital images can be sent electronically to pathologists around the world to obtain second opinions more efficiently and cost effectively (39, 40).

Arsho Medical laboratory (AML) is located in the capital Addis Ababa and is the first privately owned medical laboratory testing centre in Ethiopia. The main laboratory is located at Meskel Flower area and has several branches in the city (41).

4.4 Population

4.4.1 Source Population

The source population was all hospitals and stand alone laboratories in Ethiopia.

4.4.2 Study population
The study population was all health facilities in Ethiopia which own histopathology laboratory.

4.5 Eligibility

4.5.1 Inclusion Criteria
Active histopathology laboratories in Ethiopia during the study period were included.

4.5.2 Exclusion Criteria
All medical laboratories, in Ethiopia which were not performing the histopathology laboratory activities were excluded.

4.6 Sample Size
The sample size was all active histopathology laboratories; that is, 10 governmental and 5 privately owned histopathology laboratories.

4.7 Sampling Method
Purposive sampling technique was applied.

4.8 Data Collection tools
A structured checklist was used for both Quantitative and Qualitative data collection.

4.8.1 Quantitative method
A checklist was used to collect quantitative information. The number of pathologists, laboratory personnel, biopsies analyzed and FNAC practiced per year were quantified.

4.9 Data collection procedure
The data were collected in April 2015. The histopathology basic equipment checklist was prepared and filled by principal Investigator (PI). Data of the availability of basic histopathology equipment, number of pathologists in the laboratory, number of histopathology laboratory personnel, and the number of FNAC and biopsy collected per year were recorded.

4.10 Data Quality Assurance
The checklist was evaluated by a pathologist and correction was made before applying to the actual data collection area. Clear information was given to the histopathology laboratory personnel on how the data were collected. The PI carefully collected the data.

4.11 Study variables

4.11.1 Dependent variables

Histopathology laboratory facility services. Number of pathologists, laboratory personnel, biopsy and FNAC performed per year.

4.12 Data Processing and Analysis

Data was entered using the Microsoft Excel 2010. The proportion of histopathology specimens (biopsy, and FNAC) per laboratory per pathologist (and laboratory personnel) per year were computed by the mean of the performed number of biopsy and FNAC.

4.13 Ethical Considerations

The study was first approved by Addis Ababa University, School of Allied Health Science, and Department Research Ethics Review Committee (DRERC) of department of Medical Laboratory Science. An official letter was written to the respective health facilities and the study was conducted after obtaining their approval. The data in hard copy is kept secured and its confidentiality is reserved.

5 Results

5.1 Locations of Histopathology laboratory in Ethiopia

A total of fifteen histopathology laboratories in different Health institutions were assessed throughout the country Ethiopia. Out of these; 7 of them are located at the capital, Addis Ababa; 1 University Hospital (Tikur Anbessa Specialized Hospital), 1 Public Health Laboratory (EPHI working with St. Paul Millennium Medical College), 2 Independent Advanced Laboratories (Arsho Medical Laboratory (AML) and International Clinical Laboratories (ICL), 1 Armed Forces General Hospital, 1 Public General Hospital (AHRI), 1 Private General Gospital (Kadisco). And out of the remaining 8 health institutions out of Addis Ababa; 4 of them are University Hospitals (Mekelle, Jimma, Hawassa, and Gondar), 2 Private General Hospitals (Gambi in Bahrdar, and Adama in Nazareth), and 2 Public General Hospitals (Dessie and Harar).

The available histopathology laboratories with set up in the country are 11, which are located in Figure 1 below. There are 5 histopathology laboratories in the capital Addis Ababa equipped with histopathology laboratory set up. And there is 1 in Tigray region (Ayder), 1 in Southern Nations Nationalities People region (SNNPR) (Hawassa), 2 in Oromia region (Jimma and

Adama), 2 in Amhara region(Gondar and Bahrdar), whereas there are no histopathology services at Afar and Somali region.

On the other hand, our assessment revealed that Dessie General Hospital has one pathologist and has FNAC facility only and the services given in Harar on schedule basis. Pathologist from Addis Ababa travels every two weeks to perform FNAC and brings biopsies back to Addis Ababa.

