

**ADHERENCE TO ANTI-TUBERCULOSIS TREATMENT AMONG PATIENTS
ATTENDING TUBERCULOSIS CLINICS IN NYATIKE SUB-COUNTY, MIGORI
COUNTY, KENYA**

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DECLARATION

This thesis is my original work and has not been presented for a degree in any other University.

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DEDICATION

It is with uttermost humility that I dedicate efforts, hard work and commitment that were put on this paper to my caring, loving and supportive parents to whom I am forever indebted. They have been a supportive pillar throughout my academic journey to this end.

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DEFINITION OF OPERATIONAL TERMS

Adherence- The degree to which a patient's records of drug-taking is in line with what has been prescribed to him/her.

Community Health Volunteers- These are lay people in the health sector acting as champions in the community, linking the community to the health care system as outlined in the community health strategy in Kenya.

Continuation Phase- Anti-Tuberculosis treatment given to patients in the last phase usually four months for drug-sensitive TB patients and twelve months for drug resistant TB patients usually consisting of two drugs (rifampicin and isoniazid) for DS-TB or three drugs for MDR-TB (Bedaquin, cycloserine and Levofloxacin) with an aim of clearing any remaining or dormant bacilli and preventing subsequent disease relapse

Directly Observed Treatment Short course- it is a TB control strategy whereby a patient on anti-TB treatment takes the prescribed medicine while under the watch of a healthcare worker or a trained individual mandated to watch over the patient but not a family member. The role of the observer is to oversee the ingestion of medicine, check and report side effects and answer questions a patient may be having. .

Drug Resistant TB- A type of TB which is caused by *M. tuberculosis* complex characterized by resistance to at least Isoniazid and Rifampicin which are the most effective first-line regimen for treatment of TB

Drug-sensitive TB/Drug-Susceptible TB- This is a case that is bacteriologically confirmed or clinically diagnosed to be TB but there is no evidence of infection with the strains that are resistant to rifampicin and isoniazid

Incidence Proportion- The probability that a particular disease or condition will occur in a specified population over a given time period

Intensive phase-Anti-Tuberculosis treatment given to patients in the first two months of treatment for drug sensitive cases and first six months for drug resistant cases with an aim of achieving a rapid killing of the bacteria actively dividing thus reduce the bacillary load, negative smear and disappearance of clinical symptoms

Non-adherence: This is characterized by Failure to consume at least ten percent of the prescribed medication.

Prevalence- Population proportion affected by a particular disease over a specified period of time (i.e period prevalence)

Tuberculosis- A communicable disease whose cause is *Mycobacterium tuberculosis* contracted by inhaling droplets containing the bacteria from an infected person. Mainly, it infects the lungs, although other organs such as brain, kidneys, spinal cord and intestines can be affected as well.

Pill burden_ It is the number of tablets or capsules that a person takes on a regular basis

ABBREVIATIONS AND ACRONYMS

Bdq-	Bedaquine
CCC-	Comprehensive Care Clinic
CFZ-	Clofazimine
Cs-	Cycloserine
Dlm -	Delamanid
DS-TB-	Drug-sensitive Tuberculosis
FGD-	Focus Group Discussion
HCW-	Healthcare Worker
IGRA-	Interferon Gamma Release Assay
LF0-LAM-	Lipoarabinomannan Assay
Lzd-	linezolid
MDR-TB-	Multidrug-resistant tuberculosis
Mfx-	Moxifloxacin
MMAS-8 -	Morisky medication adherence scale
NAA	Nucleic Acid Amplification
RR TB-	Rifampicin Resistant Tuberculosis
TB-	Tuberculosis

UNAIDS- United Nations Acquired Immunodeficiency Syndrome Agency

Z Pyrazinamide

ABSTRACT

Tuberculosis is a communicable disease whose cause is *Mycobacterium tuberculosis*. Main mode of spread is through coughing or sneezing from an infected person, which expels the droplets and when they remain suspended in the air, a susceptible host inhales the contaminated air, they get lodged in the lungs and later cause an active TB disease when not suppressed by the immune system. Symptoms most reported include: persistent cough with sputum, night sweats, appetite loss, weight loss among others. Approximately 10.6 M people contacted the disease and 1.30M died from it in the year 2022. Of all the TB disease burden globally, 23% are from Africa but the region led in mortalities, being 33%. Kenya had an incident rate of 233 per 100,000 and mortality rate of 32 per 100,000. Adherence in Kenya according to a national survey was 75% and several factors had been found to affect it including socio-demographic, individual and health system related factor. The study aimed determine factors affecting adherence to anti-TB treatment in all treatment phases among patients in Migori County. In Nyatike, there were concerns in rising cases of re-treated TB patients and rifampicin resistant cases. The cure rate in Nyatike was 76% which was lower than Migori County which was at 81.3%. The study therefore sought to ascertain the adherence level among the TB patients in Nyatike sub-county. This would be important to help the healthcare givers to know how much to invest in adherence given the high incidence rate in the sub-county (209 per 100,000) against that of the sub-county (155 per 100,000). The study's main objective was to assess adherence to anti-tuberculosis treatment among patients attending tuberculosis clinics in Nyatike, Migori County, Kenya. Specific objectives were to: determine the demographic, individual and health system factors associated

with adherence to anti-TB treatment, to determine the knowledge level and its association to adherence among patients in Nyatike sub-county and to determine the prevalence of adherence levels among patients in Nyatike sub-county. The study's area was Nyatike, which is among the sub-counties in Migori with a population of 176,162 people. The area's major economic activities include fishing, farming, livestock keeping, gold mining and bee keeping. Cross sectional was the Study design of choice. Census method was the sampling technique used to sample participants while purposive sampling was used to sample FGD and KII participants. A total of 200 participants, 18 years or more and consented to participate were included in this study. Questionnaires, key informant guide and FGD guides were the data collection tools with the pre-test done in Kuria West sub-county. Morisky medication adherence scale (MMAS-8) and Knowledge assessment was adopted from the Global TB community advisory board (TBCAB) were adopted in the study to measure adherence and knowledge levels respectively to ensure validity. Data was analysed using SPSS version 25 after a descriptive summary while qualitative data was summarised and organised into themes. Data dissemination was in form of tables, graphs and pie charts for quantitative and captions for qualitative data. Due ethical clearance was granted from KU ethics review committee, NACOSTI and Migori County health authority. Factors found to be associated with adherence following a regression analysis included: HIV status (AOR1.152; 95%CI: 0.408-3.691, $p=0.029$), money for other needs (AOR2.363; 95%CI: 0.934-5.981, $p= 0.007$), use of other non-TB drugs (AOR 0.418; 95%CI: 0.157-1.109, $p=0.008$) and knowledge (OR: 2.856; 95%CI: 1.282-6.365; $P= 0.01$). No socio-demographic and health system factors were found to be statistically significant. Adherence level among participants was 78% whereas the knowledge level was 70%. Stock-out of pyridoxine drug and lack of regular update from the TB program among healthcare givers in the private hospitals were the challenges facing the health system. Organization of Peer-to-peer groups among TB patients at the health facility level, incorporation of community health practitioners in TB care for patients, conducting health education to the communities and advocacy as well as provision of nutrition guidance for TB patients in the sub-county were among the recommendations arrived at from this study. Conducting adherence study among children under 18 years, knowledge assessment among TB patients in other parts of the County and conducting a similar study in future to ascertain whether demographic and health system factors are associated with adherence are the recommendations for future studies.

CHAPTER ONE: INTRODUCTION

1.1 Background Information

Tuberculosis (TB) is a disease caused by *Mycobacterium tuberculosis*, mostly affecting the lungs. It spreads through air, when an active case sneezes or coughs. The bacteria remain suspended in the air and get into a susceptible host, when they breathe in the contaminated air, which may develop into an active disease later in life. The latent bacterium, commonly known as latent TB, has infected a third of global population, 10% of who are estimated are estimated to develop active TB (WHO, 2018). TB is ranked the top killer disease among infectious diseases globally and for people living with HIV/AIDS, the disease leads in preventable deaths in this population (UNAIDS, 2019). However, in 2022, it was the second leading killer disease, having claimed approximately 1.30 million lives. According to the available report, the incident cases were 10.6 million people, up from 10.3 million in 2021. This could be attributed to Covid-19 disruption that hindered most people from accessing prompt diagnosis and treatment (WHO, 2023).

Africa is ranked second at 23% among the WHO regions as far as TB burden is concerned, after South-East Asia but leads in TB mortality rates worldwide with 33% of all cases being accounted for from the continent (WHO, 2023). On a positive note, the continent has made remarkable milestones as far as 'End TB Strategy' is concerned. A 38% reduction of deaths from TB has been achieved against the set target of 35% by WHO whereas 23% reduction of new TB cases has been achieved against the set target of 20%. The rate of TB diagnosis increased to 70% in 2022 from 60% that was reported in the year 2020 (WHO Africa, 2024).

