SCHOOL OF MEDICINE AND HEALTH SCIENCES

DEPARTMENT OF PUBLIC HEALTH

THE IMPACT OF LATERAL FLOW URINE LAM TEST ON TB CASE NOTIFICATIONS AMONG PEOPLE LIVING WITH HIV AT LEVY MWANAWASA TEACHING HOSPITAL, ZAMBIA: QUASI EXPERIMENTAL STUDY DESIGN

A dissertation for the Bachelor of Science in Public Health degree of the University of Lusaka

Submitted

By

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BSPH18212966

DECLARATION

I hereby declare that the work presented is my own original work undertaken in partial fulfillment for a bachelor's of science degree in Public Health and that it has not been submitted before for any degree in any other university or college and that all the sources I have used or quoted have been indicated and acknowledged as complete references

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CERTIFICATE OF APPROVAL

The University of Lusaka approved this dissertation of Robertson Chibumbya as partial fulfillment of the requirement for the award of the bachelors of public health degree in public health.

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Date of Approval

Acknowledgement

I would like to express my gratitude to my supervisor Professor Andrew Mbewe for the tireless support during my research. My knowledge in Research would not have been what it is today without the input of my Research methodology lecturer Prof E Kazonga and all the lecturers that taught me during my study at the University of Zambia.

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Dedication

This dissertation is dedicated to my beloved wife Christine Chibumbya, children Tuliya Chibumbya and Sibalabala Chibumbya. I would not have accomplished all this without all of you.

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List of acronyms

ACF	Active Case Finding
AHD	Advanced HIV Disease
AIDS	Acquired Immunodeficiency Syndrome
ART	Anti-retroviral Therapy
HIV	Human Immune Virus
LF LAM	Lateral Flow Lipoarabinomannan
MoH	Ministry of Health
NGO	Non-Governmental Organization
NTLP	National Tuberculosis Leprosy Control Program
PLWHIV	People Living with HIV
TB	Tuberculosis
WHO	World Health Organization

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ABSTRACT

INTRODUCTION:

Tuberculosis detection in people living with HIV remains a challenge. This is due to paucibacillary nature of the sputum specimens. In 2020, the World Health Organisation recommended the use of GeneXpert for diagnosis of TB but its use has been limited in immunocompromised individuals. The LAM test was later recommended to be used in people with HIV with a view to improve TB notifications. This test requires the use of urine instead of sputum.

OBJECTIVES:

The main aim of this study was to assess the impact of LF- LAM test on TB notifications. The specific objectives was to describe trends in TB notifications among people living with HIV, determine the effect of LAM test introduction on TB case notification among HIV positive individuals and compare the median turnaround time of results between GeneXpert and LAM test.

METHODOLOGY:

This research was a quasi-experimental study design which was conducted at Levy Mwanawasa Teaching Hospital in Lusaka with a focusing on determining improvement in TB notifications following the introduction of urine Lam test. TB notifications were collected from 2017 to 2021 and data divided into 2 segments; the first segment comprised notifications before the introduction of TB LAM, and the second segment was the TB notifications after the intervention.

RESULTS:

A total of 404 records for HIV infected TB patients in the TB registers were reviewed for 18 quarters from 2017 to 2021. The median (IQR) age of the patients was 38 years. The interrupted series results showed a non-significant reduction of 0.74 points per quarter prior to the implementation. The post intervention trend in TB notifications reduced by 0.1 points (95% CI-6.2-6.0), though not statistically significant reduction.

CONCLUSION:

The introduction of TB LAM was not associated with improved TB case notification. The current Xpert test being used for TB diagnosis is remains appropriate for the present treatment

algorithm. However, there is still need to conduct future studies at a non-referral site to establish the real impact of the use of TB LAM in people living with HIV.

Chapter 1.0: Background/ Introduction

Tuberculosis (TB) is an airborne disease that has killed millions of people. In 2019, about 10 million people were infected with TB while 1.4 million died from the disease worldwide. In total, 7.1 million people were newly diagnosed and notified, representing about 1% increase compared to 2018. There were 456 426 patients that had both TB and HIV (WHO, 2020). In Zambia, the country recorded a total notifications of 40, 000 in 2020. On the other hand, the TB program has continued to miss TB patients. An estimated number of 22,000 patients were missed in 2020 (MoH, 2021).

In an effort to improve TB diagnosis, the World Health Organization (WHO) has continued to recommend several new rapid TB diagnostics to increase case detection. In 2010, WHO endorsed the use of GeneXpert technology for rapid detection of mycobacterium and rifampicin resistance. However, its sensitivity is still limited in people living with HIV (PLWHIV) with immunosuppression. This is usually attributed to paucibacillary nature of the sputum specimens and poor quality of samples. To increase case notifications, WHO has recommended the use of lateral flow urine lipoarabinomannan (LF-LAM) tests. LF-LAM is a point of care test which detects LAM antigen in urine. LAM is a lipopolysaccharide which is found on the cell wall of mycobacterium (WHO, 2016). This tests has shown improved sensitivity especially in HIV positive patients with low CD4 count and those that are seriously ill in both outpatient and inpatient settings(WHO, 2016). Multi study results demonstrated that LF LAM had a pooled sensitivity of 42% in HIV positive adults with TB symptoms while HIV positive adults irrespective of TB signs and symptoms had a pooled sensitivity of 35%(WHO, 2021). This shows the benefit of LF LAM when used in PLWHIV and the likelihood of increasing case detection in this target group.

In Zambia, implementation of LF LAM is in the early stages and only few facilities are using the test for TB diagnosis. Early results have shown that LF LAM can contribute greatly to TB notifications. However, evidence to show this potential at program level is minimal. There are few published data on the impact of LF LAM. A study conducted in South Africa evaluated the potential impact of the test on TB incidence and mortalities and demonstrated that LF LAM could prevent mortalities in HIV positive individuals with advanced HIV infection. However, the study pointed out that achieving population level impact assessment will require expansion of LF LAM roll out in non HIV care settings (Ricks et al 2020). Another study conducted in Zambia

explored the performance of LF LAM in HIV positive adults in peri-urban sites. This study showed overall sensitivity of 31.7% and 81.8% in those individuals with low CD4 count of 50 cells/ml[6].