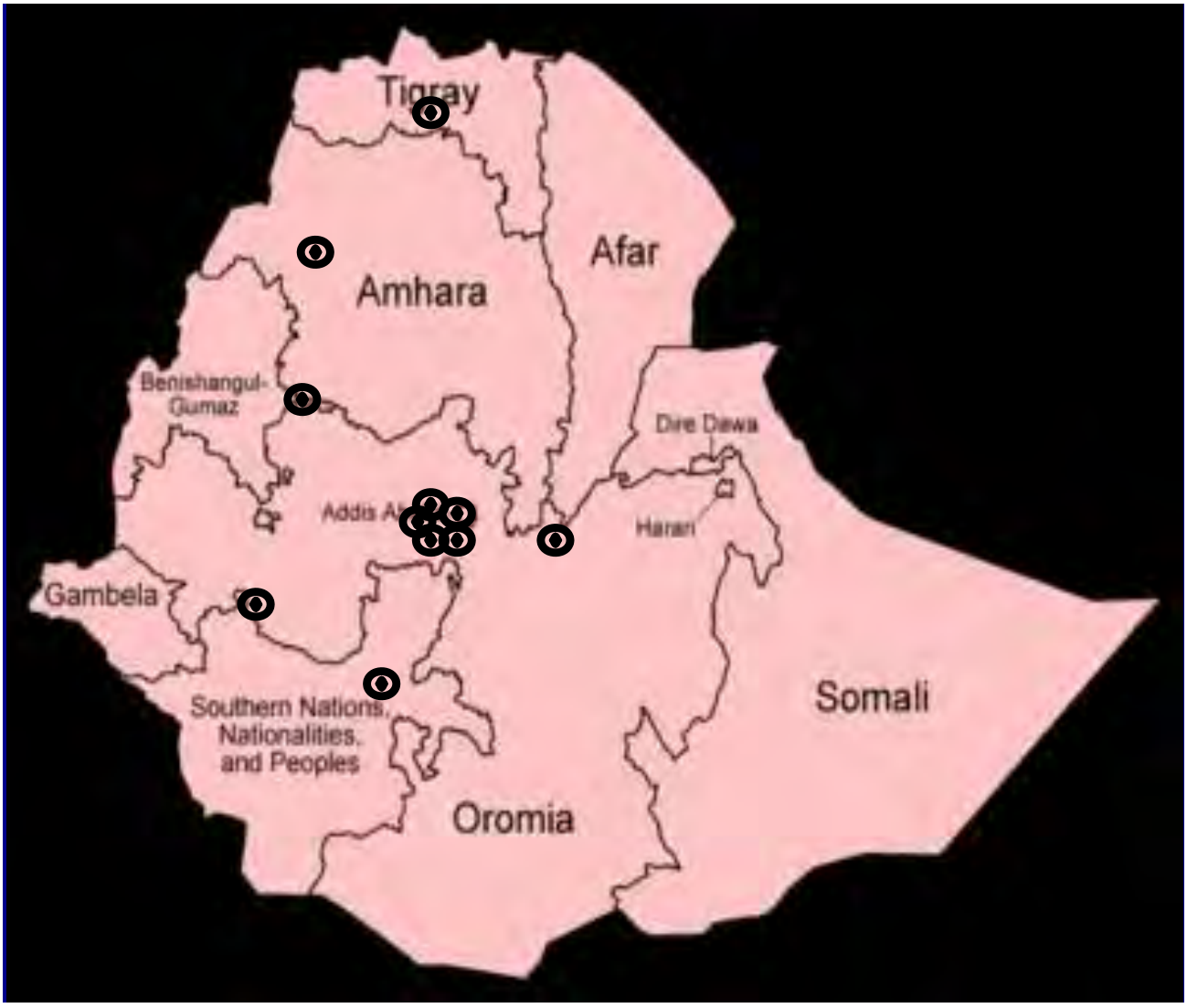

Figure 1: Map of Ethiopia showing the location of histopathology laboratory in the country . Black points showed cities of Ethiopia with availability of histopatholoogy laboratory set up. In