Kenya is one of those countries bearing a high prevalence of TB, the incidence rate estimated at 266 per 100,000 population against the global 133 per 100,000 population, mortality rate being 32

per 100,000 population against the global 16.4 per 100,000 population (NTLP 2022; WHO 2022). Despite the high prevalence of the disease in Kenya, there is much progress. It has achieved and surpassed the target set by the WHO of reducing the new infections by 32% against the set target of 20% and reduction of TB-related deaths by 44% against the set target of 35% between the year 2015-2020 (NTLP 2022). Similarly, Kenya has made tremendous efforts and is no longer among the 30 MDR high burden countries (WHO, 2023).

Globally, TB patients have differing levels of knowledge on TB in terms of causality, communicability, treatment among others. In Uttarakhand, India one study found out that 43.2% of study participants knew TB is caused by a bacterium whereas in Mumbai it was 35.2% (Nautiyal, et al, 2019). However, in South Africa and Chhattisgarh India, there were fairly high levels of knowledge on the causality of TB by the bacterium at 60.2% and 95.0% respectively (Kigozi et al, 2017; Samal, 2017). In Ethiopia, a study found 68.7% of participants had high knowledge scores on TB disease (Amare et al, 2022) as compared to 44% found in Tanzania (Kazaura & Kamazima, 2021). A qualitative study carried out in Kenya found a low knowledge among TB patients in regards to the cause and transmission of the disease. They attributed the disease` cause to factors such as trauma, alcohol abuse, smoking and bad omen (Mbuthia et al, 2018). Another study found out differing levels of knowledge on various aspects of TB disease; only 50% of patients could identify cough as a sign of TB, 75% understood the importance of Anti-TB medication is to get cured while 88.2% were aware that Anti-TB drugs are available in health facilities (Kimwele 2012).

Adherence to Anti-TB medication is a significant factor in TB management, because sixty percent of the disease prevalence can be eradicated with proper adherence (Du Vaure et al, 2016). However, this has not been possible as there are various factors hindering proper adherence varying from one patient to the other in different parts of the world. Patient-related factors include low knowledge

about TB disease and risks one is exposed to if not adherent, forgetfulness and education level of patients (Woimo et al, 2017; Mekonnen and Azagew, 2018). Various studies found social factors to be influencing how patients adhere to Anti-TB medication. Among them include limited social support mostly on matters to do with finances and medication reminders (Getahun and Nkosi 2017). Stigma, either experienced or perceived, is equally a potential factor, whose impact cannot be neglected, especially among patients who are HIV co-morbid (Ayele et al, 2016). Economic factors are also potential factors determining Anti-TB medication adherence, despite TB medication being given free. This is because, sometimes patients are unable to cater for treatment related needs such as nutritional supplements and transport costs (Ayele et al, 2016). Health systems equally contribute to patient adherence especially on patient-provider relationship, patient satisfaction among other reasons (Gube et al, 2018).

Adherence to anti-tuberculosis medication is a challenge in various parts of the world. In Mumbai, India and Schenzhen, China however, rates of adherence were lower (50%) compared to that of Gondar (66.26%) (Kulkarni et al, 2013; Tang et al, 2015). In Ethiopia, a study found adherence to be at 78%, most of whom had been lost to follow-up (Mekonnen & Azagew, 2018). The rate is not significantly different from the adherence rate in Tanzania, as found by one study in the country, which found a 79% adherence (Sumari-de Boer et al, 2019). In Kenya, the most recent survey on adherence to anti-TB treatment showed the national average stands at 75% (NTLD, 2018) although different studies show different rates. In Baringo, adherence was reported to be at 54% (Obwoye et al, 2016) whereas in Nairobi it was reported to be 83% (Muture et al, 2011). However, peer reviewed studies to estimate the burden of the problem in Migori and Nyatike specifically have not been published. For this reason, the study was conducted to ascertain the prevalence of adherence and factors associated with it.

1.2 Problem Statement

The long term goal of WHO is to eradicate TB globally by the year 2035 and commitments have been made from leaders both globally and country levels (WHO, 2015). Kenya is at the forefront of this battle marked with achievements such as: the first country globally to adopt and roll out baby-friendly TB medicine (CHS, 2016) and that it was among the three high burden countries to surpass the 'End TB Strategy' goals of reducing new cases by 32% and TB-related deaths by 44% against the set targets of 20% and 32% respectively (NTLD, 2022). Despite the efforts Nyatike Sub-county is making to keep a breast with the national strides, there have been concerns of declining rates on adherence to anti-TB treatment in all phases of treatment (intensive and continuation) among TB patients, characterized with rising number of lost-to-follow up cases (KELIN, 2018).

The sub-county had the largest portion of the disease in Migori County in 2019, contributing 21% of the disease hence with the rise in non-adherent cases, the disease is bound to increase even more in the sub-county. The rise in number of re-treated cases in the County from 56 in 2019 to 87 in 2020 and rise in number of rifampicin resistant cases from 5 in 2019 to 17 in 2020 could be a sign of reduced adherence in the County, Nyatike included (NTLD, 2020). In addition, the rate of cure from TB in Nyatike (76%) is lower compared to that of Migori County (81.3%) (NTLD, 2020) raising the need to establish the adherence levels in the sub-county as well as ascertain the factors affecting this adherence to institute evidence-based measures. Given that Migori County has not met the Country's target of reducing death rates from TB to less than 5% as the death rate is 5.1%, more lives are at risk of being lost if adherence is not addressed in the area, which has a higher rate of incidence at 209 per 100,000 population compared to that of Migori County at 155 per 100,00 population (NTLD, 2020). This study therefore undertakes to identify the level of adherence in the sub-county

as well as determine the factors associated with adherence, which will help the sub-county address adherence using informed, data-driven measures.

1.3 Justification

The study findings would be essential given the uncertainties surrounding the rising figures of essential indicators surrounding adherence such as rise in rifampicin resistant cases, number of re-treated cases and low cure rates (NTLD, 2020). The study findings could be of help to the County health authorities in making evidence-based decisions on how much to invest with the scarce resources as far as adherence to anti-TB treatment is concerned, considering the fact that Nyatike has a very large area (677 sq. Km) characterised with poor road network and few health facilities offering anti-TB treatment services (KNBS, 2019; NTLD, 2020). In addition, the County has been on course to identify more active TB cases with case notification rate increasing in Nyatike sub-county from 109 to 124 per 100, 000 population in 2019 and 2020 respectively (NTLD, 2020). Similarly, 62 more cases were identified in Migori County as a result of active case finding efforts in the year 2019 (NTLD, 2020) and with poor adherence, these efforts could turn to be a waste of resources hence the need to address adherence to anti-TB treatment so that the new patients would be completely cured following appropriate adherence.

Addressing adherence in Nyatike is very important, considering this is a hardship area, as categorized by the national Assembly with high poverty levels and scarcity of food and clean drinking water plaguing the area (National Parliament, 2024). Non-adherence has been found to thrive in areas with high poverty levels (Tola *et al*, 2015) and as such this could threaten the lives of the already vulnerable population which also has poor road transport to access health services. The threat of TB and HIV co-infection cannot go unmentioned. This is because, the TB and HIV Co-infection in Nyatike (46%) is higher than that of Migori (41%), and higher than the national average

of 24.9% (NTLD, 2020) and given the fact that TB is the leading killer for people living with HIV (WHO, 2023), there is greater need to address adherence to safeguard the lives of this vulnerable population. With the country achieving greater heights, more than the globally set targets as far as fight against TB is concerned (reduction of TB deaths by 44% and reduction of TB new cases by 32%), Nyatike has a role to play in this success story and as such, this study is important for highlighting hindrances to achieving optimal adherence levels so that proper measures can be instituted. In addition, to the best of my knowledge, there is no published work in regards to adherence to anti-TB treatment in Migori County, Nyatike sub-county included hence this study could be essential for comparison with studies in future.

1.4 Research questions

- i. Which socio-demographic and individual factors are associated with adherence to anti-Tuberculosis treatment among patients in Nyatike, Migori County?
- ii. Which health system factors are associated with adherence to anti-Tuberculosis treatment among patients in Nyatike, Migori County?
- iii. What is the level of knowledge of patients on tuberculosis and how is it associated with adherence to anti-tuberculosis treatment in Nyatike, Migori County?
- iv. What is the prevalence of adherence to anti-Tuberculosis treatment among patients in Nyatike, Migori County?

1.5 Null Hypotheses

- i. There is no association between socio-demographic, individual and health system factors and patient adherence to anti-tuberculosis treatment among tuberculosis patients in Nyatike, Migori County.
- ii. Level of knowledge on importance of adherence to anti-tuberculosis treatment among tuberculosis patients in Nyatike, Migori County is not associated with adherence to anti-tuberculosis treatment.