In this study, we intend to evaluate the impact of LF LAM on TB notifications in Lusaka District.

1.1 Statement of the Problem

There was a decline in TB notifications from 57,601 in 2003 to 40,000 in 2020. This is attributed to failure to detect cases or inability to notify detected cases. In an effort to improve TB notifications, MoH has initiated interventions such as active case finding (ACF) activities with no remarkable improvement. The major challenges are missing TB cases among patients who visit the facilities and reduced sensitivity of diagnostic tests in HIV immunosuppressed patients. If these cases are not detected in the community in a timely manner, there will be continuous transmission of infections leading to high levels of mortalities, increased catastrophic costs associated with tuberculosis care at household level and diminished productive workforce. WHO has endorsed the use of LF- LAM to detect cases in PLWHIV which may lead to an increase in TB case detection, though the benefit of this new test on TB notification is not well documented in Zambia. Based on the above statement it became necessary for the researcher to undertake a study that described the impact of LF-LAM on TB notifications in Lusaka District.

1.2 Significance of the Study:

The results of the study will assist to make sound policy decisions on the role LF-LAM will play in detection of TB cases especially in those patients where TB is difficult to find. Once more cases are found and put on treatment; it will lead to reduced number of TB related death. Based on the study results, the TB program may decide to revise the algorithm and make it more comprehensive to ensure the right people are tested using LF-LAM.

1.3 General Research Objective: To assess the impact of LF- LAM test on TB notifications at a selected health facility.

1.4 Specific Research Objectives:

- To describe trends in TB notifications among people living with HIV
- To determine the effect of LAM test introduction on TB case notification among HIV positive individuals.

- To compare the median turnaround time of results between GeneXpert and LAM test

1.5 Research Questions:

- What are the trends in TB notifications among people living with PLWHIV
- What is the difference in TB notifications among PLWHIV before and after LF-LAM introduction?
- What is the median turnaround time of receiving TB laboratory results for GeneXpert and LAM test

Chapter 2: Literature Review

Minion et al (2011) reviewed nine (9) studies to examine the accuracy of the LF LAM in the detection of active TB. The study revealed that sensitivity ranged between 13% and 93%. When LAM was used in HIV positive individuals, the incremental yield increased between 3% and 51.8%. The study further explained that more TB positive cases were found among those who were immunosuppressed. Shah et al (2009) also examined the accuracy of LAM for detection of TB. The study findings revealed that the sensitivity of LAM was 59% among bacteriologically TB confirmed cases. The test was also more sensitive than acid fast bacilli smear microscopy, detecting 56% of smear negative TB cases.

De Vasconcellos, Ramjathan & Singh (2021) evaluated the usefulness of the LF LAM test in a prospective observational study which was focused on presumptive TB patients with or without HIV who were seriously ill and being managed in intensive care unit (ICU). They found that LAM had a sensitivity of 50% in those patients with confirmed TB disease. In a study conducted by Sangkhla et al (2019) to determine the accuracy of the LF LAM in adults with advanced HIV disease, the yield improved by 11% when both smear microscopy and LF LAM were used at the same time. The study also noted increased sensitivity in people with advanced HIV disease and in those patients who were co-infected.

Mutemba et al (2017) evaluated the value of including LF LAM test in the diagnostic algorithm in Mozambique. The study revealed that the use of point of care test improved TB case finding among HIV positive patients. In Brazil, research was carried out to determine the diagnostic performance of LF LAM in people with HIV using the public health diagnostic algorithm. The findings showed that the test had clinical value to rapidly diagnose TB in immunosuppressed individuals (Benjamin et al, 2019). The accuracy was 79.9% while sensitivity was 46.9%. People with very low CD4 count had an improved sensitivity of 70.4%.

Stephen et al (2009) conducted a cross sectional study to examine the utility of LF LAM in HIV positive individuals with high prevalence of smear negative results. The study found that a positive LF LAM tests was strongly associated with low CD4 count and all those patients with immune reconstituted disease had a positive LF LAM test at baseline.

Huerga et al (2021) examined the diagnosis of TB among 387 patients admitted in hospital settings. Among the patients, 54% had a CD4 <200 cells/mm^3, 64% were classified as

presumptive TB, and while 90% had one or more TB symptoms. LAM results were available for 99.0% of patients. They found that 26.1% (100/383) had LAM-positive results and among those who had not received Xpert result, 28.5% (43/151) were LAM-positive. In another study, Huerga et al (2017) assessed the incremental yield of LAM in HIV positive individuals when based on TB symptoms, smear microscopy, x ray and GeneXpert test. They found that LAM increased the diagnostic yield from 47.4% to 84.0% when used in combination with clinical signs and X-ray; with clinical signs and microscopy from 62.2% to 82.1%, and from 74.4% to 87.8% when used based on clinical signs and Xpert.

Another research was conducted by Peter et al (2013) to examine if the use of LF LAM can add value to the decisions made by the clinicians empirically. In this research, treatment of patients based on the result from LAM strip testing was better than empirical treatment as LF LAM detected more TB cases in persons with advanced immunosuppression and greater disease severity.

Mathabire et al (2019) evaluated the utility of LAM in resource limited settings using HIV positive adults as a study group. They found that time to treatment was reduced due to improved turnaround time as results were available on the same day. The people that received LAM test results were more than those that received smear microscopy results.

Singhroy et al (2020) conducted a study to ascertain challenges that come with the introduction of LF LAM in 31 high TB and HIV/AIDS countries. They found that the challenges such as lack of specific allocated budget, poor coordination between TB and HIV programs, product approval hurdles and consideration of the test as benefiting only a few individuals affected the smooth implementation of the test.

