Assessing Barriers to Medical Laboratory Diagnostic Service Delivery in Mzuzu City

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ABSTRACT

Medical laboratories provide confirmatory diagnosis and evidence based management of diseases, essential public health information and disease surveillance. A wide variety of research studies suggest that breakdowns in the diagnostic process result in a staggering toll of harm, patient deaths and wastage of valuable medical resources already constrained in the developing world. The objective of this study was to assess barriers to delivery of optimal laboratory diagnostic services in Mzuzu city. This was a descriptive cross-sectional study using quantitative research approach. Three categories of laboratories were selected from the public, faith based and private health systems. Stratified sampling was used to select laboratory practitioners while purposive sampling was used to select administrators from each health facility. The data was analysed by the measures of central tendency mean plus measures of variability, range, standard deviation and standard error, using SPSS version 20. The findings of the study were that laboratory practitioners identified several barriers to affect quality diagnostic services: 79% of laboratory staff reported short supply of laboratory supplies, work overloads (69%), frequent equipment failure (22%), scarcity of modern equipment (20%) and others. Administrators (67%) reported a limited budget allocation to the public and faith based hospitals. The study also found that there were some barriers that were more frequent than others such as shortage of laboratory supplies (84%), work overloads (70%), lack of refresher training (34%), frequent equipment failure (28%) and others. The study also found that laboratory practitioners employed several countermeasures to overcome technical barriers to diagnostics. 44% reported that they would stop tests when reagents run out of stock, wait for maintenance of equipment and stop tests (38%), higher cadres would delegate work to lower level cadres (31%), improvise on faulty equipment and expired reagents (26%) and many others. No laboratory had adequate quality management systems in place. The recommendations of this study were to strengthen human resources planning for laboratory professionals, establish or strengthen national laboratory regulatory and representative bodies to improve governance and enhance quality, and promote work and competency based in-service training to ensure that staff skills are up to date and competency is demonstrated. (Int J Biomed Sci 2019; 15 (1): 32-56)

Keywords: barrier; clinical laboratory; Countermeasure; frequent barrier; quality assurance; quality control
INTRODUCTION

According to Wolcott et al (28), a clinical laboratory is a facility for the biological, microbiological, serological, chemical, immunohaematological, haematological, bio-physical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings. The practice of laboratory medicine implies a broader scope of influence beyond the activities in the laboratory, such as consultations with clinicians to assist with test ordering and results interpretation, performance measurement for quality improvement in the delivery of patient care, and, on a small yet growing scale, direct interactions with patients and the public. Laboratory scientists, therefore, are vital healthcare detectives, uncovering and providing laboratory information from laboratory analyses that assist physicians in patient diagnosis and treatment, as well as in disease monitoring or prevention (maintenance of health), using sophisticated biomedical instrumentation and technology computers and methods requiring manual dexterity to perform laboratory testing on patient specimens (1). Diagnostic services, in particular, are those aiming at uncovering the cause of ailments so as to influence therapies.

Laboratories provide confirmatory diagnosis and evidence-based management of diseases, essential public health information and disease surveillance. Due to this wide-ranging role, laboratories are an important part of many disease control programmes; yet laboratory services are often ignored or taken for granted (5). Laboratory testing is an integral part of the decision-making process, and results of laboratory testing often strongly influence medical diagnoses and therapies (5). For this reason, it has a central role to play in supporting the delivery of Malawi’s healthcare package. However, without effective diagnosis, patient treatment and care is often compromised, expensive drug treatments are squandered, diagnoses are missed and information about the public health is inaccurate (27). The barriers to laboratory diagnostic services adversely affect the quality performance of laboratory scientists, who are the backbone of quality diagnostics (25). As a result, clinicians lose confidence in laboratory services, and often resort to presumptive diagnoses rather than evidence-based laboratory confirmation and their empirical clinical judgment leads to misuse of drugs and other valuable resources (22). It was, therefore, the purpose of this research to quantitatively assess the barriers to laboratory diagnostic service delivery in Mzuzu city. The research will ultimately render reliability of core public health diagnostic functions of the laboratory in Malawi.

Background Information

Wolcott et al (28) indicated that the history of laboratory medicine extends to the first recorded examination of human bodily fluids during the time of the ancient Greek physician Hippocrates around 300 BC. Two thousand years later, the first true clinical laboratory opened in 1896 at Johns Hopkins Hospital. Discovery of the disease-causing agents of epidemics such as tuberculosis, diphtheria, and cholera and the development of tests to detect their presence throughout the end of the 19th century propelled the laboratory to a position of importance by the early 20th century (28). The American Society of Clinical Pathologists (ASCP) was formed in 1922 as the first professional society supporting physicians specializing in pathology (28). In 1926, all hospitals accredited by the American College of Surgeons were required to establish a clinical laboratory under the direction of a physician. Today, the clinical laboratory serves a vital role in the health care system, spanning research, clinical care, and public health surveillance (28).

Laboratories have historically been under supported in developing countries health systems resulting in poor quality diagnosis and inadequate disease surveillance (25). This has resulted into unnecessary wastage of drugs and inadequate data for interventions. Additionally, laboratory staffing has not figured prominently in discussions of human resources at national or global levels with these workers being among the neglected cadres in Africa (25). Even when there is a willingness to recruit more laboratory professionals, governments have not been able to match their aspirations to their capacity to recruit more highly skilled personnel (25). This understaffing bar disease diagnosis, for instance increased workloads puts personnel work under pressure. Safety standards may not be systematically respected due to fatigue. In addition, lack of modern essential devices tempt laboratory workers to rely on old equipment that may compromise diagnosis. Inappropriate testing, therefore, causes unnecessary patient discomfort, entails the risk of false-positive results, leads to overloading of the diagnostic services, waste of valuable healthcare resources and is associated with other inefficiencies in laboratory healthcare delivery, undermining the quality of laboratory services (27).

According to Schneidman et al (25), laboratory professionals figure prominently among neglected cadres in
health systems across sub-Saharan Africa and often work in facilities which are poorly equipped and do not systematically respect safety and infection control standards. This is due to inadequate safety equipment and poor physical facilities. Eventually, personnel are also predisposed to risk of exposure to communicable diseases. In addition, old devices that require frequent maintenance are used. These devices need a lot of funds for maintenance, which are not adequately available in the developing world. Generally speaking, this puts personnel in dilemma and not motivated to work as expected, hence low productivity. Usually, poorly diagnosed and managed cases keep do not meet required interventions hence high morbidity and deaths altogether. This assertion is supported by Graber (12) who stated that wide variety of research studies suggest that breakdowns in the diagnostic process result in staggering toll of harm and patient deaths. And when the patient is not improving, further diagnosis is required for further treatment, accelerating wastage of resources in already resource constrained settings of the developing world. This, therefore, had served as a rationale behind assessing the barriers that hamper delivery of optimum laboratory diagnostic services.

Statement of the problem

The quality of the laboratory diagnosis is important in achieving the national goal of improved health care. Diagnostic quality is influenced by the competence of the laboratory service providers who are the practitioners as well as the availability of the recommended working conditions. The effectiveness of service remains a growing concern even as medical diagnostic laboratories are undergoing the process of accreditation for quality services in line with WHO standards. Though there are a set of standards for quality laboratory services developed by the MoH based on WHO standards, Malawian laboratories find difficulties to deliver effective diagnostic services. These difficulties consequently hamper the ability of laboratories to achieve an optimal balance in staff distribution, skill-mix, performance, retention and maximum productivity.

Barriers to laboratory diagnoses affect evidence-based therapy because information provided to clinicians barely provide them with insights and guidance in making decisions for interventions. As a result, they resort to presumptive diagnoses that lead into wrong treatment. Misdiagnosis increases mortality and morbidity rates and accelerates wastage of medical resources. Nevertheless, in Malawi, no other studies had been made to identify technical and administrative barriers to effective diagnosis. Neither had studies been made to determine frequency with which such barriers occur in our laboratories. Furthermore, no studies had been made to investigate how laboratory personnel overcome such barriers. In order to bridge in the information gap and guide appropriate interventions, so as to improve reliability and effectiveness of laboratory diagnosis, the embarkation of this assessment was beneficial.

General Objective

The aim of this study was to assess barriers to delivery of optimal laboratory diagnostic services.

