**UNIVERSITY OF WITWATERSRAND**


**FACULTY OF HEALTH SCIENCES**

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# An exploration of organizational readiness for scaling up the use of Urine LAM tests in high TB burden districts and peripheral health facilities in Malawi.

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## Declaration

I **John Maseko Zondetsa,** student number **2215124** declare that this Research Report is my own, unaided work. It is being submitted for the MSc in Epidemiology at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.

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## Abstract

**Background:** The use of the Urine Lipoarabinomannan (LAM) test was endorsed by the World Health Organization in 2015 and it has been recommended for use in people Living With HIV. Malawi is in the process of scaling up the use of LAM urine tests in low Tuberculosis (TB) burden districts and peripheral health facilities. The scaling up of health interventions has received greater attention; however, there remains a lack of systematic exploration of organizational readiness that is deemed necessary for the scaling-up process. We aim to explore factors associated with organizational readiness for scaling up the LAM tests in high TB burden districts in Malawi

**Methods:** A narrative (in-depth) qualitative study was conducted at the Ministry of Health (MoH) department of HIV and TB, and in seven high TB burden districts. The study used a purposive sampling technique to enroll participants and enrolled twenty-eight participants who were overseeing TB and HIVAIDS programs as aimed to concentrate on participants with the precise information on TB and HIV programs, and readiness scale-up LAM urine tests. Thematic data analysis for qualitative data was conducted using MAXQDA software

**Results:** The study conducted Key Informants Interviews (KII) with participants who had a wide range of expertise in HIV and TB. Twenty-eight participants (comprising of twenty-four males and four female participants, four participants from implementing partners (Non-Governmental Organizations) and twenty-four civil servants, two participants working at the Department of HIV/AIDS(DHA) and National TB Control Program (NTP), five participants from health facilities, and four participants from central referral hospitals and seventeen from the district hospitals). The study demonstrated that the MoH has done quite a remarkable work in preparing for the scaling up of the LAM urine tests. There is various extent of organizational readiness ranging from facility to facility as some facilities have all the necessities for scaling up the LAM urine tests while some facilities are still lagging. The MoH through the DHA and NTP has taken remarkable steps in policy and guidelines formulation and dissemination, capacity building, routinizing the LAM tests in the point of care tests, and stakeholder engagement, and these have created a favorable environment for the readiness of the facilities and enable the scaling-up process to be smooth and well-coordinated.

**Conclusion:**

There are varying levels of organizational readiness for scaling up the use of LAM urine tests due to several factors including lack of or inadequate capacity building activities, lack of support from implementing partners, availability of LAM test kits, as well as dissemination of policies and guidelines. The MoH should consider

addressing factors related to the graded differences in readiness for scaling up the LAM tests by conducting periodic supportive supervision and refresher training, systematically analyzing the health systems strengths and weaknesses that will strengthen the institutional capacity, strengthen the monitoring and evaluation system, as well as continuing constant collaboration with key stakeholders. Further research studies are essential to evaluate the coverage and effectiveness of strategies to scale up and sustain the use of LAM tests for TB diagnosis.

Keywords: Implementation, Organizational Readiness, Scaling up, LAM urine tests, TB

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## List of Figures

## List of Acronyms

| | |
|---|---|
| ART | Anti-Retroviral Therapy |
| DHA | Department of HIV and AIDS |
| DHO | District Health Office |
| EGPAF | Elizabeth Glaser Pediatric AIDS Foundation |
| HIS | Health Information System |
| HTS | HIV testing Services |
| KIIs | Key informant interviews |
| LAM | Lipoarabinomannan |
| MoH | Ministry of Health |
| MSF | Médecins Sans Frontiers |
| NGO | Non-Governmental Organization |
| NTP | National TB Control Program |
| PEPFAR | U.S. President's Emergency Plan for AIDS Relief |
| PLWH | People Living with HIV |
| PIH | Partners in Hope |
| SOP | Standard operating procedures |
| TAG | Treatment Action Group |
| TB | Tuberculosis |
| USAID | United States Agency for International Development |
| WHO | World Health Organization |

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## 1.0 Chapter One: Introduction

This chapter is an introduction to the study, it briefly presents the background information on LAM urine and its usage, introduces the problem statement, the rationale and significance of the study, the research topic, the research question, as well as the objectives.

### 1.1 Background

Tuberculosis (TB) is the prominent cause of death among people living with HIV (PLWH)(1). The mortality from TB remains high among PLHIV with nearly half a million cases(1). In resource-limited settings, it has never been easy to diagnose TB, especially in places without widespread health care access. TB diagnosis is difficult in resource-constrained countries due to the lack of diagnostic tools(2). In Malawi, which is a resource-limited country, sputum microscopy has been used as a primary diagnosis. An improved molecular diagnostic test, the Gene Xpert, has good sensitivity and excellent specificity. GeneXpert has been introduced but remains not widely available across the country(3).

Another challenge in TB diagnosis is that Gene Xpert and sputum microscopy tests require sputum as a sample which is difficult to produce especially in very ill HIV patients. In addition, the bacterial burden is low which results in diagnostic test sensitivities that are lower than in HIV- uninfected people(4). There have also been issues reported in terms of transferring sputum samples from peripheral health facilities to district facilities that have the capacity for the Gene Xpert machines. This has resulted in a long turnaround time (TAT) and missing samples or results which in the end delays the TB diagnosis and treatment initiation. As a result, clinicians in these settings mainly depend on clinical judgment to make a diagnosis.

The emergence of easier to use, point-of-care tests using urine to detect TB has been a welcome idea in TB diagnosis algorithms (2,5). Lipoarabinomannan (LAM) is a lipopolysaccharide component found in the mycobacterial cell wall and can be detected in urine(6). LAM tests with a sensitivity of 45% and specificity of 92% (7) have demonstrated a substantial reduction in mortality among very ill HIV patients who have immediately initiated treatment after a LAM positive result(8,9). Several health facilities in Malawi have no access to CD count testing machines which have recently posed a challenge in the implementation of LAM tests, as LAM sensitivity is higher in patients with a CD4 count of less than 200cell/mL(10).

The World Health Organization (WHO) recommendation on CD count was probably based on the assumption that CD4 testing is a readily available machine when in fact it has been far from certain as many resources limited

contexts are still struggling with limited and inconsistent access to the CD4 testing. The use of the Urine LAM test was endorsed by the WHO in 2015 and it has been recommended for use in PLHIV(11). For inpatients settings, WHO specifically recommends LAM tests in all HIV inpatients regardless of CD4 count as they are presumed to have more advanced disease and this recommendation allows implementation of LAM tests even in other settings which have no access to CD4 testing machines(12).

Scaling up a health intervention is considered the process of expanding the coverage(13,14). With the WHO's recommendation of scaling up urine LAM tests (6), Malawi is in the process to scale up and implement the use of urine LAM tests in selected health facilities, mainly district hospitals, and selected peripheral community hospitals will start (or continue to implement for those already started) implementing urine LAM tests.

Organizational readiness is a multifaceted concept that is related to organizational or activity planning and workplace environment and as a systematic analysis of the ability and capacity of the health system to either implement or scale up an intervention. (14–17). Several studies(19–22) have reported limited success with organizational change and implementation readiness in health care intervention. Failure to implement a scaling-up process of intervention is mainly attributed to the institution's insufficient readiness.

Assessment of organizational readiness for change is a critical precursor to the successful implementation of the scaling up of the health programs(19). It is important to assess organizational readiness for change before the actual scaling u process of the intervention. An organizational readiness assessment is crucial for long-term project success as it helps in the identification of the abilities within the health system to implement a project and helps in the identification of potential challenges which might arise in the project implementation process. This also affords the platform to bridge the gaps and navigate the challenges before implementing the scaling up health intervention

## 1.2 Problem Statement

Several countries have adopted the WHO recommendation and policies on the TB diagnosis, and despite these recommendations and evidence of great impact in using urine LAM tests, the Médecins Sans Frontiers (MSF), Stop TB survey report(23), and the 2017 Treatment Action Group (TAG) report(24) revealed that many countries have still not adopted the tests in their national policies. Several countries are still lagging in adopting and implementing these guidelines, the rollout and update of the LAM urine test have been slow, and countries have

not articulated plans to scale up the use of the test(25), this is a diagnostic gap that must be addressed to achieve the End TB strategies to end TB by the year 2030(26).

In Malawi, TB diagnostic tools are chest X-rays and sputum tests (GeneXpert and microscopy smear tests) and are mainly done in central and district hospitals, and a few peripheral community hospitals. The Ministry of Health (MoH) has updated the national HIV and TB care and treatment guidelines, and the urine LAM tests have been added to the TB diagnosis algorithm to routinely test children older than 5 years and adults with signs of advanced HIV (28). The MoH is planning to implement scale-up programs in district hospitals and selected peripheral community hospitals. However, the degree of the health systems' readiness to the scaling up the use of the tests is unknown. There has been not enough available information on the organizational readiness of the health facilities to implement the LAM urine tests as a TB diagnostic.

1.3 Justification

The Urine LAM test presents a clear path to making a substantial impact on public health and enabling global TB control in peripheral health facilities(27,28). With the promising signs of Malawi's responsiveness to the new references and the scaling up of the urine LAM as a national policy and practice, there are still implementation gaps to fully adopt and translate the evidence into practice and prepare the health facilities to start using urine LAM in TB diagnostic(25). Since many of the peripheral community hospitals in high TB burden districts cannot perform chest X-ray and sputum Gene X-pert tests(29), scaling up and introducing the urine LAM presents a clear path that can improve the diagnostic and management of TB in districts and peripheral health facilities, and this, in turn, will help to reduce the congestion referral hospitals for TB care and management are facing.

The Ministry of Health seeks to scale up the use of the urine LAM tests, but if health facilities do not have the capacity for implementation of the scaling up plans, then this program might be a failure. It is necessary to determine the readiness of our health facility in the implementation of the urine LAM tests. The Ministry of Health must optimize all necessary key attributes that are deemed as requirements to successfully implement and scale up the use of urine LAM tests in the district and peripheral community hospitals. These key attributes may include the human resource and testing reagents availability, policy and guidelines availability, infrastructure, and knowledge capacity of clinician ability to identify HIV advanced diseased patients. Understanding the link between organizational readiness and scaling up the use of LAM urine tests at the microlevel which is at the organizational (district and community health facilities) and macro-level (NTP and DHA) will present a platform where baseline

information will be generated to assist the Ministry of Health in planning to implement the scaling up of urine LAM testing programs.

## 1.4 Research question

What are the factors associated with organizational readiness for scaling up the use of urine LAM tests in high TB burden TB districts and peripheral health facilities in Malawi?

## 1.5 Study Aim

The study aims to explore factors associated with organizational readiness for scaling up urine LAM tests in high TB burden districts in Malawi

## 1.6 Objectives

- To explore the levels of organizational readiness for scaling up the use of urine LAM tests in TB diagnosis in high TB burden districts in Malawi.
- To explore the aspects of organizational readiness that determines scaling up of urine LAM test in high TB burden districts in Malawi

## 1.7 Literature Review

The literature review section in this chapter discusses previous research studies that have been done regarding LAM urine tests. The section discusses the coverage and use of LAM urine tests, the TAT of LAM urine tests results, the feasibility of using and scaling up LAM urine tests in limited-resource settings, the implementation contributors to urine LAM scale-up, the levels of scale-up of urine LAM tests, the cost-effectiveness of using LAM urine tests, the simplicity of using LAM urine tests and the organizational readiness necessary to implement a new intervention.