Kasaro et al (2020) examined the overall sensitivity of LF LAM among adults with HIV who were also on antiretroviral treatment in a study conducted in Zambia. They found that LF LAM had the ability to detect positive cases by 31.7% compared to TB culture methods. For those patients with CD4 count of 50 cells/mm^3, the sensitivity improved further to 81.8% (95%CI 52.3–94.9).

The diagnosis of TB in children remains a challenge as children do not easily produce sputum samples. Schramm et al (2021) determined the value of using LAM in malnourished children. The study assessed the prevalence of TB among children with TB signs and symptoms and those

without. LAM-positivity was 52.0% for those with probable TB and 37.0% in children without TB symptoms.

2.1 Theoretical Framework: Germ Theory

The germ theory was postulated by Joseph Lister, Robert Koch and Louis Pasteur in mid-19th century. The germ theory states that there are microorganisms that are too small to be seen with unaided eyes and these organisms can cause disease. The theory was further made possible by the certain laboratory methods that allowed the study of bacteria. In this study, LF-LAM test is recommended to be used in immunosuppressed individuals such as people living with HIV and malnourished children due to its higher sensitivity. The test is capable of providing TB diagnosis by detection of lipoarabinomannan, a mycobacterium biomarker, which confirm presence of the TB disease. This theory will help understand how a newly approved LF-LAM can be used to increase TB detection and notifications among PLWHIV.

Figure 1: Conceptual Framework

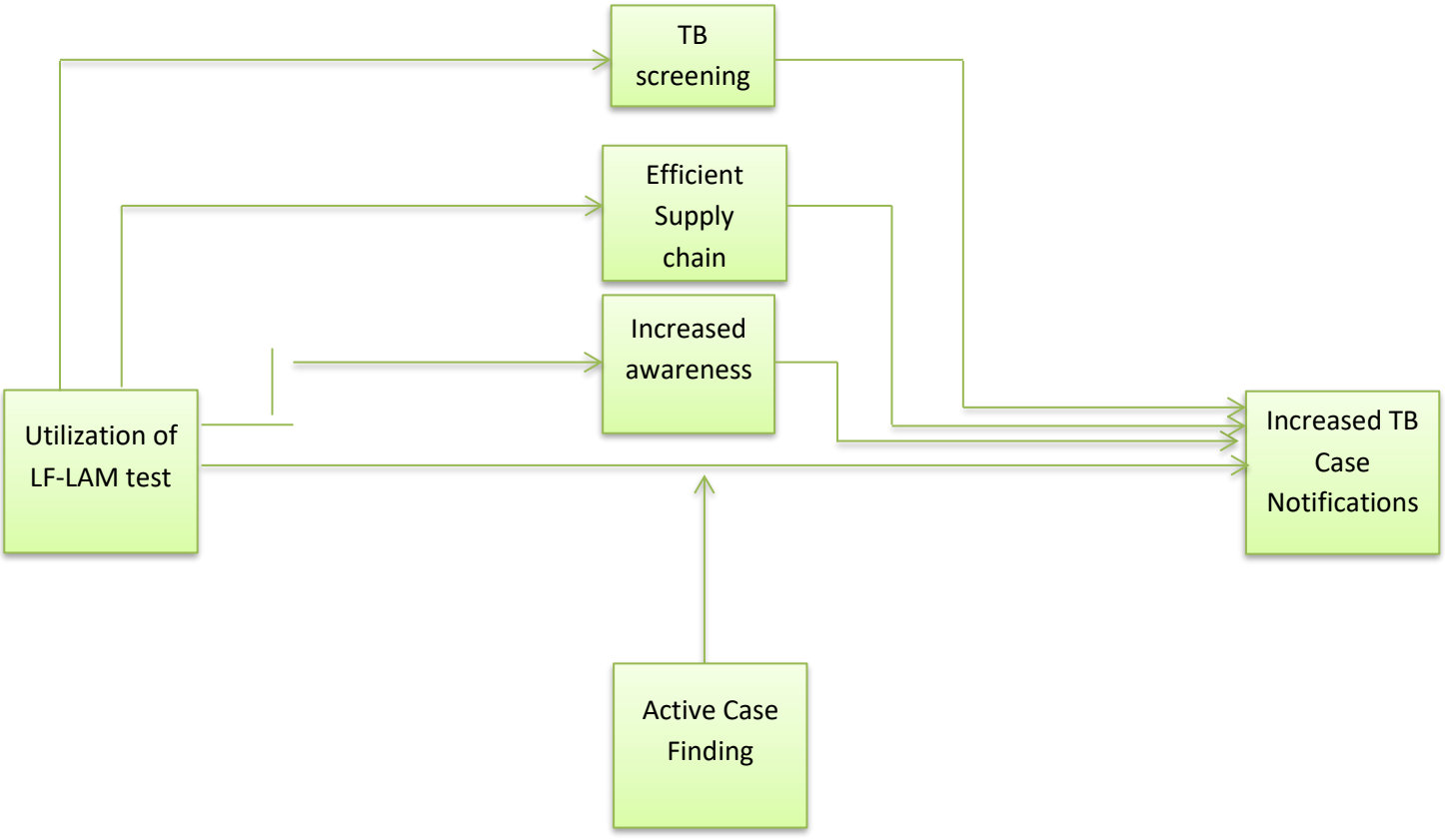


Figure 1

Figure 1: Conceptual framework on the impact of Lateral Flow Urine LAM Test on TB Case Notifications among People with HIV at Levy Mwanawasa Teaching Hospital, Zambia. This is my own model of a conceptual framework.

Narrative

The proposed conceptual framework builds on the fact that efficient supply chain of LAM test, TB screening, and increased awareness on the availability of the urine test can ensure optimal utilization of LF-LAM leading to increase in TB notifications among people living with HIV. Active case finding is a confounder variable. It can increase the TB notifications without being related to LF-LAM utilization.

Chapter 3: Methodology

This chapter outlined the methodology that was used in the study. The chapter also provided guidance on data collection and analysis based on the laid out plan.

