DETERMINANTS OF NON-ADHERENCE AND LOSS TO FOLLOW-UP AMONG TUBERCULOSIS PATIENTS ON TREATMENT AT MBAGATHI COUNTY HOSPITAL

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A dissertation submitted in partial fulfillment of the Requirements for the Award of the Master of Pharmacy in Clinical Pharmacy of the University of Nairobi.

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DEDICATION

I dedicate this work to my parents Mauritius Mbaya and Mary Igoki for their moral and financial support throughout the journey of pursuing my dreams.

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ABSTRACT

Introduction: Tuberculosis is a communicable disease caused by the bacillus Mycobacterium tuberculosis. It is one of the leading causes of death from infectious diseases in the world, and is a serious public health issue in Kenya

Tuberculosis treatment non-adherence and lost to follow up is widespread. The rate of non-adherence in Kenya is high but the current burden is not well understood. Non-adherence and loss to follow up leads to development of drug resistance, treatment failure and relapse, increased transmission of the bacilli and prolonged morbidity and mortality.

Main objective: To determine factors associated with non-adherence and loss to follow up among tuberculosis patients on treatment at Mbagathi county hospital

Methodology: The study design was mixed methods research where 137 participants, selected by simple random sampling, were interviewed using a structured questionnaire. A focused group discussion was conducted on 6 healthcare workers at the Tuberculosis clinic. Data was populated in Microsoft Excel 2010 then analyzed using Stata 13 software. Descriptive and inferential analysis (logistic regression) was done and significance set at an alpha of 0.05

Results. Out of the 137 participants who agreed to participate in the study, 90 (65.69%) were males. Participants who were non-adherent were (7.30%). Six participants lost to follow up translating to a prevalence of 2.76%. Five (83.33%) were males. Travel was a major cause of loss to follow up.

Regimen complexity was associated with higher odds of non-adherence (aOR 14.67 95% CI 2.44,88.07). Forgetting to take medication was associated with higher odds of non-adherence (aOR 9.11 95% CI 1.16,71.54). Those who reported to occasionally forget to take medications had higher odds of non-adherence (aOR 27.69 95% CI 3.72,206.09)

Conclusion: Non-adherence and loss to follow up are widespread in medical setup. Medication complexity and forgetting to take medications were identified as the significant factors determining non-adherence to tuberculosis medications while travel was the major cause of loss to follow up.

ABBREVIATIONS AND ACRONYMS

AIDS	Acquired immunodeficiency syndrome
AOR	Adjusted odds ratio
cOR	crude odds ratio
COVID-19	Corona virus 2019
DOTS	Directly observed treatment strategy
DTS	Drug sensitivity testing
FDC	Fixed dose combination
HCP	Health care providers
HIV	Human immunodeficiency virus
IQR	inter quartile range
LFTU	Loss to follow up
MDR	Multi-drug resistant
MDR-TB	Multi-drug resistant tuberculosis
MMAS-8 tool	Morisky medication adherence scale 8 tool
MT4	Moved to category 4
OR	Odds ratio
TB	Tuberculosis
WBOT	Ward-based outreach teams
WHO	World health organization
XDR-TB	Extensively drug resistant tuberculosis

OPERATIONAL DEFINITION OF TERMS

Adherence - the degree to which the person's behavior corresponds with the agreed recommendations from a health care provider."

Drug resistance - The reduction in the effectiveness of a medication such as an antimicrobial in treating a disease or condition.

Intentional non-adherence – a process in which the patient actively decides not to take medication or follow treatment recommendations, presumably having weighed the costs and benefits of treatment.

Loss to follow-up – a patient who did not start treatment or whose treatment was interrupted for 2 consecutive months or more

CHAPTER ONE: INTRODUCTION

1.1 Background of the study

Tuberculosis (TB) is a bacterial infection caused by Mycobacterium tuberculosis. TB is a global burden, with a quarter of the globe worldwide population being infected with the bacteria (1). With a projected 1.5 million fatalities in 2018, it is among the top causes of mortality from infectious illnesses worldwide. Globally, an estimated 1.7 billion individuals are affected by the illness (2).

TB poses a serious public health issue in Kenya. 120,000 people develop TB and 18,600 people die from it in a year. It is responsible for about 6% of all deaths.(3) According to the World Health Organization, Kenya is among the 30 high-burden TB, TB/HIV, and MDR nations in the world (WHO)(4).

Treatment of drug-susceptible TB normally involves using fixed drug-susceptible to avoid he development of mutations. Treatment should be directly observed to promote adherence. Rifampicin, isoniazid, pyrazinamide, and ethambutol are among the first-line medications used to treat tuberculosis. The medicines are administered in two stages: The intensive phase lasts two months and is designed to destroy actively dividing germs as quickly as possible. The continuation phase lasts four to ten months and kills any leftover or latent bacilli while avoiding recurrence (4). Following treatment, individuals with tuberculosis are assigned one of the following treatment outcomes: cured, treatment completed, treatment success, treatment failure, died, moved to Cat 4 (MT4), i.e. developed drug resistance while on first-line treatment regimen, lost to follow-up, or not evaluated (4).

Adherence is "the extent to which a patient follows medical recommendations" (5). According to studies, adherence among chronic illness patients in affluent nations averages 50% (5). Poor adherence has a significant impact in poorer nations because of low health resources and access to health care (1). Adherence to TB therapy is critical in reducing resistance development. It also increases the chances of a cure. Guidelines recommend counseling and assessment of psychological and emotional issues to be done before initiating treatment and during follow-up visits to improve adherence and promote treatment completion (4).

Non-adherence and loss to follow-up during TB therapy are common, with the consequences including initial treatment failure and relapse, which prolong morbidity and death, as well as the transfer of bacilli and the development of drug resistance. (6) WHO currently estimates 3,000 cases of MDR-TB in Kenya (2). A study conducted in a laboratory in Kenya showed 1.3% and 9.4% drug resistance among new and patients who had previously been treated, respectively(7). Despite implementation of DOTS in regions covered by WHO, TB patients are not completing their treatments (1). WHO reports have shown that a number of TB cases have developed treatment failure and relapse after completing treatment. Many cases are developing MDR-TB throughout the world among those who have undergone retreatment (20%). This is due to non-adherence to therapy and a failure to follow up(6). Improving adherence improves patient safety. Poor adherence can affect the course of the disease in a negative manner making the patients less receptive to therapy (5).

A loss to follow-up (LTFU) patient is one who did not begin treatment or whose therapy was discontinued for two months or longer. It's a form of treatment interruption and can happen during the intensive or continuation phase. It necessitates the need for retesting, performing drug sensitivity testing (DTS), and restarting anti-TB treatment. This increases the cost of healthcare (4). LTFU patients pose a great public health risk due to the increased risk of developing drug resistance. They also continue to spread the bacilli to the public leading to increased new TB cases (8).

1.2 Problem statement

TB is a big concern in the Kenyan public health. Despite significant investment by the government and partners in the TB program, the illness is the fourth biggest cause of death in the nation, with Kenya listed as one of the 30 high-burden states by the WHO. Therefore, active case finding and successful management of these cases is an important priority for the country.(9)

A study conducted in Kenya 2018 showed a high level of non-adherence at 35% (9). Adherence to treatment is key for treatment success. Inadequate adherence relates to negative outcomes such as the development of Multi-Drug Resistant Tuberculosis (MDR-TB), relapse, disease transmission, and mortality. According to the WHO 2012 global TB

report, 3.7% of new TB patients worldwide are infected with MDR-TB strains. 9% of these patients have extensively drug-resistant tuberculosis (XDR-TB).(6)

The number of deaths due to TB rose in 2020 during the covid 19 pandemic. This was a setback from the earlier achievement in the management of TB(1) This was due to non-adherence which occurred when the patients were unable to complete their treatments and failed to be declared as healed.

The current WHO report shows a considerable number of TB cases have failed to be declared as cured even after completion of treatment (6) Many occurrences of recurrence after treatment completion and MDR-TB among retreatment cases (20%) have been reported across the world. This is due to non-adherence and a failure to follow up following TB therapy.

Understanding the variables that contribute to non-adherence and lack of follow-up will result in TB treatment success.

1.3 Justification of the study

Tuberculosis is a major cause of illness around the world, especially in areas with a high prevalence of HIV/AIDS. Even though there are treatments available, many patients still struggle to stick to prescribed regimens. There is lack of understanding about the reasons patients struggle to adhere to treatment and this poses a hindrance in managing the tuberculosis(10).

Despite efforts to improve adherence, it remains a challenge because often only patient-related factors are considered and not the other four dimensions such as socioeconomic factors, health care team, system-related factors, therapy-related factors, and condition-related factors. To effectively improve adherence, all of these factors must be taken into account and addressed through targeted interventions (5).

Thus, this study purposes to investigate the various variables that contribute to non-adherence and loss to follow-up among TB patients receiving at Mbagathi.

1.4 Research questions

i. What is the prevalence of non-adherence among TB patients receiving treatment at Mbagathi County Hospital?
ii. what is the prevalence of loss to follow-up among TB patients receiving treatment at Mbagathi County Hospital?
iii. What factors contribute to non-adherence and lack of follow-up among TB patients receiving treatment at Mbagathi County Hospital?

1.5 Objectives

1.5.1 main objective

To assess the determinants of non-adherence and lost to follow-up among tuberculosis patients on treatment at the Mbagathi County Hospital

1.5.2 Specific objective

i. To determine the prevalence of non-adherence among TB patients receiving treatment at Mbagathi County Hospital.
ii. To determine the prevalence of loss to follow-up among TB patients receiving treatment at Mbagathi County Hospital.
iii. To identify factors associated with non-adherence and loss to follow-up among TB patients receiving treatment at Mbagathi County Hospital.

1.6 Delimitations

The study focused on tuberculosis patients undergoing treatment at the Mbagathi County hospital TB clinic.

1.7 Limitations

i. The survey was prone to selection bias leading to limited generalizability of the results. This was mitigated by using simple random sampling during the selection of the study participants.

ii. Use of questionnaires raised the issue of non-response bias where the study participant refused to respond to questions and response bias where they failed to give accurate information. They were also not flexible, where they provided little room for interpretation or clarification.

iii. Interviews may be prone to interviewer bias where the researcher may inaccurately interprete the participant response. This was overcome by blinding the investigator.

A pretest with a well-structured questionnaire was conducted to identify any potential problem which were then rectified, to overcome the limitations.

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

This section covers the extent of the TB issue, patients not sticking to their treatment plan and loss to follow-up, factors that contribute to these problems, and studies on why patients do not follow through with their treatment. It also provides the background information that supports the topic.

2.2 Tuberculosis burden

TB is a communicable illness that is a worldwide health problem and among the top causes of mortality. The bacillus Mycobacterium tuberculosis causes it (1). It is believed that more than 1.7 billion individuals have contracted the illness. As reported by the World Health Organization (WHO), in 2020, 9.9 million individuals were diagnosed with tuberculosis (TB) and 1.5 million of those infected individuals died from the disease.

TB is a hazard to public health in Kenya. Approximately 120,000 individuals contract tuberculosis each year, with 18,600 dying as a result. It is the fourth leading cause of death in the country, accounting for around 6% of all fatalities (3). According to the WHO, there are now 3,000 cases of MDR-TB in Kenya (7). In the year 2020, there was a rise in the number of deaths caused by tuberculosis (TB) around the world. The number of TB deaths worldwide in 2020 (1.3 million) was almost double the number of deaths caused by HIV/AIDS (0.68 million). Furthermore, the COVID-19 pandemic in 2020 had a greater effect on TB mortality than HIV/AIDS.

2.3 Non-adherence

Adherence is the degree to which a patient follows the instructions and recommendations given by their medical provider. This includes the patient's adherence to a specific drug regimen or treatment plan. Chronic underuse, in which patients take less medicine than prescribed, is the most visible manifestation of non-adherence. Patients with unpredictable adherence patterns may vary between being adherent and under-use or outright non-use (11).

2.3.1 Erratic non-adherence

This is the most common. It involves missed doses either due to: forgetting, the change of schedules or having busy lifestyles. Here the patients understand the regimen they are

taking and would like to comply fully, but they find it difficult due to their lifestyle interfering with adherence (11).

2.3.2 Unwitting non-adherence

This occurs when patients fail to take their medicine because they do not comprehend the regimen or the need for adherence. According to studies, individuals frequently forget the directions provided to them during clinic appointments (7).

2.3.3 Intelligent non-adherence.

Patients purposefully change, quit, or even fail to commence therapy. It is willful non-compliance and shows a deliberate decision rather than a prudent one (8). According to studies, adherence among patients with chronic conditions is 50% in industrialized nations. Poor adherence is much more prevalent in underdeveloped nations because of limited health resources and insufficient access to health care, which contributes to inefficient illness treatment. Poor adherence leads to physical and psychological difficulties, worse quality of life, and a waste of healthcare resources. These repercussions hinder healthcare systems' capacity to attain global population health(5).

2.4 Loss to follow up

A loss to follow-up (LTFU) patient is the one who did not begin treatment or whose therapy was discontinued for two months or longer (3). These patients do not finish the treatment regimen and this can increase their risk of developing drug resistance and this is a major health risk as they normally continue infecting the public with the disease. This makes LTFU a major concern in the battle against Tb (8). The problem of LTFU has been found to vary between countries ranging from 2.5 to 44.9% (8). Factors such age, gender, education, place of residency, financial factors, migration, and stigma have played the greatest contribution to LTFU(12).

2.5 Factors associated with non-adherence and loss to follow up

Adherence refers to how closely someone follows a treatment plan or medication regimen. It is a complex topic that can be influenced by various factors, including a person's socioeconomic status, their relationship with their healthcare team and the healthcare system, the nature of the therapy or medication they are receiving, the specific condition they are treating, and their characteristics.

2.5.1 socio-economic factors

In developing countries with low social economic status people tend to be faced with competing priorities due to limited resources and this will tend to affect adherence. Factors with significant impact in this group include poverty, low education levels, unemployment, long-distance to treatment center, illiteracy, expensive transport cost, lack of social support groups, culture and beliefs towards treatment.