### 1.7.1 Coverage, use of LAM urine test, and implementation contributors

A status update paper that was done in 2019 explored the use of Point of Care urine LAM tests in TB diagnosis. The paper highlighted some key issues surrounding the contributors to slow uptake to implement the use of urine LAM tests and presented key considerations in the scaling up of the urine LAM tests(30). Despite the WHO recommendation and the availability of funding platforms from the Global Fund and PEPFAR, the rollout, and uptake of the urine LAM tests have generally been slow in several countries(23). The slow implementation and scale of the urine LAM tests have been due to several contributing factors including the conditional WHO

recommendations and the poor coordination between the National TB programs and HIV programs, mostly in low-income countries(23,24).

The coverage and uptake of urine LAM tests have been broadened in some countries mainly by the involvement of advocacy groups, for instance, the Treatment Action Group (TAG)(24) and the inclusion of Alere LAM to the WHO essential diagnostic list. Inclusion in Global Drug Facility TB diagnostic has been a boost to the coverage and uptake of the urine LAM tests. The policies and stakeholder support at the global level have provided the much-needed support to increase the use of urine LAM in several countries(24) Considering the impact of urine LAM in clinic-based TB detection and public health, scaling up the use of urine LAM tests should be prioritized.

MSF(29) also conducted a cross-sectional study that highlighted key urine LAM implementation challenges which included a lack of urine LAM testing guidelines and protocols. Regardless of the WHO recommendations(6) on the use of urine LAM and the evidence from several studies demonstrating that urine LAM reduces the mortality in PLWH(9), the composite of several evaluation studies to date confirms that the utilization of urine LAM tests is still low in several countries with high TB/HIV burden(3,6,)

1.7.2 Turnaround time and feasibility of using urine LAM test in resource-limited settings

A cross-sectional study was conducted in DR Congo, Mozambique, and Malawi by MSF in 2016 and 2017 with the purpose to determine the feasibility of using the urine LAM test to diagnose TB in PLWH in resource-limited areas(29). This was the first study to be conducted in a resource-limited setting under programmatic conditions to assess the feasibility of urine LAM test implementation. The urine LAM test had a shorter turnaround time as compared to other tests in TB diagnostics, suggesting that the urine LAM test can be used as a diagnostic test in peripheral hospitals and resource-limited settings to enhance the diagnosis of TB.

It was also found that the test can even be done in a consultation room or bedside, tests were easy to perform, and there are no special skills and qualifications to perform the tests presenting an advantage to the sputum-based diagnostic tests that required a district laboratory. The urine tests were an ideal test in PLWH and in peripheral facilities which normally have limited diagnostic resources like Gene Xpert and Chest x-ray.

Two other studies(31,32) demonstrated similar findings in reducing the turnaround time and suitability of urine LAM tests in limited-resource settings. The microsimulation model study(32) further stated that if countries would

scale up urine LAM tests, it will help to decrease the TB burden mortality among PLWH with modest budget impacts and the economic efficiency of countries.

1.7.3 Cost-effectiveness of urine LAM tests in TB diagnosis algorithm

A STAMP Trial study used a microsimulation model to estimate the cost-effectiveness of including urine LAM test in the TB screening in hospitalized patients(32). The study demonstrated evidence that providing urine LAM tests to hospitalized HIV patients increases life expectancy and is cost-effective, especially in low-setting areas. A prospective cohort study also demonstrated the cost-effectiveness of including urine LAM test in the TB algorithm (31). This STAMP trial(32) reported that due to the high incremental yield and low additional cost compared with sputum-based diagnostic tests, urine LAM was more cost-effective compared to using sputum-based tests (GeneXpert and smear tests) alone. This in turn provides substantial evidence to support scaling up the use of the urine LAM test in HIV hospitalized patients in resource-limited settings with TB and HIV burden

Several studies have provided enough evidence to support the change in policy and guidelines to motivate the inclusion of the urine LAM test in TB screening and diagnosis, and that the urine LAM test needs to be implemented and included in TB screening to accelerate strategies to achieve the End TB Strategy targets of reducing TB mortality by 75% by 2025(11,33). Implementation and scaling up of the use of urine LAM tests in resource-limited settings would then be feasible if the tests have proven to be cost-effective, demands less complicated machine and a human capacity, and it is feasible for use in resource-limited settings. It is then necessary to determine how ready the health facilities are to accommodate the change and coming of urine Lam tests in the TB diagnosis

The inclusion of urine LAM in the Malawi TB diagnosis algorithm will provide a substantial positive impact on TB cases and treatment as it will enable and facilitate TB diagnosis and early treatment initiation(25). Considering the MoH plans of scaling up the urine LAM test, several peripheral hospitals cannot perform chest Xray and GeneXpert tests (29), scaling up the use of urine LAM is ideal in these limited resource health facilities. These health facilities may not have the full capacity for implementation of the scaling up the urine LAM tests. Assessing the organizational readiness (the capacity and ability of our health facilities to effectively accommodate the implementation and scaling up of the urine LAM tests) and the feasibility of scaling up urine LAM tests will then help the implementing agencies (Ministry of Health, District Health Offices, and other implementing NGOs) in planning health programs and best practices to navigate the implementation challenges to the scaling up on the urine LAM tests.

1.7.4 The simplicity of health intervention

An article which was written by Gavin Yamey(14) discussed several success factors that are associated with the intervention scaling up process including the attitude of the implementers, the chosen delivery strategy, the socio-political context, the attributes of the specific service being scaled up (simplicity), and the research context. The simplicity of an intervention being scaled up has been one of the attributes associated with successful scale-up(34–36), particularly if there are no nonconforming views against it.

The principles and practices of delivering the intervention in a technically simple manner were also considered a predictor in a study which was done in Malawi which looked at the rapid and massive scale-up of ART (12). An article by the World Bank that explored the scaling up of rural development interventions observed that strong efforts at simplifying the program's modality were associated with a successful scaling-up process(36)

1.7.5 Attributes associated with intervention Scaling up.

Several factors have emerged to have an impact on organizational readiness and scaling up of an intervention, and these factors range from policy, political will, and government commitment as well as stakeholders' engagement. There is a need to consider these key attributes that hinder or enable effective scale-up of a health intervention.

i. Institutional capacity, national policies, government commitment, and political will

A study which was done in Malawi investigated the scaling up of HIVAIDS services(31) and a study was conducted in Sub-Saharan Africa and China(37), and an analytical report which was produced by USAID in 2015(38) reported similar findings on barriers and facilitators for program implementation and scaling up processes. These two studies and the report found that institutional capacity, the strong commitment of the government health departments, and the availability of constructive policies have been key attributes to successfully implementing and scaling up a health intervention.

In almost all processes of scaling up health interventions, the key attributes for successful scaling up programs are mostly multiple and interconnected(38). These studies(31,37) further stated that the institutional capacity and government commitment being key attributes play a central part in effective program implementation and scaling up. Successful scaling up depends on the institutional structures which include the high capacity for strategic program management and implementation, sustainable financial resources, and leadership capacity.

These key attributes plus the availability of favorable policies must be considered in all essences as far as successful program implementation and scaling up is concerned. In addition to the financial resources and leadership capacity as elements of institutional capacity, skilled technical and managerial, and motivated human resources, and a good

health care service delivery system plays a central part in influencing the success rate of scaling up and implementing a health program(37)

National, regional, and local policies and guidelines have been referred to as important factors in the successful scale-up of any intervention. Countries with policy have high chances of making greater strides in succeeding when scaling up an intervention(39,40). District facilities have made great strides in terms of LAM tests due to the availability of national policies and the guidelines that have been made available in each health facility. The availability of the guidelines set a pace and a reference point for implementing the LAM tests.

ii. Tailoring scale-up to the local situation, and decentralizing delivery of the intervention

Implementing Interventions that are tailored to local conditions on the ground and with a decentralized delivery system to the clinics closer to the target communities have the most likely chances of success when being scaled up. The intervention must be tailored to the existing systems and processes that are already on the ground. Lam urine tests in Malawi have been tailored and will be integrated into the ART and TB systems.

Several studies(41–43) have observed that a complementary theme on successful implementation is the value of integrating scale-up activities into the health systems. Using the already existing structures and systems presents a platform where the intervention is easily absorbed within the health system as this reduces the costs and the pressure for the implementing partners to either build new structures (data management systems, infrastructures) or to build the capacity of health workers from the scratch(44–46).

iii. Stakeholder Engagement.

Engagement with key stakeholders at all levels is another important element for a program to be scaled up successfully. The buy-in from key stakeholders and local stakeholders has proven to be key in the effective implementation of any scaling-up program. Key stakeholders play a role in steering the program implementation process as they bring in a diversity of technical skills and knowledge necessary for program implementation. Some key stakeholders don't necessarily bring any scientific value to the program but their involvement in the program influences the buy-in and acceptance from local implementers or the community(14)

Some studies (47,48) have argued that involving both governmental and non-governmental actors boost the success rate in scale-up in many settings. NGOs have a higher potential and capacity to reach out to more people with intervention than the government. NGOs are quicker to implement an intervention, and more motivated to get things done as they mainly chase deadlines and targets to meet.

## 1.8 Organizational Readiness

Organizational readiness has been considered a multi-level and multi-faceted important factor at an individual, departmental, or organizational level that is connected to the successful implementation of an intervention(17,49). Several studies have well defined organizational readiness and the associated constructs and have established that measuring how ready an organization is to implement a program determines successful implementation(17,49,50).

This study will adopt the concepts and constructs from a conceptual framework that was developed and used to implement a nutrition and physical activity program in early childhood education(51). Using the conceptual framework provides a platform to systematically identify factors that have the potential in influencing the effective implementation of urine LAM tests scaling up plans. This will also highlight key organizational readiness concepts that might need to be modified, mitigated, and promoted to implement the scaling-up plans effectively. This research study adopted the three factors of the framework for change, which include the structural and external factors, staff attributes, and psychological factors.

### 1.8.1 Structural and External Factors

These are system-level constructs that affect the day-to-day functions and operations of a program. Under this critical construct, several elements are outlined that determine the program operations(49,51,52).

1. Resources: This study assessed the availability of both human and financial resources and infrastructures necessary for effective urine LAM tests scaling up.
2. Policies: This study investigated the availability of national policies and hospital standard guidelines for use of urine LAM tests.
3. Capacity building training: The study assessed the capacity building needs for health workers that will help in the effective implementation of the urine LAM tests.
4. Communication: This study assessed how communication flows and what communication mechanisms are available in place to reach out to staff in health facilities in terms of the scaling up and implementation of urine LAM tests

### 1.8.2 Staff Attributes

These are constructs operationalized at both the organizational and individual levels.

1. Openness to change: this study assessed the overall attitude and willingness of the health workers to adopt and implement the urine LAM tests

2. Clarity of goals: the study assessed the perception of how the scaling up of the use of urine LAM tests fit in within the overall health facility. This is how well the facilities and staff perceive the advantage of using urine LAM tests, and what benefits will bring to them and the patients at large.
3. Self-efficacy: The study assessed the individual capacity and confidence to implement the urine LAM tests.