3.1 Research Approach

Sacred Heart University (2020) defines research design as a strategy that coherently addresses the research problem using empirical data. It constitutes data collection, measurement and analysis. Voxco (2021) defined research design as a framework that allows the researcher to use a suitable method for the study. The researcher used quantitative study approach so as to give statistical tables and graphs showing the trends since the introduction of Lam test on TB cases at Levy Mwanawasa Teaching Hospital

3.2 Research design

The researcher employed quasi experimental study design also known as an interrupted time series design. Data was collected on TB notifications from 2017 to 2021. The main purpose was to observe changes in the dependent variable (TB notifications) for some time before and after the LF – LAM test was introduced. Ultimately, the design was to allow the researcher to investigate the impact of LF-LAM on TB Case Notifications among People living with HIV at Levy Mwanawasa Teaching Hospital, Zambia.

3.3 Study Population/ Target population

The study population included HIV positive individuals who accessed ART services at Levy Mwanawasa Teaching Hospital. Based on the MoH/NTLP diagnostic algorithm, HIV positive individuals with low CD4 count, seriously ill and advanced HIV disease (AHD) were eligible for LF LAM testing.

The target population were adults (above 14years old) living with HIV and accessing ART at Levy Mwanawasa Teaching Hospital.

3.4 Sample and sampling technique

The sample size was determined using a formula known as Yamene formula. This is because the population was already known from the facility statistics. Systematic sampling was used to obtain a representative sample by picking the nth file of the client.

The Yamane formula is as follows:

Where:

$n = N/ (1+N (e)^2)$

n signifies the sample size

N signifies population under study

e signifies the level of precision

In this study: N=1600, e=5%

$n = 1600/(1+1600\ (0.05)^2)$

$n = 1600/\ (1+1600(0.0025)$

$n = 1600/1+4$

$n = 1600/5$

$n = 320$

Therefore, thee sample size was 320 people living with HIV.

3.5 Inclusion Criteria

- People living with HIV at Levy Mwanawasa Teaching Hospital.
- HIV positive patients who were tested for TB between 2017 and 2021.
- People living with HIV between the age of 15 and 70 years.

3.6 Exclusion Criteria

- People that did not test HIV positive at Levy Mwanawasa Teaching Hospital.
- HIV positive patients who have never tested for TB
- People below the age of 15 years and above the age of 70 years at Levy Mwanawasa Teaching Hospital.

3.7 Data collection

The researcher reviewed the TB treatment register and the presumptive register as a data collection sources. TB treatment register provided the TB status of HIV positive client.

3.8 Validity and reliability

Validity and reliability are important concepts and of concern throughout the research process. They are important to the researcher during the research process and to those who read the study report as they provide a basis for making decisions as they consider using the findings in their

practice. Since Levy Mwanawasa is a big facility in the district, the findings of this study will be suitable to apply to the practice of the other health facilities in the district.

3.9 Data analysis

The researcher used interrupted time series analysis for TB notifications collected from 2017 to 2021. TB notifications were collected over time and data divided into 2 segments; the first segment comprised notifications before the introduction of TB LAM, and the second segment is the TB notifications after the intervention. Segmented regression was used to measure statistically the changes in level and slope in the post-intervention period compared to the pre-intervention period. Using segmented regression, there was a different intercept and slope coefficients for the pre and post intervention time periods; hence the trends were established. In addition, the researcher calculated and compared the median turnaround time of all TB results received in the chest clinic between GeneXpert and TB LAM test.

4.0 Ethical considerations

This research involved data collection and no interviews were conducted to the patients. The patient names were de-identified to maintain confidentiality during the data collection process. Information collected by the researcher was used for academic purposes and never availed to the public. The researcher ensured that all the respondents were free from any risk of harm. Identity numbers were used instead of names for anonymity and confidentiality.

CHAPTER 4.0: Results

A total of 404 records for TB patients in the TB registers at Levy Mwanawasa hospital were reviewed. The median (IQR) age of the patients was 38 years (30 years -47 years).Most of the patients were aged between 25-35 years of age ,135 (33%), whereas only 34 (8.4%) were aged less than 24 years. Half of the participants were female. Seventy-seven (19.1%) were tested using a LAM test while 327(80.9%) were tested Xpert TB test.

Table 1: Baseline Characteristics

	N (%)
Age	
<24	34 (8.4%)
25-35	135 (33.4%)
36-45	113 (28.0%)
45+	122 (30.2%)
Gender	
Female	202 (50.0%)
Male	202 (50.0%)
TB test	
LAM	77 (19.1%)
Xpert	327 (80.9%)

Seventy five percent of the patients got their results with a day median (IQR) 1(1-1), both before and after the intervention. The mean turnaround time for TB results was 1 day both in the pre and post intervention. Figure 1 below shows the results for the t test comparing TAT before and after the intervention. The results below show that mean turnaround time before was lower than that after the intervention by 0.30115 days (p value <0.05)

Figure 2: t test results

Group	Obs	Mean	Std. err.	Std. dev.	[95% conf.	interval]
After	**264**	**1.337121**	**.0420888**	**.6838612**	**1.254247**	**1.419995**
Before	**139**	**1.035971**	**.029612**	**.3491205**	**.9774193**	**1.094523**
Combined	**403**	**1.233251**	**.0302325**	**.6069138**	**1.173817**	**1.292684**
diff		**.30115**	**.06188**		**.1795003**	**.4227996**

diff = mean(**After**) − mean(**Before**) t = **4.8667**

H0: diff = 0 Degrees of freedom = **401**

Ha: diff < 0 Ha: diff != 0 Ha: diff > 0

Pr(T < t) = **1.0000** Pr(|T| > |t|) = **0.0000** Pr(T > t) = **0.0000**

Figure 3: Interrupted time series results

```
Time variable: quarters, 2017q1 to 2021q4
        Delta: 1 quarter

Regression with Newey-West standard errors      Number of obs     =         18
Maximum lag = 0                                 F(  3,        14) =       0.68
                                                Prob > F          =     0.5780
```