2.5.2 Condition related factors

Demands faced by the patient due to the illness will strongly determine their adherence to medications Also the impact will depend on how the patients perceive their illness. These will include severity of the illness, rate of progression, disability related to the disease, availability of treatment and how important they view the need for treatment.

2.5.3 Therapy related factors

These will include treatment duration, regimen complexity, previous treatment failure, side effects, the availability of medical help for dealing with side effects, pharmaceutical availability, frequent medication changes, and so on.

2.5.4 Health care team and system-related factors

Few studies have been conducted on these variables, even though many of them have a detrimental influence on adherence.(5) These reasons include: inadequately constructed systems, insufficient system capacity to educate patients on importance of adherence and provide follow-up, failure to generate community support, a lack of information on adherence and treatments to encourage it, and a lack of education and training of HCPs.

2.5.5 Patient related factors

These includes patient’s knowledge, expectations and perceptions. Factors reported to influence adherence negatively include: stress, anxiety on side effects, forgetfulness, low motivations, inadequate knowledge and skills in managing the disease, disbelief in diagnosis, misunderstanding of the disease, lack of acceptance of monitoring and follow up, and feeling stigmatized.

2.6 Studies conducted on non-adherence and loss to follow up

Some studies have been conducted to identify risk factors for non-adherence and loss of follow-up in patients undergoing treatment for tuberculosis. A study done in Botswana found that the male gender was more likely to be non-adherent and lost to follow-up. Non-adherent participants also had difficulty reporting their treatment regimen. However, factors such as employment, distance from the clinic, alcohol consumption, and comprehension of study requirements did not show a significant difference between the two groups. 19.0% of non-adherents cited job obligations as the reason for stopping their prescription (13).

In a study conducted in Gamo Gofa Zone in southern Ethiopia, it was discovered that 16.5% of patients were non-adherent to their anti-tuberculosis medication. Factors such as failure to reveal one's TB status to one's family, lack of information on predicted side effects, past use of anti-TB medicine, and cigarette smoking were all related to a higher likelihood of treatment non-adherence (14).

In Indonesia, a study found that male patients, lack of employment, irregular employment, lower income, and underweight body mass index (BMI) were found in higher proportions in loss to follow-up patients. Negative attitudes towards treatment, lack of social support, and dissatisfaction with healthcare were also associated with higher rates of loss to follow-up in drug-resistant tuberculosis patients (15).

A case-control study in Tajikistan revealed that loss to follow-up among tuberculosis patients was largely attributed to migration. It was also linked to TB drug adverse effects and a history of past therapy. Patient refusal, stigma, and family troubles were also noted as risk factors by medical professionals (16).

In Papua New Guinea, a retrospective cohort study found a high prevalence of loss to follow-up at 13.4%. Male gender and longer travel time to the treatment location were identified as factors linked with poor treatment adherence (17).

A study in South Africa concluded that counseling patients before testing for TB was not guaranteed due to staff shortages and frequent rotations. Participants acknowledged dissatisfaction with the services provided, and stigma due to the TB diagnosis as a

probable factor for loss of follow-up before treatment began. Staff rotations, poor contact with patients, and a lack of counseling were cited by program administrators as contributing reasons to the first loss of follow-up among TB patients (18).

A study conducted in Kenya in 2018 on factors affecting non-adherence on tuberculosis treatment identified a high rate of non-adherence at 35%. No significant association between adherence levels and gender, education level, or employment status was determined. No association was found between substance abuse or alcohol intake to non-adherence. Patients with limited availability of food had a significantly higher rate of non-adherence (41%). Long waiting time and transport cost also contributed to higher rates of non-adherence (9).

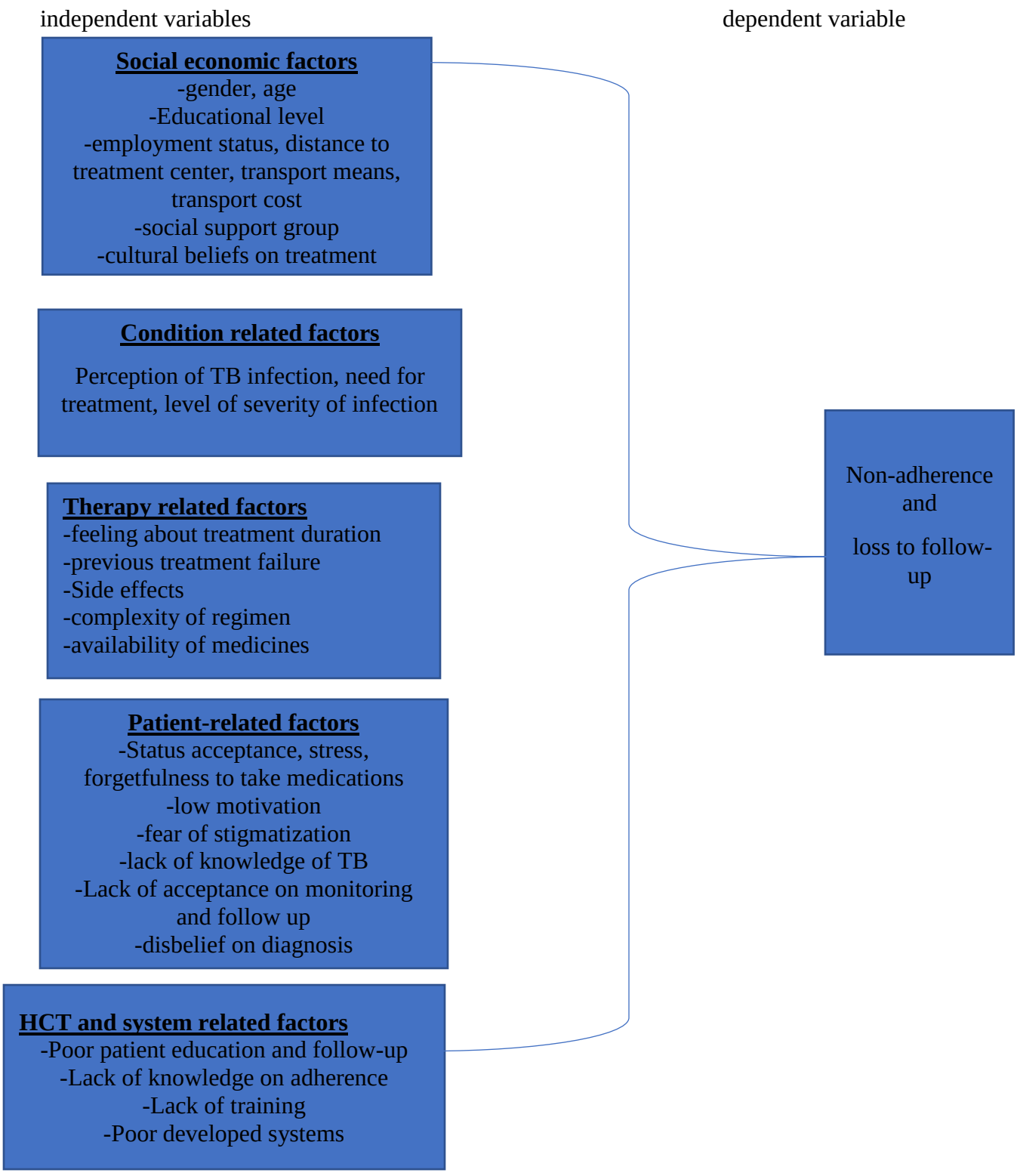
2.7 Research gap

There is lack of local studies that have been conducted on non-adherence and loss to follow up on patients taking TB medications in the country. The study conducted by *Buchanan et al* in 2018 in the country showed a high rate of non-adherence to TB medication at 35% (9) This prompted a further need to look into the factors affecting non-adherence There is also a rise in the number of TB deaths in the country following the covid pandemic (1) and no further studies have been conducted to determine the cause although its postulated that it's due to non-adherence and loss to follow up during TB treatment.

Studies conducted globally have mainly focused on patient related factors and socio-economic factors affecting adherence. Adherence is multidimensional where all the five factors have to be look upon keenly in order to develop interventions that will be able to curb the problem of non-adherence and loss to follow up. The menace has not been eradicated despite numerous recommendations and interventions that have been put in place.

This study findings will aid health care practitioners in identifying and preventing non-adherence from interfering with treatment outcomes. They will also be able to make informed decisions when dealing with adherence issues putting in place interventions to curb this widespread problem.

2.8 The conceptual framework



CHAPTER THREE: METHODOLOGY

3.1 Introduction

This section discusses the approach used for conducting the research. It includes information on how the study was designed, where it took place, the group of people it targeted, the number of participants included, the tools used to gather information, and the methods used to collect and analyze the data.

3.2 Research design

The study design was mixed methods research that has both a qualitative and quantitative (cross sectional) analysis sections, where the patients were interviewed and a focused group discussion conducted with the healthcare personnel. This approach allowed the researcher to identify the patient's adherence/defaulter status, as well as the variables contributing to non-adherence and loss of follow-up.

3.3 Study location

The study took take place at the TB clinic located at Mbagathi County Hospital in Kenyatta, Dagoretti Division, Nairobi West District. This location was chosen because it had a long history of treating infectious diseases like Tuberculosis, Meningitis, and Leprosy. Additionally, the area around the clinic had a population of about one million people, making it a suitable location for the study. Other nearby medical facilities include Kenyatta National Hospital, Forces Memorial Hospital. Currently the Tb clinic is managing 494 Tb patients who have enrolled in the clinic as at end of March 2023 monthly reports.

3.4 study population

The study population included patients on TB treatment at the Mbagathi county hospital who met the inclusion criteria.

Health care workers working at the TB clinic also participated in a focused group discussion.

3.5 The Inclusion and exclusion criteria

3.5.1 Inclusion criteria

Participants to be included in the study were:

i. Adult patients, 18 years and above,
ii. Patients with documented TB infection who were receiving treatment at the Mbagathi county hospital TB clinic and
iii. Participants willing to participate in the study.

Key informants included:

i. Health care workers who were working in the TB clinic (doctors, nurses, clinicians and counsellors)

3.5.2 Exclusion criteria

Eligible patients who were excluded from the study included:

i. Prisoners
ii. Pregnant women
iii. Patients with a compromised mental status

3.6 Sample

3.6.1 Sample size

The study sample size was computed using the Cochran (1977) Sampling Technique since it is applicable for surveys.(19)

$n= Z^2 * P (1-P) / d^2$

Whereby n is the sample size

p is the adherence level and

d the accepted level of precision and it will be set at 0.05 since the outcome is categorical

z is the confidence level according to the standard normal distribution. This shall be set at 95% where z=1.96

Using a 95% significance level, a figure of 80 % adherence level obtained as an average from previous studies (9) and 10% precision of the estimate,

The calculated sample size will be:

$n = 1.96^2 * 0.8 (1- 0.8) /0.05^2$

This gave a total of 125 TB patients who were to be interviewed.

Allowing for 10 % non-response rate, a total of 138 patients were sampled from the sampling frame.

3.6.2 The Sampling technique and recruitment

This was done from the TB clinic at the Mbagathi county hospital. A list of patients who are undergoing TB treatment at the clinic was obtained from records.

The investigator looked through the records and screen patients for eligibility using the set eligibility criteria to pick the study participants. This provided the sampling frame.

Eligible patients who were to participate in the study were chosen using a simple random sampling procedure in which a coin was thrown and the patient who received a head was enrolled in the study. This provided the patient with a 50% probability of being considered as a participant.

This method ensured the sample was representative of the target population and therefore avoiding bias.

The participants who were chosen were approached and the researcher took them through the consenting process by explaining what the study involved and answered any questions the participant had. The participants were then allowed to voluntarily participate in the study by signing the consent form.

The same process was repeated for the patients who have been identified as lost to follow up then they were contacted through telephone interviews.

For participants who failed to respond when called, additional participants were obtained from the defaulters register to replace them

The health care workers were selected to participate in the study through purposive sampling due to their work experience at the clinic.

3.7 Research instruments

Structured interviews were used to collect data. This information was filled in a pre-designed structured questioner by the investigator.

A medical adherence questionnaire derived from Morisky tool was also used to assess the patient's adherence status. The total score ranged from 0 to 8. Low adherence (total score<6), medium adherence (6 to < 8) and high adherence (total score = 8). The outcome status was determined as: adherent (total score > 6), non-adherent (total score <6).

Telephone interviews were conducted on individuals who were LTFU. A loss to follow-up (LTFU) patient was defined as one who did not begin treatment after diagnosis or one whose therapy was discontinued for two months or longer.

A discussion guide form was used to facilitate the health care workers focused group discussion.

Data collection was conducted by the principal investigator with the help of a research assistant, on a one-on-one basis to minimize errors.

3.8 Pretest

Before conducting a full-scale study, a structured interview was conducted to 10 participants at the TB clinic at random. This aided in identifying inconsistencies, any gaps, or any difficulties in attaining information before carrying out the main process of data collection. Any corrections were rectified.

3.9 validity

The study site that was selected received patients all over the country as it specialized in infectious diseases hence is ideal for generalizability of the results to the general population hence ensuring external validity.

Internal validity was ensured by using a well pre-designed structured interview guided questions that are relevant to study objectives. This was ensured by conducting a pretest to detect and correct any errors and omissions. Data collection was conducted by the principal investigator with the help of a research assistant, on a one-on-one basis to minimize errors.

3.10 Reliability

Tools for data collection were pre-tested for reproducibility before carrying out the actual study to ensure clear and precise responses throughout the study.

3.11 Data collection techniques

A mixed methods approach was applied where structured interviews was conducted of patients who meet the eligibility criteria. Adherence status and factors contributing to non-adherence were determined by asking the patient a series of questions. The interview was guided by a predesigned structured questionnaire.

Loss to follow up status was determined from the TB register then the patients were traced via a call. A telephone interview was conducted to determine reasons why they defaulted treatment.