1.6 Objectives

1.6.1 Broad objective

To assess adherence to anti-tuberculosis treatment in all phases of treatment (intensive and continuation) among patients attending tuberculosis clinics in Nyatike, Migori County, Kenya

1.6.2 Specific objectives

- i. To ascertain the socio-demographic and individual factors associated with adherence to anti-tuberculosis treatment among patients in Nyatike, Migori County
- ii. To determine the health system factors associated with adherence to anti-tuberculosis treatment among patients in Nyatike, Migori County
- iii. To determine the level of knowledge of patients on tuberculosis and its association with adherence to anti-tuberculosis treatment in Nyatike, Migori County.
- iv. To determine the prevalence of adherence to anti-tuberculosis treatment among patients in Nyatike, Migori County

1.7 Study significance

The study contributes into available knowledge body on treatment adherence to anti-TB treatment highlighting the factors applicable to Nyatike, Migori County. This is an essential study considering it was done in a rural setting, hence it would be used for comparison with other studies done in rural area settings and deductions that are backed up with data. This study would benefit Migori County at large, but of more essence, the Nyatike sub-county in determining the focus areas as far as adherence is concerned. The study also assessed the knowledge level of patients, an important aspect that would enable the care givers in Nyatike as well as Migori County to re-address patient education holistically in terms of the known and the unknown. The study gave an opportunity for the healthcare providers and patients to air their challenges and this when reviewed would help the County TB program make appropriate policies and a strategic plan that is evidence-based.

1.8 Limitations and delimitations

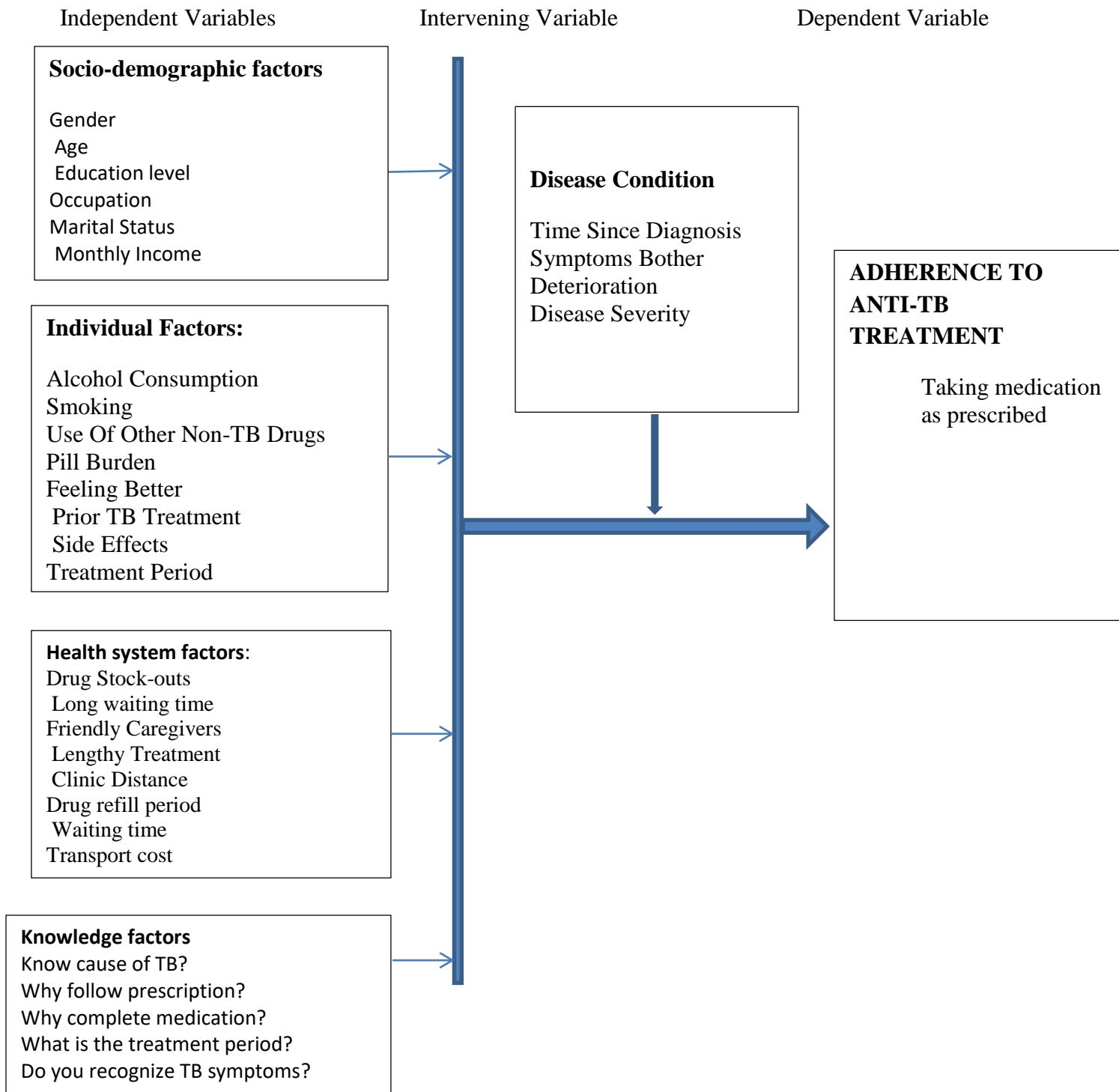
1.8.1 Limitations

Quantitative data was collected through questionnaires (, i.e., self-report) and participants were required to give brief history of medication behaviour. Recall bias may have been introduced and this could contribute to invalid conclusion. While conducting the study, medical doctors were not sampled as key informants because none of the health facilities sampled had a medical doctor offering TB services. This therefore was a limitation since their input was not incorporated in this study as one of the healthcare givers.

1.8.2 Delimitations

Recall bias was minimized by participants being asked of their medication history of not more than one month. In addition, a standardized adherence scale: Morisky medication adherence scale (MMAS-8) was used in this study to enhance validity of findings. Quantitative data was incorporated in this study to provide in-depth information thus complementing qualitative data. Clinical officers were interviewed since they were the majority in TB clinics.

1.9 Conceptual framework



Source: Adopted and modified from Peh et al (2021)

CHAPTER TWO: LITERATURE REVIEW

2.1 Overview of tuberculosis Burden

Tuberculosis still remains a global epidemic of public health significance that requires action based on the commitments reached during the global meeting on TB by different UN member states. This is considering the statistics from the TB report in 2023 which indicates 10.6M people developed the disease in 2022, whereas 1.30 million people succumbed to the disease (WHO 2023). The disease still poses a challenge because drug resistant cases (410,000) still remain high and those initiated on treatment are less than half the number of cases (175650) (WHO, 2023). The disease burden is borne largely by the 30 countries with a high prevalence of the disease, eighty seven percent of the cases originating from these countries, two thirds of the cases coming from eight countries, with India (27%) and Indonesia (10%) topping the list. Efforts have been made globally to check the progress of this disease because evidenced by declining trend in incidence from 2015-2022 by 8.7% although it's lower compared to WHO End TB Strategy milestone of 50%. Equally, the mortality rates have decreased since 2015-2022 by 19% but this is far from the WHO goal of 75% reduction by the year 2025.

Africa is the second largest bearer of the TB disease burden after South-East Asia, accounting for 23% of newly diagnosed cases (2.5 million people) and 31% (0.5 million people) of deaths arising from TB. The situation is compounded by the HIV-TB co-infection since 20% of the new cases occurred among people living with HIV/AIDS (WHO Africa, 2023). The threat of rifampicin resistant TB is equally persistent in African region, 77,000 cases having been reported in 2021, Nigeria and South Africa accounting for 53% of these cases. Important to note also is that TB high burden countries in Africa include Democratic Republic of Congo, Nigeria and South Africa.

The 'End TB Strategy' set a goal to achieve 50% reduction new TB cases by the year 2025 and in the year 2021, the African region had achieved a 22% reduction, some countries (such as Mozambique, Kenya, Togo, Uganda) going as far as achieving 35% reduction and reduction of TB-related deaths by 75% of which Africa achieved the highest rates of all WHO regions by 26% in the year 2021, a clear sign the efforts are on course to bear fruits (WHO Africa, 2023).