_tbnotif	Coefficient	Newey-West std. err.	t	P>|t|	[95% conf.	interval]
_t	-.7380952	3.961242	-0.19	0.855	-9.234115	7.757924
_x2019q3	-10.14329	25.49256	-0.40	0.697	-64.8194	44.53282
_x_t2019q3	.6471861	4.867529	0.13	0.896	-9.792626	11.087
_cons	116.8333	20.86522	5.60	0.000	72.08188	161.5848

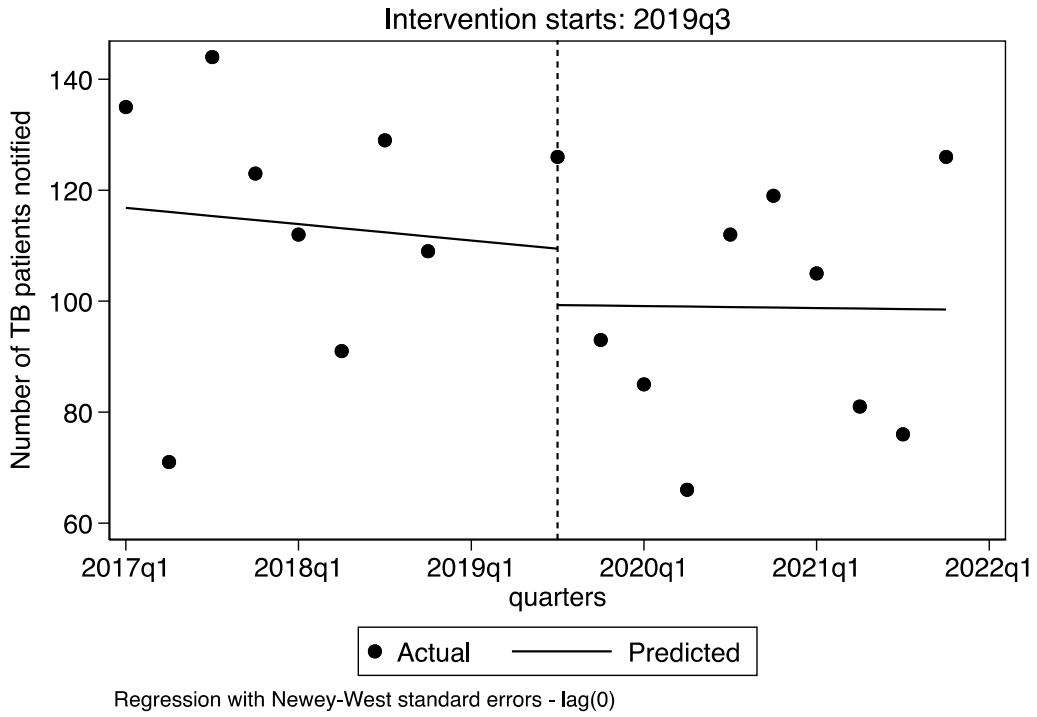
Postintervention Linear Trend: 2019q3

Treated: _b[_t]+_b[_x_t2019q3]

Linear Trend	Coef.	Std. Err.	t		[95% Conf.	Interval]
Treated	-.0909091	2.828675	-0.03	0.975	-6.157813	5.975995

There were records for 18 quarters from 2017-2021. The interrupted series results below show that in 2017 the estimated notifications were started at 116 per month then there was a non-significant reduction of 0.74 points per quarter prior to the implementation. In the first quarter of the intervention the reduction in TB notifications was estimated to be 10 points (95% CI -0.65-45, p value > 0.7). This was followed by an increase in the quarterly trend of TB notifications relative to the preintervention trend of 0.65 points (95% CI -9.7 -11.1, p value =0.90) per quarter in the post intervention trend in TB notification see figure 1 above. The post intervention trend in TB notifications reduced by 0.1 points (95% CI-6.2-6.0), though not statistically significant reduction. Figure 2 below shows the trends in TB notifications pre and post the intervention and the change in the slope pre and post.

Figure 4: Plot of the estimated and projected TB notification



CHAPTER 5.0: Discussion

The TB notifications among people living with HIV were unstable during the pre and post intervention period. During the post intervention (2021), the trend in TB notifications reduced by 0.1 points (95% CI-6.2-6.0). This post intervention period was marked by covid-19 pandemic which was marred by restrictions from government officials. The reduction in TB notifications is in line with the recent study which showed that there was a notable decease in TB case notifications among people living with HIV in Zambia during the covid-19 pandemic (Lungu et al, 2020).

The findings of the study shows that mean turnaround time before was lower than that after the intervention by 0.30115 days (p value <0.05) though the difference was very minimal. It means the use of TB LAM could not provide an additional benefit in clinical decision making for bacteriologically confirmed cases as results were received at the same time before and after the intervention. This TAT was still acceptable based on the national TB program recommendations.

There notable limitations to the study that need to be explored. The WHO recommends the use of TB LAM in immunosuppressed adults (CD4 count less than 200 for inpatients and CD4 less than 100 for outpatients), advanced HIV disease people with sepsis and seriously ill. The test has proved to be highly sensitive in those patient categories (WHO, 2020). The study did not collect data on the eligibility criteria for TB LAM. Hence could not establish whether the LAM test was correctly used. In addition, the study could not examine the supply chain of the LAM test though the findings showed that fewer tests for LAM were performed compared to Xpert. Ineffective supply chain may adversely affect case detection especially if there are frequent stock outs of laboratory reagents.

CHAPTER 6.0: Conclusion and Recommendations

The implementation of TB LAM was not associated with improved TB case finding. This can be attributed to so many factors such as inability of the clients to access services due to covid-19 restrictions, failure to follow the eligibility criteria and short supply of the commodity at the facility. Future studies are needed to establish the real impact of TB LAM test on cases detected in the TB program.