A focused group discussion was conducted with the health care providers to help determine factors that might be contributing to non-adherence and loss to follow up in the facility.

3.12 Data analysis

Data was fed into a Microsoft Excel 2010 spreadsheet and analyzed with Stata version 13 software. In frequency tables, categorical data will be summarized as frequencies and percentages. The mean and measures of dispersion, such as the standard deviation and interquartile ranges, was utilized to examine the continuous data.

A descriptive analysis was performed to better understand the respondents' socio-demographic, economic, and clinical features.

Inferential statistics such as Fischer's exact test was performed to if there was significant association between the various categorical variables and the adherence status. The level of significant was defined as $P < 0.05$. A multivariable and bivariable logistic regression analysis of adherence status was performed to identify the relationship between the predictor variable and the outcome variable.

The Shapiro-Wilk test was performed to assess the data's normality.

Qualitative data was noted down and reported in verbatim.

3.13 Ethical considerations

Before beginning the trial, the Kenyatta National Hospital and the University of Nairobi Ethics and Research Review Committee was consulted.

Before joining the study, participants were asked to sign a informed consent form.

Medical research can introduce psychological, social, emotional and physical risks. Effort will be placed to minimize the risks. One risk of participating in the study was privacy loss. Everything told by the participants will be confidential as possible. Code numbers will be used to identify to identify the participants in password-protected computer database and the paper records will be placed in a locked file cabinet.

When answering questions during the interview the participants may have felt uncomfortable or felt they do not want to answer some questions, they were allowed to skip these questions. The participants have the right to refuse the interview or questions asked.

The interviews were conducted in private as the participants may feel embarrassed. They were conducted by professionals

Also, the interview may be stressful due to event recalls etc., in case of discomfort, injury, illness or complications that is related to the study the participant can contact the staff conducting the study and they will treat the participant for minor conditions or refer them where necessary.

3.14 Data dissemination

The study findings will be disseminated to all stakeholders that are involved and to those who will benefit from the study. The Mbagathi county hospital will be beneficiary of the information that will be obtained from this research to improve patient care through better treatment outcomes.

The work will also be published in an open-access peer-reviewed publication and made available in the School of Pharmacy Library at the University of Nairobi. It will also be disseminated through Continuous Medical Education (CME) forums and conferences

CHAPTER FOUR: RESULTS

4.1 Introduction

This chapter contains the results of the study. They include participant enrollment, baseline characteristics of participants, adherence status of the patients and lost to follow up, assessment of factors associated with non-adherence and loss to follow up, and statistical analysis of the results obtained from the study.

4.2 Participant enrollment

The data collection was carried out in August 2023. It was divided into three section which involved collecting data on adherence, data on lost to follow up and conducting a focused group discussion on the health care workers.

For data on adherence, from a sample size of 138, only 137 (99.275%) patients were recruited. In the month of data collection, 150 participants were screened prior to inclusion in the study. Three did not consent, 8 did not meet the eligibility criteria and there were communication difficulties experienced between 2 individuals **(Figure 1).**

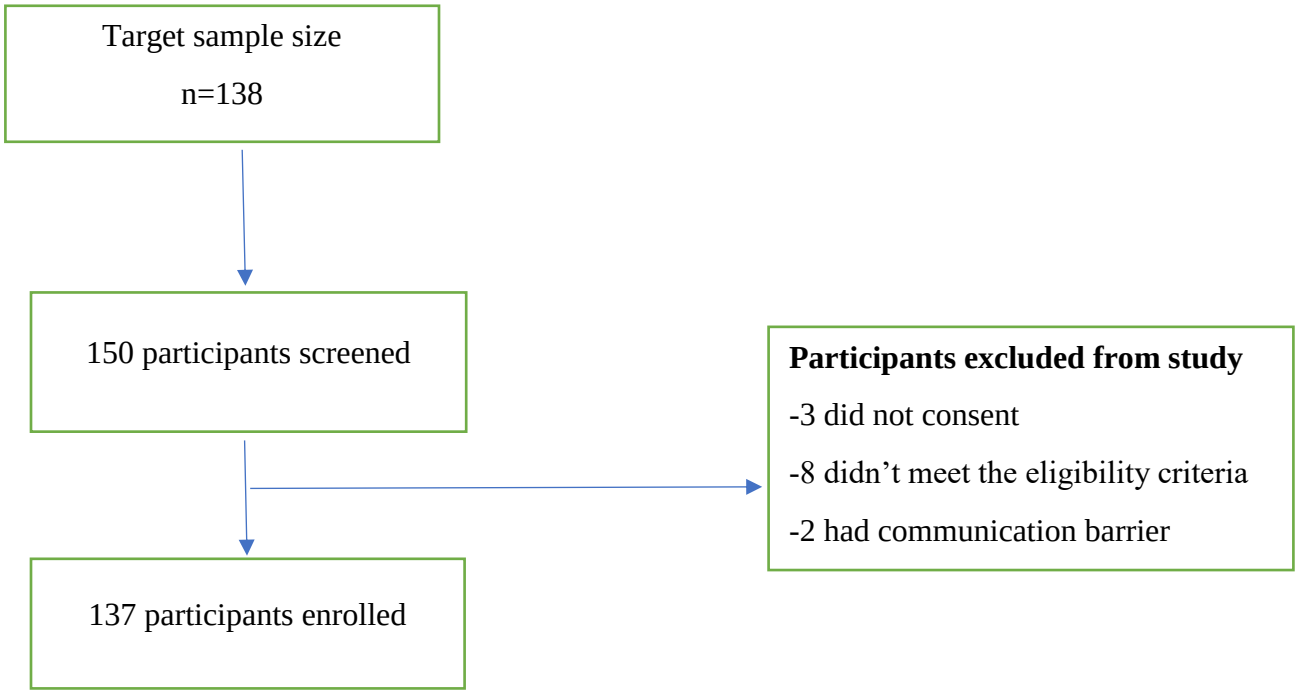


Figure 1: Screening and enrollment of study participants

For data on lost to follow up, only 6 defaulters were identified and they all agreed to participate in the study.

Six health care workers participated in the focused group discussion. These included: 2 cough monitors, 1 clinical officer, 2 senior nurse ,1 community health volunteer.

4.3 Non adherence

4.3.1 Baseline characteristics of the participants

Out of the 137 participants who agreed to participate in the study, 90 (65.69%) were males while 47 (34.31%) were females. Sixty-six participants (48.18 %) were married. Twenty-four (17.50%) participants had a history of drinking alcohol while thirteen (9.49%) reported smoking cigarettes (**Table 1)**. The median age of participants was 32 years IQR [25,42] while the median duration on treatment was 3 months IQR [2, 4.75] Sixty-seven (48.91%) had attained secondary level education. Thirty-two (30.66%) were formally employed. Sixty-five (47.45 %) had a monthly income of less than Ksh 10,000.

Table 1: Baseline characteristics of participants

Variable	n (%)	median [IQR]
Sex		
Male	90 (65.69%)	
female	47 (34.31%)	
Age in years		32 [25,42]
Duration on anti-Tb medications in months		3 [2, 4.75]
marital status		
married	66 (48.18 %)	
single	56 (40.88 %)	
divorced	10 (7.30%)	
others	5 (3.65%)	
drinking alcohol		
yes	24 (17.50%)	
no	113 (82.48 %)	
cigarette smoking		
yes	13 (9.49%)	
no	124 (90.51 %)	
Highest education level		
Primary	22 (16.06%)	
Secondary	67 (48.91 %)	
Tertiary	48 (35.04%)	
None	0 (0%)	
Occupation		
formally employed	42 (30.66%)	
casually employed	23 (16.79%)	
self-employed	26 (11.98%)	
unemployed	32 (23.23%)	
student	14 (10.22%)	
monthly income level		
0-10000	65 (47.45 %)	
10000-20000	43 (31.39 %)	
20000-30000	22 (16.06 %)	
>30000	7 (5.11%)	

4.3.2 Adherence status /level of the participants being treated for tuberculosis

Results obtained using Morisky medication adherence scale showed that majority of participants had medium level of adherence (48.18 %) followed by high adherence (44.18 %) and lastly low adherence level at (7.30 %) (**Figure 2**). The proportion of the patient who were adherent was (92.70%). The patients who were non-adherent accounted for (7.30%) (**Figure 3).** Based on the results of the MMAS 8 tool, we calculated the prevalence of non-adherence as 7.30%

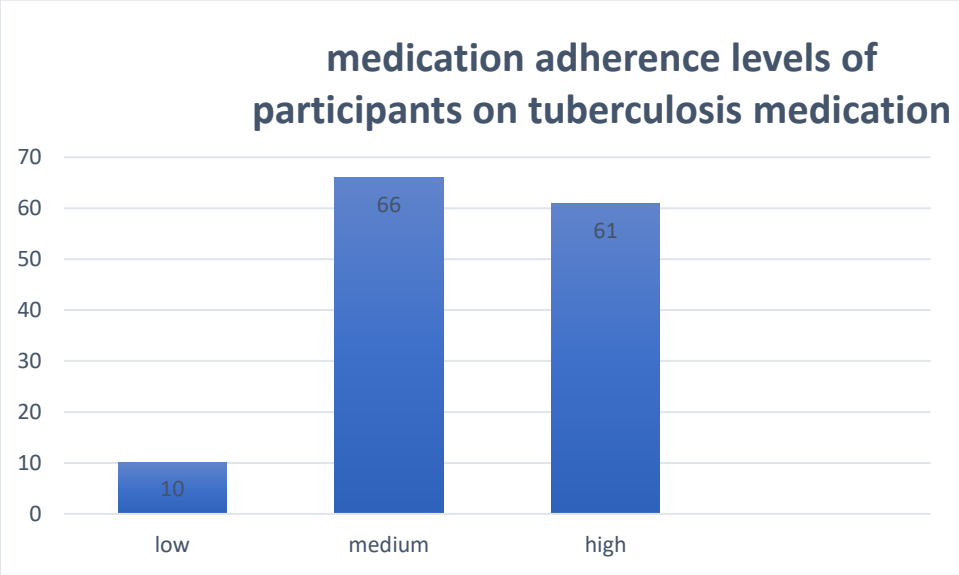


Figure 2: Medication adherence levels of participants on tuberculosis medication

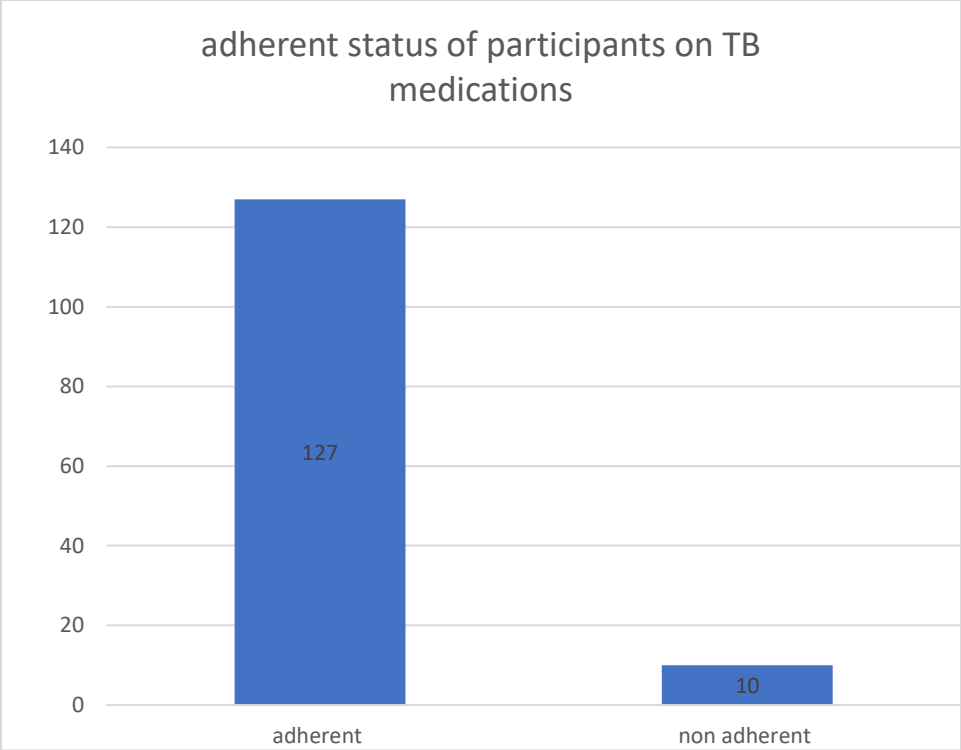


Figure 3: Adherence status of participants on TB medications

4.4 Factors associated with non-adherence to anti- tuberculous medications among the participants undergoing tuberculosis treatment

4.4.1 Description of social economic factors among the study participants undergoing tuberculosis treatment

Out of the 137 participants involved in the study, sixty-three participants (45.99%) covered a distance of 5-10km to the treatment center. Twenty-three (16.79%) reported the distance to be a deterrence to attending clinics. Ninety-eight (71.54%) participants spent 50-200 ksh as transport cost to the clinic. Eighteen (13.14%) reported the cost to be a deterrent while thirty-four (24.82%) reported to sometimes find the cost to be a hindrance to attending clinics. Twenty-five (18.25%) participants had a form of support system while one hundred and twelve (81.75%) participants didn't have any support system in place. Three patients (2.19%) had a negative belief towards treatment where they reported to believe tuberculosis is a curse and it was more of a spiritual illness, one

claimed the illness has no cure. One also confided in using herbal medication. However, one thirty-four (97.81%) participants had positive belief towards treatment and they believed in seeking medical care when they were ill. **(Table 2)**

Table 2: description of social economic factors among the participants undergoing tuberculosis treatment