### 1.8.3 Psychological Factors

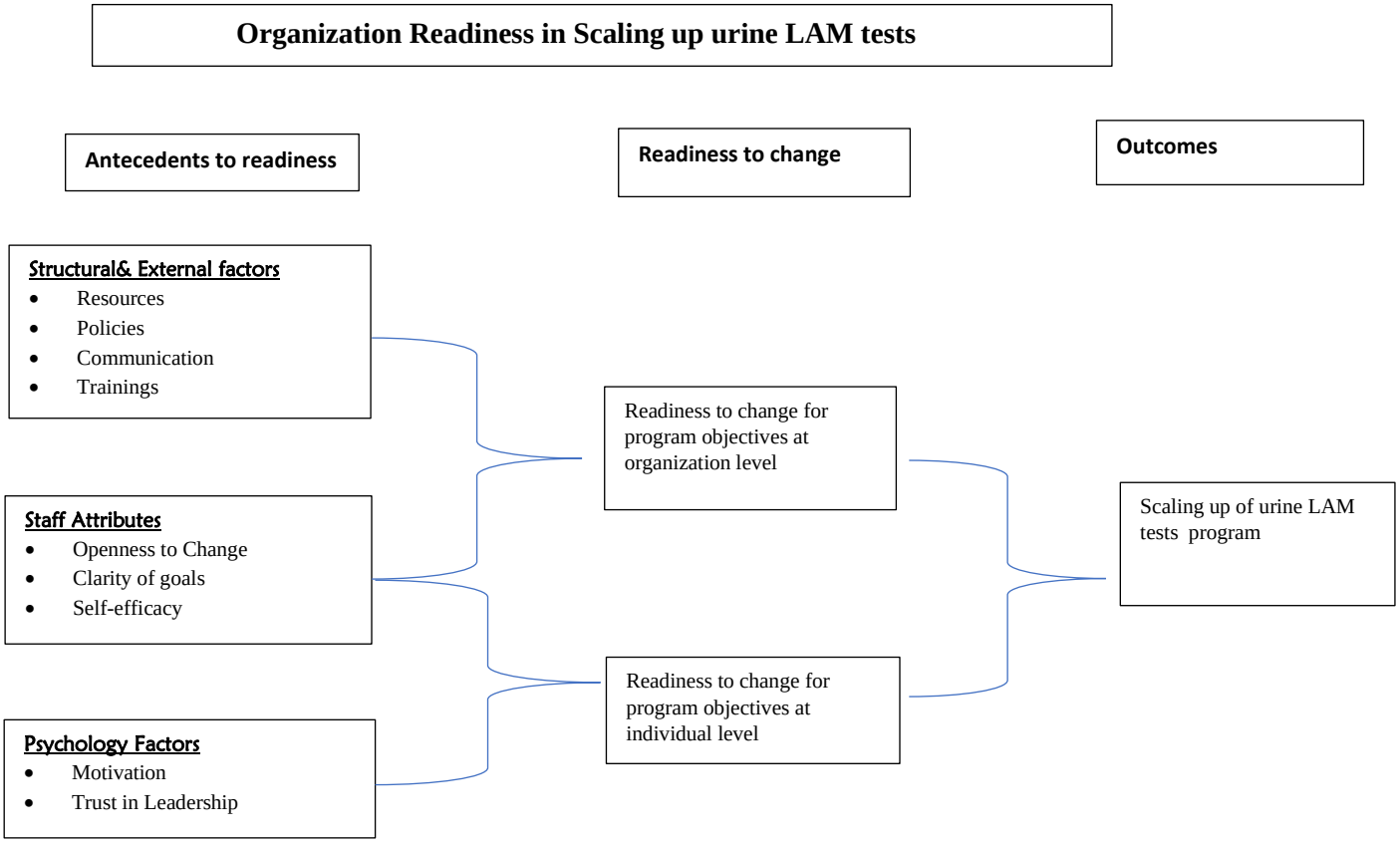
These are beliefs and attitudes that influence an individual to accept and support a change in an organization.

1. Motivation: this is a summative construct, and the study assessed the perception of the need, the value of scaling up and using the urine LAM tests, and the perceived availability of the time required for the workers to run the urine tests.
2. Trust in leadership: the study assessed the extent of sureness of workers in the decisions and actions taken by the leadership (NTP and DHA) to implement the urine LAM tests.

## 1.9 Conceptual Framework for Organizational Readiness

The conceptual framework for organizational readiness was adapted from a framework of Implementation of Nutrition and Physical Activity Programs in Early Childhood Education

Table 1: Conceptual Framework for Organization Readiness, Adapted from Sharma et al 2014 (51)



## 2.0 Chapter Two: Methodology

This chapter presents the methodology of the research study. The section has highlighted the study setting and study population, the sampling technique, and the data management plan for the study. This chapter also addresses the ethical considerations for the study.

### 2.1 Study Design

Narrative research uses several analytical practices within the social and health disciplines, and often implementing this narrative research involves studying individuals or gathering data through collecting or reporting individual or group experiences (53). A narrative (in-depth) qualitative study was conducted using key informant interviews (KIIs) and utilized an interview guide for semi-structured interviews in exploring the possible factors that are associated with the implementation and scaling up of the urine LAM tests. The organizational readiness was assessed using the KIIs guided questionnaire, and interviews were conducted in person (face to face interviews), a voice recorder was used during the interview.

### 2.2 Study Setting

Malawi has experienced gross urbanization and overcrowding in the past two decades and it has been estimated that half of all TB cases in Malawi are reported from these urban districts of Zomba, Lilongwe, and Blantyre where most of the Malawi population is found. These mentioned districts plus Nsanje, Chikwawa, and Mangochi have been regarded as some of the districts with high TB burden districts(54). The study was conducted at the national offices for TB Program (NTP) and the Department of HIV/AIDS (DHA) (located in Lilongwe district) and at the district level (seven TB/HIV burden districts) in Malawi: Karonga, Lilongwe, Mangochi, Nsanje, Blantyre, Zomba, and Chikwawa.

### 2.3 Study Population

Twenty-eight participants were involved in the study. These were key informants overseeing TB and HIVAIDS programs in the district hospital and MoH departments. Three participants were selected from each district (these were the TB coordinators, ART coordinators, and TB Clinician), two participants from the DHA and NTP, and five participants were selected from peripheral health facilities within the high TB burden districts. The key informant interviews (KIIs) were conducted in May 2021. For every uncertain response or comment, the study participants were contacted via emails and telephone calls.

## 2.4 Sampling

Purposive sampling design is typically used in qualitative research to identify and select information-rich participants for the utmost utilization of the available resources(55). The research study used a purposive sampling technique to enroll participants as we aimed to concentrate on participants who possessed the knowledge, experience, and proficiency regarding the topic of interest. Twenty-eight interviews were conducted, twenty-six across the districts and peripheral health facilities (participants included district TB officers, ART district coordinators, health centre clinicians, and laboratory technicians) and two at the national office (one oversight officer at DHA and one oversight officer at NTP). Three of those interviewed were affiliated with PEPFAR implementing partners. These participants were chosen as they were regarded as the suitable sample to have the best information on TB and HIVAIDS.

## 2.5 Data Collection

Qualitative data was collected through the KIIs. interviews were done within a period of four weeks (from April 2021 to May 2021). Questionnaires were used as a guide during the KIIs and the researcher conducted the interviews alone and there was no relationship between the researcher and the key informants. Each interview was approximately thirty minutes long. Two research assistants were contracted to assist in the transcription of the recordings. These assistants had prior experience and knowledge working on interview transcriptions and were only oriented to the study method and questionnaires so they get familiar with the study. Anonymization was observed as only the KIIs ID codes were used when naming the transcriptions and no names were used in any other settings.

Data folders were created for recordings and transcriptions which were only accessible by the researcher. A password-protected, encrypted laptop was used to keep the recordings and transcripts, and google drive was used as a backup of the recordings and the transcription. Data was secured as only the researcher had access.

## 2.6 Data Analysis

Data were cleaned before coding and analysis. Codebooks were set by the researcher and the coding was done by the researcher as well and major concepts were used as phrases in assigning codes for data structuring and labeling. Themes were identified for common responses and patterns that answer the research questions. The thematic data analysis and themes that emerged from constructs of the conceptual framework were used to analyze the data and MAXQDA as a qualitative analysis software package was used to analyze the themes/constructs.

2.7 Ethical considerations

This study involved human subjects through KIIs. All the essential information and a clear explanation of data collection methods, data usage, and results in the dissemination plan were given to all study participants. The study participants were fully informed of the study protocol as we aimed for voluntary participation and informed consent. Only ID codes were used and no names under any condition were used as one way of confidentiality and anonymity of the study participants. Research data was kept in a secure place and only the researcher had the access to the data. Ethical approval was obtained from Wits Ethical Committee in South Africa, a clearance certificate No: M210275, and the National Health Sciences Research Committee (NHSRC) in Malawi (Protocol #21/03/2667, and the Approval number of #2667)

## 3.0 Chapter Three: Results

This chapter presents the study findings using a conceptual framework that highlighted and systematically identified the key organizational readiness concepts that need modification or promotion to effectively implement the scaling up plans for urine LAM test for TB. The section also highlights the factors that have the potential to influence the organizational readiness for scale-up plans for urine LAM tests for TB diagnosis in Malawi.

KII was conducted from a wide range of officers with diverse knowledge and skills in TB and HIV, we managed to interview twenty-eight participants were four were female participants. Four participants out of the twenty-eight were from implementing partners who were working in supporting the districts in HIV and TB programs and twenty-four were civil servants. Two desk officers from DHA and NTP national officers were as well interviewed, five participants were working at health centers, four participants working at central referral hospitals, and seventeen participants from district hospitals. All these participants were directly working in TB and HIV clinical service delivery. Participants ranged from age 25 to 50 and held primarily tertiary qualifications (bachelor's degree qualifications, especially those working at district hospitals, central referral hospitals, and national officers). All these participants were health workers with medical qualification backgrounds.

Table 2: Characteristics of participants.

| | |
|---|---|
| Gender | 4 female participants |
| | 24 Male participants |
| Organizations | 4 participants from implementing partners |
| | 24 civil servants |
| Civil servants (Health workers) | 2 participants from the national level |
| | 5 participants from the health centre level |
| | 4 participants from central referral hospitals |
| | 17 participants from the district hospital level |
| Age | Participants ages ranged from 25 years to 50 years |
| Qualification | The majority (70%) with bachelor's degree qualifications (especially participants at national, central, and district facilities) |

3.1 Levels of organizational readiness

The study demonstrated that the MoH has done quite a remarkable work in preparing for the scaling up of the LAM urine tests. There are various extents of organizational readiness ranging from health facility to facility as some facilities have all the necessities for scaling up the LAM urine tests while some facilities are still lagging. The Ministry of Health has conducted several capacity-building, developed guidelines, and policies, and has routinized LAM tests into the Point of Care tests that are conducted at a facility. These factors have influenced the readiness of most facilities in the scaling-up process. Despite the capacity building done in almost every district, several health workers have still not yet been trained, and this has created a disparity in knowledge capacity and the implementation of the tests. Hence, the organizational readiness varies from district to district depending on the number of the capacity-building activities that were conducted in that districts, and the presence of implementing partners (NGO) that have been supporting the MoH in the implementation and scaling up of the LAM urine tests.

3.2 Factors affecting scale-up of LAM Tests

The themes on concepts of organizational readiness that are associated with the scale-up plans for urine LAM tests for TB diagnosis include policy availability, the resources, the government commitment/willingness, trust in leadership, health care worker's attitude (openness to change), the clarity of the scaling up plans. The themes from the conceptual framework constructs have been expanded in detail below.