Specific Objectives

Specifically, the research was designed:
- To identify technical and administrative barriers to laboratory diagnosis of diseases.
- To determine frequency of such technical and administrative barriers.
- To determine how laboratory service providers overcome these barriers

Research Questions

- What were technical and administrative barriers to laboratory diagnostic services?
- How frequent did the technical and administrative barriers occur?
- How did laboratory service providers overcome such barriers?

Significance of The Study

The results of this research would promote development of policies and appropriate strategies to help improving efficiency and reliability of diagnosis in our medical laboratories. In addition, the results would also provide information to promote evidence-based medicine, with an emphasis on reducing high mortality and morbidity rates plus unnecessary wastage of medical resources. This would be a milestone to the improvement of quality life of people in the country as well as cost effective to already constrained resources in the health sector.

LITERATURE REVIEW

Barriers to Laboratory Diagnostics

Laboratory workforce: Comprising pathologists, doctoral-level laboratory scientists, technologists/scientists, and technicians, the laboratory medicine workforce has a vital role in the health care system, managing and applying evidence-based, scientific testing techniques
to support patient care and protect against public health threats. A national status report on laboratory medicine in USA indicated that there is growing concern regarding shortages in the number of laboratory professionals entering the workforce (28). The shortage could become pronounced with the forthcoming retirement of many laboratorians, inability of governments to absorb personnel due to financial constraints, like the case in Malawi, and migration of workers in search for greener pastures to other countries. Another important study in this area by Vidal (2015) found that the cost to poor countries of emigration is seen as exacerbating already weak national health systems, challenging achievement of the United Nations Millennium Development Goals. These studies agree on the point that emigration of health workers is a contributing factor to the shortfall of health workers in source countries. As a result there are increased workloads in the medical laboratory that compromise the capability of laboratory staff to provide effective diagnosis.

There is also need to modify some migration policies and those that guide day-to-day performance of the health industry in Malawi, thus suiting the current healthcare situation. To support this assertion, Muula (18) indicated that in order to suggest policy changes and implement corrective measures, there may be need to describe the perceptions of the legislature on how they perceive as the cause of such shortfalls, which could be the solutions and the evaluation of those solutions. This differs from what the findings of the above researchers by indicating a remedial measure to the shortage of workers. An important study in this area by Wanjau (27) demonstrated that the Kenyan government in an attempt to improve its public healthcare system has been in the processes of drafting various health policies. The study recommended that management in public health sector should improve employees’ capacity to enhance provision of health service quality. Both studies suggest that policy development and modification is an important tool for retention of all health professionals at large. Thus, retention is of paramount importance if their levels are to be matched with workloads.

A growing body of research indicates that understaffed hospitals are forced to provide care for patients that reside at a great distance from the institutions themselves, sometimes more than 100 miles away (16). This has resulted in a concept called “task shifting” where medical and health service responsibilities are delegated from higher to lower cadres of health staff, in some cases non-professionals hence poor diagnostic service delivery (Zechariah et al, 2009), which is in contrast to the Ministry of Health objective, better quality health for all in all facilities. Contrary to task shifting, Muula and Maseko (19) found that a significant number of health professionals find themselves taking up enormous responsibilities that are beyond what their training and/or experience has equipped them for. From these two results, it might be visualised how a critical shortage of laboratory personnel may impact negatively on diagnosis and other services at large. Delegating health service responsibilities from higher to lower cadres including non-professionals is seen as a drawback in service provision. This is because diagnosis as well as information that guide evidence based medicine is poor, contributing to high mortality and morbidity rates, a problem that is to be addressed by this research. Through the Emergency Human Resources Programme (EHRP), health worker to population density had risen from 0.84 (2004) to 1.44 per 1000, a 66% increase. These new levels still fell below the African region average (1.91 per 1000) and the WHO’s critical threshold (2.5 per 1000) for developing countries essential health services, showing the depth of Malawi’s human resources crisis (4). This means that there is still much that has to be done to balance staff distribution, retention, skill-mix and maximum productivity to optimise laboratory services.

A great deal of misdiagnosis that ail treatment of cases: Laboratory testing is an integral part of the decision-making process, and results of laboratory testing often strongly influence medical diagnoses and therapies. A study investigating phlebotomy issues and quality improvement in result of laboratory testing in Italy found that it is undeniable that errors in medicine do exist and whatever solution for limiting their prevalence is a necessary challenge to prevent unjustified expenditure and to enable effective clinical reasoning and decision making (15). Thus, improving laboratory performance requires accurate procedures for identifying the processes which are more susceptible to errors or uncertainties. Some errors are made by staff due to incompetence and negligence thereby compromising the effectiveness of diagnosis and results to guide treatment. As a result medical resources are wasted and people die while others sustain injuries due to wrong therapies. Such errors should be avoided to improve reliability of diagnosis as well as to reducing unnecessary expenditures, mortality and morbidity rates. So many errors result from faulty equipment and maintenance of such equipment is problematic in developing nations. For example, We suffer with lack of appropriate maintenance programs [in the laboratory], and also lack of staff with [the] technical capability to manage, train, operate and provide effective equipment maintenance
BARRIERS TO MEDICAL LABORATORY DIAGNOSTIC SERVICE DELIVERY

support - District hospital laboratory manager, a report on laboratory equipment training in Ethiopia (17). According to Mamo (17), laboratory test results play a key role in 60–70 percent of all clinical diagnostic decisions. Clinicians also use laboratory tests to monitor disease over time, identify changes in patient health conditions before symptoms occur, diagnose illness, plan treatment and evaluate how well treatment is working. Therefore, well-maintained biomedical equipment is essential to any functioning health system. Lack of maintenance programs and access to modern diagnostic devices encourages reliance on archaic devices that are prone to errors. This compromises quality of diagnosis and results that are produced by the laboratory.

On the contrary, misdiagnosis is due to inadequate training provided by training institutions in developing countries as a result of shortage of teaching and learning materials (17). The personnel are not imparted with adequate practical diagnostic knowledge and skills hence laboratory services are negatively impacted. Owing to high personnel turnover rates, lack of understanding about good laboratory practices, and inadequate training, there are several opportunities for making errors during phlebotomy, which mainly concern patient misidentification and collection of unsuitable specimens for testing (15). In many developing countries, laboratory services are grossly neglected and under-utilized with the test results that are produced frequently ignored by clinicians, who often treat patients according to their empirical clinical judgment leading to the misuse of drugs and other resources (22). A study in Brazil found that misdiagnosis appeared to contribute to overall delay in diagnosis of leprosy patients in most areas of Brazil (13). In a similar study, Petti et al (23) found that the absence of laboratory support contributes to an over diagnosis of malaria that leads to a failure to treat or a delay in treatment of alternative life-threatening infections and potentially increases mortality. In this study, an analysis of children at a tertiary referral centre in Kumasi, Ghana, 40% of patients who had been given a WHO-defined clinical diagnosis of malaria were confirmed to actually have bacterial sepsis. This means that septic patients were un-appropriated with malaria regimens. This is a waste of drugs that are already in short supply in developing nations. From these two studies, misdiagnoses contribute to delays in treating life-threatening infections, increasing patient death and morbidity rates, ailing quality of laboratory medicine despite its importance to enhance diagnostic value and save lives.

Budget allocation to laboratory medicine and availability of supplies: A growing body of research indicates that most African countries are barely able to sustain the basic requirements for technology and most medical laboratories in the third world are struggling to bring in line cost effective technologies. Where laboratories are present there is often lack of diagnostic tests in the available laboratories. In several African countries, like Nigeria, Ghana, Burkina Faso, Malawi, Zambia, Uganda, Tanzania and Kenya, the laboratory assays to identify infections are routinely unavailable, and investigators frequently neglect the importance of diagnostic testing (22), and for many common infections in sub-Saharan Africa, clinical diagnosis is still not adequately sensitive or specific. A similar study indicated that poor allocation of resources to medical laboratory in many sub-Saharan African countries, it appears that diagnosis based on clinical symptoms alone, without the support of basic diagnostic tests, is the rule rather than the exception Njoroge (22). Drawing upon Njoroge (22), Petti et al (23) takes this issue further by indicating that presumptive diagnosis leads to inappropriate treatment, increased morbidity, and unnecessary loss of life. Petti et al (23) indicated that allocation of resources to diagnostic laboratory testing has not been a priority for resource-limited health care systems, but unreliable and inaccurate laboratory diagnostic testing leads to unnecessary expenditures in a region already plagued by resource shortages, promotes the perception that laboratory testing is unhelpful, and compromises patient care. It is evident, therefore, that following coherent flow of agreement among these researchers, inadequate budgetary support contributes to shortage of laboratory supplies and compromises public health functions of the laboratory. This makes it hard for a lab to perform its wide-ranging roles in disease diagnosis, hence the need for this study to assist enlightening health managers on how adequate budgetary support will benefit quality diagnostics at MZCH, EMH, MASM and Malawi at large.