Variable	**n (%)**
Transport means	
walking	20 (14.60
Public means	110 (80.29%)
private means	7(5.11%)
Transport cost	
<50 ksh	14(10.22%)
50-100 ksh	49 (35.77%)
100-200 ksh	49 (35.77%)
>200 ksh	25 (18.25%)
Transport cost as a deterrence	
Yes	18 (13.14%)
No	85 (62.04%)
Sometimes	34 (24.82%)
Distance to the treatment center	
0-5km	20 (14.60%)
5-10km	63 (45.99%)
10-20km	25 (18.25 %)
>20km	29 (21.17%)
Distance as a deterrence	
yes	23 (16.79%)
no	98 (71.53%)
sometimes	16 (11.63%)
Has support group	
yes	25 (18.25%)
no	112 (81.75%)
Treatment beliefs	
positive	134 (97.81%)
negative	3 (2.19%)

4.4.2 Description of tuberculosis related factors among the participants undergoing tuberculosis treatment

Eighty-two (59.85%) participants perceived tuberculosis to be a serious infection, but curable. One hundred and thirty-five patients (98.54%) deemed the need for treatment to be necessary while two (1.46%) patients found it unnecessary. Sixty-seven (49.26%) individuals reported the severity level of TB to be moderate while fifty-eight (42.65%) reported it to be high. **(Table 3)**

Table 3: Tuberculosis related factors among the participants undergoing tuberculosis treatment

Variable	n (%)
Perception of TB infection	
Serious	82(59.85%)
Normal	54 (39.42%)
Mild	1(0.73%)
Need for Tb treatment	
Not necessary	2(1.46%)
Necessary	135 (98.54%)
Severity level of TB	
low	11 (8.09%)
moderate	67 (49.26%)
high	58 (42.65%)

4.4.3 Description of therapy related factors among the participants undergoing tuberculosis treatment

Sixty-seven (48.91%) participants felt the duration of treatment was long. Forty-one (29.93%) reported to be okay with the duration as long as they recovered. Sixteen (11.68%) participants said the long duration affected how they took their medications. **(Table 4)**. Most said the long duration was tiring, boring, it makes them easily forget their medications and it was generally stressful **(Figure 4).**

One hundred and eight (78.83%) said medications was available during their visits, only fourteen (10.22%) reported to miss medications during their routine refill visits. Five participants (3.65%) said they had experienced past episodes of treatment failure, while seventy-two (52.55%) reported to have experienced side effects after initiation of tuberculosis medications. Out of these fifty-eight (42.34%) sought some form of medication or medical advice while seventy-nine (57.66%) did not.

The most common side effects included joint pains, numbness, fatigue, nausea, headaches etc. The others included rash, itching, joint weakness, urine discoloration, dizziness, insomnia, loss of appetite, stomach upset, fever, edema and so many more. **(Figure 5)**

Table 4:Therapy related factors among the participants undergoing tuberculosis treatment

Variable	n (%)
Feeling about duration of treatment	
short	1 (0.73%)
moderate	28 (20.44%)
long	67 (48.91%)
im okay with duration	41 (29.93%)
duration affecting how they take medication	
yes	16(11.68%)
no	121(88.32%)
tb regimen complex	
yes	28 (20.44%)
no	109 (79.56%)
availability of medications during visits	
yes	108 (78.83%)
no	14 (10.22%)
sometimes	15 (10.95%)
experienced any episodes of treatment failure	
yes	5(3.65%)
no	132 (96.35%)
experienced side effects	72(52.55%)
yes	65(47.45%)
no	
sort medical advice due to side effects	
yes	58 (42.34%)
no	79 (57.66%)

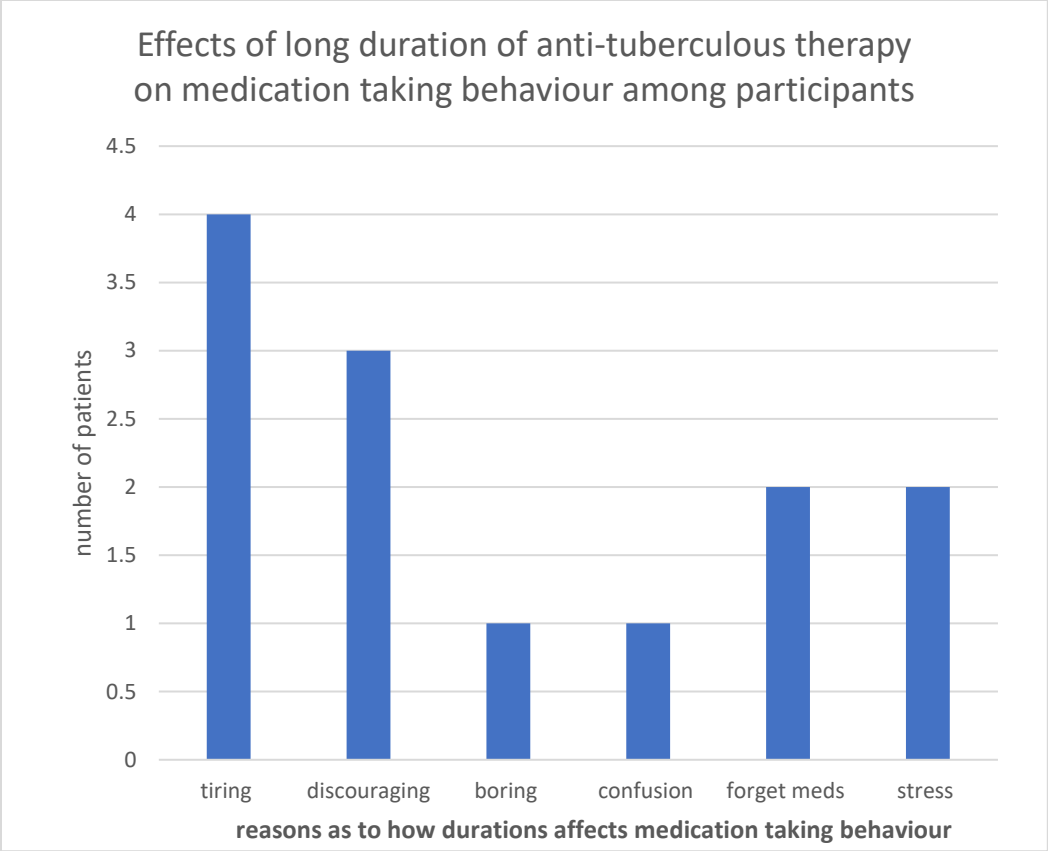


Figure 4: Effects of long duration of anti-tuberculous therapy on medication taking behavior among participants

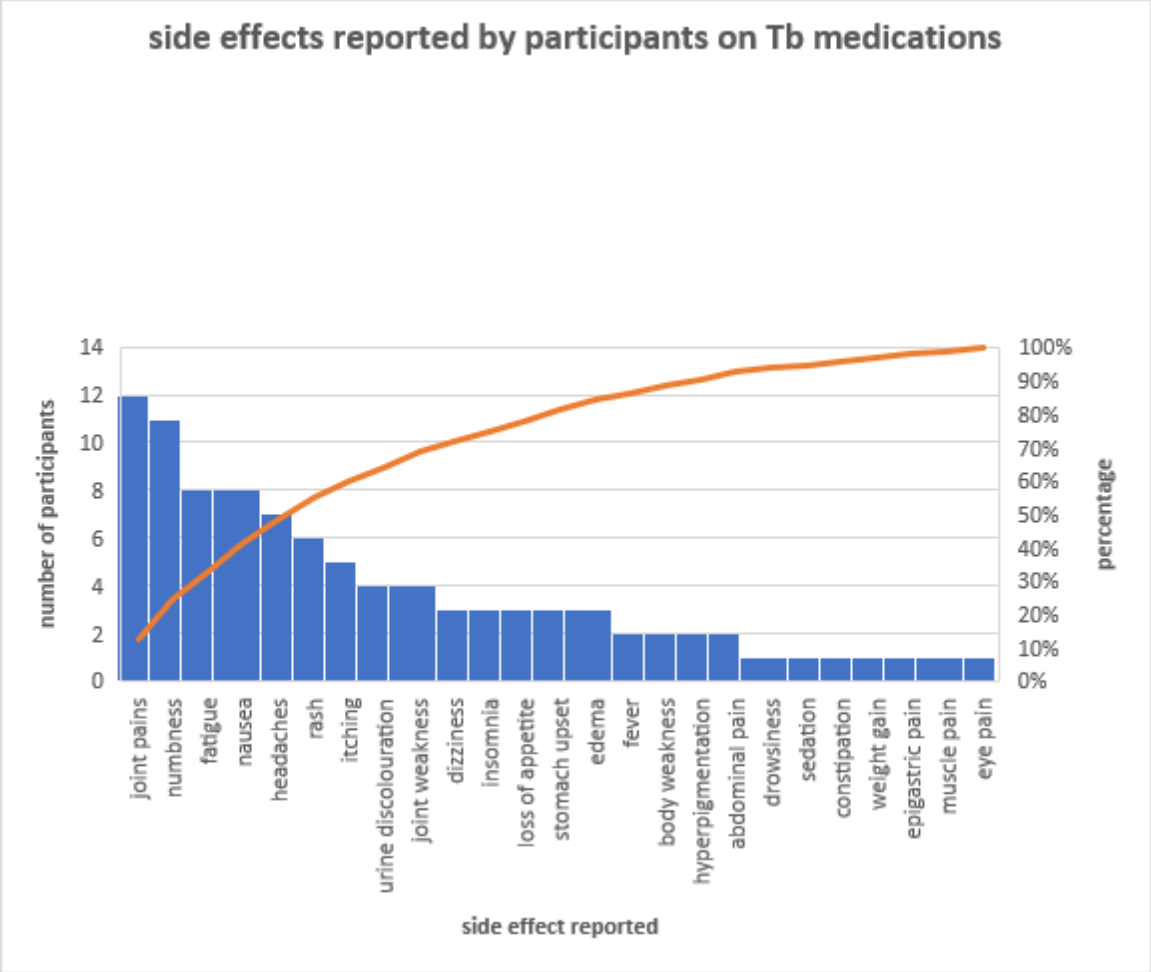


Figure 5: Side effects reported by participants on Tuberculosis medications

4.4.4 Patient related factors among the participants undergoing tuberculosis treatment

One hundred and eleven (81.02%) participants had accepted their status, forty (29.41%) confessed to being stressed due to the illness and when it came to taking medications. Twelve (8.76%) reported to forget to take their medications while one hundred and six (77.37%) remembered to take their medications. Twenty-one (15.33%) of those who forget to take their medications claimed it was just once in a while. Thirty-one (22.63%) participants reported to experience fear of stigmatization due to their illness. Ninety-nine (72.26%) participants were highly motivated when it comes to taking their medications while four (2.92%) were lowly motivated. Sixty participants (43.80%) reported to have

good knowledge on tuberculosis infection while six (4.38%) classified their level of knowledge as poor **(Table 5).**

Table 5: Patient related factors among the participants undergoing tuberculosis treatment

Variable	n (%)
Acceptance of illness status	
Yes	111 (81.02%)
No	8 (5.84%)
Cannot believe it	18 (13.14%)
Stress due to illness or taking medication	
Yes	40 (29.41%)
No	88 (64.71%)
Not sure	8 (5.88%)
Forgetting to take medication	
Yes	12 (8.76%)
No	106 (77.37%)
Sometimes	19 (13.87%)
Frequency of forgetting to take medication	
All the time	0 (0.0%)
Once in a while	21 (15.33%)
Rarely	116 (84.67%)
Fear of stigmatization due to Tb infection	
Yes	31 (22.63%)
No	98 (71.53%)
Sometimes	8 (5.84%)
Participant's motivation to take their medication	
High	99 (72.26%)
Moderate	34 (24.82%)
Low	4 (2.92%)
Participants knowledge on Tuberculosis	
Very good	29 (21.17%)
Good	60 (43.80%)
Moderate	42 (30.66%)
Poor	6 (4.38%)

4.5 LOSS TO FOLLOW UP

Six participants were identified as LTFU and they all agreed to participate in the study. This translates to a prevalence of 2.76%. Five (83.33%) were males, one (16.67%) was a female. In the telephone interview three (33.33%) participants cited travel as the cause of LTFU.

"I travelled out of the country suddenly as I had gotten some urgent work since im a freelancer and I didn't have time to pick my medications" (25-year-old male, interview)

"I travelled to the village and I didn't have fare to go to the clinic to get refill" (38-year-old female, interview)

"I separated with my husband due to family wrangles and travelled to a remote location where I could not be able to access clinics". (27-year-old female, interview)

One participant claimed it was tiring to take medications daily leading to his status.

"I felt tired to pick medications and take medication every day. This made me stop taking medications and going for refills". (32-year-old male, interview)

Another participant claimed sickness was the cause of his LTFU.

"I was too sick I was bedridden at home and I didn't have the energy to go to the clinic to pick medications. I had to wait until I felt better and had the energy to start attending clinic again." (55-year-old male, interview)

(Figure 6).

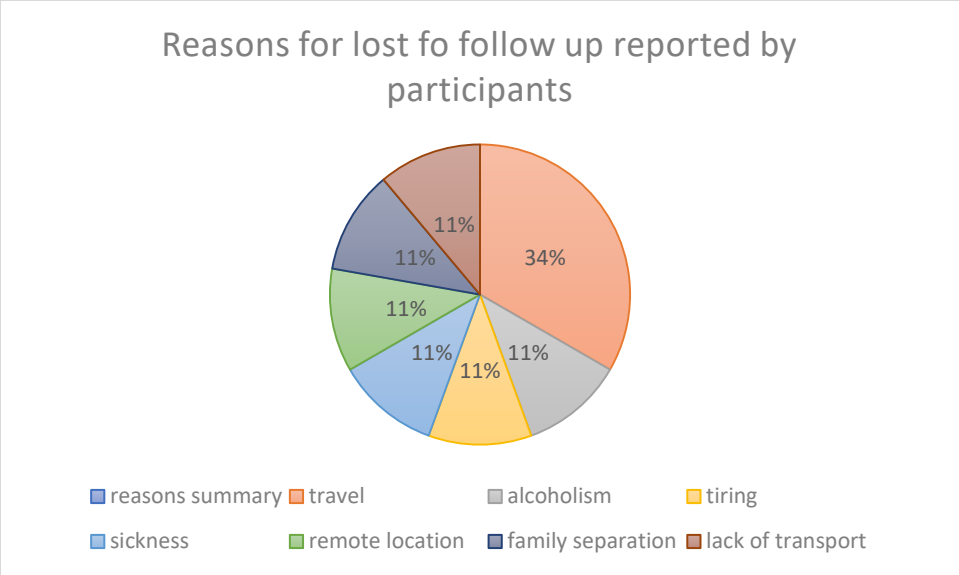


Figure 6: Reasons for lost to follow up reported by participants

4.6 FOCUSSED GROUP DISCUSSION AMONG THE HEALTH CARE WORKERS AT THE TB CLINIC

Six health care workers participated in the focused group discussion. They included: 2 cough monitors, 1 clinical officer, 2 senior nurses and 1 community health volunteer.