A table summarizing the themes that emerged from the findings.

| **CONSTRUCTS** | **SUMMARISED FINDINGS** |
|---|---|
| Resources | Health workers were trained in the Advanced HIV Disease package that incorporates urine LAM tests.<br><br>MoH is planning to train a lower cadre professional and the ministry will not be investing in infrastructure, the tests will be conducted within the existing structures, places like the laboratory. |
| Policies | Policy and guidelines adopted but the tests have routinely only been used in a few peripheral facilities |
| Communication | Advanced HIV Disease package training and orientations were conducted in district facilities implementing urine LAM, these were the means of communication the MoH did to pass the message across the districts. |

| | |
|---|---|
| Capacity building | MoH through the DHA conducted capacity-building training (and orientations) with funding from Global Funds.<br><br>Several cadres were included in the training; clinicians, nurses, pharmacy technicians, and laboratory technicians. |
| Openness to change | Health workers were more willing to perform the urine LAM tests in patients who were eligible for the tests such that workers from facilities that had not yet started implementing the tests were referring patients to sites or district hospitals for urine tests<br><br>The essence that urine LAM tests are a point of care test, simple to use, and the ability for early detection of TB and early treatment of patients boosted the willingness of workers to be conducting the tests |
| Clarity of goals | The study observed that health workers perceive the LAM test as a simple, rapid diagnostic test that does not require additional infrastructure. The test has played a key part in increasing high TB positive yield, early detention, and early treatment in TB patients, and as a gateway to achieving the End TB strategy 2035 |
| Self-efficacy | The capacity-building training and orientations developed and broadened the individual capacity (skills and knowledge) to identify the eligible patients and results interpretation of the urine LAM tests, and this also developed the confidence of several health workers in performing the LAM test. |
| Trust in leadership | Health workers applauded the DHA and NTP for scaling up the tests as many workers perceive urine LAM as a point of care test which has proven to have the ability to reduce the TB burden within districts and eventually lead to achieving the country to meet the end TB strategy targets |

3.2.1 Structural and External Factors:

These are system-level constructs that affect the day-to-day functions and operations of a program. In this study, the themes that emerged around the structure and external factors are the availability of resources (both financial resources and human resources), the capacity building activities that were done to orient health workers, the communication aspects, as well as the availability and dissemination of policies and guidelines

3.2.1.1 Resources: The study assessed the availability of both human and financial resources and infrastructures that are deemed as necessary elements for effective urine LAM implementation and scaling up. The study revealed the plans the MoH has regarding infrastructure, capacity building, supply chain management, and funding of the scaling-up plans. Regarding human resources, it was noted that most health workers at health facilities were trained in the Advanced HIV Disease package that incorporates urine LAM tests, and these trained health workers are usually available in the facilities to perform the urine LAM tests. The study also revealed the pipeline plans MoH

is taking to train a lower cadre professional, the HIV Diagnostic Assistants, to assume the conduct of the urine LAM tests given HAD's near-universal availability in peripheral health facilities

The MoH has not and might not invest in infrastructure as far as urine LAM implementation is concerned because the tests do not necessarily need special infrastructures. The study noted that urine LAM has been conducted within the existing structures, places like the laboratory, HIV/HTS clinic, TB clinic, and wards. *[Anywhere in the HTS clinic, at the ward, at TB ward, or the ART clinic, it can be done anywhere, so in terms of infrastructure the ministry hasn't done any infrastructure development for the use of specifically urine LAM.] [In terms of infrastructure, we are already using the existing infrastructure because TB LAM does not need to raise a structure or a building, we can integrate into the same clinic we are doing ART_KII-04].*

The MoH has developed a robust monitoring system to strengthen data management across the health facilities to assist in monitoring the availability and usage of the test kits, and evaluating the overall program implementation. In terms of financial resources, the study found that MoH included the procurement of the test kits within the Global Fund grant. The study further observed that there are no clear plans set by the MoH to sustain the procurement of the test kits at the end of the Global Fund grants. It is still unknown whether the MoH can afford the procurement and distribution of LAM urine tests supplies in the absence of the Global Funds grants

3.2.1.2 Policies: The study investigated the availability of national policies and hospital standard guidelines for use of urine LAM tests. Notably, national policies and guidelines for urine LAM tests were endorsed and included in the 2018 National TB guidelines. The Urine LAM test was first used as a screening test and later it has been used as a diagnostic test in presumptive TB patients. The study observed that policy and guidelines have been adopted but the tests have routinely only been used in a few peripheral facilities. Reasons for limited expansion include no immediate support from implementing partners, the MoH plans do not prioritize low TB burden districts, and persistent delays to scale up to these peripheral facilities related to training and human resources.
The tests have so far been scaled up and it is being implemented in 115 health facilities (15% of all health facilities). Standard operating procedures (SOP) and job aids were distributed to health facilities implementing urine LAM tests that have helped health workers to easily manage and interpret the test results.

3.2.1.3 Communication: The study observed that MoH has made huge efforts in the communication of the changes in the algorithm for TB diagnosis. [*Yes, am aware, I was oriented during our advanced HIV TB diagnosis training,*

*we had the feel of the policy, what is contained in the policy_KII-06]*. Through the Department of HIV and AIDS, Advanced HIV Disease package training and orientations were conducted in district facilities implementing urine LAM, this training package included urine LAM tests, and orientations were done to clinicians and all cadres who were to be conducting the tests. In addition to the official communication that the Department of HIV and AIDs made to implementing district facilities, these trainings were the main means of communication about the changes in the inclusion of LAM tests in TB diagnosis.

3.2.1.4 Capacity building: The study aimed to assess the capacity building status of health workers, and cadres that have been trained and will be performing the urine LAM tests. The study observed that MoH through the DHA had conducted capacity-building training (orientations) across districts with funding from Global Funds. In selected districts, the orientations were funded by implementing partners (EGPAF and Partners of Hope). Several cadres were included in the training; clinicians, nurses, pharmacy technicians, and laboratory technicians were all trained in the point of care urine LAM tests. *[We have oriented not all but most of the stuff, we have oriented them on the availability of urine LAM and the possibilities of scaling up urine LAM to the sites_KII-12]*

3.2.2 Staff Attributes

These are constructs operationalized at both the organizational and individual levels. In this study, the themes that emerged were mostly centered on the health worker's attributes, this included the attitude of health workers toward using LAM tests (openness to change), health worker's understanding of LAM tests (clarify of the tests), and the health workers capacity and confidence in using LAM tests.

3.2.2.1 Openness to change: This is one key element within the framework necessary for determining the organization's readiness which was designed to assess the overall attitude and willingness of the health workers to adopt and implement the urine LAM tests. The study assessed the overall attitude and willingness of the health workers to adopt and implement the urine Lam tests. Health workers were more willing to perform the urine LAM tests in patients who were eligible for the tests such that workers from facilities that had not yet started implementing the tests were referring patients to sites or district hospitals for urine tests. [*Yeah, the motivation is there. And they are well prepared for that. Because looking at the sites that have not yet started performing the urine LAM, you understand that they do ask for the test. Or they do send you the clients for that. Because in our district urine LAM in the way we say it is not a strange thing because we include it as one of our point of care tests_KII-03]*.

The essence that urine LAM tests are a point of care test, simple to use, and the ability for early detection of TB and early treatment of patients boosted the willingness of workers to be conducting the tests. *[So being one of the points of care tests, everyone knows, so long as he is an HIV positive client, they know one of the bedside tests that they must do is to conduct the urine LAM test_KII-17] [When you see a positive result from a urine LAM test, you're happy that you have saved a life. People are happy to see urine LAM test positive not that it would be good for the patient to take medication, but we know we have saved their life by finding what would have been difficult to identify TB_KII-20]*

3.2.2.2 Clarity of goals: The study also investigated the clarity of goals, this is an assessment of how the scaling up of the urine LAM tests fit in within the health facilities and staff perceiving the advantage of urine LAM tests and the overall benefits to the patient, health system and the burden of TB. The study observed that health workers perceive the LAM test as a simple, rapid diagnostic test that does not require additional infrastructure. The test has played a key part in increasing high TB positive yield, early detention, and early treatment in TB patients, and as a gateway to achieving the End TB strategy 2035 (a world free of tuberculosis) through the first pillar of integrated, patient-centered care and prevention. *[So, it is very cheap, fast, easy, not sophisticated, a doesn't need a lot of space, it doesn't need a well-advanced technician to know about sample processing. So those are some of the abilities that advantages in the use of these_KII-27].*

The use of urine LAM tests in peripheral health facilities has brought in several advantages both to the health system and the patients in reducing the congestion of samples and workload, pressure on health workers at district facilities, and as well as reducing the catastrophic costs patients encounter during hospital visits. [*As the facilities diagnose more cases it will minimize the cost that the patients encounter to come here as well as the cost that the hospital encounters, and it will also reduce the pressure on our human resources and every other resource that we have, we are economically saving the patients and saving the health system in terms of expenditure_KII-22].*

Health workers have been more able to diagnose TB presumptive patients who otherwise could have been missed if tested by other TB diagnoses requiring sputum. Urine samples are easier to get from patients who are either bedridden or unable to produce sputum or in those with advanced immunosuppression. [*Exactly, most of the TB cases go unnoticed because of the diagnostic modalities that we have, LAM can identify the most difficult community that has extrapulmonary TB, so if we would scale up then we would be able to diagnose as many as possible and put as many as possible on TB treatment_KII-22]. [So, I think it will help reduce the burden of TB*

*because more people will be diagnosed and then will be treated. And then, in the end, the burden of TB infection will be reduced_KII-24].*

3.2.2.3 Self-efficacy: Under this element, the study assessed the individual capacity and confidence to implement the urine LAM tests. The capacity-building training and orientations developed and broadened the individual capacity (skills and knowledge) to identify the eligible patients and results interpretation of the urine LAM tests, and this also developed the confidence of several health workers in performing the LAM test. Most health facilities conduct rapid, point of care tests for malaria, syphilis, HIV tests, and CD4 testing. These tests are used in both inpatient and outpatient settings

Urine LAM has been incorporated and is being performed as a point of care test. This has made it possible for easy integration and acceptance in several health facilities as most health workers are already used to performing another point of care test. [*Yes, I am a trainer, am confident I can do it, it's the simple test, is as good as doing malaria rapid test, and with a simple interpretation, with just 2 lines with the rapid test you know this one has TB_KII-25]. [Very possible because we already have the rapid test like HIV rapid test, which is being done at every facility, it is possible to row out with urine LAM test with every facility_KII-16].*

3.2.3 Psychological Factors

These are beliefs and attitudes that influence an individual to accept and support a change in an organization.