Countermeasures to Overcome Barriers to Lab Diagnostics

People and Processes First: First, laboratories need to address the personnel component of task conditions by hiring qualified technicians who have the personality traits that make them suitable for laboratory work (7). Desirable qualifications vary, depending on the type of laboratory, but suitable technicians will generally have at least some college education and some experience in a scientific setting (7). Scientific expertise is a tool in quality diagnosis. Hiring managers need not only focus on education and work experience to fill laboratory positions. They must also seek candidates with specific personality traits that fit well within their specific laboratory. Neils (20)
agrees by indicating that managers must also stay on the alert for signs of burnout, which include exhaustion, anger at decision-makers, cynicism, negativity, suspiciousness, headaches, feelings of being overwhelmed, and sensitivity to inconsequential issues. Evans and Lindsay (8) takes this issue further by indicating that managers must also provide on-going training and education in order to add to organizational capabilities. Laboratory managers need to understand their organizational needs and know which types of traits are absolutely necessary in a technician versus those that are absolutely unacceptable (2). Once a laboratory has qualified staff members, managers need to be vigilant in maintaining staff levels to avoid detrimental shortages, which have a significant effect on the balance between workload and available resources.

**Task Environment:** Beyond personnel requirements, a good laboratory incorporates a number of design requirements that facilitate workflow and provide a healthy work environment for employees. For instance, Penn state’s new Biomedical Research Building is not only visually aesthetic inside and out, but it is also designed to encourage team interaction, to allow room for expansion, and to increase the efficiency of usable space by 13% more than the old building (Fiske, 2010). Modern service laboratories incorporate a number of design features that facilitate productivity, collaboration, and flexibility: open spaces, natural lighting, semi-permanent walls, high-quality building materials, multifunctional work spaces, appealing laboratory furniture, whiteboards, and other specialty amenities (Romig, 2005). In further analysing the design of work spaces, modern laboratories are designed to increase multi-functionalism, which is the solution to having maximum efficiency (Romig, 2005). These types of advances stimulate workers and increase productivity simply by providing an environment that removes productivity barriers, which in turn relieves stress and creates a happier work force. Employees need to get involved in improving work areas, since they know best what types of arrangements will allow them to practice efficient work habits.

**Storage and Organization: Laboratory 5S:** One approach to improving work areas in a service laboratory is the application of the Japanese concept of 5S, or visual order (Galsworth, 2008). A visually ordered service laboratory will be clean, safe, and uncluttered. Work stations will only contain the most essential tools and materials, nothing more, nothing less. Barker (2) agrees by indicating that chemicals, reagents, testing supplies, notebooks, and other equipment will be properly labelled with names, safety information, expiration dates, calibration dates, and location information. Non-essential supplies, chemical or non-chemical, will be properly organized and stored in labelled drawers, cabinets, freezers, and refrigerators that are out of the immediate work area, yet easily accessible when needed (2). The implementation of visual order reduces unnecessary motion, which generates a smoother workflow, greater productivity, and fewer opportunities for bottlenecks.

**Refining the Work Climate: Temperature, Lighting & Noise:** Temperature controls are another area of improvement that can add to worker comfort and increase productivity. Any good laboratory should have temperature controls to regulate the macroclimate of the entire facility, but unique work zones may require separate controls, usually to keep instruments cool (7). In this situation, it is best to minimize the time technicians spend in cooler rooms by moving certain tasks, like data reporting, to more comfortable sections of the laboratory. Temperature-control practices support the comfort of workers who can then focus on their jobs and maintain productivity (7). Along with temperature and lighting controls, noise abatement in a service laboratory poses a considerable challenge because the laboratory is usually bustling with the activity of workers and noisy equipment (Kroemer, 2008). The first line of defence against noise in the laboratory is to avoid generating it by maintaining equipment and/or upgrading to “quieter” models whenever possible (Kroemer, 2008). All the above countermeasures will provide favourable conditions of work, ultimately quality laboratory diagnostics.

As may be depicted from the review above, researchers have reported that laboratory testing is facing a lot of barriers, compromising global healthcare package. Narrowing down to the local level, Malawi’s Essential Healthcare Package (EHP) might be victimised due to poor diagnosis, making it hard to achieve UNMDGs. None of the studies have assessed barriers to effective laboratory diagnosis in Malawi. Neither have studies assessed how to overcome such barriers nor the frequency of the barriers in medical laboratories in Malawi. Due to laboratory’s wide-ranging role in disease diagnosis and information provided to clinicians for right treatment, it is imperative, as per the overall object of this study, to assess the barriers to effective laboratory diagnostics.

**METHODOLOGY**

The areas of main focus in this section are; research design, research site description, data collection instruments,
sample size and sampling technique, inclusion and exclusion criteria as well as data analysis.

**Study Design and Approach**

This was a descriptive cross-sectional study using quantitative research approach. Data collected was coded to make it quantifiable. Cross-sectional study design was used because it helps to estimate the prevalence of the outcome of interest for a population under study, commonly for the purposes of public health planning. Furthermore, use of cross-sectional design provides a snapshot of the outcome of interest and the characteristics associated with it, at a specific point in time.

**Places of Study**

The assessment was conducted in three places, Mzuzu Central Hospital (MCH), Ekwendeni Mission Hospital (EMH) and Medical Aid Society of Malawi (MASM) Clinic in Mzuzu city, Malawi. Three sites were chosen in order to have included a representative sample size of laboratory staff in the study. In addition, to avoid biased results, there was a balance in selection of major health-care providing systems, since Malawi’s health system is a combination of public, non-profit mission and private financing health services. Therefore, a government hospital (MCH), a mission hospital (EMH) and a private hospital (MASM) were selected.

**Target Population**

The population for this study constituted laboratory practitioners of all ages, sex and qualifications in the functional medical diagnostic laboratories in the selected three health facilities. The study population also constituted directors from each health facility.

**Sampling Approach**

A probability sampling approach was used to select laboratory staff so as to avoid a biased selection. Laboratory staff were selected using a stratified sampling method – they were divided in different strata based on their level of education then selected randomly from each stratum. Administrators from each health facility were purposively included in the study.

**Inclusion And Exclusion Criteria**

This assessment included qualified laboratory professionals, both males and females, with a working experience of at least a year in all the three study sites. This was to ensure that they provide valid and consistent data so as to preserve the integrity of outcome of the study.

New recruits (with less than 1 year experience) were excluded in the study. Students from various training institutions on attachments at MZCH, EMH and MASM clinic did not take part in this study. These categories were more likely to provide poor and biased data hence they were excluded from participation.

**Sample Size Calculation**

The study sample was determined using the Taro Yamane’s formula,

\[ n = \frac{N}{1+N(e^2)} \]

where \( n \) is the required sample size, \( N \) is the estimated population of laboratory scientists at MCH, EMH and MASM clinic and \( e \) is the acceptable sampling error (GfK Polonia, 2013). There were 27, 5 and 4 laboratory staff at MCH, EMH and MASM respectively, giving a total of 36 laboratory staff. Setting the precision level at \( \pm 5\% \) with 95% confidence interval, \( p=0.05 \), the study comprised of 25 participants from MCH, 4 from EMH and 3 from MASM clinic, giving a total of 32 participants. Thus \( n = \frac{27}{1+(27*0.05^2)} = 25 \) participants from MCH, \( n = \frac{5}{1+(5*0.05^2)} = 4 \) participants from EMH and \( n = \frac{4}{1+(4*0.05^2)} = 3 \) participants from MASM clinic were calculated and surveyed.

**Data Collection Methods/Instruments**

A self-administered questionnaire was used as an instrument for collecting data on technical barriers to diagnosis from laboratory staff. A face-to-face interview was conducted to collect data on administrative barriers to diagnosis from one administrator at each health facility. The questionnaire was pretested among a group of level four Biomedical Sciences students for various practical preparations. Thus to allow identification of potential problems in the proposed research project and of course to help validating the questionnaire.