4.6.1 Adherence levels at the clinic based on the health care workers perspective

Staff level of knowledge on adherence was very good. They rated patients' level of adherence as good as patients were taking the medications as instructed and were improving clinically. They also kept up with their appointments

The staff normally conducted adherence counselling on the patients

Measures put in place in the facility to monitor adherence included:

i. Use of digital adherence technology where a code is sent once the patients takes medication
ii. Ticking on the treatment cards and indicating dates after taking medication
iii. Giving weekly and biweekly appointments for refills to promote strict compliance
iv. Self-reporting by patients

Based on the staff's experience, the causes of non-adherence in the clinic are:

i. Lack of food,
ii. Lack of transport fare,
iii. Late discharges from clinics leading them to miss medications as they find clinics are closed
iv. Some patients stop taking medications once they start feeling better
v. Lack of proper directions/ adequate instructions
vi. Side effects of the drugs
vii. Forgetting to take their medications,
viii. Forgetting clinics dates hence running out of medication

4.6.2 Appointments and loss to follow up

The staff's knowledge on the concept of loss to follow up was good. The clinical appointments at the clinic are scheduled weekly during the intensive phase and after every 2 weeks during the continuation phase.

Reasons given by patients who do not keep up with scheduled clinical appointments, based on experience included:

i. Lack of disclosure and fear of stigmatization at work hence they are scared of asking permission from work to attend appointments
ii. Lack of time /timing complications
iii. Forgetting clinic dates
iv. Refilling at other facilities
v. Giving patients excess medications

Measures put up by the facility to ensure patients keep up with appointments included:

i. Strict prescribing
ii. Weekly /2 weekly scheduling of appointments to ensure strict adherence
iii. Online monitoring using an application

iv. They call patients who miss appointments/ contacts the listed alternative contact person
v. Transfer outs to the patient's clinic of choice, and that which is more accessible to them to ensure they keep up with appointments to pick medications

Rate of loss to follow up at the clinic was found to be low. Measures used to trace those who are lost to follow up included:

i. Weekly tracking on manual TB4 register (the book was not fully updated)
ii. Use of HCW to trace individuals in nearby areas
iii. Calling/notifying treatment supporters using contacts given by patients during registration
iv. Online tracking at subcounty county level using a program

4.6.3 Healthcare team and system related factors affecting adherence and loss to follow up:

To promote adherence, we found that health systems were set up to support the following:

i. Patients' notification via calls
ii. Strict prescribing duration
iii. Adherence counselling sessions

Patient education on importance of adherence was conducted at the clinic. It normally occurs during initiation of treatment and during routine clinical visits. The facility initially used to conduct monthly staff trainings on adherence although currently none had taken place.

The facility had put measures in place to track defaulters such as:

i. Contacting HCWS to trace individuals in nearby areas
ii. Contacting treatment supporters from contact details issued by the patient during the registration process.

Medical supply

During the year 2023, the clinic has experienced some hitches in medical supplies leading to rationing of medications by issuing medication to cover a week or two. This is opposed to prior times when the staff used to issue out patient packs.

There has also been shortage of the combined pills, leading dispensing of single pills which has led to increased pill burden to the patients. (for the last 3 months)

There have been shortages with pyridoxine leading to rationing and requesting patients to purchase the drugs from local chemist

4.7 Association between baseline characteristics of the study participants with their adherence status

Various baseline characteristics of the participants were correlated with the adherence status of the participants (**Table 6).** No associations were found between any of the participants' baseline characteristics and the adherence status

Table 6: Association between baseline characteristics of the study participants with their adherence status

Baseline characteristics of Of participants	Adherence status		p-value
	Non adherent	Adherent	
Sex			
Male	7	83	0.532[i]
Female	3	44	
Marital status			
Married	6	60	0.721[i]
single	3	53	
divorced	1	9	
other	0	5	
Drinking alcohol			
Yes	4	6	0.074[i]
No	6	107	
Cigarette smoking			
Yes	3	10	0.055[i]
No	7	17	
Highest education level			
Primary	0	22	
Secondary	5	62	0.336[i]
Tertiary	5	43	
none	0	0	
Occupation Formally employed	2	40	0.526[i]
Casually employed	3	20	
Self employed	1	25	
Unemployed	2	30	
Student	2	12	

Key: [i]Fischer's exact

4.8 Association between social economic factors and adherence status

There was no significant association between adherence status of the participants and social economic factors **(Table 7).**

Table 7: association between social economic factors and the adherence status

Social economic factors	**Adherence status**		**p-value**
	Non-adherent	**adherent**	
distance to treatment center			
0-5km	2	18	0.933[i]
5-10km	4	59	
10-20km	2	23	
>20km	2	27	
Distance as a deterrence from getting refills and attending clinics			
Yes	2	21	0.874i
No	7	91	
Sometimes	1	15	
Transport means used			
Walking	3	17	0.308i
Public	7	103	
Private	0	7	
Amount of money used for transport to treatment center			
<50 ksh	1	13	0.236[i]
50-100 ksh	5	44	
100-200ksh	1	48	
>200 ksh	3	22	
Transport cost as a hindrance to accessing treatment center			
Yes	2	16	0.707[i]
No	5	80	
Sometimes	3	31	
In a support group			0.208[i]
Yes	0	25	
No	10	102	
Belief towards treatment			0.205[i]
Positive	9	25	
Negative	1	102	

Key: [i]Fischer's exact

4.9 Association between condition related factors and adherence status

There was a statistically significant association between the adherence status of the participants and perception of tuberculosis infection (p-value 0.012). **(Table 8)** There was no significant association between adherence status and severity level of Tuberculosis infection or feel for treatment need of the infection.

Table 8: Association between condition related factors and adherence status

condition related factors	**Adherence status**		**p-value**
	Non adherent	**Adherent**	
Perception of tuberculosis infection			
Serious			
Normal	0	72	**0.012**[i]
Mild	10	54	
	0	1	
Need for Tb treatment			
Not necessary			
Necessary	0	2	0.859[i]
	10	125	
Severity level of TB			
low	1	10	0.690[i]
moderate	4	63	
high	5	54	

Key: [i]Fischer's exact p-value

4.10 Association between therapy related factors and adherence status

There was a statistically significant association between the adherent status of the participants and the complexity of the regimen (P-value 0.001 **(Table 9)** No other associations were identified.

Table 9:Association between therapy related factors and adherence status

therapy related factors	Adherence status		p-value
	Non adherent	Adherent	
Participants thoughts on Duration of Tb treatment			
Short	0	1	0.175[i]
Moderate	0	28	
Long	8	59	
Okay with duration	2	39	
Does duration affect medication taking behavior			
Yes	3	13	0.094[i]
No	7	114	
Complexity of Tb regimen			
Yes	7	21	**0.001[i]**
No	3	106	
Availability of medication during visits			
Yes	8	100	0.254[i]
No	2	12	
Sometimes	0	15	
Experienced side effects due to medication			
Yes	5	67	1.000[i]
No	5	60	
Sought medical advice following side effects			
Yes	3	55	0.518[i]
No	7	72	

Key: [i]Fischer's exact

4.11 Association between patient- related factors and adherence status

There was a significant association between the adherence status of the individual and the stress due to the illness or taking medications (p-value 0.030) forgetting to take medications (p-value 0.001), frequency of forgetting to take medications (p-value 0.001) and the motivation level of the participants (p-value 0.010). There were no other statistically significant associations. **(Table 10)**

Table 10: Association between patient- related factors and adherence status

Patient - related factors	**Adherence status**		**p-value**
	Non adherent	**Adherent**	
Acceptance of illness status			
Yes	6	105	
No	1	7	0.127[i]
Cannot believe it	3	15	
Stress due to illness			
Yes	7	33	
No	3	85	**0.030[i]**
Not sure	0	8	
Forgetting to take medication			
Yes	3	9	
No	2	104	**0.001[i]**
Sometimes	5	14	
Frequency of forgetting to take medication			
All time	0	0	**0.001[i]**
Once in a while	6	15	
Rarely	4	112	
Fear of stigmatization due to Tb infection			
Yes	5	26	
No	4	94	0.051[i]
Sometimes	1	7	
Participants knowledge on Tuberculosis			
Very good	1	28	
Good	4	56	0.497[i]
Moderate	4	38	
Poor	1	5	
Participant's motivation to take their medication			
High			
Moderate	4	95	**0.010[i]**
Low	4	30	
	2	2	

Key: [i]Fischer's exact p-value

4.12 Logistic regression analysis of determinants of non -adherence among tuberculosis patients

The dependent variable is adherence status. Only the variables that had a statistically significant association with the adherence status of the participants in the chi-squared test were included in the analysis. They included stress due to illness or taking medications, forgetting to take medications, frequency of forgetting to take medications, and motivational level of the participants when it comes to taking medications.

Bivariable and multivariate logistic regression was carried out to adjust for any confounders and to predict the relationship between the dependent and independent variables (Table 11)

There was a statistically significant effect observed from the bivariate analysis between the adherence status and regimen complexity (cOR11.78 95% CI 2.82,49.28, P-value 0.001) participants who felt the regimen was complex were 11.78 more times likely to be non-adherent compared to those who felt the regimen wasn't complex. In the multivariate analysis this effect was further amplified and remained statistically significant (aOR 14.67 95% CI 2.44,88.07 p-value 0.003)

There was a significant effect between the adherence status and forgetting to take medications in both bivariable and multivariable analysis. Participants who reported to forget to take their medications were 17.33 times more likely to be non-adherent compared to those who did not forget to take their medications (cOR 17.33 95% CI 2.56,117.57 P-value 0.003. This effect was slightly diminished in the multivariable analysis but remained statistically significant (aOR 9.11 95% CI 1.16,71.54 P-value 0.036) Participants who reported to sometimes forget to take their medications were 18.57 times more likely to be non -adherent as compared to those who never forgot to take their medications as seen in the bivariable analysis (cOR 18.57 95% CI 3.29,104.98 P-value 0.001). This effect was more pronounced in the multivariable analysis where it increased to 27.69 times (aOR 27.69 95% CI 3.72,206.09 P-value 0.001). However, the confidence intervals are too wide thus reducing the precision of the results.

Table 11: Bivariable and multi variable logistic regression of determinants of adherence among tuberculosis patients

Variable	cOR 95% CI	P-value	aOR 95% CI	P-value
Complexity of the Tb regimen				
No	**Ref**			
Yes	11.78 (2.82, 49.28)	**0.001**	14.67 (2.44,88.07)	**0.003**
Stressed about the illness or taking medications				
No	**Ref**			
Yes	3.46(0.77,15.70)	0.107		
Not sure	1.00 _			
Forgetting to take Tb medications				
Yes	17.33(2.56,117.57)	**0.003**	9.11 (1.16,71.54)	**0.036**
No	**Ref**			
Sometimes	18.57 (3.29, 104.98)	**0.001**	27.69 (3.72,206.09)	**0.001**
Frequency of forgetting to take medications				
All time	-			
Once in a while	2.97(0.26,33.63)	0.379		
Rarely	**Ref**			
Patients' motivation when it comes to taking Tb medications				
High	**Ref**			
Moderate	2.94 (0.43, 20.18)	0.273		
Low	018.93(0.12,3034.91)	0.256		

CHAPTER FIVE: DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1 DISCUSSION

The prevalence of non-adherence was found to be 7.30% The prevalence of LTFU was determined to be 2.76%. Factors found to be associated with to non-adherence among patients on tuberculosis medications and they included: regimen complexity of tuberculosis medication and forgetting to take medications. Factors that were found to be associated with LTFU included travelling, alcoholism, sickness and lack of transport.

Majority of the patients had medium adherence level from MMAS-8 tool. The prevalence of non-adherence to tuberculosis medication was 7.30% which was lower compared to a study previously carried out in Kenya by Buchanan *et al* in 2018 where prevalence was 35%. This could be due to the small sample size in our study. The study was carried out in numerous hospitals across fifteen counties in the country hence increasing the chances of getting the true prevalence (9). The prevalence was also lower compared to a study carried out in Ethiopia by Zegeye *et al* which found prevalence to be 21.29% (20). This can be attributed to the programs efforts put by the government to aggressively manage tuberculosis in Kenya with aim of promoting cure and preventing relapses and development of multidrug resistant infections(2).

The prevalence of LTFU was found to be 2.76%. This was lower compared to a study carried out in Kilifi county by Chebet *et al* in 2018 where prevalence rate was high at 23% (21). Our prevalence was lower due to use of a smaller sample size. The lower rates of LTFU in the facility also can be explained by the systems put in place in the facility to minimize LTFU such as contact tracking by HCWs, notifying treatment supporters, and weekly tracking of the manual TB4 register to detect any patient who missed their clinics. A study conducted in Ethiopia in 2023 by Birhane *et al* showed the rate of LTFU was 16.6%. This was attributed to the inaccessibility of the treatment centers where most individuals were living far from the health centers (22). This is in contrast with this study where we determined most individuals to be living nearby to the facility.