3.2.3.1 Trust in leadership; The study also investigated the extent of sureness of health workers in the decision and the actions taken by the Department of HIV and AIDS and the National TB Control Program in implementation and scaling up the use of LAM tests. The study observed a high acceptance rate of urine LAM tests programs at the district and health centers. Apart from urine LAM being one test that has increased the diagnostic yield of TB, reduced the congestion of patients, and improved the turnaround time of results, health workers applauded the DHA and NTP for scaling up the tests as many workers perceive urine LAM as a point of care test which has proven to have the ability to reduce the TB burden within districts and eventually lead to achieving the country to meet the end TB strategy targets. *[The goal of the national TB control program is to end TB by 2035 so we need to identify more TB cases for us to achieve this, so the coming in of urine LAM can assist in this because we would like to identify more TB patients_KII-08].*

Despite the concerns several health workers have concerning urine LAM that it is being scaled up as a replacement for other diagnostic tests, this study observed that the MoH made it clear in their guidelines and during the

orientation sessions that urine LAM tests are being implemented and being scaled up as one test in the TB diagnostic algorithm and not replacing the Gene Xpert or chest Xray. *[I will just say that it is a good development that the Ministry is thinking of scale-up urine LAM, I think it has been so helpful like it has changed to some extent how we manage TB patients_KII-10]. [So, for me the use of urine LAM is a plus to the program and it should be adopted and scaled up_KII-26].*

3.3 Health Systems building blocks and LAM test scaling up process

A thorough analysis of different health system's building blocks is necessary for a process when an intervention is being scaled up as the intervention scaling up process presents an opportunity to strengthen the health system(56). This study analyzed the key component within the building blocks with the implementation and scaling up of LAM urine tests.

- Governance: the study observed that the national policies are in place supporting the implementation and scaling up plans, and these policies have been made available to all district health facilities and implementing partners implementing LAM tests. The MoH has incorporated the use of LAM tests in the national guidelines for TB diagnosis.
- Human Resources: The MoH has invested many efforts in building the capacity of the health workers to implement the LAM tests and the plans to train a specific cadre to implement the LAM test. The study also observed that the use of LAM tests will not present a burden in terms of increasing the workload and responsibilities health workers have in their day-to-day activities.
- Service Delivery: LAM tests might not affect the delivery of other services. LAM tests require little equipment and have a shorter TAT of results hence will not present a burden on the workload of health workers.
- Health Financing & Supplies and equipment: LAM test commodities have been included in the Global Funds grant and supplies are being procured using this grant. Implementing partners have also been involved in the procurement of the LAM test commodities. The existing structures and equipment available within the health facilities are enough to implement the scaling-up process. There will not be any need to bring in extra equipment or machines specifically for LAM tests, apart from CD4 testing machines that have been distributed to most health facilities.
- Health Information System: A robust monitoring and evaluation system has been developed and incorporated into the HIS systems at the district facilities. The study observed that indicators and registers related to the use of LAM tests have been developed and distributed in the health facilities.

## 4.0 Chapter Four: Discussion

This chapter highlights the discussion of key elements of study findings including organizational readiness considering the existing literature. Key themes that emerged as determinants of scaling up of LAM tests will also be discussed in this section including resource availability (human capacity and staff turnover), policies (political will, and the policy and guidelines dissemination), the psychological factors, the clarity of the LAM tests, capacity building activities (orientations) the importance of LAM tests, mortality rate reduction, CD4 testing, staff turnover. This section has also covered the recommendations based on the study results and the conclusion.

The study focused on interviewing participants with a wide range of knowledge and skills in HIV and TB at all levels of health care. In addition to interviewing district coordinators and health center clinicians, the study interviewed participants under implementing partners (PIH and EGPAF) at central referral hospitals, and desk officers for HIV and TB at national levels, these included experts with technical experience and knowledge in the field of HIV and TB programs.

### 4.1 Organizational readiness

Across the themes that emerged from this study, there were differing perceptions about organizational readiness ranging from facility to facility as some facilities reported to be ready and having the necessities in terms of organizational readiness while some facilities reported not being sure and some were not ready for the scaling up of the LAM tests. Most of the facilities were observed to have the requirements for implementation of the test, taking advantage of the existing infrastructure, the availability of trained health workers, and the already routine point of care services that are offered at most facilities, LAM urine tests being routinized in the point of care tests, has created a platform for easy incorporation into the existing structures of service delivery. Several health workers were as well observed to be motivated in using LAM tests in presumptive TB patients, this has created a routine in the use of the LAM tests as a screening and diagnosing tests in presumptive TB patients.

The active engagement from stakeholders and the support most district facilities have received from implementing partners played an integral part in the readiness of these facilities. These partner organizations have done much work on capacity-building training and intensified the dissemination of the guidelines and policies to the peripheral health facilities. Most of the supportive supervision and on-job training activities have been driven by the implementing partners. The support from implementing partners has a direct linkage and explanation as to why few district facilities have lagged in implementing and getting ready for the scale-up plans. Despite the support that district hospitals receive from the DHA and NTP, we observed that the district with implementing partners

was far ahead in the preparedness of the scaling up plans than those districts that did not have direct support from an implementing partner.

4.2 Themes emerging as determinants of scaling up LAM tests

Several themes emerged from the participants during the interviews in addition to the constructs/themes from the conceptual framework, and these themes include the coverage and usage of LAM tests, the cost-effectiveness, and TAT for using LAM tests, morbidity and mortality averted with LAM tests, the use of CD4 count testing and LAM tests, the political will and policies, staff turnover, as well as the barriers and facilitators in LAM tests scaling up.

4.2 1 Coverage and usage of LAM tests: an emerging theme that is directly linked to objective one exploring the levels of organizational readiness.

This study's findings demonstrated that implementing and scaling urine LAM tests is likely to be a smooth process with limited challenges as the MoH has put in place several structures and systems in preparing for the scaling-up process, for instance, the capacity building, secure findings for commodity procurements, routinized LAM tests as a point of care. The simplicity of LAM tests is one factor that will make the scaling up to be possible as the test has proved to be fast, easy to perform, and required little effort and making it possible for early TB treatment initiation. This study showed that LAM positive test results have the capability of significantly reducing the congestion of TB presumptive patients at health facilities as it enables early treatment initiation. This reduces the visits patients make to health facilities to access TB health services unlike with sputum tests and chest Xray. A study which was done in Tanzania found that TB presumptive patients were making an average of two or three visits to a health facility before being initiated TB treatment if being tested by sputum tests(57).

4.3 Cost-effectiveness of LAM urine tests and Turnaround Time for LAM urine test results: emerging themes linked to resources construct (structural and external factors).

Although our study did not directly assess the costs of implementation or scaling up the use of LAM tests, several participants reported the LAM test has the potential to reduce the catastrophic costs patients encounter during hospital visits as it reduces the number of hospital visits, and the short turnaround time for the test result provide the capacity for health workers to initiate TB treatment same time. The increase in the number of hospital visits means patients spend more money on transportation and other costs associated with the visits.

This study also found that the TAT is shorter as the urine LAM test has been performed as a point of care test, making it possible to reduce the risk of patient-loss-to-follow up. Studies in Tanzania and South Africa (57), showed that the time taken for a TB diagnosis to be made leads to both direct and indirect costs to both the patients

and the health facility and emphasized that using the LAM test which gives same-day results reduces the costs met during the TB diagnosis period(58). Other studies have found that it is highly cost-effective for both the patient and the health system when LAM tests have been included in the diagnosis of TB in the HIV patient population(59–61).

4.4 LAM tests and the TB HIV morbidity and mortality rate: A theme emerged which is directly linked to the motivation construct (under psychology factors) and openness to change (under staff attributes) from the conceptual framework

Our study results observed that the ability of LAM tests to detect patients who otherwise would have been missed if not done LAM test has proven to be one key reason health workers have continuously been motivated to use LAM tests in presumptive TB patients. It was observed that the scaling up of LAM would meet few or no resistances in many facilities as health workers have been motivated to use LAM as they have seen the benefit of LAM competence in diagnosing TB in severely ill HIV inpatients and asymptomatic advanced HIV out-patients. Health workers are compelled to continue using LAM to diagnose more TB which is a good indicator for successful scaling up programs.

LAM test has been a marker of greater disease dissemination and higher mycobacterial burden. There has been a robust association between a LAM positive test and an increased risk of mortality(62–65). This study revealed that health workers (who were participants) have seen severely ill patients who were at high risk of dying who received LAM testing and started on TB treatment and improved after a few weeks. This has improved the attitude, motivation, and willingness of health workers to perform LAM tests in all severely ill HIV patients for they know they will save a life.

Our study also observed that despite the clear guidelines for using LAM tests in ill HIV patients, some health workers (especially those who were not initially trained) were performing LAM tests in severely ill HIV-negative patients to rule out TB. This study has observed that health workers have been pushing the MoH to train more staff at the peripheral facilities and scale up the use of LAM at their facilities. It is feasible to scale up the use of LAM tests in peripheral health facilities because several health workers have a good perception of LAM tests for their ability to diagnose TB in populations that were previously missed when other diagnostic modalities such as sputum tests and chest Xray were used. This concurs with previous work conducted by MSF in Chiladzuru Malawi(29) demonstrating particular usefulness in resource-limited health facilities where there is no capacity for gene Xpert and chest Xray and severely ill patients unable to produce sputum

Two studies which were done in South Africa(28,66) showed that the use of urine as a sample for TB diagnosis has presented a severe advantage in presumptive TB patients especially the severely ill HIV positive population, who eventually many are unable to produce sputum. The study findings showed that non-sputum-based tests such as urine are preferred in diagnosing hospitalized and severely ill patients as it is easier to collect than sputum or Chest X-ray in this population.

Several studies have also demonstrated that urine LAM being used as a point of care test is clinically valuable in the hospitalized HIV population as an adjunct TB diagnostic. Using the LAM test at the first contact of presumptive TB patients can confirm the diagnosis and allow initiation of treatment in an important proportion of TB cases(3,27,28,64,65,67–70).

4.5 LAM tests and CD4 count testing: This theme is directly linked to the resource construct from the framework as the CD4 testing machines are used to determine the cutoff point of performing the LAM tests in patients.
The National HIVAIDS standard guidelines for use of LAM tests are to test patients with a CD4 count of fewer than 200 cells/mm^3 or those with a WHO stage 3 or 4 disease. For inpatients, the LAM test is indicated for all PLWH regardless of CD4 counts as they are presumed to have more advanced disease. Our study observed that only district hospitals and selected peripheral referral facilities have functional CD4 machines. Most of the peripheral facilities do not have the machines and clinicians have been using the WHO staging to select patients eligible for the urine LAM test.

Despite the practical advantages of LAM tests: point of care, requires minimal logistic inputs, little extra workload, and short TAT, the systematic urine LAM test in severely ill HIV patients might be complicated by its dependence on CD4 measurements as one standard guideline for selection in outpatients setting(29,67,71–73). The MOH has distributed PIMA machines to 80% of the facilities implementing the advanced HIV disease program and plans to procure and distribute additional Despite this effort, the study observed that the availability of the PIMA machines has been a heavy challenge in the implementation of the LAM tests and might continue to pose a barrier in the scaling-up process.

The implementation of the LAM test has been recommended based on the assumption that CD4 count test results will be available at the time the LAM test is conducted(74). The MOH plans to expand the recommendation

criteria for LAM to rely on WHO stages 3 and 4 in facilities with no CD4 count machines. Although the gene Xpert testing remains a gold standard for TB diagnosis(74), in resource-limited health facilities regardless of the CD4 testing the LAM tests have proven to be a useful parallel option in TB diagnosis.

4.6 LAM tests and the communication and leadership aspects: an emerging theme that is linked to leadership construct under psychology factors), communication construct, and capacity building (under the structural and external factors).

Our study demonstrated that the Ministry of Health made huge efforts to first train key health workers (ART district coordinators and District TB coordinators) and most clinicians in district facilities. This approach made it easy for these key workers to advocate and promote the use of LAM tests to their peers working with them at the district level. There has been a lot of on-job orientation as health workers who were trained have been able to orient other workers in the use of LAM tests.