Kenya was removed from the 30 countries with high prevalence of MDR TB but still remains among the 30 countries with high prevalence of the disease, contributing 90% of the global TB burden. However, in 2021, Kenya surpassed the set target of reducing TB-related incidents by 32% against the set target of 20% by the year 2020 and 44% reduction in TB-related deaths against the set target of 32% by the year 2020 with the year 2015 acting as the baseline, becoming one of the three countries from among the high burden countries to make such a progress (DQA 2023). Despite the efforts made so far, there is still need to double the efforts to reduce the disease's burden on the country further as the latest report shows a rise (16.7%) in the number of new drug-susceptible TB cases in the year 2022 (90,560) compared to the previous year (77,854). Even though there was a decline in drug-resistant TB cases in 2022 (752) compared to those reported in 2021 (804), the numbers still remain high and as such the economic cost of treating the disease is equally high (DQA, 2023). There is therefore need to uphold and even double the efforts and commitment from the global to the local level in the fight against TB to save more lives and eradicate the disease as it is a threat especially for HIV patients.

2.2 Socio-Demographic And Individual Factors Associated With Adherence To Anti-Tuberculosis Treatment

2.2.1 Socio-Demographic Factors

Health is a dynamic subject requiring a holistic approach to address it. Adherence to anti-TB treatment involves long treatment time, drug resistance, drug side effects, disease-related malnutrition among others. It is therefore embedded in one`s daily life, hence is affected by an individual`s daily life routine and environment, which majorly constitute the inevitable socio-demographic aspects of one`s life, which include: gender, age, income, occupation, marital status and education . Studies have indeed shown a relationship between adherence to anti-TB treatment and socio-demographic factors, influencing both positively and negatively. In China, patients were drawn from different part of Anhui province and were found to be affected by these socio-demographic factors.

Patients earning less than five thousand Yuan annually were less adherent compared to those earning twenty thousand *Yuans* and above. This was as a result of patients having to incur other opportunity costs arising from management of the disease such as transport to the clinic and buying nutritious foods among others, hence the need for a stronger economic support to maintain adherence (Fang *et al*, 2019). Such condition was found by a study in Bolivia whereby patients found to abandon their treatment and structural barriers were found to abound more than the cultural barriers as earlier perceived, most patients citing hidden costs in TB treatment, which they were unable to meet given their low socioeconomic status . The influence of this poverty level was also reported to have an overarching effect on the patients` ability to meet their transport cost as well as food hence contributing to default from treatment (Tola *et al*, 2015). In Kenya, monthly income was found to

have an impact on patient adherence where patients earning less than Ksh. 10,000 were less adherent compared to those earning more than the said amount, necessitating the need for economic empowerment of this population (Wanyonyi *et al*, 2017).

Marital status impacted adherence as far as anti-TB treatment is concerned since this factor was found among Chinese patients to positively influence adherence as compared to the unmarried counterparts (Fang *et al*, 2019). In Ethiopia, the findings were corresponding whereby the married participants were found to be more adherent than the unmarried (Tola *et al*, 2017). Age is an equally important factor to consider in adherence, a highly dynamic factor with varied possibilities. Whereas it may be thought that the younger aged could be more adherent because of the limited chances of being weighed down by the side effects and instead cope with them, a Botswana-based study found younger patients of the reproductive age to be 0.95 times more likely to interrupt treatment (Gust *et al*, 2011). On the other hand, in Nigeria, patients tended to be more non-adherent with old age (Ifebunandu & Ukwaja 2012). A similar trend was observed in Ghana where the younger population aged 20-29 had an adherence rate of 56% but as the age increased to over 60 years, the adherence rate proportionally increased to 71% hence age in this study being a factor influencing adherence (Danso *et al*, 2015).

In Kenya, results showed the younger population to be most affected by this disease (25-34) which is the reproductive age, whose adherence rates were much lower than the national average (Kimani *et al*, 2021). In another Kenyan based study however, it was found that the aged population (36-45 years) tended to be more adherent than the younger population aged less than 36 years (Mbuti *et al*, 2019). A Ugandan-based study did not find an a relationship between an individual`s age and adherence to anti-TB treatment (Robsky *et al*, 2021)

Gender is also an important factor to consider while assessing adherence. This is owing to the fact that some societies have appreciated the male dominance and this affects decisions made even in matters to do with health in families (Hay *et al*, 2019). As far as TB infection is concerned, the male gender is the most affected, with a greater risk of contracting and even dying from the disease (WHO, 2018). This is further evidenced by the fact that 56% of all new TB cases recorded in 2020 were of the male gender (WHO, 2021). This could be attributed to the poor health seeking behavior and the introvert nature of men (Hay *et al*, 2019).

In Tanzania, it was realized that female gender had twice as high chances of adhering to treatment than the male gender, despite the fact that the male participants were the majority in this study (Mkopi *et al*, 2012). However, a study done in Ghana found contrary results whereby the male gender was found to be more adherent to anti-TB treatment compared to the female and in fact, they were found to be three times more adherent. However, no specific reason was alluded to this observation hence necessitating a need for more comparison to other studies (Dogah *et al*, 2021). In Kenya, a study showed the male gender to be more non-adherent compared to the female (Kimani *et al*, 2021). While exploring the possible reasons for male non-adherence compared the female gender, it was found out that their mobile nature, poor health seeking behavior, the social behavior are possible reasons for this poor adherence in this gender (Dogah *et al*, 2021).

Occupation is equally a significant factor and can potentially affect one`s adherence when there is low knowledge on the disease and there is little or no effort from the healthcare workers to enlighten patients. This is because, some employments demand much from an individual so much that it will require them to appreciate the severity and danger of the disease to sacrifice their time to pick medication and create time to take them. In Morocco, it was found out that some patients defaulted from treatment because their work schedule demanded much of their time and so they felt that if

they missed from the job to pick their medication then it would mean a lesser pay hence opted to go for work rather than picking their medication (Tachfouti *et al*, 2013). In Sudan, being employed in a white collar job was found to be associated with adherence, characterized by movement from one place to the other. This was exacerbated by some patients giving wrong home addresses hence became difficult to follow them up (Ali & Prins, 2016). In Ethiopia, patients cited being away for work as a reason for their non-adherence, which required them to work for long hours before getting back home. This could possibly lead to forgetfulness or missing to take the drugs in time (Mekonnen and Azagew, 2018) in Kenya, patients practicing farming were found to be more adherent to anti-TB treatment than the formally employed and business men (Mumbe *et al*, 2020). Such were the results reported in another study in Kenya where it was found that patients in the agricultural sector were the most adherent while those formally employed and in the business sector were found to be least adherent (Mbuthi *et al*, 2019).

The role of education cannot be undermined also as it has been found to influence adherence to anti-TB treatment. Though it is widely agreed in a wide range of population, this view has been challenged, arguing this is just a myth and rather presupposes that it really depends on how information is given to the patient, emphasizing the need for shared decision making between the patient and the healthcare provider (Driever & Brand 2020). In Peru, a study revealed an association between adherence to anti-TB treatment and level of education. Those who had their education not going beyond secondary were found be less adherent to treatment (Lackey *et al*, 2015). Similarly, in Pakistan, a study on non-adherence found out this association whereby, those who had not obtained formal education were prone to loss-to-follow up and majority of them gave wrong contact address, re-affirming the importance of education in promoting treatment adherence (Mukhtar and Butt 2017).

2.2.2 Individual Factors

Tuberculosis affects all population groups regardless of social behaviour, health status, economic background, age among others. People therefore respond differently to this disease and its treatment and as such will have varied side effects, treatment time among others. Some of the individual factors that have been found to impact patients` adherence to anti-TB treatment include but not limited to: Alcohol consumption, smoking, use of other Non-TB drugs, pill burden, feeling better, Prior TB treatment, Side effects, Treatment period, stigmatization and social support among others.

Social support is a very important tool not only for TB patients but also for the general population, which is to a great extent a determinant of mental health, which together with other components make up the health of a whole being. In its broader sense, social support means belonging to a social community or rather circle, being valued, getting emotional support in times of crisis and being guided when in need of it (Drageset 2021). In Tuberculosis care, WHO recognized the power of social support and introduced this as part of TB treatment, termed as DOTS strategy, which requires that every patient to have a treatment support partner, preferably a healthcare provider or any other designated person such as a community health practitioner who watches the patient swallow TB dose (Otu, 2013). To this effect, social support has been found to have an influence as far as anti-TB treatment adherence is concerned.

In Shanghai, China, patients who had a treatment support from the family level were found to have less chances of defaulting from treatment compared to those who had none (Chen *et al*, 2013). In Anhui province of China, patients who had a health professional visiting them were found to be more adherent. The adherence was more so lower among patients who had a health provider visting them from the county level compared to those visited by a village doctor (Fang *et al*, 2019). In Morocco, DOTS was categorized as a predictor for treatment default because the time taken by

clinicians to administer drugs would have otherwise been spent attending to other important issues and as such the more adherent patients were visited a few times a week to check on their progress (Cherkaoui *et al*, 2014). In Zimbabwe, analysis showed that patients receiving adequate amount of social support exhibited increased health-related quality of life compared to those receiving sub-optimal amount, characterized with events such as reduced pain, less stress and anxiety (Zarova *et al*, 2018).