There was a significant association between adherence status and regimen complexity. Individuals who reported to experience complexity of regimen were more likely to be non-adherent as opposed to those who did not. A study carried out in 2020 by Elnaem *et al* showed medication regimen complexity is one of the major contributors of high prevalence of non-adherence further supporting our study findings (23). Issuing of individual drugs as opposed to FDC pills increased the pill burden of the patients increasing the risk of non-adherence. This was confirmed in this study as most participants complained the medications were too many. It was also supported by Pan *et al*(24). A study carried out in Botswana by Gust et al which showed significant association between non-adherence and having difficulties with the regimen(13). A study carried out in 2011 by Jimmy and Jose found medicine complexity to negatively affect adherence further supporting our findings(25). Medication regimen simplification should be applied as one of the strategies to promote adherence(23).

Forgetting to take medication showed significant association with the adherence status. Individuals who forgot to take medications were more likely to be non-adherent as opposed to those who did not forget to take their medication. This was further supported by a study carried out by Makonnen and Azagew in Northwest Ethiopia in 2018(26). A study by Tesfahuneygn *et al* found one of the main reason for non-adherence was forgetting to take medication which agreed with our study findings (27).

The main reason cited for the LTFU was travel. Other reasons included alcoholism, sickness, lack of transport, and relocation to remote areas. The results differ with those obtained from the study carried out by Birhane *et al* in eastern Ethiopia which showed being aged between 55-60 years, being of male gender, living more than 10km from the health facility and having a previous history of tuberculosis treatment, had a higher likelihood of being LTFU(22). The latter was a retrospective study and this could be prone to recall or information bias causing the difference in the findings. A study by Kimani *et al* also reported lack of knowledge and frequent migrations to be the main reason for treatment interruption further supporting our findings (28). A study carried out in Nandi by Wanyonyi *et al* found the major cause of LTFU was alcohol consumption, low monthly income and average waiting time at the facility(29). This further supported

out study where alcoholism was one of the reasons for LTFU. A study by Muture *et al* showed similar association between alcohol abuse and travelling away from the treatment site (30). The findings were further supported by Jakubowiak et al where there was significant association between alcohol abuse, unemployment and the LTFU(31).

Following the assessment of the healthcare team and related factors affecting adherence and LTFU in the facility, it was determined that there were adequate systems put in place by the clinic to minimize non-adherence and LTFU. The staff knowledge on adherence and LFTU was good and they regularly conducted adherence counselling among the patients. This is contrary to a study carried out by Mwansa-Kambafwile *et al* which showed patients counselling was not guaranteed due to frequent staff rotations and shortages. The staff team rarely had trainings on adherence(18). The difference could be due to the level of the staff that was interviewed as they interviewed only the ward-based outreach teams and the program managers.

5.2 LIMITATIONS OF THE STUDY

The study was faced by four limitations. Some data was being obtained from the TB4 register and this was a challenge due to poor record keeping leading to missing and lack of up-to-date data. The study was also curried within a short duration of time and this could have affected the results obtained especially the data on LTFU. There was communication barrier between some respondents making it difficult to collect the data. The survey design that was applied was prone to selection bias and had limited generalizability of the results. The interviewing method of data collection was also prone to interviewer bias especially where the interviewer could already be knowing the expected response of the participants.

5.3 STRENGTHS OF THE STUDY

The strength of the study was that it used simple random sampling when selecting the study participants. This increased the generalizability of the results by minimizing selection bias

5.4 CONCLUSION

The prevalence of non-adherence was found to be 7.30% while the prevalence of LTFU was determined to be 2.76%. The major associated factors of non-adherence were participants forgetting to take their medication and also the feeling of regimen complexity. The study also revealed that travel was the major cause of LTFU. Attention should be paid to these factors by facilitating ways to help the patients remember to take their medications, using of FDCs to minimize patients pill burden and organizing for patients to have adequate medications during their travel period.

5.5 RECOMMENDATIONS

5.5.1 Recommendations for Change of Practice

Adherence is a multidimensional phenomenon where various factors come into play. All these factors have to be considered and addressed to promote adherence.

i. Promoting patient's education and counselling will help promote adherence. Patients should ensure they are conversant with the medications and the illness they have to be able to take their medications as required.
ii. The health care team should ensure the registers are well updated to help in tacking patients who are LTFU.
iii. The hospital should come up with computerized system of storing patient's information on medications as opposed to the manual registers. This will help in quick retrieval of data and tracking of adherence if needed.
iv. The hospital should ensure they order adequate amounts of drugs, and in the right combinations i.e., FDC and this minimizes stock outs and increased pill burden which negatively affects adherence.

5.5.2 Recommendations for further research

i. Considering that this study was carried out within a short duration of time, a prospective study where patients would be followed up for longer duration would provide more evidence.
ii. Prospective studies with larger sample size and encompassing multiple sites may give more reliable and conclusive evidence of association between adherence status and various variables affecting adherence

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APPENDIX 1: Study eligibility screening form

STUDY TITLE: Determinants of non-adherence and loss to follow up among tuberculosis patients on treatment at Mbagathi County Hospital

PATIENT INFORMATION

Patient identification code:_____

Gender: Male ( ) Female ( )

INCLUSION CRITERIA

The following four questions must be ticked yes for the subject to be included in the study.

1. Is the patient above 18 years of age?
   Yes ( ) No ( )
2. Does the patient have a documented diagnosis of Tb infection?
   Yes ( ) No ( )
3. Is the patient receiving treatment for tuberculosis at Mbagathi county hospital?
   Yes ( ) No ( )
4. Is the patient willing to participate in the study?
   Yes ( ) No ( )

EXCLUSION CRITERIA

The following three questions should be ticked No for the patient to be included in the study

1. Is the patient pregnant?
   Yes ( ) No ( )
2. is the patient a prisoner?
   Yes ( ) No ( )
3. Does the patient have a compromised mental status?
   Yes ( ) No ( )

If inclusion and exclusion criteria is met proceed to the questionnaire.

APPENDIX 2A: Researcher information and participant's consent declaration form in English

Study title: Determinants of non-adherence and loss to follow up among tuberculosis patients on treatment at Mbagathi County Hospital

Principal Investigator: Mbaya Jackline Kathomi , Masters of Pharmacy in Clinical Pharmacy, University of Nairobi. P.O Box 142-60402 Meru.

Supervisors:

Dr. George Arthur Mugendi, PhD, UoN
Dr. Judith A. Odenyo, MPharm (Clinical Pharmacy), UoN.

Introduction

I'm Mbaya Jackline Kathomi, a 3rd year postgraduate student at the school of pharmacy, University of Nairobi. As part of the curriculum, I am conducting a study on non-adherence and loss to follow up among tuberculosis patients on treatment at Mbagathi County Hospital

The purpose of this consent form is to provide you with the information you will need to help you decide whether or not to be a participant in this study.

Feel free to ask any questions about the purpose of the research, what transpires if you choose to participate, the risks and benefits of participating, your rights as a volunteer, and any other doubts you have concerning the research.

When all your questions have been answered to your satisfaction, you are free to choose whether to participate or not participate in this study. This is what we describe as an 'informed consent'. Once you understand and agree to be in this study, I will request you to sign your name on this form. It is important to understand the general principles which apply to participants in medical research;

1) Your decision to participate is completely voluntary

2) You are allowed to withdraw from the study without necessarily giving any reasons as to why you choose to withdraw.

3) If you decide to not participate it will not affect the services you are entitled to in this facility or any other facility. We will provide you with a copy of this form for your personal records.

This study has received the approval by the Kenyatta National Hospital- University of Nairobi Ethics committee.

What is this study about?

Tuberculosis is a major public health concern in Kenya and is the 4th leading cause of death in the country. Studies have shown there is a low level of adherence in the country to TB medications. Inadequate adherence is associated with the development of drug resistance, leads to relapses, and continued transmission of the TB bacteria and ultimately death. This study seeks to determine the prevalence of non-adherence and loss to follow up among TB patients at Mbagathi county hospital while also trying to determine the factors contributing to non-adherence and loss to follow up among this group of patients.

The results obtained from this study will help in putting up measures to curb the issue of non-adherence and loss to follow up among TB patients for successful management of tuberculosis.

What will happen if you decide to be a participant in this study?

Upon agreeing to be a participant you will be provided with a questionnaire where you will be required to fill information regarding your medication use, adherence behavior and factors affecting how you take your medications. Also, information on biodata will be extracted from your records. The whole data collection process will take 60 minutes.

Are there any risks, harms, discomforts associated with this study?

There will be no direct risks to the patients since there will be no drug or intervention administered to the patients. However, one possible risk you may encounter is lack of

privacy. You are assured that the information will be handled with extreme confidentiality. All data collected will be stored under password protected computer databases. The hard copies will also be protected by putting them in a locked office cabinet.

Are there any benefits?

The findings of this study will raise awareness on the extent of non-adherence and loss to follow up among patients undergoing tuberculosis treatment to the prescribers and pharmacists. This in turn will in turn help in developing and instituting interventions that will help aid the problem of non-adherence to medications. It will also help prevent loss to follow up among patients who are initiated to long term therapies. severe reactions that may occur.

Will enrolling for this study cost you anything?

This study will not cost you anything apart from your valued time to go through this consent form.

Are there any reimbursements?

There will be no payments in form of monetary, gifts or incentives upon participating in this study.

What if you want to ask any questions?

In case you have any queries on participation in this study you can send a text or email the study staff through the contact details provided on the front page. For more information concerning your rights as a participant you can contact the principal investigator, my supervisors or the KNH-UON ethics committee.

If you feel as if you were not treated well during this study, or have questions concerning your rights as a research participant call **The Secretary/Chairperson KNH-UoN ERC on Tel. No. 2726300 Ext 44102.**

If in agreement, kindly sign the participants consent form below;

Participant's consent declaration

I have read this research information and consent form or have had it read to me. I have had my questions answered in a language that is understandable to me. The risks and benefits have been explained to me. I understand that my participation in this study is completely voluntary and that I'm able to withdraw from participating at any time.

I freely approve to participate in this research study. I understand that all efforts will be made to keep my personal information confidential.

By signing this consent form, I have not given up any of the legal rights that I have as a study participant.

I agree to participate in this study

YES ( ) NO( )

I agree to provide contact information for follow up

YES( ) NO( )

Participant's name:_____

Participant's signature/ thumb print_____

Researcher's Statement

I, the undersigned, have fully explained the relevant details of this research study to the participant named above. The participant has understood and has freely given his/her consent.

Researcher's name:_____

Signature:_____

Date:_____

Role in the study:_____

For more information contact;

Principal investigator: Jackline K. Mbaya

Contact: 0714646069

Email: jacklinembaya@yahoo.com

1st Supervisor; Dr. George Mugendi

Telephone number: 2726771/2726300 Ext.43791

Email: george.mugendi@uonbi.ac.ke

2nd Supervisor; Dr. Judith A. Odenyo, MPharm (Clinical Pharmacy), UoN.

Mobile: 0722499345

Email : juodenyoa@gmail.com

APPENDIX 2B: Maelezo ya mtafiti na fomu ya tamko la idhini ya mshiriki kwa Kiswahili

Kichwa cha utafiti: Maamuzi ya kutofuata kanuni na hasara kufuatilia wagonjwa wa kifua kikuu wanaopata matibabu katika hospitali ya kaunti ya Mbagathi.

Mpelelezi Mkuu: Mbaya Jackline Kathomi , Masters of Pharmacy in Clinical Pharmacy, Chuo Kikuu cha Nairobi. P.O Box 142-60402 Meru.

Wasimamizi:

Dk. George Arthur Mugendi, PhD, UoN

Dk. Judith A. Odenyo, MPharm (Clinical Pharmacy), UoN.

Utangulizi

Mimi ni Mbaya Jackline Kathomi, mwanafunzi wa mwaka wa 3 wa shahada ya uzamili katika shule ya duka la dawa, Chuo Kikuu cha Nairobi. Kama sehemu ya mtaala, ninafanya utafiti kuhusu kutofuata kanuni na hasara ili kufuatilia wagonjwa wa kifua kikuu wanaopata matibabu katika hospitali ya kaunti ya Mbagathi.

Madhumuni ya fomu hii ya idhini ni kukupa taarifa utakayohitaji ili kukusaidia kuamua kama utashiriki au usiwe mshiriki katika utafiti huu.

Jisikie huru kuuliza maswali yoyote kuhusu madhumuni ya utafiti, nini kinatokea ukichagua kushiriki, hatari na manufaa ya kushiriki, haki zako kama mtu wa kujitolea, na mashaka mengine yoyote uliyo nayo kuhusu utafiti.

Wakati maswali yako yote yamejibiwa kwa kuridhika kwako, uko huru kuchagua kushiriki au kutoshiriki katika utafiti huu. Hiki ndicho tunachoeleza kuwa ni ‘ridhaa iliyoarifiwa’. Ukishaelewa na kukubali kuwa katika utafiti huu, nitakuomba utie sahihi jina lako kwenye fomu hii. Ni muhimu kuelewa kanuni za jumla zinazotumika kwa washiriki katika utafiti wa matibabu;

1) Uamuzi wako wa kushiriki ni wa hiari kabisa

2) Unaruhusiwa kujiondoa kwenye utafiti bila kutoa sababu zozote za kwa nini unachagua kujiondoa.

3) Ukiamua kutoshiriki haitaathiri huduma unazostahiki katika kituo hiki au kituo kingine chochote. Tutakupa nakala ya fomu hii kwa rekodi zako za kibinafsi.

Utafiti huu umepokea idhini ya Hospitali ya Kitaifa ya Kenyatta- kamati ya Maadili ya Chuo Kikuu cha Nairobi.

Utafiti huu unahusu nini?