Addis Ababa 5 histopathology laboratories are available (Tikur Anbessa Specialized Hospital, Armaeur Hansen Rsearch Institute (AHRI), Armed Forces General Hospital, Kadisco General Hospital, Ethiopa Public Health Laboratory (EPHI), Nazareth, Jimma, Hawasa, Bahr dar, Gondar, Mekelle. (Map Source: Wikipedia)

5.2 Availability of Histopathology equipment

Availability of equipment in the 11 assessed histopathology laboratories was checked against the National Standard list set by the Ethiopia Food, Medicine, and Healthcare Administration & Control Authority (EFMHACA). The regulatory body has issued list of medical instruments, under the title of histopathology laboratory equipment. Table 1 shows the availability of histopathology equipment in the assessed facilities according to the EFMHACA standard list. Accordingly, only 55% (6 out of 11) of the laboratories in the country owned cryostat. All assessed laboratories possess microtome, 82% (9/11) of the laboratories use automatic tissue processing and embedding machine, whereas the rest perform manually. All facilities use manual mounting and staining method and 36.4% (4/11) owned automatic staining machine. Grossing equipment and oven are available at all facilities. Besides, 54.5% (6/11) of the laboratories prepared slide and have block storage cabinet. But one hospital has only a microtome. In this laboratory tissue processing and embedding are performed manually while in the other laboratories they are mostly done by machines.

Table 1: Availability of histopathology laboratory equipment at different health facilities according to Ethiopian Food, Medicine and Healthcare Administration and Control Authority (EFMHACA), National minimum standard list; Y= Yes (available) and N=No (Not available).

S.No	Name of the Health Institutions	Cryostat	Microtome	Tissue Processing		Embedding		Staining		Mounting		Grossing	Slide/Block Storage cabinet	Oven
				Manual	Automatic	Manual	Automatic	Manual	Automatic	Manual	Automatic			
1	Tikur Anbessa specialized University Hospital (TASH)	Y	Y	N	Y	N	Y	Y	Y	Y	N	Y	N	Y
2	Jimma University Specialized Hospital (JUSH)	N	Y	N	Y	N	Y	Y	N	Y	N	Y	N	Y
3	Hawassa University Hospital (HUH)	Y	Y	N	Y	N	Y	Y	N	Y	N	Y	Y	Y
4	Ayder Specialized University Hospital (ASUH)	Y	Y	N	Y	N	Y	Y	N	Y	N	Y	Y	Y
5	Gondar University Hospital (GUH)	N	Y	N	Y	Y	N	Y	Y	Y	N	Y	N	Y
6	Kadisco General Hospital (KGH)	N	Y	N	Y	N	Y	Y	Y	Y	N	Y	N	Y
7	Armaeur Hansen Research Institute (AHRI)	Y	Y	Y	N	N	Y	Y	N	Y	N	Y	Y	Y
8	Armed Force General Hospital (AFGH)	Y	Y	N	Y	N	Y	Y	N	Y	N	Y	Y	Y
9	Adama General Hospital and Medical College (AGHMC)	Y	Y	N	Y	N	Y	Y	Y	Y	N	Y	Y	Y
10	Gambi General Hospital (GGH)	N	Y	Y	N	Y	N	Y	N	Y	N	Y	N	Y
11	Ethiopia Public Health Institute (EPHI)	N	Y	N	Y	N	Y	Y	N	Y	N	Y	Y	Y

5.3 Workload of pathologists and laboratory personnel

In the 11 assessed histopathology laboratories there were 27 pathologists and 38 histopathology laboratory personnel actively working at the time of the study. Table 2 shows the proportion of biopsy and FNAC services per pathologist or histopathology technicians per year. It also shows the number of population to be served as per the health tier system. Tertiary level health facilities like the University Hospitals (TASH, GUH, JUSH, HUH, ASUH) and EPHI are expected to serve approximately 3.5 to 5 million people while the rest are expected to serve 1 to 1.5 million population. The workload of pathologists/ biopsies analyzed/ year was computed. As shown in

Table 2, the proportion of biopsy analyzed by one pathologist per year ranged between 228 and 1144 in the different health facilities.