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Appendices

Appendix 1: Gantt chart

	Activity	Responsible person	Aug 2021	Nov 2021	Jan 2022	Feb - Apr 2022	May-Jun 2022
1	Research Topic Submission	Researcher	X				
2	Research Proposal Submission	Researcher		X			
3	Proposal Presentation	Researcher		X			
3	Testing of data collection tools	Researcher			X		
4	Data collection	Researcher				X	
5	Data entry and cleaning	Researcher				X	
6	Data analysis	Researcher				X	
7	Report writing	Researcher				X	
8	Submission of Final Dissertation	Researcher					X

Appendix 2: The Budget

Research on the impact of lateral flow urine LAM test on TB Case notifications among people living with HIV at Levy Mwanawasa Teaching Hospital, Zambia					
Budget Description	**No. of People/units**	**Unit Cost**	**No. of Days**	**No. of times**	**Total**
Transport for Researcher	1	100	5	1	500
Research assistants	2	200	5	1	2,000
Lunch allowance for Research team	3	100	5	1	1,500
Stationary (realm of paper and pens)	1	400	1	1	400
Printing	100	5	1	1	500
Ethical clearance	1	500	1	1	500
Total					**5,400**

Appendix 3: Consent Form

Hello! My name is_____ and I am a student from the University of Lusaka. I am conducting a study to assess the impact of lateral flow urine lam test on TB Case notifications among people living with HIV at Levy Mwanawasa Teaching Hospital, Zambia. This study is part of my course requirement and findings can be used to inform the government and other relevant non-governmental organisations (NGOs) who implement various TB related intervention.

Participants for this study will be males and females supporting either TB or HIV program. Participating in this study is a personal choice.

What will happen if I join the study?

If you accept to take part in the study, you will be asked a set of questions which might take around 30 minutes. Your participation is completely voluntary and you have the right to refuse.

What are the risks and benefits for being in the study?

This study involves asking questions about how the TB LAM is implemented. However, there are no risks involved in participating in the study.

There will be no direct benefit for taking part in the study. The data we get from the study will help know the situation on the ground; this will put us in a better position to give advice to agencies who want to roll out intervention programs. The study findings will also add to the body academics.

Confidentiality

Your responses to the questionnaire will be kept as private as possible. I will keep the records using numbers, not names. Your name or other things that may identify you will not appear when I discuss the results of the study.

What are my rights if I join the study?

Taking part in this study is your choice. You can choose to take part in the study or not. You may also leave the study at any time, for any reason.

Who can answer my questions about the study?

If you have any question concerning the study, you can contact Robertson Chibumbya on 0963747745.

STATEMENT OF CONSENT

I want to be sure that you have read this form and understood it. You should sign below only if the interviewer has explained the form to you clearly and answered all your questions. If you want to participate, please sign below.

The interviewer has explained all the procedures of the study to me. I agree to join the study. I have had a chance to ask questions and I feel that all my questions have been answered. I know that participating in this research study is my choice. I know the information will be kept as private as possible. I have received a copy of this consent form. I agree to complete the questionnaire.

[ ] I agree [ ] I don't agree

Appendix 4:

Data Collection Tool I

Year	Quarter	Number of PLWHIV in ART	Number of TB patients notified
2017	One		
	Two		
	Three		
	Four		
	Total		
2018	One		
	Two		
	Three		
	Four		
	Total		
2019	One		
	Two		
	Three		
	Four		
	Total		
2020	One		
	Two		
	Three		
	Four		
	Total		
2021	One		
	Two		
	Three		

	Four		
	Total		

Data Collection Tool II

Serial Number	Sex	Age (in years)	Residence	TB Test performed	Turnaround time (TAT)	Quasi Condition (Before or after intervention)

Appendix 5: Ethical Clearance

UNIVERSITY OF LUSAKA
SCHOOL OF MEDICINE AND HEALTH SCIENCES
LEOPARDS HILL CAMPUS
Plot No. 37413, Off Alick Nkhata Mass Media. P. O Box 36711, Lusaka.
Phone: +260211258505, 258409 Fax +260211233409; Cell +260976075850,961917862,
E-mail:unilus@zamnet.zm,ictar@zamnet.zm

SCHOOL OF MEDICINE AND HEALTH SCIENCES RESEARCH ETHICS COMMITTEE

Ref no: IORG0010092-2022/043

Date: 17th January, 2022

ROBERTSON CHIBUMBYA – BSPH18212966

Re: Research Title; THE IMPACT OF LATERAL FLOW URINE LAM TEST ON TB CASE NOTIFICATIONS AMONG PEOPLE LIVING WITH HIV AT LEVY MWANAWASA TEACHING HOSPITAL, ZAMBIA: QUASI EXPERIMENTAL STUDY DESIGN

The above research was submitted to the research ethics committee for review. The study has no major ethical problems and is approved subject to the following:

1. The study cannot be changed without express permission of the UNILUS Research ethics committee
2. Approval from the Lusaka District health Management or equivalent health authorities should be sought.
3. The study tools should be added.
4. An informed consent form should be attached and filled by all study participants (If dealing with primary data)
5. The risks and benefits should be included in the consent form.

Congratulations and the committee wishes you success in your work.

Prof Kasonde Bowa
MSc(Glasgow),M.Med(UNZA),FRCS(Glasgow),FACS,FCS,DPH(LSTMH),MPH(UCL)
Chairman- UNILUS REC
Professor of Urology and Consultant Urologist
Executive Dean
University of Lusaka and University Teaching Hospital
School of Medicine and Health Sciences.

Appendix 6: Permission Letter

UNIVERSITY OF LUSAKA
SCHOOL OF MEDICINE AND HEALTH SCIENCES
LEOPARDS HILL CAMPUS
Plot No. 37413, Off Alick Nkhata Mass Media. P. O Box 36711, Lusaka.
Phone: +260211258505, 258409 Fax +260211233409; Cell +260976075850,961917862,
E-mail:unilus@zamnet.zm,ictar@zamnet.zm

Date: 17th January, 2022

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……..