Kifua kikuu ni tatizo kubwa la afya ya umma nchini Kenya na ni sababu ya nne ya vifo nchini. Tafiti zimeonyesha kuna kiwango kidogo cha ufuasi nchini kwa dawa za TB. Ufuasi usiofaa unahusishwa na ukuzaji wa ukinzani wa dawa, husababisha kurudi tena, na kuendelea kwa maambukizi ya bakteria ya TB na hatimaye kifo. Utafiti huu unalenga kubaini kuenea kwa kutofuatwa na hasara ya kufuatilia wagonjwa wa Kifua Kikuu katika hospitali ya kaunti ya Mbagathi huku pia ukijaribu kubaini sababu zinazochangia kutofuatwa na hasara ya kufuatilia miongoni mwa kundi hili la wagonjwa.

Matokeo yaliyopatikana kutokana na utafiti huu yatasaidia katika kuweka hatua za kukabiliana na suala la kutofuatwa na kupoteza ufuatiliaji miongoni mwa wagonjwa wa Kifua Kikuu kwa ajili ya kudhibiti mafanikio ya kifua kikuu.

Je, nini kitatokea ukiamua kuwa mshiriki katika utafiti huu?

Baada ya kukubali kuwa mshiriki utapewa dodoso ambapo utahitajika kujaza taarifa kuhusu matumizi yako ya dawa, tabia ya uzingatiaji na mambo yanayoathiri jinsi unavyotumia dawa zako. Pia, maelezo kuhusu data ya kibayolojia yatatolewa kutoka kwa rekodi zako. Mchakato mzima wa kukusanya data utachukua dakika 60.

Je, kuna hatari yoyote, madhara, usumbufu unaohusishwa na utafiti huu?

Hakutakuwa na hatari za moja kwa moja kwa wagonjwa kwani hakutakuwa na dawa au uingiliaji kati utakaotolewa kwa wagonjwa. Hata hivyo, hatari moja unayoweza kukutana nayo ni ukosefu wa faragha. Umehakikishiwa kuwa habari hiyo itashughulikiwa kwa usiri mkubwa. Data zote zilizokusanywa zitahifadhiwa chini ya hifadhidata za kompyuta

zilizolindwa kwa nenosiri. Nakala hizo ngumu pia zitalindwa kwa kuziweka kwenye kabati ya ofisi iliyofungwa.

Je, kuna manufaa yoyote?

Matokeo ya utafiti huu yataongeza ufahamu juu ya kiwango cha kutofuata kanuni na hasara ya kufuatilia kati ya wagonjwa wanaopata matibabu ya kifua kikuu kwa watoa dawa na wafamasia. Hii nayo itasaidia katika kuandaa na kuanzisha afua ambazo zitasaidia kusaidia tatizo la kutofuata dawa. Pia itasaidia kuzuia upotevu kufuatilia kati ya wagonjwa ambao wameanzishwa kwa matibabu ya muda mrefu. athari kali ambazo zinaweza kutokea.

Je, kujiandikisha kwa utafiti huu kutakugharimu chochote?

Utafiti huu hautakugharimu chochote kando na wakati uliothaminiwa wa kupitia fomu hii ya idhini.

Je, kuna malipo yoyote?

Hakutakuwa na malipo kwa njia ya fedha, zawadi au motisha baada ya kushiriki katika utafiti huu.

Je, ikiwa unataka kuuliza maswali yoyote?

Iwapo una maswali yoyote kuhusu kushiriki katika utafiti huu unaweza kutuma maandishi au barua pepe kwa wafanyakazi wa utafiti kupitia maelezo ya mawasiliano yaliyotolewa kwenye ukurasa wa mbele. Kwa maelezo zaidi kuhusu haki zako kama mshiriki unaweza kuwasiliana na mpelelezi mkuu, wasimamizi wangu au kamati ya maadili ya KNH-UON.

Iwapo unahisi kama hukutendewa vyema wakati wa utafiti huu, au una maswali kuhusu haki zako kama mshiriki wa utafiti piga simu kwa **Katibu/Mwenyekiti KNH-UoN ERC kwa Simu. Nambari 2726300 Ext 44102.**

Ikiwa unakubali, tafadhali saini fomu ya idhini ya washiriki hapa chini

Tangazo la idhini ya mshiriki

Nimesoma taarifa hii ya utafiti na fomu ya ridhaa au nimesomewa. Nimejibiwa maswali yangu kwa lugha inayoeleweka kwangu. Hatari na faida zimeelezewa kwangu. Ninaelewa kuwa ushiriki wangu katika utafiti huu ni wa hiari kabisa na kwamba ninaweza kujiondoa kutoka kwa kushiriki wakati wowote.

Ninaidhinisha bila malipo kushiriki katika utafiti huu wa utafiti. Ninaelewa kuwa juhudi zote zitafanywa ili kuweka maelezo yangu ya kibinafsi kuwa siri.

Kwa kusaini fomu hii ya idhini, sijaacha haki zozote za kisheria nilizo nazo kama mshiriki wa utafiti.

Ninakubali kushiriki katika utafiti huu

NDIO( ) LA ( )

Ninakubali kutoa maelezo ya mawasiliano kwa ufuatiliaji

NDIO ( ) LA( )

Jina la mshiriki: _____

Sahihi / alama ya kidole gumba ya mshiriki_____

Kauli ya Mtafiti

Mimi, aliyetia sahihi hapa chini, nimeeleza kikamilifu maelezo muhimu ya utafiti huu kwa mshiriki aliyetajwa hapo juu. Mshiriki ameelewa na ametoa ridhaa yake kwa uhuru.

Jina la mtafiti: _____

Sahihi:_____

Tarehe:_____

Jukumu katika utafiti:

_____

Kwa maelezo zaidi wasiliana na;

Mpelelezi mkuu: Jackline K. Mbaya

Mawasiliano: 0714646069

Barua pepe: jacklinembaya@yahoo.com

Msimamizi wa 1; Dkt George Mugendi

Nambari ya simu: 2726771/2726300 Ext.43791

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Msimamizi wa 2; Dkt Judith Odenyo Dk. Judith A. Odenyo,

Mfamasia Mwandamizi, Idara ya Huduma za Dawa.

Hospitali ya Kitaifa ya Kenyatta

Nambari ya simu: 0722499345

Barua pepe: juodenyoa@gmail.com

APPENDIX 3: QUESTIONNAIRE 1

STUDY TITLE: DETERMINANTS OF NON-ADHERENCE AND LOSS TO FOLLOW-UP AMONG TUBERCULOSIS PATIENTS ON TREATMENT AT MBAGATHI COUNTY HOSPITAL

Please fill or tick in the questionnaire appropriately.

1. Patients Identifier _____

Section 1: Demographical data

2. Gender: 1=male ( ) 2=Female ( )
3. Age in years_____
4. Date of Tb diagnosis_____
5. Date of initiation Anti-Tb medications_____
6. Duration on Anti -TB medications_____
7. What is the patients marital status

1= married ( ) 2=single( ) 3=divorced( ) 4=others (specify)_____

8. Do you take alcohol 1=yes ( ) 2=no ( )
9. Do you smoke cigarettes 1=yes ( ) 2=No( )

Section 2: social economic factors

10. What is your highest education level attained?

1=primary ( ) 2=secondary ( ) 3=Tertially ( ) 4= none( )

11. Are you employed? 1=YES ( ) 2=NO ( )

12. What is your occupation

1=formally employed ( )

2= casually employed ( )

3=self employed ( )

4= unemployed ( )

5=student ( )

13. What is your monthly income level in Ksh?

1= 0-10000 ( )

2=10000-20000 ( )

3=20000-30000 ( )

4= >30000 ( )

14. What is the distance to the treatment center from your home?

1= 0-5km ( )

2= 5-10km ( )

3=10-20km ( )

4=>20km ( )

15. Does the distance deter you from getting refills and attending clinics on scheduled dates?

1=yes ( )

2=No ( )

3= sometimes ( )

16. What means of transport do you use to arrive at the treatment centre?

    1= walking ( )

    2= public means ( )

    3= private means ( )

17. How much money do you use for transport to arrive at the treatment centre?

    1=<50ksh ( )

    2=50-100 ksh ( )

    3=100-200ksh ( )

    4= >200 ksh( )

18. Does the transport cost hinder you from accessing the treatment centre?

    1=yes ( )

    2=no ( )

    3=sometimes ( )

19. Are you in any support groups

    1=YES ( ) 2=NO ( )

20. What are your beliefs towards treatment?

    _____

Section 3: condition related factors

21. How do you perceive tuberculosis

    infection_____

    _____

    _____?

22. How do you feel about the need for treatment for Tb?

    _____

    _____?

23. According to the level of severity, what do you feel about Tb infection?

    1=low ( )

    2=moderate ( )

    3=high ( )

Section 4: Therapy related factors

24. How do you feel about the duration of treatment of Tb?

    1= short ( ) 2= moderate ( ) 3= long ( ) 4= im okay with the duration ( )

25. Does the duration affect how you take you medications?

    1= yes ( ) 2= No ( )

    If yes how_____?

26. Do you feel the Tb regimen is complex?

    1=yes ( ) 2=no ( )

27. Are medications used to treat Tb available during your visits

    1= yes ( )

    2=no ( )

    3= sometimes ( )

28. Have you experienced any past episodes of treatment failure?

    1=yes ( ) 2=no ( )

29. Have you experienced any side effects since you started the TB medications

1=yes ( ) 2=no ( )

    If yes specify_____

30. Did you seek any medical advice or take any medication due to the side effect experienced above?

    1=yes ( ) 2=no ( )

Section 4: patient related factors

31. Have you accepted your status of having Tb infection?

1=yes ( ) 2 = no ( ) 3= cannot believe ( )

32. Are you stressed about your illness or taking your Tuberculosis medication?

1=yes ( ) 2=no ( ) 3=not sure( )

33. Do you sometimes forget to take your Tb medications?

1=yes ( ) 2= No ( ) 3= sometimes ( )

34. If yes how frequent?

1= all the time ( ) 2=once in a while ( ) 3=rarely ( )

35. Do you fear stigmatization due to your Tuberculosis diagnosis?

1=yes ( ) 2=no ( ) 3=sometimes ( )

36. How motivated are you when it comes to taking your Tb medication?

1= highly motivation ( )

2=moderate motivation ( )

3=low motivation ( )

37. How would you classify your knowledge on Tuberculosis?

1= very good ( )

2=Good ( )

3=Moderate ( )

4=poor ( )

APPENDIX 4: MEDICATION ADHERENCE QUESTIONNAIRE (Morisky Medication Adherence Scale)

You indicated you are taking your medications for management of Tuberculosis. Individuals have identified several issues in regard to their medication taking behavior and we are interested in your experience. There is no right or wrong answer. Please answer each question based on your personal experiences in regard to your tuberculosis medications.

Please tick the correct answer.

1. Do you sometimes forget to take your tuberculosis medication?
   1= yes ( ) 2= No ( )
2. People sometimes forget to take their medications due to other reasons other than forgetting. Thinking back, within the last two weeks were there any days you did not take your medications?
   1= yes ( ) 2= No ( )
3. Have you ever stopped taking your medication without telling the doctor because you felt worse when you took it?
   1= yes ( ) 2= No ( )
4. When you travel or leave home do you sometimes forget bringing along your tuberculosis medication?
   1= yes ( ) 2= No ( )
5. Did you take your tuberculosis medication yesterday?

   1= yes ( ) 2= No ( )

6. Do you sometimes stop taking your medications if you start feeling better?
   1= yes ( ) 2= No ( )
7. Taking medications every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your tuberculosis treatment plan?
   1= yes ( ) 2= No ( )
8. How often do you have difficulty remembering to take your medication? Tick

0= Never/rarely ( )

1= once in a while ( )

2=sometimes ( )

3=usually ( )

4= all the time ( )

The total score ranges from 0 to 8.

low adherence (total score<6), medium adherence (6 to < 8) and high adherence (total score = 8)

Adherent (total score > 6) Non adherent (total score <6)

APPENDIX 5: Health care workers consent form (verbal consent)

Hello, my name is Dr. Mbaya Jackline Kathomi, the principal investigator and the consenting person in this study and a postgraduate student at the School of Pharmacy, University of Nairobi. You have been chosen as a key informant participate in this study on determinants of non-adherence and loss to follow up among tuberculosis patients on treatment at Mbagathi County Hospital
Tuberculosis is a major public health concern in Kenya and is the 4th leading cause of death in the country. Studies have shown there is a low level of adherence in the country to TB medications. Inadequate adherence is associated with the development of drug resistance, leads to relapses, and continued transmission of the TB bacteria and ultimately death. This study seeks to determine the prevalence of non-adherence and loss to follow up among TB patients at Mbagathi county hospital while also trying to determine the factors contributing to non-adherence and loss to follow up among this group of patients. Having a discussion with the heath care team working at the Tb clinic at Mbagathi hospital will help unveiled any underlying healthcare team and system related factors that affect adherence. Also based on their experience they will provide additional information on other factors contributing to non-adherence and loss to follow up in the facility.
The results obtained from this study will help in putting up measures to curb the issue of non-adherence and loss to follow up among TB patients for successful management of tuberculosis.
This will take 15 minutes of your time. If you choose to be in the study, I will provide a discussion guide to follow as we go through it answering the questions provided. You will be expected to answer all the questions honestly. There are no foreseeable risks or benefits to you for participating in this study. There is no cost or payment to you. If you have questions while taking part, please stop me and ask. We will do our best to keep your information confidential. We will however use codes so as to protect your identity.

If you have questions about this research study you may contact Jackline Kathomi Mbaya at 0714646069 or Dr. George Mugendi Tel: 2726771/2726300 Ext.43791 If you feel as if you were not treated well during this study, or have questions concerning your rights as a research participant call The Secretary/Chairperson KNH-UoN ERC on Tel. No. 2726300 Ext 44102. Your participation in this research is voluntary, and you will not be penalized or lose benefits if you refuse to participate or decide to stop. May I continue?

Your participation in this research is voluntary, and you will not be penalized or lose benefits
if you refuse to participate or decide to stop. May I continue?

I certify that I have consented the participant (code no.)