The workload data presented here cover past one year data from 2006 Ethiopian Calendar. Figure 2 and Figure 3 show the proportion of biopsy, FNAC analyzed in each laboratory per year, and the proportion of biopsy, FNAC practiced per year by a pathologist, respectively. Accordingly as shown in Table 2 and Figure 2 Tikur Anbessa specialized Hospital (6500) followed by EPHI/St. Paul (4577), Gondar (1530), Ayder (1507), Jimma (1250), Universities and Gambi General Hospital (1008) received the highest number of biopsies. Whereas the highest number of FNAC was practiced by Gambi (4800) followed by EPHI/ St. Paul (4542), Ayder (2976), Tikur Anbessa (2932), Gondar (2392), Armed Forces (1365) and Adama General Hospital and Medical College (1000).

As shown in Table 2, the number of pathologists range between one and eight where AFGH, AGHMC, and GGH have one, AHRI, KGH, GUH, ASUH, HUH and JUSH have two, EPHI/St. Paul have four, and TASH has eight pathologists. Thus the highest proportion of biopsies per pathologist per year was received by EPHI (1144), GGH (1008), and TASH (813) (Figure 3). The highest FNAC per pathologist per year was practiced by GGH (4800), ASUH (1488), AFGH (1365), HUH (1200), and GUH (1196). The overall average proportions of biopsies and FNAC per pathologist per year were 715 and 901 respectively. Whereas the respective average proportions of histopathology personnel per year were 508 and 640. The lowest turnaround time (TAT) of 1 week for biopsy samples analysis was achieved by KGH and AFGH while three teaching hospitals had longer TAT of 30 days (JUSH, HUH, ASUH)

Table 2: Workload of pathologists and histopathology laboratory personnel and the number of population to be served as per the health tier system.

S.No.	Name of Health Institutions	Number of Biopsy analyzed per year	Number of FNAC practice per year	Number of Pathologist	Number of Histopathology Laboratory personnel	Proportion of biopsy per a pathologist per year	Proportion of FNAC per a pathologist per year	Proportion of Biopsy/ lab personnel/year	Proportion of FNAC /lab personnel/year	Stated TAT for biopsy	Number of population intended to use the health institution
1	TASH	6500	2932	8	7	813	367	929	419	15 days	3.5-5 Million
2	JUSH	1250	1500	2	3	625	750	417	500	30 days	3.5-5 Million
3	HUH	900	2400	2	2	450	1200	450	1200	30 days	3.5-5 Million
4	ASUH	1507	2976	2	7	754	1488	215	425	30 days	3.5-5 Million
5	GUH	1530	2392	2	3	765	1196	510	797	15 days	3.5-5 Million
6	KGH	456	141	2	2	228	71	228	71	7 days	1-1.5 Million
7	AHRI	500	275	2	2	250	138	250	138	20 days	1-1.5 Million
8	AFGH	765	1365	1	2	765	1365	383	683	8 days	1-1.5 Million
9	AGHMC	300	1000	1	4	300	1000	75	250	15 days	1-1.5 Million
10	GGH	1008	4800	1	1	1008	4800	1008	4800	15 days	1-1.5 Million
11	EPHI(St. Paul)	4577	4542	4	5	1144	1136	915	908	15 days	3.5-5 Million