PERMISSION FOR **ROBERTSON CHIBUMBYA No. BSPH18212966** TO CONDUCT A RESEARCH STUDY AT YOUR FACILITY/ INSTITUTION/ ORGANIZATION
Reference is made to the above subject matter

The University of Lusaka, School of Medicine and Health Sciences here by requests for permission for **Robertson Chibumbya** a Public Health Student to conduct research at your facility/ institution/ organization, entitled**; THE IMPACT OF LATERAL FLOW URINE LAM TEST ON TB CASE NOTIFICATIONS AMONG PEOPLE LIVING WITH HIV AT LEVY MWANAWASA TEACHING HOSPITAL, ZAMBIA: QUASI EXPERIMENTAL STUDY DESIGN.**

The research is in partial fulfillment of the requirements for the degree of Bachelor of Science Public Health. This is purely for academic purposes and information gained in such a way will not be used in the public domain without prior authorization from the institutions/ organizations involved.

The research topic has been cleared by the University of Lusaka, School of Medicine and Health Sciences Research Ethics Committee as per the attached copy. Data collection is expected to be done from **1st February, 2022 to 29th April, 2022**.

The University of Lusaka avails itself of this opportunity to review to your office the assurances of its highest considerations and looks forward to your timely and favorable response.

Prof Kasonde Bowa
MSc(Glasgow),M.Med(UNZA),FRCS(Glasgow),FACS,FCS,DPH(LSTMH),MPH(UCL)
Chairman- UNILUS REC
Professor of Urology and Consultant Urologist
Executive Dean University of Lusaka and University Teaching Hospital
School of Medicine and Health Sciences.

Appendix 7: NHRA Research Approval

NATIONAL HEALTH RESEARCH AUTHORITY
Paediatric Centre of Excellence, University Teaching Hospital, P.O. Box 30075, LUSAKA
Chalala Office Lot No. 18961/M, Off Kasama Road, P.O. Box 30075, LUSAKA
Tell: +260211 250309 | Email: znhrasec@nhra.org.zm | www.nhra.org.zm

Ref No: NHRA000008/25/02/2022 **Date: 25th Febuary, 2022**

The Principal Investigator,
Robertson Chibumbya,
University of Lusaka,
Lusaka, Zambia

Dear Robertson Chibumbya,

Re: Request for Authority to Conduct Research

The National Health Research Authority is in receipt of your request for authority to conduct research titled **"The Impact of Lateral Flow Urine Lam Test on TB Case Notifications among People Living With HIV At Levy Mwanawasa Teaching Hospital, Zambia: Quasi Experimental Study Design."**

I wish to inform you that following submission of your request to the Authority, our review of the same and in view of the ethical clearance, this study has been **approved** on condition that:

1. The relevant Provincial and District Medical Officers where the study is being conducted are fully appraised;
2. Progress updates are provided to NHRA quarterly from the date of commencement of the study;
3. The final study report is cleared by the NHRA before any publication or dissemination within or outside the country;
4. After clearance for publication or dissemination by the NHRA, the final study report is shared with all relevant Provincial and District Directors of Health where the study was being conducted, University leadership, and all key respondents.

Yours sincerely,

Prof. Godfrey Biemba
Director/CEO
National Health Research Authority

Appendix 8: Lusaka Provincial Health Office Research Clearance

All correspondence should be addressed to the
Provincial Health Director
Telephone: +260 211 256813
Fax: +260 211 256814
Telephone: +260 211 256815
Cell: +260 974 787873
+260 963 908260

REPUBLIC OF ZAMBIA
MINISTRY OF HEALTH

In Reply please quote:
PHOLSK/101/8/1
File No.

Lusaka Provincial Health Office
P.O. Box 32573
LUSAKA

29th March, 2022

Robertson Chilumbya
Principal Investigator
University of Lusaka
Lusaka, Zambia

RE: PERMISSION TO CONDUCT RESEARCH

Lusaka Provincial Health Office is in receipt of your request for permission to conduct research titled **"THE IMPACT OF LATERAL FLOW URINE LAM TEST ON TB CASE NOTIFICATIONS AMONG PEOPLE LIVING WITH HIV AT LEVY MWANAWASA UNIVERSITY TEACHING HOSPITAL, ZAMBIA: QUASI EXPERIMENTAL STUDY DESIGN".**

My office is glad to inform you that it has no objection to your request provided that;

1. The relevant Institution Director where the study is being conducted are fully appraised;
2. Progress updates are provided to Lusaka Provincial Health Office and the District Health Office biannually from the date of commencement of the study;
3. The final study report is cleared by NHRA before any publication or dissemination within or outside the country;
4. After clearance for publication or dissemination by NHRA, the final study report is shared with all relevant Provincial and District Directors of Health where the study was being conducted, University Leadership and all key respondents.

Kindly ensure minimum interruption in health service delivery to the selected health facility.

By copy of this letter, the District Health Office / facility in charge are advised to allow you undertake the above mentioned research and provide you with the relevant support.

Yours faithfully,

Dr Consity Mwale
Provincial Health Director
LUSAKA PROVINCE

REPUBLIC OF ZAMBIA
MINISTRY OF HEALTH
LUSAKA PROVINCIAL HEALTH OFFICE
30 MAR 2022
PROVINCIAL HEALTH DIRECTOR
P. O. BOX 32573, LUSAKA

CC. Lusaka District Health Director
CC: Senior Medical Superintendent – Levy MUTH

Physical Address: 3 Saise Road, Longacres, Lusaka, Zambia.

Appendix 9: Levy Mwanawasa Research Clearance Application

7 April 2022

University of Lusaka

Pioneer Campus plot no. 37413

P.O Box 36711

Lusaka

The Senior Medical Superintendent

Levy Mwanawasa Teaching Hospital

Lusaka

Dear Sir/Madam

Ref: Application for Study Clearance of my Academic Research Proposal

I would like to request for clearance of my academic research. The research proposal has been ethically approved by University of Lusaka (UNILUS) Ethics committee. Furthermore, the research has been approved by the National Health Research Authority (NHRA) and study clearance given by the Ministry of Health Lusaka Provincial Health Office.