Similar to our study findings, a study was conducted by Pierre M. Barker, Amy Reid1, and Marie W. Schall in Ghana and South Africa to explore a framework for scaling up health interventions(75). The study outlined areas that impact the implementation and scaling up of an intervention. One key area in their study(75) was communication. They explained that communication becomes crucial when scaling up any program. Leadership must take a leading role to communicate any other information about a program to the frontline implementers (health workers) and this helps to draw the attention of the frontline workers to accept the intervention and become promoters of the intervention to their peers(75,76).

Support systems are the third key areas discussed in the study(75) that enable the scaling up of an intervention. Support systems include the infrastructure, data collection, and reporting systems, and human capability. The study(75) explained that infrastructure can either be innovated or redesigned to accommodate the new health intervention, it further explained that a data management system has proven to be essential in scaling up an intervention. Human capability is essential as these forms the workforce to implement the scaling up of the intervention.

Regarding the support systems as outlined in the Pierre M. Barker, Amy Reid, and Marie W. Schall study results(75), our study findings have presented a strong suggestion that LAM tests in Malawi could easily be scaled up with minimal or no resistance based on the concepts of the support systems. Our study found that health workers

across the districts implementing LAM are well equipped with knowledge on how to conduct LAM. The robust data management system that was set by the MoH can monitor and track the progress of the test usage and scaling up process. The already existing infrastructure across health facilities present an opportunity for smooth implementation and scaling up of the LAM tests, there is minimal demand to renovate or redesign special rooms for LAM tests as HIV and TB clinic, or consultation rooms will equally be used for the tests.

4.7 LAM tests, Political will, and National Policies: a theme that is linked to policy construct under the structural and external factors.

Aligning the LAM test within the MoH commitment to reduce the TB burden and achieve the ambitious objectives set in the End TB Strategy is supreme to the success plans of scaling up the use of LAM. Our study found out that there has been a supportive political climate from the MoH, the favorable support has made it easier to consider the LAM tests as a diagnostic test and integrate it into the TB algorithm hence the successful scaling up of the tests can easily be achieved. The contextual factors which are critical for an effective program scaling-up process include an enabling policy environment and the strong commitment of the government(77).

Incorporating the LAM urine test into sectoral programming, the structures being run by the MoH have also been considered as a direct translation for the effective scaling up of the LAM urine tests. LAM urine tests have been integrated into the existing MoH structures through the planning processes, budget processes, and service delivery activities. This urine LAM test incorporation into the existing structures has resulted in higher confidence in its potential to be scaled up and hope to be sustained because the MoH engrossed the program as an important priority in TB diagnosis and treatment and being on track to achieve the End TB strategies.

On policy issues, our study also observed that the MoH endorsed the WHO recommendation on LAM tests and included the recommendations in the National ART and TB guidelines. Policies and guidelines were distributed and made available in all implementing districts. Health workers have been motivated to use LAM tests based on the proven efficiency and benefits to diagnose TB in severely ill patients. The endorsement of the policies further enhanced the motivation of health workers, this has created a conducive environment for easy scaling up of the LAM tests. The development of conducive policies and guidelines have proven to be important environmental factors that accelerate the adoption and scaling up of a health intervention. This was one key area that was also discussed in the study conducted in Ghana and South Africa (75) and it further explained that policies which most

associated with positive incentives can motivate and enhance a huge acceptance and rapid adoption of the intervention

4.8 LAM tests and the Psychology for Change factors: this theme is directly linked to the trust in leadership construct under the psychological factors

A clear lead was taken by the Malawi Ministry of Health through the Department of HIV/AIDS (and National TB Control Program) which assumed the responsibilities of the national implementation and scaling up plans of LAM tests. In response to this leadership, several implementing partners including Partners of Hope and EGPAF have shown the desire to work together with the MOH and they have been involved in capacity-building training in specific districts of their operation. It was reported in a USAID analytical report that environment and psychology for change have proved to be crucial factors in the ability to foster the pace and extent of implementation and scaling up of a health program, as scaling up of a program might face challenges to occur in a health system environment that is unreceptive. An intervention needs to attune closely to the health system practices and closely being integrated with the policies, and other health system structures(77).

4.9 LAM tests and Staff turnover: a theme that is linked to capacity building and human resources constructs under the structural and external factors

Staff turnover has created a gap across several facilities as those workers who were trained are not available hence creating the knowledge gap in HIV disease management at these facilities. To strengthen the scaling-up process of the LAM test, MoH must continue implementing capacity-building activities to train more health workers and cover the gap due to the staff turnovers

4.10 LAM tests and the barriers and facilitators

It is equally necessary to explore barriers (knowledge gap for the health workers in advanced HIV/TB management, short shelf life for LAM test kits) to scaling up a health intervention as it is in identifying sound strategies that enable effective scale-up of an intervention. In a scaling-up process, it is necessary to highlight the hindrances and key facilitators(9). An analytical report which was produced by USAID (77) highlighted constraints that might act as obstacles when scaling up a health intervention, these included lack of support and political commitment from the government health department, weak institutional capacity, recourse, and financial constraints, and weak demand for the intervention.

Our study explored these constraints and we found out that there have been a strong political commitment and leadership from the MoH department of HIVAIDS, our study also found that there is a strong institutional capacity to support the scaling-up processes in terms of the availability of trained health workers to implement the LAM tests, there is the financial support as LAM tests commodities are included in the Global Funds grants. This study also found that there is a strong desire to implement and scale up the use of LAM tests from the districts as health workers have seen the benefits of LAM tests in TB diagnosis.

Table 3: A summary of the themes that emerged and linkage to objectives and the constructs from the conceptual framework

| **Emerging Themes** | **Conceptual framework Antecedent Construct** | **Objectives** |
|---|---|---|
| Coverage and usage of LAM tests | Resources construct | Linked to the objective one |
| Cost-effectiveness and TAT of LAM tests | Resources construct | Linked to objective two |
| TB morbidity and mortality rate | Motivation construct<br>Openness to change construct | Linked to objective two |
| CD4 count testing | Resource construct | Linked to objective two |
| Communication and leadership aspects | Trust in leadership construct<br>Communication construct<br>Capacity building construct | Linked to objective two |
| Political will and national policies | Policy construct | Linked to objective two |
| Psychology for change factors | Trust in leadership construct | Linked to objective two |
| Staff turnover | Resource construct | Linked to objective two |
| Barriers and facilitators | | Linked to the objective one |

4.11 Limitations

This research had the advantage of using the conceptual framework that provided a platform to systematically identify the key factors that are associated with effective implementation, scaling up of health intervention, and assessing organizational readiness concepts that need modification, mitigated, or promoted. The researcher managed to interview the key informants from all levels: national, district, and health center levels, this study was able to collect information from these KI who are expertise in the area of study. However, the study had some limitations that may influence the current study findings. This study focused on sites where the LAM test had been

implemented. The study did not evaluate the readiness in low TB burden districts due to the limited financial resources. Evaluation from these sites could have highlighted important additional information barriers and facilitators in organization readiness to implement and scale up the use of LAM tests in peripheral facilities. In some settings, we were unable to interview our desired number of respondents.

However, given the consistencies of reporting across sites and apparent saturation of themes in our interviews, we believe we have accurately described the readiness situation. This readiness evaluation was done in the clinical setting, assessing the outpatient and inpatient setting. Further readiness evaluation might be required to be done at the high-level offices for instance the donor community (Global Fund or PEPFAR) and the implementing partner's senior management to understand their prioritization of Advanced HIV and the urine LAM in relation to other programming.

## 4.12 Conclusion

In addition to the contextual factors, aligning the LAM tests within the MoH commitment to reducing the TB burden and the End TB strategies have been supreme to the success plans of scaling up the use of LAM tests. The incorporation of LAM urine tests into sectoral programming that is run by the MoH is one way of indicating a direct translation for the scaling up. The MoH should consider periodic supportive supervision and refresher training as crucial activities to maintain the momentum, motivation, and level of knowledge of health workers. The MoH must as well systematically analyze the health system's strengths and weaknesses which will further strengthen the institutional capacity in enhancing organizational readiness. MoH should consider continuing to strengthen the robust monitoring and evaluation system which have been put in place, a continuance review of the indicators and reporting tools might be necessary within the scaling-up process, and consider the collaboration with key stakeholders as a continuance process in the scaling-up process.

As the DHA moves towards scaling up LAM tests to the peripheral health facilities, it is necessary to map out a clear plan for sustainability of the efforts been done in preparation for the scaling up including the realistic projections of the LAM commodity costs, and the cost to fully implement the scaling up the LAM tests. Further research studies are essential as well to understand the coverage and effectiveness of using LAM tests in children and severely ill HIV-negative presumptive TB patients, as well as to the evaluation of scaled-up interventions. This study's findings suggest that further operational and implementation research might be essential in near future. Further research might be done to understand the coverage and effectiveness of using LAM tests in children and

severely ill HIV-negative TB presumptive patients as well as conducting further studies (to confirm these findings) in other settings and low TB burden districts.

4.13 Recommendations

The MoH through the DHA and NTP must systematically analyze the health system's strengths and weaknesses and plan the LAM test scaling up activities that will further strengthen the institutional capacity. DHA and NTP should consider continuing to strengthen the robust monitoring and evaluation system which have been put in place, a continuance review of the indicators and reporting tools might be necessary within the scaling-up process. Successful scale-up requires strategic planning, which includes a comprehensive analysis of the system into which the intervention will be introduced. A growing body of evidence identifies key barriers to, and facilitators of, successful scale-up, from which organizations and experts have developed guidance(78). The study found out that the DHA has done remarkable work in information dissemination, the DHA and NTP should continue sending out important and clear communication to implementing districts as of any change in the guidelines or any communication that is considered important to clear out any possible misconceptions.

The DHA and NTP should consider collaboration with key stakeholders as a continuance process in the scaling-up process. Scaling up the LAM test will most likely be a success when key stakeholders like the policymakers, researchers, and the beneficiaries (health workers and patients) are all engaged in the scaling-up process. Several studies have previously indicated that steady funding for an intervention over time greatly facilitates a smoother scale-up of an intervention(14,78). The financial commitment towards LAM implementation (Advanced HIV disease management) and scaling up from the Global Funds grant is a strong indicator that demonstrates the steady funding over the period covered by the grant.

The robust monitoring and evaluation system that the DHA developed and is being in use in districts implementing LAM tests must be put in use and the data and reports generated from these systems must be used to produce a comprehensive picture of the scaling-up process. This monitoring and evaluation system is crucial to collecting information about the scaling-up process as this will assist the DHA and NTP to understand the unexpected events that might be inevitable in the scaling-up process hence the DHA can develop and implement corrective adjustments to the scaling-up process.

There might be a need to continually motivate and build the capacity of the health workers directly working in the LAM test implementation. The DHA should consider periodic supportive supervision, refresher training, and on-job training as crucial activities to maintain the momentum and level of knowledge of health workers.

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## 6.0 Appendices

Appendices 1: Wits Ethics Committee Approval certificate

| UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG | HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL) |
|---|---|

**Office of the Deputy Vice-Chancellor (Research and Postgraduate Affairs)**

**TO:** Mr JM Zondetsa and Professor M Hosseinipour
School of Public Health
Division of Epidemiology and Biostatistics
Medical School
University

E-mail: 2215124@students.wits.ac.za

**CC:** Supervisor: Dr J Kagura
<Juliana.Kagura@wits.ac.za>
and <HREC-Medical Research Office@wits.ac.za>

**FROM:** Mr Iain Burns
Human Research Ethics Committee (Medical)
Tel: 011 717 1252

E-mail: Iain.Burns@wits.ac.za

**DATE:** 2021/05/20

**REF:** R14/49

**PROTOCOL NO:** **M210275** (This is your ethics application reference number. Please quote it in all enquiries, oral or written, relating to this study.)