A similar phenomenon was observed in Pakistan, patients receiving support and progressing with treatment to completion showed improved levels of health-related quality of life with each successive stage of treatment (Saleem *et al*, 2018). A study conducted in Kenya equally found lack of social support as a significant predictor of non-adherence to anti-TB medication (Chebet *et al*, 2022). Stigma has also been a hindrance in combating TB in some communities because of the myths and superstitions linked with the disease. In East Africa, TB is linked with a familial curse and poor hygienic standards with the disease being considered to be highly contagious, to the extent even healthcare providers are scared handling the patients. Patients are deterred from seeking healthcare services and instead opt to self-medication, cheap herbal medication or seeking spiritual intervention (Msoka *et al*, 2021).

In Kenya, stigma has been associated with default from treatment among patients (Muture *et al*, 2011). While undergoing TB treatment, patients experience side effects and these too can contribute to non-adherence. Patients Some of the side effects likely to be incurred by patients include: skin rashes, flu-like symptoms, vomiting, nausea, feeling dizzy, pins and needles and in adverse cases jaundice. In addition, some patients experience adverse events as a result of taking TB drugs such as: appetite loss, vomiting and nausea, blurred vision, easily bruised, persistent fatigue and body weakness and persistent tingling or burning hands or feet (CDC,2016). In India, patients were

reported of Lost-to-follow up and when they were contacted, they reported to have experienced drug adverse events (Imam et al., 2020). Similar reports have been observed in Ethiopia and Kenya (Tesfahuneygn et al, 2015; Muture *et al*, 2011). History of some harmful behavioural factors such as smoking, alcohol and substance abuse and characteristics such as anemia and old age increase an individual's chances of experiencing adverse events (Chung-Delgado et al., 2011). Side effects as a result of medication have also been mentioned in a study conducted among TB patients in western Kenya (Ayisi *et al*, 2011) and Ethiopia (kebede *et al*, 2012).

Patients who had relapsed have also been found to cite this as a cause of non-adherence. Among South African patients, this was mentioned among those patients who had previously been treated of this disease and when symptoms disappeared, they thought they had got well since they had previously been treated. There is therefore need for healthcare workers to get in close contacts with such cases since they can easily develop MDR-TB. Some also feel discouraged because the first round of treatment was unsuccessful and as such feel this time it is also likely to fail (Finlay *et al*, 2012). Default among re-treatment cases has also been reported previously among Kenyan patients (Muture *et al*, 2011). Most patients always stop taking medication especially for communicable diseases when they feel the symptoms have disappeared and so even with TB, several studies have found out this to be one of the reasons for treatment default (Muture *et al*, 2011; Tola *et al*, 2015). This feeling usually comes as a result of anti-TB drugs acting on the Mycobacteria and once they are suppressed, patients feel much better and with limited knowledge, some skip their medication. In Morocco, 73% of defaulting patients who had been initiated on treatment in the intensive phase cited the sensation of feeling better as a reason for their default (Tachfouti *et al*, 2012). Among patients in Kisumu, some of them reported they stopped taking medication when they felt better (Ayisi *et al*,

2011) whereas in Baringo, 41% of patients who defaulted mentioned symptom relief as the main cause of non-adherence (Obwoye *et al*, 2021).

Treatment burden described as workload endured by patients while taking care of their health and the impact it has on the patient's life (Ting *et al*, 2020), has been reported to bother patients as it comes with a few life adjustments (in time and effort) and has to be repeated over a relatively long time of at least six months. The situation is worsened when in some cases treatment is on clinical DOT. Patients in an Australian based study reported the clinic-based DOT to be mentally and physically draining and almost defaulted if this was not altered (Ting *et al*, 2020). Similar sentiments were echoed by a similar study in Singapore (Lee *et al*, 2016). In Eritrea, patients felt the treatment period was lengthy and this was found to contribute to non-adherence (Gebreweld *et al*, 2018).

Pill burden, defined as the number and (or) size of pills a patient has to take has been a concern to some patients who have attributed this to treatment default in Australia and Peru (Ting *et al*, 2020; Culqui *et al*, 2012). There is therefore need for a fixed dose combination therapy as previously proposed by WHO requiring 2 to 4 anti-TB drugs to be combined (Bloomberg *et al*, 2001) as is the case for Diabetes therapy who have expressed drug satisfaction and increased treatment adherence (Hutchins *et al*, 2011). However, this has to be carefully considered since some patients may have side effects with some drugs and become hard to change their medication.

Smoking, alcohol and substance abuse have been found to have negative health implications upon the human body, affecting the physiology and the behaviour of users. In TB treatment, this habit is discouraged for obvious reasons of contributing to non-adherence (Lost-to-follow-up) as well as contributing to adverse drug events which may turn fatal instead of bringing remedy upon the user

(Chung-Delgado et al., 2011). In Peru, alcohol and smoking were found to be the strongest predictors for non-adherence among patients hence the need for more efforts among these groups to encourage them to be adherent (Lackey *et al*, 2015). In Moldova, a similar observation was reported that alcoholism was contributing to non-adherence (Jenkins *et al*, 2013). Among Morocco patients, smoking was observed as a risk factor for treatment loss-to-follow-up whereas the reverse was observed to be protective (Cherkaoui *et al*, 2014). In Kenya, alcoholism has been reported to have negative implications on adherence since 50% of patients were lost to follow up during a study in Baringo (Obwoye *et al*, 2021). In Nairobi, patients who were given to alcoholism were found to default from treatment hence, the need to emphasize more on adherence in this class of TB patients (Muture *et al*, 2011).

Co-morbidity which necessitates use of other drugs alongside TB regimen has also been found to have a double play both as protective factor as well as a contributing factor to non-adherence. TB-HIV co-infection remains to be a threat among HIV patients, as TB remains the leading cause of hospitalization and deaths among HIV patients, accounting for one in five HIV-related deaths (WHO, 2021). In a retrospective study in South Africa, HIV co-morbidity was found to be a protective factor, in which patients initiated on ARTs were 40% less likely to default from treatment compared to those who were not initiated (Kigozi *et al*, 2017). In Ethiopia, patients' unsuccessful treatment outcome, most of whom had died (58%) was associated with HIV infection thus reaffirming the threat posed by HIV-TB co-morbidity (Tesfahuneygn *et al*, 2015). In Kenya, HIV-TB co-infection is equally a common challenge, studies showing that this is a contributor to treatment default (Muture *et al*, 2011). A nationwide TB survey found that being HIV positive was a protective factor indicating that with appropriate counseling and moral support, HIV patients become adherent to medication (NTLD, 2018).

Malnutrition increases the chances of one contracting TB and TB can lead to malnutrition (WHO, 2023). Given the two conditions are intertwined, there is need for healthcare givers to assess patients` condition before initiating them on treatment to minimize chances of adverse drug events and even defaulting. The burden of malnourishment cannot be undermined in Kenya with recent reports indicating that at the time of diagnosis, 45.4% of DS-TB and 53.9% of DR-TB were facing malnourishment, the greatest challenge to this condition being lack of skill among healthcare workers to assess the condition and unreliable supply of nutritional supplements to the vulnerable patients (CHS Kenya, 2020).

Diabetes and Cancer have also been found in studies to influence adherence to anti-TB treatment. In Kuwait, patients found to default from treatment had a history of concomitant diabetes Mellitus, lung cancer and liver disease (Zhang *et al*, 2014). Among patients in Peru however, being diabetic was protective in that these patients were less likely to default from treatment, probably because they were used to the lifestyle of daily drug consumption hence this was just a normal routine or them (Lackey *et al*, 2015). It could also be motivated by the risk associated with being TB-Diabetes co-morbid, evidence showing that diabetes increases the risk of getting TB three times and that the patients are likely to have worse TB treatment outcomes compared to the non-diabetic (WHO, 2023).

2.3 Health System Factors associated with adherence to anti-tuberculosis treatment

The ministry of health is the department charged with healthcare provision to patients on behalf of the government in most countries. Patient interaction with the health system also plays a role

whether they will seek health services or not. For a health system to be functional, health equity and access are among the very fundamental pillars. Equity in this case entails availability of a fair and just opportunity for attaining the highest quality and optimal healthcare to everyone, notwithstanding their race, sexual orientation, socioeconomic background, ethnic background, geography or any factor hindering access to care (CMS, 2023). Access on the other hand entails the ability to receive timely care when there is perceived need for it and from a source with whom patient-provider relationship can be established to promote, maintain, prevent and manage a disease and reduce unnecessary disability or premature death (NIH, 2012).