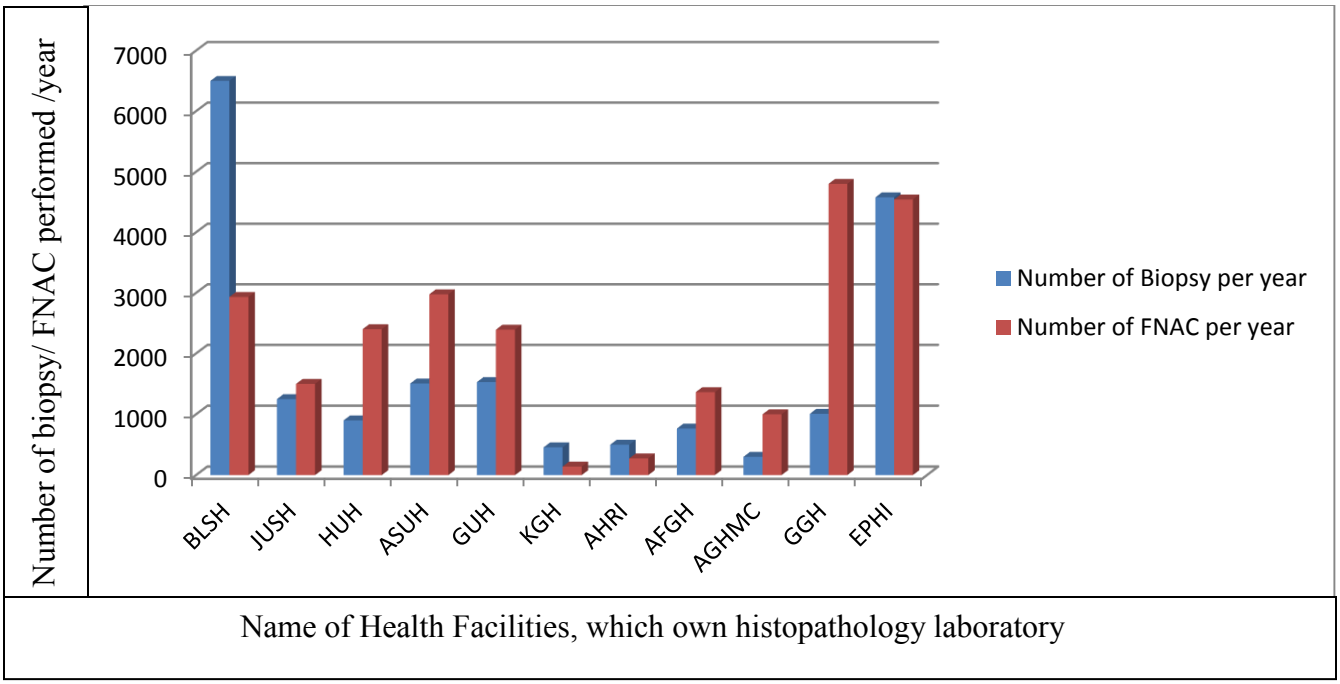

Figure 2: Number of Biopsy and FNAC practiced by health facilities' histopathology laboratory per year.