**Data Analysis**

The data was double-entered into Microsoft Excel and subsequently exported into a Statistical Package for Social Science, SPSS V20, which offers extensive data handling capabilities and numerous statistical analysis routines that can analyse small to very large data statistics. Double entry allows cleaning data to get rid of errors. Analysis was mainly done using quantitative descriptive statistics using mean, mode and median which are a measure of central tendency. Tables and charts were used to draw data relationships.
Ethical Considerations

The research proposal was submitted to Mzuzu University Research Ethics Committee for careful scrutiny as well as approval. Written permission to conduct the study at MZCH, EMH and MASM clinic was obtained from research committees and/or responsible authorities of the institutions. To make sure that autonomy and confidentiality were fully exercised throughout the study, both written and oral informed consent was obtained from the participants prior to participation. In addition, the participants were informed about the purpose of the study. A coding system was used to conceal the identity of the participants thus addressing the issue of confidentiality. Participants were not required to give their names, thus anonymising participants’ information. Also the benefit of this study was explained to them and that no harm would result from participation, like dismissal or punishment. Additionally, an explanation was offered that no payment would be given to them upon participation. Participation was entirely voluntary and no participants were compelled to provide information in any way.

Limitations of The Study

This study was not conducted on a large scale, like the whole Northern Malawi. Therefore, the results could not be generalised to the country wide laboratory medicine situation. Global, regional or local literature for frequency of barriers to diagnostics was scarce.

Dissemination of Results

The findings of this research were presented to the Department of Biomedical Sciences and a copy was submitted to the Mzuzu University Library. In addition, copies were submitted to international online journals, Biomed Central, Journal of Young Investigators (JYI) and International Journal of Biomedical Science (JIBS), significant developments for disseminating biomedical and scientific research results. Other copies were sent to study sites and Ministry of Health (MoH).

PRESENTATION OF RESULTS

Participants’ Demographic Characteristics

Table 1 shows demographics of study participants in terms of gender, age ranges and qualification.

Technical and Administrative Barriers to Laboratory Diagnostic Service Delivery

Table 2 shows technical barriers affecting quality diagnosis in different categories of laboratory performance.

Table 3 shows descriptive statistics, in terms of mean, range and standard deviation, for technical barriers affecting different categories of laboratory performance.

Frequency of Technical and Administrative Barriers Affecting Quality Laboratory Diagnostics

Table 5 shows frequency of technical barriers affecting quality laboratory diagnostics in different categories of laboratory performance.

Table 6 shows descriptive statistics, in terms of mean, range and standard deviation, for frequency of technical barriers affecting different categories of laboratory performance.

How Medical Laboratorians Overcome Technical Barriers Affecting Diagnostic Service Delivery

Figure 1 shows different ways how laboratory professionals overcome technical barriers due to equipment use in the work place.

Figure 2 shows different ways how laboratory professionals overcome technical barriers due to reagents’ use in the work place.

Figure 3 shows different ways how laboratory professionals overcome technical barriers due to inadequate Human Resources for Health (HRH) at MCH, EMH and MASM clinic in Mzuzu city.

Table 7 shows descriptive statistics, in terms of mean, range and standard deviation, for how lab practitioners overcome technical barriers affecting different categories of laboratory performance.

Figure 4 shows different time periods at which equipment that malfunctions is likely to be maintained by laboratory practitioners and/or contract service engineers.

![Figure 1](image-url)
Table 1. Demographic characteristics of participants

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<tr>
<td>Total</td>
<td>32</td>
<td>100.0</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Figure 2.

Figure 3.
Table 2. Technical barriers to quality laboratory diagnostic service delivery

<table>
<thead>
<tr>
<th>Category</th>
<th>Barrier</th>
<th>Count(n)</th>
<th>%count</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Barriers due to equipment use</strong></td>
<td>Frequent equipment failure</td>
<td>7</td>
<td>22%</td>
</tr>
<tr>
<td></td>
<td>Scarcity of modern equipment</td>
<td>6</td>
<td>20%</td>
</tr>
<tr>
<td></td>
<td>Lack of equipment refresher training</td>
<td>10</td>
<td>31%</td>
</tr>
<tr>
<td></td>
<td>Conditions not suitable for equipment operation</td>
<td>3</td>
<td>9%</td>
</tr>
<tr>
<td></td>
<td>Don’t know</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td></td>
<td>None</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td></td>
<td>N/A</td>
<td>1</td>
<td>3%</td>
</tr>
<tr>
<td></td>
<td>Others</td>
<td>5</td>
<td>15%</td>
</tr>
<tr>
<td><strong>TOTALS</strong></td>
<td></td>
<td>∑N=32</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Barriers due to reagents use</strong></td>
<td>Short supply of reagents</td>
<td>25</td>
<td>79%</td>
</tr>
<tr>
<td></td>
<td>Poor reagent storage conditions</td>
<td>1</td>
<td>3%</td>
</tr>
<tr>
<td></td>
<td>Short shelf life of reagents</td>
<td>5</td>
<td>15%</td>
</tr>
<tr>
<td></td>
<td>None</td>
<td>0</td>
<td>0%</td>
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<tr>
<td></td>
<td>Others</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td></td>
<td>N/A</td>
<td>1</td>
<td>3%</td>
</tr>
<tr>
<td><strong>TOTALS</strong></td>
<td></td>
<td>∑N=32</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Human resource barriers</strong></td>
<td>Work overload</td>
<td>22</td>
<td>69%</td>
</tr>
<tr>
<td></td>
<td>Overwhelming test orders</td>
<td>1</td>
<td>3%</td>
</tr>
<tr>
<td></td>
<td>Tests beyond personnel training capability</td>
<td>3</td>
<td>9%</td>
</tr>
<tr>
<td></td>
<td>Environment not conducive for work</td>
<td>1</td>
<td>3%</td>
</tr>
<tr>
<td></td>
<td>Don’t know</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td></td>
<td>Others</td>
<td>1</td>
<td>3%</td>
</tr>
<tr>
<td></td>
<td>None</td>
<td>4</td>
<td>13%</td>
</tr>
<tr>
<td><strong>TOTALS</strong></td>
<td></td>
<td>∑N=32</td>
<td>100%</td>
</tr>
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</table>
Table 3. Descriptive statistics for technical barriers affecting diagnostic service delivery

<table>
<thead>
<tr>
<th>Barrier Category</th>
<th>N</th>
<th>Range</th>
<th>Mean</th>
<th>Std. Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Statistic Statistic Statistic Std. Error Statistic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equipment barriers</td>
<td>32</td>
<td>7.00</td>
<td>3.3750</td>
<td>0.41821</td>
</tr>
<tr>
<td>Reagents' barriers</td>
<td>32</td>
<td>5.00</td>
<td>1.5000</td>
<td>0.19572</td>
</tr>
<tr>
<td>Human resource barrier</td>
<td>32</td>
<td>6.00</td>
<td>2.2187</td>
<td>0.38030</td>
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</table>

Table 4. Administrative barriers to laboratory diagnostic service delivery

<table>
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<tr>
<th>CATEGORY</th>
<th>BARRIER</th>
<th>count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barriers to lab budgetary support</td>
<td>Limited budget allocation to the MoH</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Pilferage of available funds by those in charge</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Negligence of authorities to what is required to the lab</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Don’t know</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Others</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>N/A</td>
<td>1</td>
</tr>
<tr>
<td>Administrative barriers to lab quality diagnostics</td>
<td>Lack of supervision to the lab</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Lack of equipment training assessments</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Recruitment of inadequately trained lab staff</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Lack of reagents for quality controls</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Shortage of lab staff due to limited vacancies</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Others</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>N/A</td>
<td>1</td>
</tr>
<tr>
<td>Administrative barrier affecting release of results</td>
<td>Low levels of staff, work overloads</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Overwhelming test orders by clinicians due to poor guidelines of test ordering</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Tests ordered are beyond staff training capability</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Lab environment not conducive for work</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Don’t know</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Others</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>N/A</td>
<td>1</td>
</tr>
</tbody>
</table>
Table 5. Frequency of technical barriers to medical laboratory diagnostic service delivery