Due to the complex nature of TB disease characterized with drug resistance and high mortality rates, TB drugs and diagnosis is given to patients free of charge, as part of the WHO goal to end TB globally (Pedrazzoli *et al*, 2018). Even with all the efforts from the health authorities at country and global levels to ensure equity and access to TB services, there are health related factors that hinder patients from completely adhering to anti-TB care, contributed by the health system. Such factors are discussed in this section, including but not limited to: Drug stock-outs, long waiting time, friendly, caregivers, distance to health facility, drug refill period and transport cost.

Long distance from home to the clinic has been raised as a point of concern while undergoing anti-TB treatment as was reported by patients in Eritrea, having to walk for more than two hours a day to access the clinic. This has however been addressed by the government by empowering the community TB promoters to deliver the drugs in the patients` when they are unable to access health facilities (Gebreweld 2018). In Uganda, similar concerns were raised by patients who had to commute more than 10 KM to access a TB clinic and this contributed to defaulting from treatment (Elbireer, *et al*, 2011). In Nigeria, a rural residence was found to be a predictor of treatment default, which necessitated patients to travel to the urban area to access care and the long distance, coupled

with difficulties reaching there was seen as a great challenge for the patients (Ifebunandu *et al*, 2012). Among patients in Baringo, Kenya, 53% of the patients attributed their adherence to long distance to access healthcare, coupled with poor road network hence the need to re-think on how patients can be easily reached (Obwoye *et al*, 2021).

Drug stock-out can also discourage patients from attending their clinic in time considering that some travel for long distances to access the clinic, some having to postpone important duties to attend their clinics for drug re-fill and other services. This challenge was reported among patients in Uganda and was found to significantly influence their adherence to treatment (Elbireer, *et al*, 2011). Kenya has had an unfortunate tale of drug stock-outs when during the implementation of devolution, the mandate to purchase drugs was a sole responsibility of the county governments. The technicalities involved in purchase of these drugs caused a stock-out of TB drugs for two consecutive financial years, leading to a nationwide crisis, with significant economic losses, default from treatment and higher treatment costs for the country, forcing the national government to intervene so as to remedy the situation (Collins and Njuguna. 2016)

The busy schedule of some patients requires them to spend as minimum time in the health facility whenever visiting the clinic, as possible and as such long waiting time before being served becomes a potential factor for their default to treatment. This has been reported in several studies and hence the need to address this issue to favour such patients in Ethiopia, patients waiting for one to two hours to be served were 14 times more likely to default from treatment compared to those waiting for a shorter time period (Gube *et al*, 2018). Similar results were reported elsewhere, patients who waited for more than 30 minutes were at a greater risk of defaulting from treatment as they felt discouraged to wait (Workie *et al*, 2021). Among TB patients in Nandi, Kenya, patients waiting for

more than one hour were more likely to default from treatment compared to those reporting less than the mentioned time (Wanyonyi *et al*, 2017).

Patient-provider relationship is at the core of quality healthcare as embedded in the tenets of access to healthcare. Since TB patients are equally humans, they too deserve to be listened to as much as they are the recipients. Poor relationship has indeed been found to influence patient adherence to anti-TB treatment, a factor that needs to be considered with seriousness as patients can influence each other to develop a negative attitude towards a healthcare provider, hence have an overarching negative effect as far the End TB strategy is concerned. In India, patients reported their relationship with health providers to be poor, thus hindering information dissemination to the patients (Roy *et al*, 2015). Similar reports have been reported in Kenya where treatment default was also associated with poor relations between patients and health providers (Muture *et al*, 2011). Transport cost, an indirect cost related to TB was another challenge identified by patients in Ghana who claimed that they lost jobs upon testing positive for the disease and as such affording the money was a great deal (Appiah *et al*, 2023). Similar sentiments were also reported among patients in Ethiopia, who had inadequate funds to finance their journey to and from the clinic, a factor which was associated with their non-adherence (Nezenega *et al*, 2020).

2.4 Level of knowledge of patients on tuberculosis and its association with adherence to anti-tuberculosis treatment

2.4.1 Tuberculosis Disease Transmission

Tuberculosis is an infectious disease, caused by the bacteria *Mycobacterium tuberculosis* that gets into uninfected person when they inhale the droplets from an infected person when they cough, sneeze, speak or sing. The bacteria start to grow and multiply in the lungs, which are mostly affected by the bacteria, commonly referred to as pulmonary TB, although in some individuals they can move and affect other parts including the kidney, brain, lymph nodes, bones and the spine, referred to as extra-pulmonary TB (CDC, 2023).

Tuberculosis bacteria remain suspended in the air when exhaled from an infected person for several hours, especially in an enclosed environment. Risk factors for contracting the disease include: weakened immunity, living or working in overcrowded areas, living in areas with high TB incidence or spent time with a person who has active TB, under the age of 5 years, alcohol and substance abuse addicts. Common misconceptions held by the population but are not true about TB transmission are that one is likely to contract the disease when: they share food or drink, shake hands with an infected person, share toothbrush or utensils, kiss with an infected person, touch the beddings, toilet seats or linen of an infected person (CDC, 2023).

2.4.2 Tuberculosis Signs and Symptoms

Some people can get infected with TB and still do not show signs and symptoms, commonly known as latent TB. When signs and symptoms exhibit, this is known as active TB with the following signs and symptoms showing when it is pulmonary TB: Persistent cough lasting more than three weeks

sometimes accompanied by mucus and even blood in it, general fatigue, high temperatures (night sweats), appetite loss, loss of weight and feeling generally sick. In the cases of extra-pulmonary TB, patients experience pelvic pain, constipation, swollen joints, swollen glands, body aches, cloudy urine, headache, feeling sick. Skin rash on the face, legs or other body parts, stiff neck and feeling confused (NHS, 2023).

2.4.3 Tuberculosis Management

2.4.3.1 Prevention of Tuberculosis

Prevention is the best cure, as it is commonly agreed in the field of health and for TB to be completely eliminated, prevention is the ideal way to go. The most reliable source of prevention is a strong body immunity, which has the potential to completely kill the tuberculosis bacteria in 60% of adults with strong body immunity. Unfortunately, approximately 5-10% of individuals with latent TB are likely to develop active TB hence the need for more prevention measures (Chandra *et al*, 2022).

Vaccines are the immediate options for disease prevention when the body's immunity fails. In the case of TB however, efforts to come up with a more effective vaccine have not borne fruits so far, the only option available being the BCG (*Bacille Calmette-Guérin*) vaccine, which has been in use for more than a century now (since 1921) and the vaccine has been found to have a limited effectiveness. The shortcomings of this vaccine include: ability to prevent development of TB for 15 years upon administration into the body, limited effectiveness for people above 35 years of age, less effectiveness among the population in equatorial regions because of the naturally occurring environmental mycobacteria (Davenne & McShane, 2016). The limited functionality of this vaccine is evidenced by the high number of new cases of TB occurring every year despite the administration of

this vaccine to newborn babies hence the need for a more effective vaccine. However, research on TB vaccines has been done extensively, with several of them under clinical trials, including viral vector vaccines, DNA vaccines, live attenuated vaccines, recombinant BCG vaccines and subunit vaccines (Zhuang *et al*, 2023).

Contact tracing is another method that can be used to prevent the spread of the disease among the population, given that the disease spreads in the community, when unsuspecting active TB cases release contaminated droplets to the atmosphere, which are then inhaled by uninfected individuals (TB Alert, 2022). The high risk populations likely to develop active TB include as specified NTLD include: people living with HIV, household contacts of persons with bacteriologically confirmed pulmonary TB, prisoners and prison staff members, those working in healthcare settings, patients on treatment for cancer, patients with silicosis, patients on dialysis and patients undergoing organ transplant (NTLD, 2021). According to guidelines provided on TPT by the national TB program, treatment is given depending on the age and underlying conditions as follows: for those aged 15 years or less, and are HIV positive, Isoniazid is administered daily for six months whereas HIV negative rifampicin and Isoniazid daily for three months is administered.

If aged above 15 years, notwithstanding the HIV status, Isoniazid and Rifapentine is administered once a week for three months. If in pregnancy or individual has contraindications with a combination of Isoniazid/Rifapentine or Isoniazid/Rifampicin, then the recommended dose is Isoniazid daily for six months (NTLD, 2021). Most important, checking on the environment of not only the infected people but also for general health and wellbeing is of importance as this will reduce chances of disease spread and preventing occupied areas from being diseases breeding zones. These measures include but not limited to: ensuring good ventilation in the house since TB bacteria can remain suspended in the room for long period of time, ensuring natural light gains access to the house as

Ultra-violet light rays kill a wide range of bacteria and practicing good hygiene such as covering the nose and mouth while coughing or sneezing to prevent release of droplets into the air (TB alert, 2022).