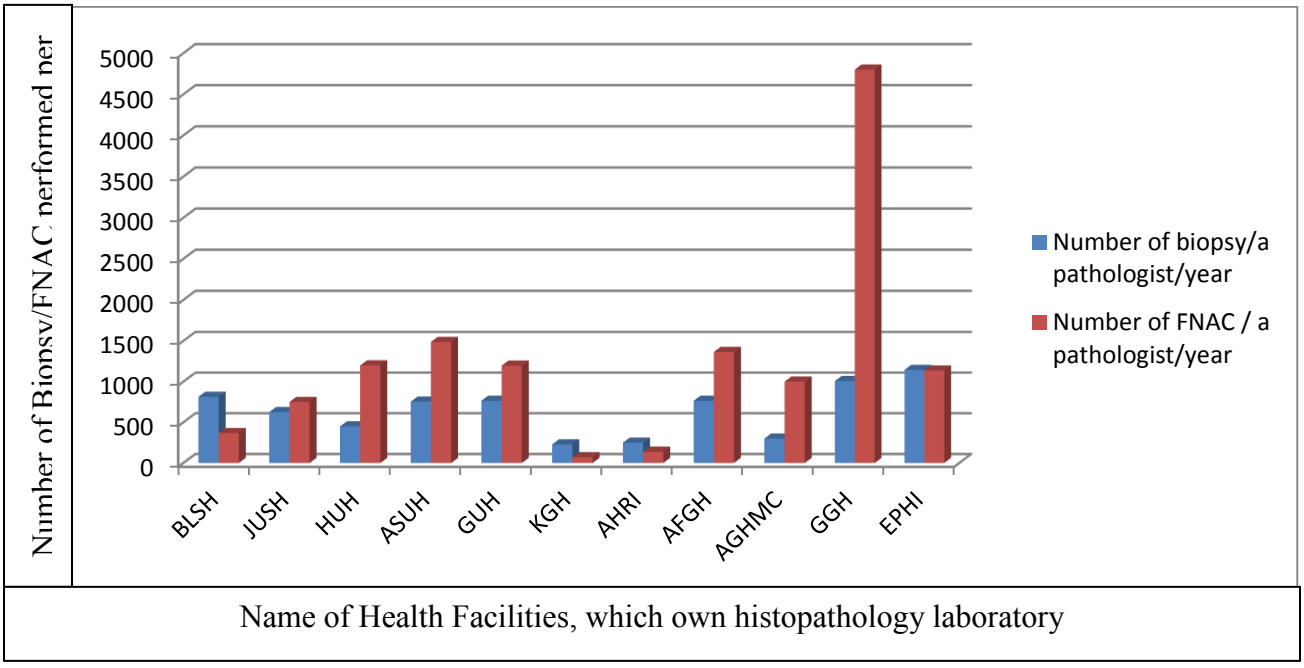

Figure 3: Proportion of Biopsy and FNAC practiced by a pathologist at the specified hospitals histopathology laboratory per year

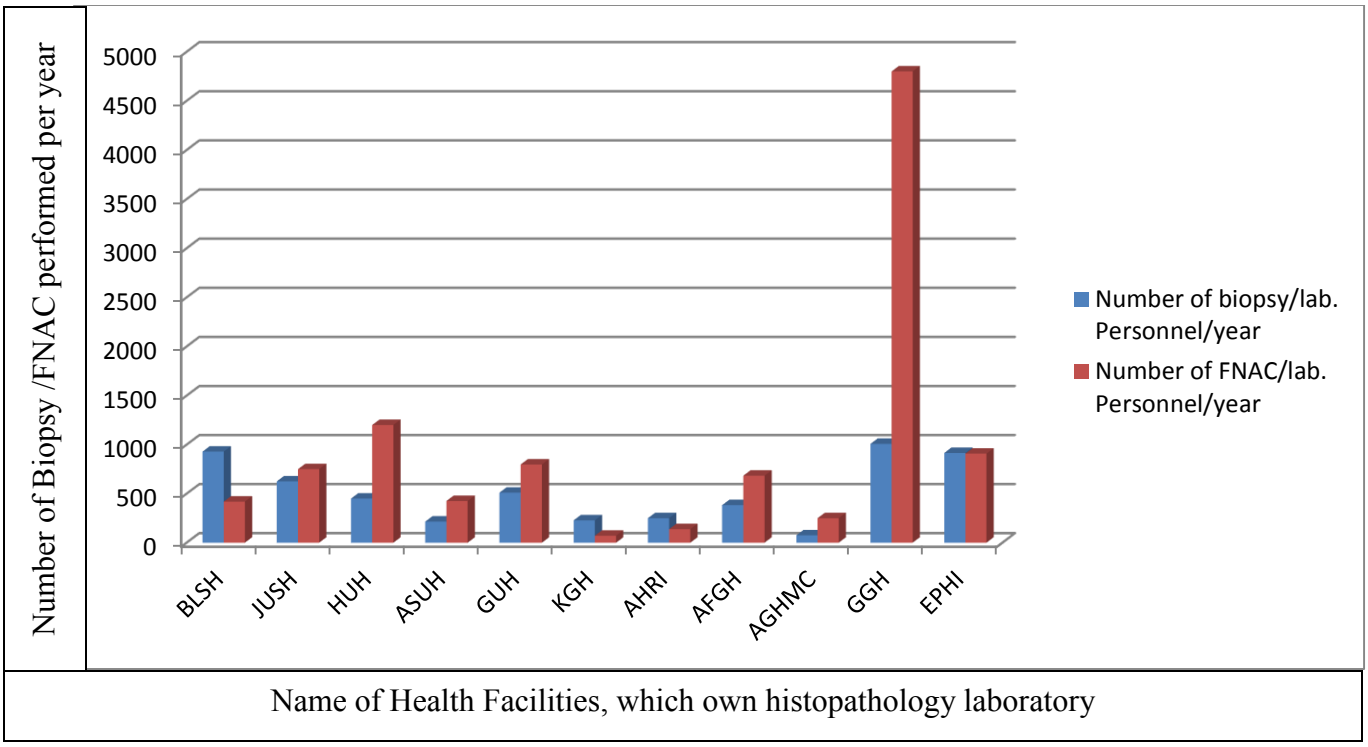

Figure 4: Proportion of biopsy and FNAC practiced by histopathology laboratory personnel per year.