<table>
<thead>
<tr>
<th>Category Barrier</th>
<th>Frequency</th>
<th>%frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Barriers due to equipment use</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequent equipment failure</td>
<td>9</td>
<td>28%</td>
</tr>
<tr>
<td>Scarcity of modern equipment</td>
<td>5</td>
<td>16%</td>
</tr>
<tr>
<td>Lack of equipment refresher training</td>
<td>11</td>
<td>34%</td>
</tr>
<tr>
<td>Conditions not suitable for equipment operation</td>
<td>1</td>
<td>3%</td>
</tr>
<tr>
<td>Don’t know</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>None</td>
<td>1</td>
<td>3%</td>
</tr>
<tr>
<td>N/A</td>
<td>1</td>
<td>3%</td>
</tr>
<tr>
<td>Others</td>
<td>4</td>
<td>13%</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>∑f=32</td>
<td>∑%f=100%</td>
</tr>
<tr>
<td><strong>Barriers due to reagents use</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short supply of reagents</td>
<td>27</td>
<td>84%</td>
</tr>
<tr>
<td>Poor storage conditions of reagents</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Short shelf life of reagents</td>
<td>4</td>
<td>13%</td>
</tr>
<tr>
<td>None</td>
<td>1</td>
<td>3%</td>
</tr>
<tr>
<td>Others</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>∑f=32</td>
<td>∑%f=100%</td>
</tr>
<tr>
<td><strong>Human resource barriers</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Work overloads</td>
<td>22</td>
<td>70%</td>
</tr>
<tr>
<td>Overwhelming test orders</td>
<td>1</td>
<td>3%</td>
</tr>
<tr>
<td>Tests beyond personnel training capability</td>
<td>3</td>
<td>9%</td>
</tr>
<tr>
<td>Environment not conducive for work</td>
<td>2</td>
<td>6%</td>
</tr>
<tr>
<td>Others</td>
<td>1</td>
<td>3%</td>
</tr>
<tr>
<td>N/A</td>
<td>3</td>
<td>9%</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>∑f=32</td>
<td>∑%f=100%</td>
</tr>
</tbody>
</table>

Table 6. Descriptive statistics for frequency of technical barriers affecting diagnostic service delivery

<table>
<thead>
<tr>
<th>Barrier Category</th>
<th>N</th>
<th>Range</th>
<th>Mean</th>
<th>Std. Deviation</th>
</tr>
</thead>
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<tr>
<td></td>
<td>Statistic</td>
<td>Statistic</td>
<td>Statistic</td>
<td>Std. Error</td>
</tr>
<tr>
<td>Equipment barriers</td>
<td>32</td>
<td>7.00</td>
<td>3.1563</td>
<td>2.31558</td>
</tr>
<tr>
<td>Reagents' barriers</td>
<td>31</td>
<td>3.00</td>
<td>1.2903</td>
<td>0.78288</td>
</tr>
<tr>
<td>Human resource barrier</td>
<td>32</td>
<td>5.00</td>
<td>2.0000</td>
<td>1.70389</td>
</tr>
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</table>

Table 7. Descriptive statistics for overcoming technical barriers affecting diagnostic service delivery

<table>
<thead>
<tr>
<th>Barrier Category</th>
<th>N</th>
<th>Range</th>
<th>Mean</th>
<th>Std. Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Statistic</td>
<td>Statistic</td>
<td>Statistic</td>
<td>Std. Error</td>
</tr>
<tr>
<td>Equipment barriers</td>
<td>31</td>
<td>5.00</td>
<td>4.1613</td>
<td>1.43983</td>
</tr>
<tr>
<td>Reagents' barriers</td>
<td>30</td>
<td>4.00</td>
<td>2.9333</td>
<td>1.55216</td>
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<tr>
<td>Human resource barrier</td>
<td>32</td>
<td>4.00</td>
<td>3.1563</td>
<td>1.11034</td>
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</tbody>
</table>
Table 8 shows agents who are responsible for maintenance of equipment in case of failure.

**Quality Assurance of the Analytical Process in Medical Laboratories**

Table 9 shows summarises the degrees to which analytical quality assurance measures are carried out in laboratories of the three selected health facilities.

**DISCUSSION**

**Technical Barriers to Laboratory Diagnostic Service Delivery**

The study identified several technical barriers to affect delivery of medical laboratory diagnostic services in Mzuzu city. Barriers were categorized based on different levels of laboratory operation such as barriers affecting use of equipment, reagents and those affecting laboratory human resources (Table 2).

**A) Barriers Affecting Use of Laboratory Equipment**

The responses of participants to questions on equipment barriers had a mean absolute count of 3, standard error of 0.4 with a standard deviation of 2 (Table 3). The barriers were:

**a) Lack of equipment refresher training**

Majority (31%) of laboratory practitioners indicated that there was lack of equipment refresher training for laboratory staff (Table 2). Refresher training is the process of bringing employees to an agreed standard of proficiency by practice and instruction in order to ensure that skills remain current (3). Skills and knowledge on use of laboratory equipment degrade with time. This can occur through lack of use, preferring alternative work methods, etc. For whatever reason, the need for refresher training should be identified in order to keep laboratory professionals up to date.

Similarly, a study in Ethiopia found that health system laboratories were characterised by a lack of equipment refresher training hence the need for an integrated approach to make sure these training are provided to laboratory workers (17). The similarity between these studies may suggest lack of financial support for such training initiatives. Lack of such training may be seen as a threat to quality laboratory diagnostic services because personnel are not kept abreast of equipment use and troubleshoot-
ing in case of minor equipment malfunctions. When their knowledge and/or skills on how to use particular equipment degrade, diagnosis with that equipment might be poor and results that influence evidence based medicine would likely be compromised. As a result, poorly diagnosed cases have a greater likelihood of missing treatment hence high morbidity and mortality rates.

**b) Frequent equipment failure**

Results showed that frequent laboratory equipment failure is another barrier to diagnostic services as revealed by 22% of laboratory practitioners (Table 2). Diagnosis ceases in case of equipment failure. This bars diagnosis because some tests that require equipment that is out of order may not be performed. As a result, patients are sent back to clinicians without results of the tests that had been ordered. A laboratory equipment training conducted in Ethiopia indicated that non-functioning laboratory equipment, a lack of training in equipment operation and maintenance, and lack of equipment maintenance programs present major challenges that impede delivery of health care at both regional and national levels (17). These two studies agreed on the point that equipment failure is an impediment to delivery of laboratory care.

Oftentimes, like in our case, the laboratory staff need to wait for contract service engineers for equipment servicing. This is because laboratory scientists may not have adequate technical knowhow to maintain major technical faults of equipment. As a result, the equipment is out of order for a long time, barring diagnosis. Sometimes clinicians may be notified that certain equipment, in the laboratory, is out of order such that they may not order for particular laboratory tests. This would prompt clinicians to presumptive diagnoses that do not always systematically influence evidence based therapy. Presumptive diagnoses might lead to misdiagnosis and misuse of drugs and other medical resources in trying to cure clinical ailments presented by patients.

**c) Scarcity of modern laboratory equipment**

The results indicated that 20% of laboratory practitioners, in all the three study sites, reported that there was a scarcity of modern equipment in their laboratories (Table 2). This finding was similar to that of Petti et al (23) who indicated that laboratory medicine in sub-Saharan Africa is characterised by an acute shortage of modern equipment. These results may suggest inability of health systems in sub-Saharan Africa to purchase modern equipment because they are expensive. Scarcity of modern equipment is a barrier to service delivery as it may increase reliance on old equipment. Outdated instruments and other equipment can contribute to decreased productivity and stress.

Edwards (7) takes the above issue further by indicating that older instruments have fewer capabilities, tend to break down more, and are more difficult to calibrate, maintain, and repair. The equipment that is difficult to calibrate would negatively affect results of tests, thereby compromising patient treatment.

**B) Barriers Affecting Use of Laboratory Reagents**

The responses of participants to questions on barriers affecting use of reagents had a mean absolute count of 2, standard error of 0.2 with a standard deviation of 1 (Table 3).

**a) Short supply of reagents**

The majority (79%) of laboratory practitioners, including those in the private system, reported that reagents were in short supply in the laboratories (Table 2). Reagents are used in conjunction with a given sample and expected to produce a measurable or noticeable change. Shortage of reagents is a barrier to diagnosis because almost all tests require their usage. Consequently, this might cause unexpected failures in vital cases which would have been prevented if the appropriate reagents were available, exacerbating morbidity and mortality rates. Muula and Maseko (2006) agree with findings of this study by indicating that in many other cases, the reagents, equipment or other supplies required to enable healthcare providers perform their duties so as to deliver high quality health services are not available. Thus, performance of qualified staff, in terms of diagnosis, may greatly be affected.