2.4.3.2 Tuberculosis Diagnosis

In Kenya, there are three most preferred TB diagnosis methods namely: AFB (Acid Fast Bacilli) microscopy, GeneXpert and culture (NTLD, 2021). AFB microscopy is basically bacteriological examination of smears to check for the presence of tuberculosis causing bacteria and other types of mycobacteria. Smear positive result implies presence of TB disease whereas a smear negative result implies absence of tuberculosis. However, either of the results does not confirm a diagnosis of TB since some stained mycobacteria are not *M. tuberculosis* hence a culture is mandatory for all specimen to confirm presence of *M. tuberculosis*. Culture is the gold standard for TB laboratory confirmation. The patient is asked to cough deeply so as to obtain a sputum from the lungs and is then placed in a special dish and sent to the lab where it is cultured which in other words means giving the bacteria time to grow, and this can go up to six weeks. During this period, the growing bacteria are required to perform drug susceptibility testing and genotyping (CDC, 2020).

GeneXpert is a type of molecular test that uses Nucleic Acid Amplification (NAA) to reliably detect *M. tuberculosis* DNA in a matter of hours as compared to longer durations in culture. If NAA results turn positive, in correspondence with AFB smears, then it is presumed the patient is TB infected and should be initiated on medication. When NAA results turn negative while AFB smear turns positive, chances are the patient is infected with non-tuberculous mycobacteria, hence culture will be depended upon for confirmation. A limitation with NAA test is that, it cannot differentiate live and dead organisms hence positive results may turn negative after culture. In Kenya, the Xpert MTB/RIF (Genexpert) is the preferred device that uses NAA test and has an advantage of detecting not only *M.*

tuberculosis complex but also the mutations in the genetics of the bacteria, associated with rifampin resistance, an essential drug used to treat TB (NTLD, 2021). Testing positive for both tests implies the patient could have MDR-TB whereas testing negative for rifampin resistance means the infection is susceptible to rifampin (CDC, 2023). For people living with HIV/AIDS and are severely immune-compromised, an add-on test known as Lateral flow urine lipoarabinomannan assay (LF0-LAM) is used to increase diagnostic yield, in addition to Genexpert test. Tuberculin skin test and Interferon Gamma Release Assay (IGRA) is used for detection of latent TB (NTLD, 2021).

2.4.3.4 Tuberculosis Treatment

Treatment of TB is very essential as it helps to cure the disease thereby alleviating suffering of the patient and this goes a long way to stopping disease transmission. TB is a top killer disease hence treating it stops TB-related deaths, prevents the long term complications as a result of TB when death does not occur. When not treated properly, it can cause TB relapse hence it's important to treat the disease and in some cases drug resistant TB develops when not treated. Four first-line drugs are used in treating drug-sensitive TB and these include: Rifampicin, Isoniazid, Pyrazinamide and Ethambutol. During the intensive phase (first two months), the drugs are administered in a fixed-dose combination and dosage depends on the patient's age and weight (between 2-5 tablets for adults and 1-4 tablets for children) whereas in the continuation phase (lasts four to ten months), two drugs namely rifampicin and isoniazid are used (NTLD, 2021)

When a child is detected with rifampicin resistant TB (RR TB and MDR TB), the recommended regimen is a combination of linezolid(Lzd)/ moxifloxacin (Mfx)/ Clofazimine (CFZ)/ Cycloserine (Cs) for intensive phase lasting six months and Mfx/ Cfz/ Cs for continuation phase lasting 12 months. When a child is diagnosed with pre-XDR TB, the recommended regimen is a combination of Bedaquine (Bdq)/ Delamanid (Dlm)/ Linezolid (Lzd)/ Clofazimine (Cfz)/ Cycloserine (Cs)/

Pyrazinamide (Z) during the continuation phase lasting 6 months and Dlm/ Cfz/ Cs/ Z lasting 14 months.

For adults diagnosed with MDR/RR TB the recommended dosage is Bdq/Cfz/Lfx/Cs/Lzd for 6 months in the intensive phase whereas in the continuation phase, the recommended dosage is Cfz/Lfx/Cs for 12 months in the continuation phase. In the event of pre-XDR TB, it depends on the type of resistance found. When found to be injectable resistant, a patient is put under Bdq/ Cfz/ Lfx/ Cs/ Lzd for six months in the continuation phase and then Cfz/ Lfx/ Cs for 12 months. In the event the pre-XDR resistance is fluoroquinolones resistant, the patient is put on a six months intensive phase with the regimen Bdq/ Dlm/ Lzd/ Cfz/ Cs, followed by a 14 month regimen consisting of Dlm/ Cfz/ Cs. For all treatment categories, the period of treatment either at the intensive or continuation phase may be extended depending on the culture results and the adherence level of the patient (NTLP, 2021).

2.4.4 Patients` knowledge level on Tuberculosis and its association to adherence

Knowledge incorporates acquisition of skills and information via education and/or experience (Oxford languages, 2024) and in this case, knowledge is imparted to patients via education and partly via experience as they have a first-hand experience of the disease. This is an important aspect in TB management because when patients are empowered with knowledge, improved adherence levels will be realized, increased, prompt healthcare seeking behaviour and improved cure rates among patients (Anaam *et al*, 2023). Patient knowledge varies in different studies, depending on the researcher`s criteria on knowledge categorization, some scoring high while some score low. This section will compare some of the studies done to test patient knowledge and how it influences their adherence to anti-TB treatment.

In Bengal India, two thirds of participants had satisfactory knowledge levels on various aspects of the disease and this had a positive correlation on adherence as they were found to be more adherent than those with low knowledge (Roy *et al*, 2015). Saudi Arabian patients were found to have average knowledge level on TB, the cumulative average score on all questions being 55.3% with varying scores on individual questions. The poorly answered question that could propagate stigma in the community is the belief that sharing utensils can spread TB, which only 6% of the participants were able to correctly answer (Anaam *et al*, 2023). In Brazil, comprehension levels on treatment guidelines was found to be low among participants which necessitated the need for more health education to patients to be familiar with TB disease and the treatment guidelines (Viegas *et al*, 2017).

In USA, comparison in knowledge showed the whites to have higher awareness about TB compared to the blacks although the overall knowledge score was high at 85%. However, misconceptions about latent TB still remained high especially among the blacks necessitating the need for increased awareness in this group about TB (Howley *et al*, 2015). In Pakistan, knowledge level among the population was low, with those residing in the rural scoring lower than those in the urban. The misconception of sharing utensils with TB patients was widespread, 44% alluding to this notion. However, nearly the whole population (97%) knew the site of treatment for TB to be in health facilities. This study showed the gap in knowledge that should be addressed in this country, which is among the TB high burden countries (Mushtaq *et al*, 2011).

Studies in Africa have also had varied findings on matters knowledge as far as TB is concerned, as well as association of knowledge with adherence. In Ghana, a qualitative study found some patients to have very low knowledge about the TB to the extent of not knowing the cause and mode of transmission of this disease (Appiah *et al*, 2023). In another study in Ghana however, patient

knowledge was found to be very high, the overall score being 95.2%. Patients were highly informed of the TB symptoms such as cough (100%), chest pain (93.6%) and loss of weight (81.6%) (Dogah *et al*, 2021). In Nigeria, knowledge levels were high among patients, 97% of them knowing that TB is treatable whereas only 46% were aware that coughing without covering the mouth is the principal mode of TB transmission. Noteworthy, only 1.2% of patients expressed the TB misconceptions such as sharing clothes and abstaining from sex as TB preventive measures but did not find association with adherence to anti-TB treatment (Adisa *et al*, 2021).

Among TB patients in South Africa, 60% of patients were able to identify the aetiology of TB disease, 84.6% were aware that TB is highly transmissible in crowded places and 73% knew that the disease is contagious. However, misconceptions associated with TB were high in this population, 55.2% associating the disease with strangers rather than family members, 85% of participants claiming the disease can be transmitted through sharing toothbrushes and 65% felt the disease can be transmitted through kissing (Kigozi *et al*, 2017). The study did not show correlation with adherence to anti-TB treatment. In Ethiopia, two studies found knowledge to be associated with adherence to anti-TB treatment where low knowledge was associated with poor adherence to treatment (Mekonnen & Azagew 2018; Gashu *et al*, 2021).

Knowledge assessment on TB among patients in Tanzania showed low scores among patients especially among those residing in urban areas. In the study, the average knowledge score of the disease was 44.2% those in the urban scoring fairly well (64.2%) compared to those in the rural areas (22%). In regard to TB symptoms, the overall score was good, the average score being 83.9%, those in the urban having a score of 92% compared to those in the rural at 75.8% . this therefore shows knowledge disparities among rural populations compared to those in the urban areas (Kazaura & Kamazima, 2021). Uganda reported higher levels of knowledge (61.9%) compared to that

reported in Tanzania (44.2%) and when correlated with adherence, there was a positive correlation to adherence (Ogwok *et al*, 2022).