6 Discussions

6.1 Georgraphical Distribution of Histopathology Laboratory in Ethiopia

There are 5 histopathology laboratories in the capital Addis Ababa (17 pathologists), 2 in Amhara region (5 pathologists), 2 in Oromia region (3 pathologists), 1 in Tigray region (2 pathologists), and 1 in SNNPR (2 pathologists). However, there is no histopathology laboratory in Eastern part of Ethiopia in Afar and Somali region. This uneven distribution of histopathology laboratory is the problem of developing countries. For instance, in Nigeria; the distribution of pathologists varies widely from state to state. They are concentrated mainly in the teaching hospitals and a few are in the federal medical centres. For example, there are 15 pathologists in Kwara state, (all in the University of Ilorin Teaching Hospital) for a population of 2.4million, in Oyo state; there are about 30 pathologists (24 are in the University College Hospital) for a population of 5.6 million, and Kaduna state in the Northern part of Nigeria, has 15 pathologists for a population of 6.1million. These three states are among 36 states of Nigeria in which they have highly privileged because they have one or two teaching hospitals attached to universities. However, in many states there are no pathologists at all. This lack of adequate number of personnel has an effect not only on training but also on the provision of services to the population in both countries of Ethiopia and Nigeria (14).

6.2 The workload of histopathology laboratory in Ethiopia

The lowest Proportion of biopsy analyzed per year by each pathologist in histopathology laboratory assessed in Ethiopia is 228 (Kadisco General Hospital) and the highest is 1008 (Gambi General Hospital). The overall average proportions of biopsies and FNAC per pathologist per year were 715 and 901 respectively. Whereas the respective average proportions of biopsies and FNAC for histopathology laboratory personnel per year were 508 and 640. The suggested optimum and maximum number of biopsy analyzed per year for university hospitals is 4,267/5,858. Only 2 (18.2%) of university hospitals; TASH (6500 biopsies/year) and EPHI (St. Paul) (4577 biopsies/year) perform the suggested number of biopsy analyzed per year. Whereas 4 (36.4%) of university hospitals (JUSH, HUH, ASUH, GUH) didn't perform.

The suggested optimum and maximum number of biopsy analyzed per year at non-training hospitals is 7435/1478. 5 (45.5%) of the studied laboratories didn't perform the suggested number of biopsies per year (KGH, AHRI, AGHMC, GGH, AFGH) (Hye KY et. al) (4).

6.3 The turnaround time (TAT) of the histopathology laboratories in Ethiopia

Out of the 11histopathology laboratories assessed, the minimum stated TAT was 7 days and the maximum was 30 days; and on average it is18 days to have a result for a biopsy. According to The Royal college of Pathologists guideline the recommended TAT is 7 calendar days. TAT is one of the performance indicators to histopathology laboratories (46).

7 Strength and Limitations of the Study

7.1 Strength of the Study

- The study has provided base line information to histopathology laboratory and input for further other research.
- The study is done at the time of the importance of histopathology laboratory as cancer is growing concern in Sub Saharan African countries like Ethiopia.
- The combination of pathologists, histopathology laboratory personnel and equipment help to have sufficient figure on the service given by the laboratory.

7.2 Limitation of the Study

- Includes only health facilities which own histopathology set up.
- Doesn't include the referral system of biopsy from non accessible health facilities to the availability of histopathology laboratory.
- The study only assesses the availability of histopathology laboratory equipment but exclude the functionality, maintenance, supply and type of the instrument.

8 Conclusion

There are only 11 histopathology laboratories in Ethiopia, which are active to receive, process, and diagnose biopsies and practice FNAC. These laboratories are active with the scarcity of resource inside them. Many of them have as one to two full time pathologists. There are no histopathology laboratories with a biopsy analyzing service at Afar and Somali region. Even in

the regions where histopathology laboratory is available, the catchment area they cover is too large. Patients who seek FNAC service may not find the practice due to the distance of the health institution or financial limitation for transportation fee or too weak to reach.