**PROJECT TITLE:** *An exploration of organizational readiness for scaling up the use of Urine LAM tests in high TB burden districts and peripheral health facilities in Malawi*

Please find attached the Clearance Certificate for the above project. I hope it goes well and that an article in a recognized publication comes out of it. This will reflect well on your professional standing and contribute to Government funding of the University.

MSWorks2000/Iain0007/Clearscan.wps

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R49 Mr JM Zondetsa and Professor M Hosseinipour

# HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
# CLEARANCE CERTIFICATE NO. M210275

| | |
|---|---|
| **NAME:** **(Principal Investigator)** | Mr JM Zondetsa and Professor M Hosseinipour |
| **DEPARTMENT:** | School of Public Health<br>Division of Epidemiology and Biostatistics<br>Medical School<br>University |
| **PROJECT TITLE:** | *An exploration of organizational readiness for scaling up the use of Urine LAM tests in high TB burden districts and peripheral health facilities in Malawi* |
| **DATE CONSIDERED:** | 2021/02/26 |
| **DECISION:** | Approved unconditionally |
| **CONDITIONS:** | |
| **SUPERVISOR:** | Dr J Kagura |
| **APPROVED BY:** | Dr CB Penny, Chairperson, HREC (Medical) |
| **DATE OF APPROVAL:** | 2021/05/20 |

**This Clearance Certificate is valid for 5 years from the date of approval. An extension may be applied for.**

## DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office secretariat on the 3rd floor, Phillip Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated from the research protocol as approved, I/we undertake to submit details to the Committee. **I agree to submit a yearly progress report**. When a funder requires annual re-certification, the application date will be one year after the date when the study was initially reviewed. In this case, the study was initially reviewed in **February** and therefore reports and re-certification will be due in the month of **February** each year. Unreported changes to the study may invalidate the clearance given by the HREC (Medical).

Signature of Principal Investigator _____ Date _____

UNITY AND FREEDOM

# CERTIFICATE OF ETHICS APPROVAL

This is to certify that the National Health Sciences Research Committee has reviewed and approved the study titled:

Study Title: Protocol # 21/03/2667: An Exploratory of Organizational Readiness for Scalling Up the Use of Urine LAM Tests in High TB Burden Districts and Peripheral Health Facillities in Malawi

Investigator: John Maseko Zondetsa

StartDate: 12/03/2021 EndDate: 11/03/2022

Date of issue: 12/03/2021

Dr Collins Mitambo
For Chairperson-NHSRC

National Health Sciences Research Committee
2021 -Mar- 12
APPROVED

Mr Billy Nyambalo
NHSRC Administrator

## Appendices 3: Malawi National Health Sciences Research Committee Approval Letter

Telephone: a + 265 789 400
Facsimile: + 265 789 431

All Communications should be addressed to:

The Secretary for Health and Population

*In reply please quote No.*

.....

MINISTRY OF HEALTH AND POPULATION

P.O. BOX 30377
LILONGWE 3
MALAWI

12th March, 2021

**John Maseko Zondetsa**
University of Witwatersrand

**RE: Protocol # 21/03/2667: An Exploratory of Organizational Readiness for Scaling Up the Use of Urine LAM Tests in High TB Burden Districts and Peripheral Health Facilities in Malawi**

Thank you for the above titled proposal that you submitted to the National Health Sciences Research Committee (NHSRC) for review. Please be advised that the NHSRC has **reviewed** and **approved** the above titled study.

- **APPROVAL NUMBER : 2667**
- The above details should be used on all correspondences, consent forms and documents as appropriate.
- **APPROVAL DATE : 12/03/2021**
- **EXPIRATION DATE : 11/03/2022**
  This approval expires on **11/03/2022**. After this date, this project may only continue upon renewal. For purposes of renewal, a progress report on a standard form obtainable from the NHSRC Secretariat should be submitted one month before the expiration date for continuing review.
- **SERIOUS ADVERSE EVENT REPORTING:** All serious problems having to do with subject safety must be reported to the NHSRC within 10 working days using standard forms obtainable from the NHSRC Secretariat.
- **MODIFICATIONS**: Prior NHSRC approval using forms obtainable from the NHSRC Secretariat is required before implementing any changes in the protocol (including changes in the consent documents). You may not use any other consent documents besides those approved by the NHSRC.
- **TERMINATION OF STUDY**: On termination of a study, a report has to be submitted to the NHSRC using standard forms obtainable from the NHSRC Secretariat.
- **QUESTIONS**: Please contact the NHSRC on phone number *+265 999397913* or by email on mohdoccentre@gmail.com.
- **OTHER**: Please be reminded to send in copies of your final research results for our records (Health Research Database).

Kind regards from the NHSRC Secretariat.

National Health Sciences Research Committee
2021 -03- 17
APPROVED

.....
For **CHAIRPERSON, NATIONAL HEALTH SCIENCES RESEARCH COMMITTEE**
Promoting Ethical Conduct of Research

Appendices 4: Thesis Report Turnitin Report

2215124:Thesis_Report_John_Zondetsa.docx

ORIGINALITY REPORT

| 6% | 1% | 5% | % |
|---|---|---|---|
| SIMILARITY INDEX | INTERNET SOURCES | PUBLICATIONS | STUDENT PAPERS |

PRIMARY SOURCES

| | | |
|---|---|---|
| 1 | Sekai Chenai Mathabire Rucker, Loide Cossa, Rebecca E. Harrison, James Mpunga et al. "Feasibility of using Determine TB-LAM to diagnose tuberculosis in HIV-positive patients in programmatic conditions: a multisite study", Global Health Action, 2019<br>Publication | 1% |
| 2 | Gavin Yamey. "Scaling Up Global Health Interventions: A Proposed Framework for Success", PLoS Medicine, 2011<br>Publication | 1% |
| 3 | Helena Huerga, Sekai Chenai Mathabire Rucker, Mathieu Bastard, Andrew Dimba, Cosmas Kamba, Isabel Amoros, Elisabeth Szumilin. "Should Urine-LAM Tests Be Used in TB Symptomatic HIV-Positive Patients When No CD4 Count Is Available? A Prospective Observational Cohort Study From Malawi", JAIDS Journal of Acquired Immune Deficiency Syndromes, 2020<br>Publication | 1% |

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| 4 | m.cdc.gov<br>Internet Source | 1 % |
| 5 | Diane N. Singhroy, Emily MacLean, Mikashmi Kohli, Erica Lessem et al. "Adoption and uptake of the lateral flow urine LAM test in countries with high tuberculosis and HIV/AIDS burden: current landscape and barriers", Gates Open Research, 2020<br>Publication | <1 % |
| 6 | Yuan Zhang, Marian Flum, Cheryl West, Laura Punnett. "Assessing Organizational Readiness for a Participatory Occupational Health/Health Promotion Intervention in Skilled Nursing Facilities", Health Promotion Practice, 2015<br>Publication | <1 % |
| 7 | core.ac.uk<br>Internet Source | <1 % |
| 8 | Krishna P Reddy, Ankur Gupta-Wright, Katherine L Fielding, Sydney Costantini et al. "Cost-effectiveness of urine-based tuberculosis screening in hospitalised patients with HIV in Africa: a microsimulation modelling study", The Lancet Global Health, 2019<br>Publication | <1 % |
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| 10 | Janneke A. Cox, Robert L. Lukande, Sam Kalungi, Eric Van Marck et al. "Is Urinary Lipoarabinomannan the Result of Renal Tuberculosis? Assessment of the Renal Histology in an Autopsy Cohort of Ugandan HIV-Infected Adults", PLOS ONE, 2015<br>Publication | <1 % |
| 11 | "Implementation Science 3.0", Springer Science and Business Media LLC, 2020<br>Publication | <1 % |
| 12 | Milly E. Attema-de Jonge, Suzanne Y.G. Peeters, Eric J.F. Franssen. "Performance of Three Point-of-care Urinalysis Test Devices for Drugs of Abuse and Therapeutic Drugs Applied in the Emergency Department", The Journal of Emergency Medicine, 2012<br>Publication | <1 % |
| 13 | hdl.handle.net<br>Internet Source | <1 % |

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| Exclude quotes | On | Exclude matches | < 7 words |
| Exclude bibliography | On | | |

Supervisor Name: Dr Juliana Kagura

Signed: 25/11/2025

Dr J Kagura: 

Supervisor Name: Prof Mina

Appendices 5: Support Letter from Lilongwe DHO

Ref. No.:
Telephone No.: 265 726 466/464
Telefax No.: 265 727817
Telex No.:
E-Mail. lilongwedho@malawi.

COMMUNICATIONS TO BE ADDRESSED TO:

*In reply please quote NO DZH/MALAWI.*
Lilongwe District Health Office
P.O. Box 1274
Lilongwe
Malawi

22nd February, 2021

The Chairperson
National Health Science Research Committee
Ministry of Health
P.O. Box 30377
Lilongwe

**Dear Sir/Madam**

**RE: LETTER OF SUPPORT FOR AN EXPLORATION OF ORGANISATIONAL READINESS FOR SCALING UP THE USE OF URINE LAM TESTS IN HIGH TB BURNED DISTRICTS AND PERIPHERAL HEALTH FACILTIES IN MALAWI".**

We write to support **John Maseko Zondetsa** – Investigator for the research titled " **An Exploration of Organisational readiness for scaling up the use of Urine LAM tests in High TB Burden Districts and Peripheral Health Facilities in Malawi".**

The findings of this study will assist to explore factors associated with implementation readiness for scaling up urine LAM tests in high TB burden district, to explore the levels of implementation readiness for scaling up the use of urine LAM tests in TB diagnosis and to explore factors associated with implementation readiness for scaling up of urine LAM tests.

We fully support this application and look forward to working with the Investigator to conduct this important study in our district.

Yours faithfully,

22 FEB 2021

Dr M. Kamvaunamwali
**For : DIRECTOR OF HEALTH AND SOCIAL SERVICES**

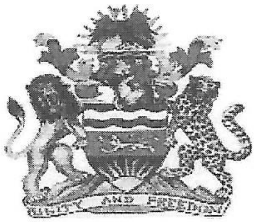
Appendices 6: Support Letter from Karonga DHO

Telephone: +265 01311576

Email: karonga.districthealthoffice@gmail.com

All Communications should be addressed to:

DISTRICT HEALTH OFFICER



In reply please quote no. REF KA/ADMN/19/10

MINISTRY OF HEALTH

The District Health Officer

Karonga District Health Office

Private Bag I

Karonga

MALAWI

26 February 2021

The Chairman

National Health Science Research Committee

Ministry of Health

P.O Box 30377

Lilongwe

**Dear Sir/Madam**

**RE: LETTER OF SUPPORT FOR AN EXPLORATION OF ORGANISATIONAL READINESS FOR SCALING UP THE USE OF URINE LAM TESTS IN HIGH TB BURNED DISTRICTS AND PERIPHERAL HEALTH FACILITIES IN MALAWI.**

We write to support **John Maseko Zondetsa** – Investigator for the research titled **An exploration of organizational readiness for scaling the use of urine LAM tests in High TB Burden Districts and Peripheral Health Facilities in Malawi .**

The findings of this study will assist to explore the factors associated with implementation readiness for scaling up urine LAM tests in high TB Burden districts, to explore the levels of implementation readiness for scaling up the use of urine LAM tests in TB diagnosis, and to explore factors associated with implementation readiness for scaling up of urine LAM tests.