_____

Researcher's name: _____

Signature: _____

Date: _____

APPENDIX 6: DISCUSSION GUIDE FOR HEALTH CARE WORKERS AT THE TB CLINIC

Study title: Determinants of on-adherence and loss to follow up among tuberculosis patients on treatment at Mbagathi County Hospital

Code no_____ date _____

Background information on the HCW

Let's begin by introduction.

Let the staff talk about their profession, their role in Tb clinic, and the years they have been working in the Tb program.

Adherence

Inquire on staff level of knowledge on adherence

How would they rate the level adherence among the patients on Tuberculosis medications attending clinics? (good, very good, fair, poor) and the reason for their response.

What measures have been put in place in the facility to monitor adherence?

For patients who do not take their medication as require or instructed, what could be the cause based on your experience at the Tb clinic?

Appointments and loss to follow up

Make inquiry on staff's knowledge on the concept of loss to follow up.

How are clinical appointments scheduled in the clinic?

For patients who do not keep up with their scheduled clinical appointments, what reasons do they give?

What measures have been put in the facility to ensure patient keep up with their appointments?

What is the rate of loss to follow up in the clinic? What measures have been utilized to trace those who are lost to follow up?

Health care team and system related factors affecting adherence

Inquire what systems are in place at the clinic to promote adherence.

Inquire on conduction of patient's education on importance of adherence and the frequency

Probe if the facility normally conducts staff trainings on adherence and the frequency of the trainings

What measures has the facility put in place to track patients who have defaulted treatment?

How is the supply of the medications at the clinic, check if there are episodes of shortages that may lead to treatment interruption.

Is there any question that is relevant to adherence that I have not asked?

Thank you for your participation.

APPENDIX 7: DATA ANALYSIS

Table 1:1 demographic data

variable	**Frequency (n)**	**Percentage %**
Gender	Male Female	
Marital status	married single divorced others(specify)_____	
History of alcohol drinking	Yes no	
History of cigarette smoking	Yes no	

Table 1.2 social economic status

variable	Frequency (N)	Percentage (%)
Highest level of education attained	primary secondary Tertiary None	
Employment status	Employed Not employed	
occupation	1=formally employed ( ) 2= casually employed ( ) 3=self-employed ( ) 4= unemployed ( )	

	5=student ( )	
your monthly income level in Ksh?	1= 0-10000 ( ) 2=10000-20000 ( ) 3=20000-30000 ( ) 4= >30000 ( )	
distance to the treatment center from home	1= 0-5km ( ) 2= 5-10km ( ) 3=10-20km ( ) 4=>20km ( )	
t means of transport use to arrive at the treatment center	1= walking ( ) 2= public means ( ) 3= private means ( )	
transport cost being a hindrance to accessing the treatment centre?	1=yes ( ) 2=no ( ) 3=sometimes ( )	
Membership to a support group	Yes no	
Treatment beliefs	Positive Negative	

Table 1.3 Therapy related factors

variable	Frequency (n)	Percentage %
Participants thoughts on Duration of Tb treatment	short ( ) 2= moderate ( ) 3= long ( ) 4= im okay with duration ( )	
Does duration affect medication taking behavior	Affect Doesn't affect	
Complexity of Tb regimen	Complex Not complex	
Availability of medication during visits	Available Not available Sometimes available	
Experienced side effects due to medication	Yes no	
Sought medical advice following side effects	Yes no	

1.4 patient related factors

variable	Frequency (n)	Percentage %
Acceptance of illness status	1=yes ( ) 2 = no ( ) 3= cannot believe ( )	
Stress due to illness	1=yes ( ) 2=no ( ) 3=not sure( )	
Forgetting to take medication	1=yes ( ) 2= No ( ) 3= sometimes ( )	
Frequency of forgetting to take medication	1= all the time ( ) 2=once in a while 3=rarely ( )	
Fear of stigmatization due to Tb infection	1=yes ( ) 2=no ( ) 3=sometimes ( )	
Participant's motivation to take their medication	1= highly motivation ( ) 2=moderate motivation ( ) 3=low motivation ( )	
Participants knowledge on Tuberculosis	1= very good ( ) 2=Good ( ) 3=Moderate ( ) 4=poor ( )	

Table 1.5 condition related factors

variable	**Frequency (n)**	**Percentage %**
Patients' perception on Tb infection	Serious Normal mild	
Patients' perception on treatment need	Necessary Not necessary	
Based on level of severity how severe is Tb infection?	1=high ( ) 2=moderate ( ) 3=severe ( )	

Table 1.6 Medication adherence (morisky medication adherence scale)

variable	Frequency(n)	Percentage (%)
Adherence level	Low Medium high	
Adherence status	Non adherent Adherent	

APPENDIX 8: ETHICAL APPROVAL

UNIVERSITY OF NAIROBI
FACULTY OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
Tel:(254-020) 2726300 Ext 44355

KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/220

5th June, 2023

Jackline Kathomi Mbaya
Reg No. U56/38372/2020
Dept. of Pharmacy
Faculty of Health Sciences
University of Nairobi

Dear Jackline,

ETHICAL APPROVAL-RESEARCH PROPOSAL: DETERMINANTS OF NON-ADHERENCE AND LOSS TO FOLLOW-UP AMONG TUBERCULOSIS PATIENTS ON TREATMENT AT MBAGATHI COUNTY HOSPITAL (P53/01/2023)

This is to inform you that KNH-UoN ERC has reviewed and approved your above research proposal. Your application approval number is **P53/01/2023.** The approval period is 5th June 2023 –4th June 2024.

This approval is subject to compliance with the following requirements;

i. Only approved documents including (informed consents, study instruments, MTA) will be used.
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by KNH-UoN ERC.
iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to KNH-UoN ERC 72 hours of notification.
iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH-UoN ERC within 72 hours.
v. Clearance for export of biological specimens must be obtained from relevant institutions.
vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
vii. Submission of an executive summary report within 90 days upon completion of the study to KNH-UoN ERC.

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) https://research-portal.nacosti.go.ke and also obtain other clearances needed.

Yours sincerely,

DR. BEATRICE K.M. AMUGUNE
SECRETARY, KNH- UoN ERC

c.c. The Dean, Faculty of Health Sciences, UoN
The Senior Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information Dept., KNH
The Chair, Dept. of Pharmacy, UoN
Supervisors: Dr. George A Mugendi, Dept. of Pharmacy, UoN
Dr. Judith A Odenyo, Senior Pharmacist, KNH

APPENDIX 9: NACOSTI RESEARCH LICENCE

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: **123686**

Date of Issue: **06/July/2023**

RESEARCH LICENSE

This is to Certify that Dr., JACKLINE Kathoni MBAYA of University of Nairobi, has been licensed to conduct research as per the provision of the Science, Technology and Innovation Act, 2013 (Rev.2014) in Nairobi on the topic: Determinants of non-adherence and loss to follow up among tuberculosis patients on treatment at Mbagathi County Hospital for the period ending : 06/July/2024.

License No: **NACOSTI/P/23/27308**

123686

Applicant Identification Number

Director General
NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Verification QR Code

NOTE: This is a computer generated License. To verify the authenticity of this document, Scan the QR Code using QR scanner application.

See overleaf for conditions

THE SCIENCE, TECHNOLOGY AND INNOVATION ACT, 2013 (Rev. 2014)
Legal Notice No. 108: The Science, Technology and Innovation (Research Licensing) Regulations, 2014

The National Commission for Science, Technology and Innovation, hereafter referred to as the Commission, was the established under the Science, Technology and Innovation Act 2013 (Revised 2014) herein after referred to as the Act. The objective of the Commission shall be to regulate and assure quality in the science, technology and innovation sector and advise the Government in matters related thereto.

CONDITIONS OF THE RESEARCH LICENSE

1. The License is granted subject to provisions of the Constitution of Kenya, the Science, Technology and Innovation Act, and other relevant laws, policies and regulations. Accordingly, the licensee shall adhere to such procedures, standards, code of ethics and guidelines as may be prescribed by regulations made under the Act, or prescribed by provisions of International treaties of which Kenya is a signatory to
2. The research and its related activities as well as outcomes shall be beneficial to the country and shall not in any way;
    i. Endanger national security
    ii. Adversely affect the lives of Kenyans
    iii. Be in contravention of Kenya's international obligations including Biological Weapons Convention (BWC), Comprehensive Nuclear-Test-Ban Treaty Organization (CTBTO), Chemical, Biological, Radiological and Nuclear (CBRN).
    iv. Result in exploitation of intellectual property rights of communities in Kenya
    v. Adversely affect the environment
    vi. Adversely affect the rights of communities
    vii. Endanger public safety and national cohesion
    viii. Plagiarize someone else's work
3. The License is valid for the proposed research, location and specified period.
4. The license any rights thereunder are non-transferable
5. The Commission reserves the right to cancel the research at any time during the research period if in the opinion of the Commission the research is not implemented in conformity with the provisions of the Act or any other written law.
6. The Licensee shall inform the relevant County Director of Education, County Commissioner and County Governor before commencement of the research.
7. Excavation, filming, movement, and collection of specimens are subject to further necessary clearance from relevant Government Agencies.
8. The License does not give authority to transfer research materials.
9. The Commission may monitor and evaluate the licensed research project for the purpose of assessing and evaluating compliance with the conditions of the License.
10. The Licensee shall submit one hard copy, and upload a soft copy of their final report (thesis) onto a platform designated by the Commission within one year of completion of the research.
11. The Commission reserves the right to modify the conditions of the License including cancellation without prior notice.
12. Research, findings and information regarding research systems shall be stored or disseminated, utilized or applied in such a manner as may be prescribed by the Commission from time to time.
13. The Licensee shall disclose to the Commission, the relevant Institutional Scientific and Ethical Review Committee, and the relevant national agencies any inventions and discoveries that are of National strategic importance.
14. The Commission shall have powers to acquire from any person the right in, or to, any scientific innovation, invention or patent of strategic importance to the country.
15. Relevant Institutional Scientific and Ethical Review Committee shall monitor and evaluate the research periodically, and make a report of its findings to the Commission for necessary action.

National Commission for Science, Technology and Innovation(NACOSTI),
Off Waiyaki Way, Upper Kabete,
P. O. Box 30623 - 00100 Nairobi, KENYA
Telephone: 020 4007000, 0713788787, 0735404245
E-mail: dg@nacosti.go.ke
Website: www.nacosti.go.ke

APPENDIX 10: COUNTY APPROVAL

NAIROBI CITY COUNTY
www.nairobi.go.ke

HEALTH, WELLNESS AND NUTRITION

Office of the County Chief Officer – Medical Services

REF: NCCG/HWN/REC/393 **DATE: 14th July 2023**

JACKLINE KATHOMI MBAYA
UNIVERSITY OF NAIROBI
NAIROBI

Dear Dr. Jackline,

RE: RESEARCH AUTHORIZATION

This is to inform you that the Nairobi City County – County Health Research Ethics Committee (REC) reviewed the documents on the study titled " Determinants of non-adherence and loss to follow up among tuberculosis patients on treatment at Mbagathi County Hospital."

I am pleased to inform you that you have been authorized to carry out the study in Nairobi County. The researcher will be required to adhere to the ethical code of conduct for health research in accordance with the Science Technology and Innovation Act, 2013 and the approval procedure and protocol for research for Nairobi.

On completion of the study, you will submit one hard copy and one copy in PDF of the research findings to the REC. In addition, you will disseminate recommendations of the research at a virtual meeting organized by the REC. By copy of this letter, the Medical Superintendent - Mbagathi Hospital are to accord you the necessary assistance to carry out this research study.

Yours sincerely,

DR. IRENE MUCHOKI
CHIEF OFFICER MEDICAL SERVICES &
Ag. CHIEF OFFICER NUTRITION, WELLNESS & SCHOOL FEEDING PROGRAM

Cc: Chief Officers – Public Health and Health Facilities
Medical Superintendent – Mbagathi Hospital

APPENDIX 11: HOSPITAL APPROVAL

NAIROBI CITY COUNTY

Tel: 2724712, 2725791, 0721 311 808
mbagathihosp@gmail.com

Mbagathi Hospital
P.O. Box 20725- 00202 Nairobi

HEALTH, WELLNESS AND NUTRITION SERVICES

REF: MDH/RS/VOL.3/11/255

25TH JULY, 2023

JACKLINE GATHONI
UON
NAIROBI

Dear,Ms.Gathoni

RE: RESEARCH AUTHORIZATION.

This is in reference to your application for authority to carry out research, on ***'Determinants of non-adherance and loss to follow up among tuberculosis patients on treatment at Mbagathi County Hospital.'***

I am pleased to inform you that your request to undertake research in the hospital has been granted.

On completion of the research, you are expected to submit one hard copy and one soft copy of the research report/ thesis to this office.

MBAGATHI HOSPITAL NAIROBI CITY 25 JUL 2023 TEL:0721 311 808 P.O. Box 20725 - 00202, NAIROBI

Dr. Nicolas Tinega
Medical Superintendent
Mbagathi hospital

12 Oct 2023

APPENDIX 12: SIMILARITY INDEX AND ORIGINALITY REPORT

DETERMINANTS OF NON-ADHERENCE AND LOSS TO FOLLOW-UP AMONG TUBERCULOSIS PATIENTS ON TREATMENT AT MBAGATHI COUNTY HOSPITAL

ORIGINALITY REPORT

9%	7%	5%	2%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	erepository.uonbi.ac.ke Internet Source	1%
2	erepository.uonbi.ac.ke:8080 Internet Source	1%
3	Deborah A. Gust. "Risk Factors for Non-Adherence and Loss to Follow-Up in a Three-Year Clinical Trial in Botswana", PLoS ONE, 04/25/2011 Publication	1%
4	bmcinfectdis.biomedcentral.com Internet Source	1%
5	Soedarsono Soedarsono, Ni Made Mertaniasih, Tutik Kusmiati, Ariani Permatasari et al. "Determinant factors for loss to follow-up in drug-resistant tuberculosis patients: the importance of psycho-social and economic aspects", BMC Pulmonary Medicine, 2021 Publication	<1%