Economic instability of the general population might have also contributed to this barrier in the private and not for profit faith based health systems. This is because people may not be able pay for user fees, particularly in the private sector, hence low profits to cater for adequate medical resources.

**b) Short shelf life of reagents**

It was discovered that reagents that were available usually had a short shelf life as reported by 15% of laboratory staff (Table 2). Thus it took short period of time before reagents would expire. These would perhaps be reagents that were donated by charitable organisations and other well-wishers because donations would sometimes come fewer days before the products reach expiration dates. Usually, reagents that have short shelf lives are cheaper than those with long shelf lives. Procurement systems in developing countries would favour the purchase of cheaper reagents, in order to buy more and save costs. In the case, like this one, where reagents procured have a short shelf life, a lot of reagents may remain unused and discarded, contributing to short falls of reagents in laboratories. In laboratories
hit by a shortage of reagents, diagnosis is almost impossible, exacerbating mortality and morbidity.

C) Barriers Affecting Laboratory Human Resources

The responses of participants to questions on barriers human resources barriers had a mean absolute count of 2, standard error of 0.4 with a standard deviation of 2 (Table 3).

a) Work overloads

Majority (69%) of laboratory practitioners reported work overloads as a barrier to diagnostic service delivery (Table 2) in public and not-for-profit faith based clinical laboratories. In the private sector, there was a good number of personnel that would match the workloads. Similarly, Schneidman et al (25), in a case study conducted in four African countries, indicated that public sector demand for laboratory workers has been historically weak given the inability of Ministries of Health to recruit personnel, and/or lack of prioritisation in broader health policy discussions.

In addition, private, for-profit sector institutions have a greater capacity to attract qualified laboratory professionals and are willing and able to offer better working conditions with access to the latest advancements, more attractive salary and benefit packages, and innovative incentive schemes (25). As a result, they are better placed to compete with the public sector for the most qualified professionals. For example, in Zambia, the private sector was identified as a significant attraction with laboratory technicians being paid three times as much (25).

The number of laboratory practitioners was estimated to be 34 in Mzuzu, thus including private, public and faith based health systems. According to the 2008 Malawi Population and Housing Census, there was an estimated population of 128432 people in Mzuzu city (NSO, 2008). This indicated a 1:3777 health worker/patient ratio. Thus one laboratory personnel would be required to serve 3777 population. This is contrary to WHO recommended threshold of 2.28 health care professionals per 1000 population (30). Working under such work overloads increases likelihood of fatigue to health practitioners. Adherence to testing procedures may be difficult and this may result to misdiagnoses leading poor treatment, accelerating mortality and morbidity rates plus a wastage of medical resources.

b) Tests beyond personnel training capability

Results indicated that laboratory practitioners (9%) reported that they would receive test orders beyond what their training equipped them for (Table 2). This might be due to domination of low level qualified staff (56% for diploma and certificate holders) in Biomedical Sciences (Table 1). Their level of knowledge may not tally with higher level qualified practitioners (bachelor’s degree and above). So the likelihood of inabilities to perform some tasks that would require special training skills and knowledge might not be ruled out.

Muula and Maseko (19) agree to this finding by stating that due to high turnover ratios of lab staff, lower level cadres might find themselves taking enormous responsibilities some of which would not reflect their training capabilities. This would negatively affect quality of disease diagnosis and treatment.

D) Other Barriers

On the questionnaires that were distributed among laboratory staff, 15% of participants specified other barriers that they thought would bar service delivery (indicated as others in Table 2). Below are some barriers that participants specified.

a) Poor remuneration and conditions of service

“For the last three years, I have never known on which day I would receive my monthly pay sometimes it would be up to two months between payments”, participant 019 reported. What might be of great concern is the survival strategies that HCP might follow in order to make ends meet.

Pilferage of medical resources, by HCP, especially in the public health sector might be an alternative source of money for survival. Muula and Maseko (19) produced similar results and stated that while unknown robbers are among the culprits, some health workers are reported to be involved in stealing drugs and selling them to drug vendors or private clinics. This might have adverse effects on provision of health services.

b) Lack of professional laboratory associations/boards

“We do not have an independent professional board to represent us at policy level, and this affects us in one way or another”, reported participant 026. This was a different situation from other cadres like Nursing and Midwifery and Pharmacy which have their representative boards such as the Nurses and Midwives Council of Malawi and Pharmacy, Medicines and Poisons Board of Malawi respectively. These boards represent their members at policy level thereby influencing changes that might enhance service delivery. The boards also exercise objective quality control measures such as supervision and accreditation to their members in order to improve standard of care.

Administrative Barriers to Laboratory Diagnostic Service Delivery

a) Limited budget allocation to the MoH

Directors of public and faith-based hospitals reported
that there was inadequate funding allocated to the MoH (Table 4), whereas this barrier was not applicable to the private sector. “In most cases we rely so much on donors and other partners to support us with equipment and funds for the day-to-day running of the hospital”, participant 035 reported. This would be a clear indication that the government’s budget allocation to the MoH was inadequate. Diagnostic services might be greatly affected because medical laboratory supplies would continuously be in short supply.

A study conducted in Kenya by Wanjau et al (27) found similar results and indicated that public hospitals in Kenya are in dire need of funding to rehabilitate, redesign, equip and staff them to ensure effective and efficient service delivery to Kenyans. Wanjau et al (27) take this finding further by stating that political and bureaucratic leakage, fraud, abuse and corrupt practices are likely to occur at every stage of the process as a result of poorly managed expenditure systems, lack of effective auditing and supervision, organisational deficiencies and lax fiscal controls over the flow of public funds. These results might also be inferred to our situation in Malawi.

b) Inadequate supervision to the laboratory staff

Results showed that there was inadequate supervision to laboratories (Table 4). Effective laboratory service delivery requires workers to know exactly what tasks they are expected to perform, have the necessary skills and resources to perform these tasks, and receive feedback that assists them in improving their performance. Supervision plays an important role in the performance and motivation of health workers by ensuring that the health system’s requirements are met, rather than addressing the development of skills and competencies of individual health workers. Recognition is a vital aspect of supervision that is oftentimes neglected. It plays a key role in the motivation and retention of health workers.

An important study in this area, in Malawi, by Muula and Maseko (18) found similar results and indicated that health workers reported they were either poorly or inadequately supervised. Those that were supervisors reported that lack of resources and especially transport to rural remote areas coupled with other commitments and responsibilities prevented them from making supervisory visits. Lack of supervision might result in workers feeling unappreciated, de-motivated and frustrated hence low productivity.

A) Other Administrative Barriers

Participants (administrators), specified other barriers that they felt would bar laboratory service delivery.

a) Poor utilization of research results

Participants specified other barriers that might have contributed to ineffective diagnostic service delivery. “Students and independent researchers have conducted a lot of research that might promote policy formulation and bring change in the health sector, but utilisation of research results, in our setting, is a big challenge”, participant 033 reported. In this case, there might be possibilities that policy making is not always based on evidence. In addition, research that is not locally driven and not responsive to local needs might not influence policy making, therefore it might be difficult for our health systems to effect changes that would help improve service delivery.

Frequency of Technical and Administrative Barriers

A) Most Frequent Technical Barriers to Equipment Use

As it may be depicted in Table 6, the responses of participants to questions on frequency of barriers regarding equipment use had a mean frequency of 3, standard error of 0.4 with a standard deviation of 2.

a) Lack of equipment refresher training

Majority (34%) of laboratory staff reported that lack of equipment refresher training was the most frequent barrier (Table 5). For such training to be feasible, there might be need for adequate resources. The reason why this barrier was more frequent might be due to inadequate funding in our health systems.

b) Frequent equipment failure

It was shown that 28% of the staff reported that frequent equipment failure is another more frequent barrier following lack of equipment refresher training (Table 5). This might be due to use of outdated equipment that has served for a long time. Thus, they might be prone to failure.

B) Most Frequent Technical Barriers to Reagents’ Use

The responses of participants to questions on frequency of barriers to reagents’ use had a mean frequency of 1, standard error of 0.1 with a standard deviation of 0.8 (Table 6).

a) Short supply of reagents

Majority (84%) of laboratory practitioners indicated that most of the times reagents are in short supply (Table 5). The reason might be due to inadequate funding, poor procurement procedures and pilferage of reagents by health personnel and sell in the private sector in order to survive remuneration hardships.