We fully support this application and look forward to working with the investigator to conduct this important study in our district.

Yours faithfully

Dr. Mphatso Kantonya, Senior Medical Officer (Ag Chair KDH Research Committee)

**For: DIRECTOR OF HEALTH AND SOCIAL SERVICES**

KARONGA DISTRICT HOSPITAL

P/BAG 1, KARONGA

KARONGA DISTRICT HOSPITAL

P/BAG 1, KARONGA

Appendices 7: Support Letter from Zomba DHO

Telephone: + 265 1 524 588
Facsimile: + 265 1 524 320
All Communications should be addressed to:
***The Director of Health and Social Services***

MINISTRY OF HEALTH
ZOMBA DISTRICT HEALTH OFFICE
PRIVATE BAG 18
ZOMBA, MALAWI

**Ref. No: ZA/H/02**

**04th March, 2021**

The Chairperson,
National Health Sciences Research Committee,
Ministry of Health,
P.O Box 30377,
Lilongwe 3.

**Dear Sir**

**LETTER OF SUPPORT TO CONDUCT RESEARCH TITLED "AN EXPLORATION OF ORGANIZATION READINESS FOR SCALING UP THE USE OF URINE LAM TESTS IN HIGH TB BURDEN DISTRICTS AND PERIPHERAL HEALTH FACILITIES IN MALAWI"**

We write in support of the study titled *"An exploration of organizational readiness for scaling up the use of urine LAM tests in high TB burden districts and peripheral health facilities in Malawi"*, which will be conducted towards completion of a Masters degree thesis in Epidemiology. Zomba has been selected as one of the districts where the research study will be conducted.

The methodology of the study will include Key Informant interviews with district level officers implementing TB/HIV programs in advanced HIV disease using an interview guide for semi-structured questionnaire.

The findings of this study will assist to explore the levels of implementation readiness and factors associated with implementation readiness for scaling up urine LAM tests in high TB Burden districts. As the findings from the study will be used to inform policy to scale up and improve service delivery, hence our support for this study. The Zomba DHO therefore anticipates dissemination of the findings through a report that will be shared with us also.

Yours faithfully,

Dr. Alexander Chijuwa,
**DIRECTOR OF HEALTH AND SOCIAL SERVICES**

Appendices 8: Support Letter from Chikwawa DHO

(+265) 01420266
Fax: (+265) 01420264
chikwawadhss@gmail.com

Communications should be addressed to:
Director of Health and Social Services
Chikwawa District Hospital
P.O Box 32
Chikwawa

4th June 2021

The Chairman

National Health Science Research Committee

Ministry of Health and Population

P.O Box 30377

Lilongwe 3

Malawi

Dear Sir,

SUPPORT LETTER FOR THE STUDY 'AN EXPLORATION OF ORGANISATIONAL READINESS FOR SCALING UP THE USE OF URINE LAM TESTS IN HIGH TB BURDEN DISTRICTS AND PERIPHERAL HEALTH FACILITIES IN MALAWI'.

I write in support of the above-mentioned study which is planned to take place in Chikwawa. The office of the Director of Health and social services in Chikwawa expects to be kept aware of the progress of the study and study results.

Looking forward to your assistance.

2021 -06- 09

Dr Sheena Kaunda Khuwi

FOR THE DIRECTOR OF HEALTH AND SOCIAL SERVICES

Appendices 9: Support Letter from Nsanje DHO

Telephone: +265 (0) 1 456 222/242
Facsimile: +265 (0) 1 456 258
E-mail: Chapweteka47@gmail.com

All Communications should be addressed to:
Director of Health & Social Services

In reply please quote Ref. No.
Ministry of Health,
Nsanje District Hospital,
P.O. Box 30,
NSANJE.

Date: 07/05/2021

John Maseko Zondetsa

University of Witwatersrand

South Africa

+27 78 398 4795/ +265 995313231

Email: johnzondetsa@gmail.com

Dear Sir,

**PERMISSION TO CONDUCT RESEARCH IN NSANJE DISTRICT**

Following your application for permission to conduct research in Nsanje district, am pleased to inform you that your request has been approved by the District Research Coordinating Committee. The approval gives you an opportunity to carry out a research titled **"An Exploration of Organizational readiness for scaling up the Use of Urine LAM tests in High TB Burden Districts and Peripheral Health Facilities in Malawi".**

This means that you have access to Health facilities in Nsanje, you also have access to data and equipment and that you can work with government staff being targeted to assist in the research process.

We expect you to operate within the ethical standards as indicated in the research protocol

MINISTRY OF HEALTH
DIRECTOR OF HEALTH AND SOCIAL SERVICES
11 MAY 2021
NSANJE DISTRICT COUNCIL
PRIVATE BAG 1, NSANJE

Yours faithfully,

Chancy Banda (District Research Committee Coordinator)

For Dr Gilbert Chapweteka

**(DIRECTOR OF HEALTH AND SOCIAL SERVICES)**

Appendices 10: Support Letter from Blantyre DHO

Telephone: Blantyre 0 1875332 / 01 877 401
Fax: 01 875 430 / 01 872 551

Communication should be addressed to:
**Blantyre District Council**
**Director of Health and Social Services**

**0882002533; gkawalaziira@yahoo.co.uk**

In reply please quote No. .....

DISTRICT HEALTH OFFICE
P/BAG 66
BLANTYRE
MALAWI

**Ref No: BTDHO/DRCom/062101**

**2ND JUNE 2021**

The Chairperson
College of Medicine Research and Ethics Committee
Private Bag 360,
**Blantyre 3**

Dear Sir

RE: Support letter for the study titled "An exploration of organizational readiness for scaling up the use of Urine LAM tests in high TB burden districts and peripheral health facilities in Malawi."

I write to confirm that Blantyre District Health Office is in support of John Maseko Zondetsa study "**An exploration of organizational readiness for scaling up the use of Urine LAM tests in high TB burden districts and peripheral health facilities in Malawi.".**

The protocol was presented to our District Research Committee (DRCom) on 2nd June 2021 for our assessment. The DRCom has accepted that the study be conducted in Blantyre after carefully examining implications of the study.

This is a significant study as the findings will help to determine the readiness of our health facilities in the implementation of the urine LAM tests and will lead to optimize all necessary key attributes that are deemed as requirements to successfully implement and scale up the use of urine LAM tests in the district.

If may you require any further information; please do not hesitate to contact the undersigned.

Yours faithfully,

Blantyre District Council Director of Health & Social Services 02 JUN 2021 Private Bag 66 Blantyre

Dr. Gift Kawalaziira
**Director of Health and Social Services for Blantyre District**

Cc.: John Maseko Zondetsa, MSc Epidemiology Student-University of Witwatersrand, SA

Appendix 11: Questionnaire 1

This is the questionnaire that was used during the interviews for 26 key informants responsible for HIV and TB programs at district hospitals and non-governmental organization

KIIs ID number:

1. Tell me more about your experience working in TB and HIV?
2. Tell me more about your experiences with TB diagnostic tools like Chest- Xray, Gene Xpert, and LAM urine tests?

   What is the current algorithm for TB diagnosis at your health facility?

   What diagnostic tools have you been using so far in TB diagnosis?
3. As you have heard, the Ministry of Health has included the LAM urine test as one tests to be done in TB presumptive patients.

   Explain to me what you know about the Malawi national policy inclusion of the LF LAM test in its TB or HIV program guidelines?
4. What is your take on integrating LAM tests in TB diagnosis being done in peripheral health facilities?

   Tell me more about the usage of the tests, their importance, and the feasibility of using urine LAM tests in TB diagnosis in peripheral hospitals?
5. What are the existing structures that the health facilities have in place to support the LAM test programs?

   Explain to me what the Ministry of Health or the DHMT has done so far in terms of preparing for the implementation and scaling up plans of LAM test plans?
6. Tell me more about what modalities/systems or any other structures have been put in place for the scale-up plans?

   What specific existing structures/things are in place now that will enable the scale-up plans to a success story?

   In your own words, what can you say about the possibility of scaling up the use of LAM tests considering the existing structures that we have in our health facilities?
7. In your own words, tell me more about what has been the biggest barrier preventing the integration/implementation of the LAM tests and the integration of the tests in the TB diagnosis algorithm?

8. What do you think can be done by both the MoH and the hospital management team to sustain the implementation of the LAM test in TB diagnosis in the health facilities?
9. Have you ever gone to any capacity-building trainings about the use of urine LAM tests?

    Do you consider yourself having the necessary competence to perform urine tests?

    Are the health workers under you able to perform the tests, how many were trained?
10. In your own words, are you confident in using urine LAM tests?

    Are you and other health workers willing to be using the tests?
11. Do you consider urine LAM tests to fit in within the health facilities as in TB diagnosis and overall in helping Malawi in reducing the TB burden?
12. In your own words, are you motivated in using the urine LAM tests? Do you think the tests have been helping you diagnose TB patients?

Appendix 12: Questionnaire 2

This questionnaire was used mainly for key informants working at NTP and DHA as these are national desk officers responsible for HIV and TB programs.

KIIs ID number:

1. What is your take on integrating LAM tests in TB diagnosis being done in peripheral health facilities?
    a. Tell me more about the usage of the tests, their importance, and the feasibility of using urine LAM tests in TB diagnosis in peripheral hospitals?
    b. In your own words, what can you say about the possibility of scaling up the use of LAM tests considering the existing structures that we have in our health facilities?
2. Do you consider urine LAM tests to fit in within the health facilities as in TB diagnosis and overall in helping Malawi in reducing the TB burden?
3. What are the existing structures or systems that the health facilities have in place to support the LAM test programs?
    a. Explain to me what the Ministry of Health has done so far in terms of preparing for the implementation and scaling up plans for the LAM test?
    b. What plans have been put in place in terms of infrastructures?
    c. And the storage for the test kits, what plans do you have in plan?

        i. In terms of supply chain management, what plans do you have in place to avoid prevent issues of stock-outs, and strengthen the availability of test kits in the health facilities?

4. How do you make sure that the health workers who were trained, stay motivated and remain willing to perform the tests?
5. There might be a need to supply the CD4 count machines to health facilities since urine Lam tests will mainly be done in PLHIV with a CD4 count less than 200, will you provide the CD4 count machine to the facilities when scaling up to these facilities.
    a. Will it be only facilities that are implementing AHD that will also be doing urine LAM tests?
    b. Specifically, where exactly have you planned for conducting the urine LAM tests, will the tests be done at the ART clinic or the TB clinic or the laboratory, or the consultation room?
6. Do you have the job aide or the guidelines that you planning to disseminate to the facilities?
7. In your own words, tell me more about what has been the biggest barrier preventing the integration/implementation of the LAM tests and the integration of the tests in the TB diagnosis algorithm?
8. What do you think can be done by both the MoH and the hospital management team to sustain the implementation of the LAM test in TB diagnosis in the health facilities?
    a. What advice can you give to the MoH or the district management in terms of urine LAM test implementation and scaling up plans?
    b. A few facilities are supported by partners, what plans do you have in place in terms of sustainability after the partner's projects end?