In terms of equipment 55% of the laboratories in the country owned cryostat. All laboratories own microtome, 82% of the laboratories use automatic tissue processing and embedding machine, whereas the rest use manually. All facilities use manual mounting and staining method and 36.4% owned automatic staining machine. Grossing equipment and oven is available at all facilities. 54.5% of the laboratories possesses slide and block storage cabinet.

The workload of the pathologists and laboratory personnel shows it requires initiating the practice of histopathology to serve more cases per year. The number of population in- tended to use the health institution versus histopathology cases is not encouraging. Training of the pathologists and histotechnologists is vital to improve the histopathology services throughout the country. The average TAT is 18 days to all histopathology laboratories.

9 Recommendations

- The FMoH must give attention to the regular distribution of histopathology laboratory service to avoid unnecessary traveling to find FNAC by the population.

- Tertiary level and teaching health facilities like Tikur Anbessa Specialized Hospital, Pathology Department should be encouraged to arrange travelling of residents to where there are no FNAC services and then collect the samples bring the slides to training centre, diagnose and send the result back to the health institutions.

- There is a need to increase the number of trained pathologists and histotechnologists to establish a referral network which help address the unmet need of the service.

- The average TAT of a biopsy require attention and thus has to be minimized to help the people who came from far areas for diagnosis and minimize the expense as well as the impatient staying time.

- EFMHACA needs to revise its list of equipment to establish a new histopathology laboratory, as there are new developments in the instruments used by the laboratory.

- EFMHACA should also specify which level of healthcare institutions must have histopathology laboratory. And there is no guideline at this moment on which type of healthcare level the histopathology laboratory should be setting up.

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Annex I: Consent Form
Code Number _____

Head of the Laboratory _____

My name is Giorgis Okbazgi, MSc student of Addis Ababa University, Department of Medical Laboratory Sciences. I am trying to assess the status of histopathology laboratories in Ethiopia. The study will help to identify gaps in the histopathology laboratories and suggest for improvement. As cancer is increasing at an alarming rate, assessing the status of histopathology laboratories, identifying gaps and taking an immediate action is a timely agenda. For this study true and direct information is needed to fill the questionnaire and a facility observation will be performed. Your participation is highly valuable to address the issue. However, your participation is purely voluntary and has the right to withdraw from the study or not to answer any question that you do not want to all the information contained within the questionnaire is to be kept confidential.

I the undersigned with full understanding of the situation have given my 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.

Participation's Signature/ finger print _____

Name of Interviewer _____ Signature _____ Date _____

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

Name: Giorgis Okbazgi

Mobile: +251935352425

Email: georgeokb@gmail.com

Annex II Data Collection tool

Name of the Hospital (Medical School) _____

Number of Pathologists _____ (Male_____ Female_____)

Number of Histotechnologists _____ (Male _____Female _____)

Number of Histotechnicians _____(Male_____ Female_____)

Number of Medical Laboratory Technicians (Male _____Female _____)

- **(Non-trained of histopathology technicians)**

Number of Medical Laboratory technologists (Male _____Female _____)

- **(Non-trained of histopathology technologists)**

S.No	Description	Availability	Remark
1	Tissue Processing machine		
2	Embedding Machine		
3	Microtome		
4	Microtome Knife		
5	Microscope		
6	Manual Staining		
7	Automatic staining		
8	Immunohistochemistry (IHC)		
9	Special stains		
10	Number of cytology cases/year		
11	Number of FNAC cases/year		
12	Number of Biopsies /year		
13	Safety Materials		
14	Storage of chemicals		
15	Cryostat		
16	TAT		

Annex III. Declaration

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

MSc. Candidate:- Giorgis Okbazgi (BSc.)

Signature: _____Date of submission: _____

This thesis has been submitted with our approval by advisors;

Aster Tsegaye (MSc, PhD Addis Ababa University)

Signature: _____ Date_____ Place: Addis Ababa, Ethiopia

Fatuma Hassen (BA, BSc, MPH, Addis Ababa University)

Signature:_____ Date_____ Place: Addis Ababa, Ethiopia.

Mesfin Negussie (MD, Pathologist, ICL, Addis Ababa)

Signature: _____Date_____ Place: Addis Ababa, Ethiopia.