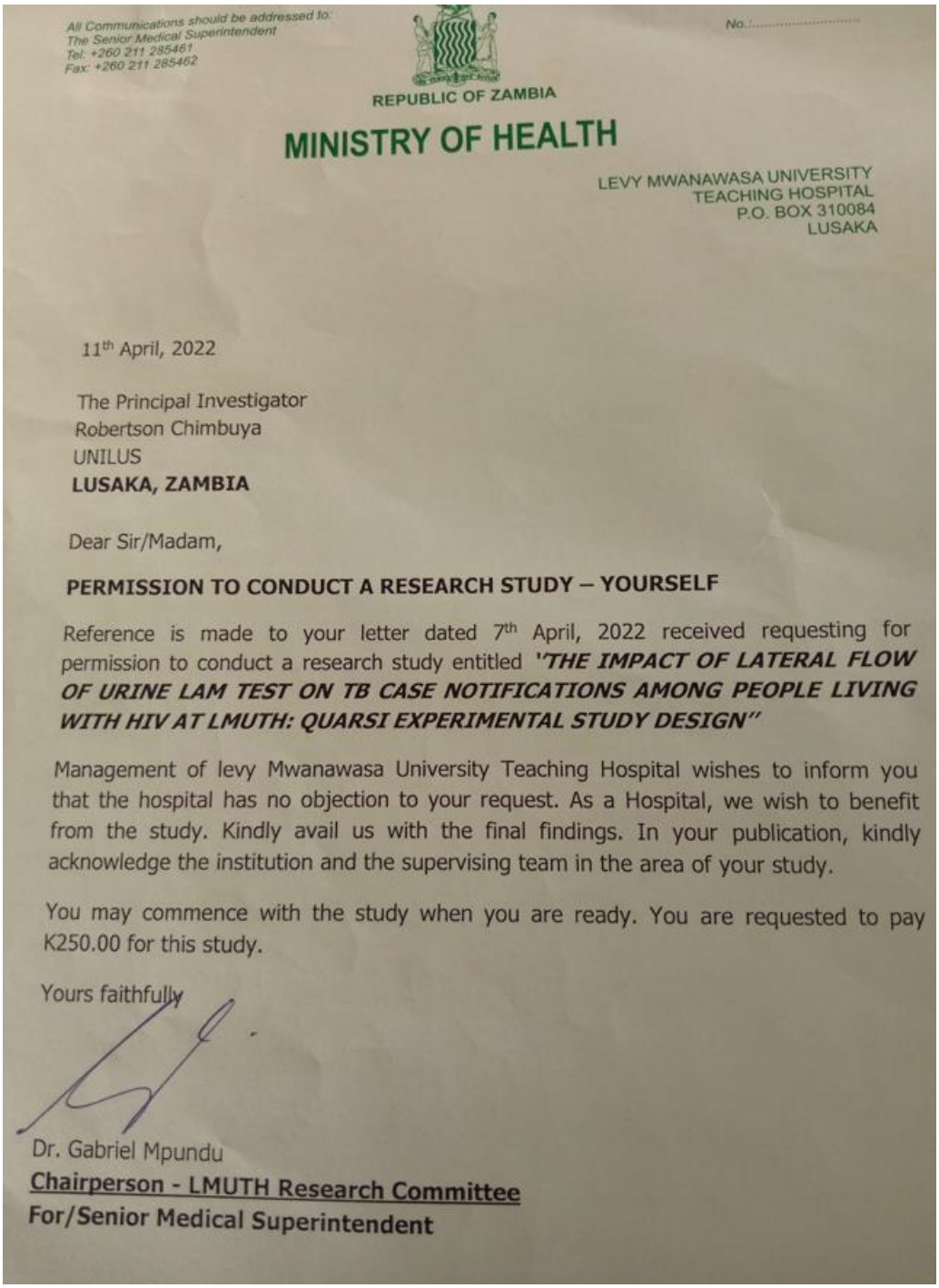
I am a fourth year student at UNILUS pursuing a degree program in Public Health. My student number is BSPH18212966. Before I complete my studies this year, am required to conduct research as a pre-requisite. The research will be conducted in Lusaka District at Levy Mwanawasa University Teaching Hospital. My research title is "The Impact of Lateral Flow Urine Lam Test on TB Case Notifications among People Living With HIV At Levy Mwanawasa Teaching Hospital, Zambia: Quasi Experimental Study Design". For details find the attached research proposal.

I hope my request will be considered.

Sincerely Yours,

Robertson Chibumbya

Appendix 10: Levy Mwanawasa Research Clearance



All Communications should be addressed to:
The Senior Medical Superintendent
Tel: +260 211 285461
Fax: +260 211 285462

No.:.....

REPUBLIC OF ZAMBIA

MINISTRY OF HEALTH

LEVY MWANAWASA UNIVERSITY
TEACHING HOSPITAL
P.O. BOX 310084
LUSAKA

11th April, 2022

The Principal Investigator
Robertson Chimbuya
UNILUS
LUSAKA, ZAMBIA

Dear Sir/Madam,

PERMISSION TO CONDUCT A RESEARCH STUDY – YOURSELF

Reference is made to your letter dated 7th April, 2022 received requesting for permission to conduct a research study entitled ***"THE IMPACT OF LATERAL FLOW OF URINE LAM TEST ON TB CASE NOTIFICATIONS AMONG PEOPLE LIVING WITH HIV AT LMUTH: QUARSI EXPERIMENTAL STUDY DESIGN"***

Management of levy Mwanawasa University Teaching Hospital wishes to inform you that the hospital has no objection to your request. As a Hospital, we wish to benefit from the study. Kindly avail us with the final findings. In your publication, kindly acknowledge the institution and the supervising team in the area of your study.

You may commence with the study when you are ready. You are requested to pay K250.00 for this study.

Yours faithfully

Dr. Gabriel Mpundu
Chairperson - LMUTH Research Committee
For/Senior Medical Superintendent