C) Most Frequent Technical Barriers to Human Re-
sources
The responses of participants to questions on frequency of barriers to HRH barriers had a mean frequency of 2, standard error of 0.2 with a standard deviation of 2 (Table 6).

a) Work overloads
Majority (70%) of participants reported that work overloads figured prominently on the human resources barriers (Table 5). This might be due to high turnover levels of laboratory practitioners in the public and faith based hospitals. Shortage of HCP might be contributed to by lack of recruitment of staff into the health system, and low output levels by training institutions in Malawi to a certain extent. Migration of HCP to developed countries, in search for greener pastures, might also contribute to short falls of laboratory workers in Mzuzu.

D) Most Frequent Administrative Barriers
a) Limited budget allocation to the MoH
Majority (67%) reported that budget allocated to MoH was inadequate to carter for day to day running of public health institutions (Table 4). Inadequate funding might make it difficult for health systems to procure medical supplies and diagnostics become a problem. Embezzlement of public funds by those in authority, including politicians, might exacerbate the barrier.

How Laboratory Professionals Overcome Technical Barriers to Diagnosis
A) Overcoming Equipment Barriers
The responses of participants to questions on overcoming equipment barriers had a mean absolute count of 4, standard error of 0.3 with a standard deviation of 1 (Table 7).

a) Maintain the equipment
Majority (38%) reported that in case of equipment failure, they would wait for maintenance of equipment (Figure 1). “We maintain the equipment when the fault is in our capacity. But when we cannot handle it, we call and wait until an international contract service engineer comes”, reported participant 08. The time intervals with which the equipment would be maintained was variable. Majority of participants (43%) reported that it would take some days to maintain the equipment and two other categories of participants (19% in each category), reported that it took weeks and months respectively before the equipment would get repaired (Figure 2).

According to this study, 100% of laboratory practitioners indicated that the equipment was being repaired by international contract service engineers in case of major faults (Table 8). International contract engineers do not work in Malawi alone. In this case, laboratory practitioners waited for weeks and sometimes months before the equipment got repaired. This meant that tests that required use of equipment that was out of order would remain unperformed. Treatment would be affected as it may be based on presumptive diagnoses, hence accelerating mortality and morbidity rates to a great extent.

b) Stop tests altogether
Some participants (19%) reported that they would altogether stop tests with the faulty equipment (Figure 1). Probably, patients would be sent back to clinicians without results that would guide evidence based therapy.

c) Improvise on faulty equipment
Other participants (13%) indicated that they would improvise on faulty equipment and keep on performing tests. Improvising on equipment might be possible if the equipment has a minor fault. But the test results, from the faulty equipment, might not be effective to influence proper treatment hence high mortality and morbidity rates.

B) Overcoming Reagents’ Barriers
Participants’ responses to overcoming reagents’ barriers had a mean absolute count of 2, standard error of 0.2 with a standard deviation of 2 (Table 7).

a) Stop tests altogether
Majority (44%) of laboratory personnel indicated that they would stop certain tests when reagents got out of stock (Figure 2). This might mean that some patients would not access laboratory confirmation hence would be given treatment based on empiricism. And there might be a high likelihood of mistreating patients and wastage medical resources.

b) Getting reagents from other hospitals
Public and faith based hospitals would share reagents when one stock outs. 31% of participants (indicated as others in Figure 2), from public and faith based laboratories, specified that sometimes they would get reagents from other related hospitals when they had run out of reagents. “Sometimes we go to Mzimba District Hospital to get reagents for viral load monitoring but sometimes we find difficulties to travel because we do not have enough fuel”, participant 011 from MCH specified.

C) Overcoming Laboratory Hrh Barriers
The responses of participants to questions on overcoming barriers to laboratory HRH barriers had a mean absolute count of 3, standard error of 0.1 with a standard deviation of 1 (Table 7).

a) Delegating work to lower level cadres
Due to work overloads in the public and mission hos-
pitals, majority (31%) reported that they were delegating some work to lower level practitioners in the laboratory (Figure 3). A study by Muula and Maseko (19) corroborates finding of this study and states that lower level cadres might find themselves delegated enormous responsibilities some of which would not reflect their training capabilities. This might be seen as a drawback in delivery of quality services and would negatively affect quality of disease diagnosis.

b) Stop performing other tests

It was found that 25% of laboratory practitioners reported that they would stop performing other tests, in case clinicians ordered for multiple tests in order to save time and attend to all patients (Figure 3). Some tests that are ordered by clinicians might not help improve condition of the patient. So based on clinical history of the patient, laboratory personnel would skip tests that would likely be unhelpful. In so doing, they would concentrate on and perform important tests, which they feel would influence better patient treatment. In this case, time would be saved so as to attend to almost all patients on a long waiting queue, overcoming a work overload barrier.

Analytical Quality Assurance Measures in the Laboratories

As seen in Table 9 routinely repeating sample assays was reported as rare and in some laboratories never done. Almost none of the laboratories routinely performed triplicate assays. Standardized kits were reported to be frequently used by 91% of the respondents. Control samples were used regularly. In all categories of laboratories, inter laboratory trials were rare.

Conclusion

In conclusion, the aim of this study was to identify barriers affecting laboratory diagnostic service delivery. The found technical and administrative barriers to laboratory diagnostic service delivery as per the objective. Technical barriers included frequent equipment failure, inadequate laboratory supplies, work overloads, lack of equipment refresher training and many others. Administrative barriers included limited budget allocation to public and faith based hospitals, inadequate supervision to laboratory staff and poor utilisation of research results. This study also found that the most frequent technical barriers were frequent equipment failure, lack of equipment refresher training, work overloads, inadequate laboratory supplies and others. The most frequent administrative barrier was limited budget allocation to the MoH. The study also found that laboratory practitioners employed some countermeasures to overcome technical barriers that were identified. Such countermeasures were to improvise on faulty equipment and expired reagents, stop testing until the equipment is repaired, delegating work to lower level cadres in case of work overloads and many others. It was also discovered that some findings applied to all the three categories of laboratory systems thus in public, private and faith based health systems where as others applied to specific health systems.

Recommendations

The following recommendations were made:
- Strengthen human resources planning for laboratory professionals and ensure that this neglected cadre becomes an integral part of broader human resources planning at country level which will assist MoH to progressively address shortages and skills gaps.
- Establish or strengthen national laboratory regulatory and representative bodies to improve governance and enhance quality. Proper regulation of laboratory services through activities such as setting and supervising laboratory standards and standardizing and regulating pre- and in-service training will help improve morale and the quality of services. Representative bodies need to be better organized to effectively represent the interests of laboratory professionals and allow them greater voice in the system.
- Promote work and competency based in-service training to ensure that staff skills are up to date and competency is demonstrated. Strategies such as work place based mentorships, e-learning, flexible working hours, and rotational deployment should be used to promote training opportunities.

Areas of Further Studies

The aim of this study was to assess barriers to laboratory diagnostic delivery in Mzuzu city. However, further research needs to be conducted to better understand laboratory healthcare situation in Malawi. These areas include:
- Scale up research on issues related to laboratory workers to inform public policy. Research is needed to better understand the specific labour market situations in different countries and the factors which influence the supply and demand for laboratory cadres as well as the combination of policies and practices which will improve performance of laboratory workers and of public health laboratories.
- Conduct a large-scale study to assess challenges affecting laboratory medicine in Malawi. This is crucial if
the national efforts are employed to uplift laboratory medicine in our country.

**DEFINITION OF TERMS**

Clinical Laboratory: A facility used for examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings. Barrier: Any condition that makes it difficult to make progress or to achieve an objective; Quality assurance: Quality systems that include non-operational functions involving statistical process control; Quality control: Laboratory self-inspection using planning, statistics and process performance data.

**ACKNOWLEDGEMENTS**

I thank God Almighty for everything, He is the reason I am this far. My sincere gratitude goes to my supervisor, Mr. A.S. Mwenifumbo, for exceptional mentorship, motivation, and encouragement, with respect to the writing of this dissertation. I also wish to thank Dr. J. Kaunda and Dr. J. Affone of Mzuzu University for tireless guidance and synergy in the production of this dissertation. Thanks also go to the entire Mzuzu University Biomedical Sciences Department team for the research knowledge and immeasurable expertise rendered to me during the four years period at Mzuzu University. Just to name a few, Mr Pizga Kumwenda, Dr. T. Salim, Dr. M. Ngwira, Hsin-yi Lee and Mr. F. Dambula. God bless you all.

I acknowledge Research Ethics Committees from Mzuzu Central Hospital, Ekwendeni Mission Hospital and MASM-MEDI Clinic for authorising this research to be conducted in these health facilities. I also wish to express my gratitude to all laboratory staff members and administrators in all the three institutions for participating in this study. I am grateful to them for their time in this regard.

I also acknowledge Luke International for partly funding this research project during the data collection process.

Special thanks go to my parents and relatives who assisted in any way to add value to this work even by providing mental, emotional, physical, financial and spiritual support. Your help is greatly appreciated. Many thanks should go to my brothers and sister, Thomas, Owen, Stevie and Eveless for kindness and support. All classmates and friends at Mzuzu University made my stay away from home lively. I do not take this for granted. God bless you all.

Most importantly, I thank my uncle, Mr Patrick Mkwezalamba, for educating me, his unconditional support and encouragement to pursue my career, his trust in me and for being my backbone in my life.

Finally, sincere gratitude goes to my wife and daughter, Elita and Fionley respectively. Your love and patience was a fountain of encouragement in the accomplishment of this project. God bless you.

**ABBREVIATIONS**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ASCLS</td>
<td>American Society for Clinical Laboratory Scientists</td>
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<tr>
<td>CDC</td>
<td>Centre for Disease Control and Prevention</td>
</tr>
<tr>
<td>DLS</td>
<td>Division of Laboratory Systems</td>
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<td>EHRP</td>
<td>Emergency Human Resources Programme</td>
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<td>EHP</td>
<td>Essential Healthcare Package</td>
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<td>EMH</td>
<td>Ekwendeni Mission Hospital</td>
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<td>HCP</td>
<td>Health Care Provider</td>
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<td>HRH</td>
<td>Human Resources for Health</td>
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<td>MASM</td>
<td>Medical Aid Society of Malawi</td>
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<td>MoH</td>
<td>Ministry of Health</td>
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<tr>
<td>MCH</td>
<td>Mzuzu Central Hospital</td>
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<tr>
<td>UNMDGs</td>
<td>United Nations Millennium Development Goals</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organisation</td>
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</table>

**REFERENCES**

12. Graber ML. *The Incidence of Diagnostic Error in Medicine.* Open


APPENDIX 1: APPROVAL LETTER FROM BIOMEDICAL SCIENCES DEPARTMENT

MZUZU UNIVERSITY

FACULTY OF HEALTH SCIENCES
DEPARTMENT OF BIOMEDICAL SCIENCES

5th June, 2017

To whom it may concern,

RE: ROBERT CHIDZAYE

I refer to you Robert Chidzaye who is a level four Bachelor of Science in Biomedical Sciences degree program student at Mzuzu University. As one of the requirements for successfully completing the course, a student is required to undertake a research project. The student has shown interest in the area expressed by his/her research proposal which has been submitted to you. I kindly ask your office to support our student conduct his/her research at your facility.

Yours faithfully,

DR THOMAS SALIMU
HEAD OF DEPARTMENT, DEPARTMENT OF BIOMEDICAL SCIENCES
APPENDIX 2: REVIEW REPORT (RESEARCH COMMITTEE)

MZUZU UNIVERSITY
FACULTY OF HEALTH SCIENCES
Research Committee
fohs.rc@mzuni.ac.mw, fohs.researchcommittee@gmail.com
+265111401932
Number: Fhsrc/17/0017
Student Research Proposal Review Report

Name: Robert Chidzaye
Date: 3rd June, 2017

The committee after a thorough ethical review of your Research Proposal approves your research study with the Title: Assessing Barriers to Medical Laboratory Diagnostic Service Delivery in Mzuzu City using the Approach: Quantitative Design: Cross Sectional With sample size of 32 Laboratory Scientists, recruited through: Stratified Random Sampling.

We expect that your research procedure will stick to the standards as stipulated in your proposal.

Dr. J.C Afonne
Ms. T Phiri
For the Committee

Chairman-Dr. J.C Afonne    Secretary-Ms. T Phiri
APPENDIX 3: INFORMED CONSENT FORM

Hello. My name is Robert W. Chidzaye, a student at Mzuzu University and I’m conducting a study to assess barriers to medical laboratory diagnostic service delivery at this hospital. This is in partial fulfilment for the award of a Bachelor of Science degree in Biomedical Sciences. The study is intended to give an in-depth assessment of barriers to laboratory medicine and will give a comprehensive approach on how to solve such barriers, with an emphasis on making laboratory services a higher priority in disease diagnosis and monitoring. You have been chosen to participate in this study because you have an experience on the situation of laboratory services delivery at this hospital.

I would like to assure you that all your responses to the questions will be treated with high confidentiality throughout the study process using the coding system that will be managed by the researcher. After data analysis and writing of the final dissertation, your personal identifiers will be removed to ensure anonymity. You have the full right to refuse, withdraw or completely reject participation in the study. But your participation is of great importance as the answers you give on this form are very essential to addressing challenges to quality laboratory medicine. Do you correctly understand the information? If you have questions or need more information on this study, contact the researcher on 0882736798/0993767139. You can also write the researcher on these addresses: Mzuzu University, Private Bag 201, Luwinga, Mzuzu 2 or chidzayerobert@gmail.com.

Participant Code #: ……………….

PARTICIPANT DECLARATION

I have read/understand the information above and clearly understood the purpose and anticipated benefit of the research. I hereby assure with my signature below that without being coerced by the researcher in any way, have decided to voluntarily participate in the study.

Participant’s Signature: ………………….
Date: …………………………………
Your cooperation is highly appreciated.
APPENDIX 4: PERMISSION LETTER (MZUZU CENTRAL HOSPITAL)

Telephone: 01 320 916 / 878
Fax: 320223/320973/270
directormch@malawi.net

Robert W Chidzaye
Mzuzu University
P/Bag 201
Mzuzu 2

In reply please quote No...............................
The Hospital Director,
Mzuzu Central Hospital,
Private Bag 209,
Luwinga,
Mzuzu 2.
15th June, 2017.

Dear Sir,

REQUEST FOR PERMISSION TO CONDUCT A RESEARCH STUDY AT MZUZU CENTRAL HOSPITAL

Refer to your letter dated 12th June 2017, in which you requested for permission to carry out a study at Mzuzu Central hospital titled “Assessing Barriers to Medical Laboratory Diagnostic Service Delivery in Mzuzu City”.

I am pleased to inform you that permission has been granted. You will be required to present this copy to the in-charge of the wardor department you have selected before you can start your data collection.

Wishing you nice studies.

Yours sincerely,

BK Nyirenda.

For: THE HOSPITAL DIRECTOR
APPENDIX 5: PERMISSION LETTER (EKWENDENI MISSION HOSPITAL)

From: The Human Resource Management Officer
To: Robert Chidzaye
Date: 13th July, 2017

Subject: Permission to conduct a study at Ekwendeni Mission Hospital

I hereby refer to a letter from Mzuzu University dated 27th June, 2017.

This letter serves to grant you permission to conduct your study at our Hospital on a topic; Assessing Barriers to Medical Laboratory Diagnostic Service Delivery in Mzuzu City.

It is our hope that you will conduct yourself professionally throughout the study and that this study will contribute positively towards your career path.

Regards,

Joyce Nyirenda Gondwe
Human Resource Management Officer
For and on Behalf of the Chief Medical Officer in Charge
Ekwendeni Mission Hospital
APPENDIX 6: PERMISSION LETTER (MASM-MEDI CLINIC)

Masm Medi Clinic
P.O Box 973
Mzuzu
Date: 17.07.2017

RE: APPROVAL TO CONDUCT A RESEARCH AT THIS INSTITUTION

This is to certify that Mr Robert Chidzayi has conducted his research here at Masm Medi Clinic Katoto under the topic TO ACCESS BARRIERS TO MEDICAL LABORATORY DIAGNOSTIC SERVICE DELIVERY.

We hope this is in order.

Best Regards

Dr I Gasiga
Medical Officer In Charge
P.O.Box 30361
Lilongwe.