In a study conducted in Kilifi, Kenya, adherence was positively correlated to knowledge, those with high knowledge having higher chances of adhering (Chebet *et al*, 2022). In Nandi County, participants who had adequate knowledge on TB disease transmission were more likely to adhere to treatment compared to those with low knowledge level (Wanyonyi *et al*, 2017). A qualitative study done among pastoralist community assessing their knowledge on TB attributed its cause to be a hereditary disease hence was bound to affect more than one family member. Some attributed it to smoking and alcohol consumption on disease transmission, they believed the disease spreads through sharing utensils and casual contact and as such a patient was isolated and even had their own utensils set aside, a notion that propagates stigmatization in the community (Mbuthia *et al*, 2018). In Kiambu County, patients who defaulted from treatment cited lack of knowledge as the main predictor for their non-adherence hence the need to beef up efforts to educate the communities and patients on this disease (Kimani *et al*, 2021).

2.5 Prevalence of adherence to anti-tuberculosis treatment

Adherence is "the degree to which the person's behaviour corresponds with the agreed recommendations from a health care provider" (Sabaté, 2003) Compliance is sometimes used to refer to adherence but there is a difference between the two. Compliance implies that a patient follows strictly the advice given by the health care provider in respect to the authority bestowed upon the provider. Adherence on the other hand means the healthcare provider together with the patient reach to a consensus on the treatment plan, with the major goal of improved health for the patient, by integrating the opinion of the healthcare provider and the patient's preferences, values and lifestyle (Jimmy & Jose, 2011). There are several types of non-adherence but the most common

types alluded to include: non-fulfillment adherence that entails a patient given a prescription but the medication is not initiated. The second type is non-persistence that entails the patient inconsistently taking the medication and at some point the patient stops taking the medication, without the health care providers direction. The third type of non-adherence is non-conforming that involves the patient fails to take medication as prescribed, sometimes skipping the dose, taking at incorrect times, incorrect doses or even taking more than prescribed (Jimmy & Jose, 2011). This study will be dealing with non-conforming and non-persistence types of non-adherence to TB treatment.

Adherence can be measured either directly or indirectly. The direct means of measurement include: Direct observed therapy (DOT), measurement of the drug levels or its metabolites in urine or blood or measuring biological markers of the given drug in blood. Indirect methods include: self report from the patient, using questionnaires to interrogate the patient, pill counts electronic medication monitors, measuring physiologic markers and assessing patient diaries and clinical response. Every method has got its own merits and demerits and as such there is no gold standard of these methods. Self report from the patient is however considered the simplest method of assessing adherence (Jimmy & Jose, 2011). Because there is no gold standard of measuring adherence especially for anti-TB treatment, assessment varies from one country and region to the other. In Kenya, adherence is measured in terms of pills taken and clinic appointments attended over a given period of time and failing to take at least 10% of medication and missing at least one clinic appointment amounts to non-adherence (NTLD, 2018).

The World Health Organization recommends more than 90% adherence to anti-TB treatment for effective management of the disease (Sabaté, 2003). However, this has not been met as much as it is the ideal standard as studies around the globe show prevalence of adherence to vary by region and country and even within the country, contributed by various factors. In Eastern China, 66.37% of

participants were adherent, the rate being higher among those who were monitored under DOTS strategy (Fang *et al*, 2019) while in Western China, 64% adherence was observed in a prospective study, re-affirming the need for supervision of patients since those supervised were more adherent to medication. However, those under family members` supervision were not as adherent as those under a visit by an outsider and phone thus raising the need to re-evaluate the effectiveness of using a family member (Lei *et al*, 2016).

In Kosovo, a cross-sectional study found out 85.5% adherence to anti-TB treatment among patients (Krasniqi *et al*, 2017) higher than was reported in an adherence study in Bangalore of 68.33% (John & Parasuramalu , 2023). In South Korea, DS-TB patients were assessed for adherence where 56.5% of patients were found to be adherent, those on quadruple regimen found to be more adherent than those on triple regimen (Bea et ak, 2021). In Brazil, the findings were slightly similar (58.5%) to those found in South Korea, the study participants in both studies being mostly the aged (Roy *et al*, 2017). A study in India employing self-report and urine test to measure adherence found conflicting results as far as adherence is concerned (63.7% and 53.4% respectively) thus raising the need to verify self-reported adherence measures (Thamineni *et al*, 2022).

A study combining results from various countries` prevalence on adherence found a pooled prevalence of 60% in Sub-Saharan Africa, with variations between countries (Zegeye *et al* 2019). In Nigeria, the reported prevalence on adherence to anti-TB treatment was 75.8% (Ifibunandu & Ukwaja, 2012) whereas those of Ethiopia and Uganda were 75.5% and 75.0% Respectively (Mekonnen & Azagew, 2018; Elbireer *et al*, 2011). In a different study, the prevalence of adherence was found to be 86% in Sudan (Ali and Prins, 2016) while another study in Zambia found out the prevalence of adherence to be 75.1% (Ubajaka, *et al* 2015). In South Africa, a retrospective study comprising of a large sample size found that only 7.2% of the participants had defaulted from

treatment, which was lower than 20% found in a similar study in Cameroon (Kigozi *et al*, 2017; Yone *et al*, 2011). In Tanzania however, satisfactory results were found after a study measuring adherence used a urine lab analysis at 91.1%, further raising the need for integration of more than one method in assessing patient adherence to anti-TB treatment as opposed to the commonly used self-reports (Mkopi *et al*, 2012). Findings in Uganda however were much lower than was found in Tanzania, the adherence being 75.5% (Zegeye *et al* 2019).

Kenya Tuberculosis and Leprosy program conducted a nationwide survey on adherence and the national average was found to be 75% (NTLP, 2018). However, different studies have been done and found out varying results in different parts of the country. In Kilifi, patient adherence to anti-TB was found to be 65%, which was much lower than the national average (Chebet *et al*, 2022). The result in Kilifi were slightly different from what was found among patients from Nandi who reported 69% adherence to the treatment regime (Wanyonyi *et al*, 2017) necessitating more efforts to address adherence. The two findings were however much lower than was found in Nairobi, where patients were found to be adherent more than the national average at 83.3% (Muture *et al*, 2011). Among patients in Baringo, during the intensive phase, patients were 54% adherent to their treatment regime but this decreased during the continuation phase to 46% (Obwoye *et al*, 2021).

2.5 Summary of literature review

Various socio-demographic factors were found to influence adherence to anti-TB treatment, notwithstanding the population type and position on the globe. Demographically, men seem to be the most affected and unfortunately the least adherent to anti-TB treatment compared to the women as found out in most studies. This should therefore be a point to note among healthcare givers to have a keen look at the male gender as far as adherence is concerned. Socio-economic factors were found to be a challenge among patients in LMIC countries compared to first world countries. The DOTS

strategy as initiated and advocated for by WHO was meant to improve adherence to treatment but this was found to be a hindrance among patients in high income countries such as Saudi Arabia claiming to inconvenience their daily routine hence the need to re-evaluate and customize this strategy to patients. Steps to eradicate TB are on the right trajectory hence partners should work relentlessly and even double the efforts because the morbidity and mortality rates are declining at a slow pace.

There is no universal definition of adherence and as such no gold standard method has been developed yet to assess adherence and as such this subject needs frequent evaluation so as to capture the most important tenets to include while studying this subject. Equally, there are no universally agreed tools for knowledge assessment and as such different researchers package their knowledge assessment tools depending on what they are really interested to find out. Knowledge level therefore differs from one study to the other depending on how the questions were packaged. However, misconceptions related to spread of TB such sharing utensils, toothbrush, casual touch and handling linen for TB patients among others still remain persistent among communities which in the long run propagates discrimination and stigmatization among the patients hence the need to propagate the right knowledge across different media. These misconceptions are also prevalent in Kenya as was highlighted by two studies in Kisumu and Baringo hence the need to advocate for knowledge dissemination using the media.

Adherence in Kenya is still low as found by most studies, ranging between 65% _ 83.3% with the national average being 75%. For all the published papers reviewed in these studies, knowledge was found to be a factor directly associated with adherence. However, the studies did not dig deep to ascertain the level of knowledge among patients.

2.6 Gaps in Literature Review

At the time of conducting this study, no peer reviewed study was found done in Migori County as far as patient adherence to anti-TB is concerned and as such this study would address this gap in Migori. For all the studies reviewed as far as adherence to anti-TB treatment is concerned in Kenya, no study categorized knowledge level among patients. Rather, knowledge was assessed as a variable influencing patients` adherence to treatment and when done, it was not categorized to give scores in form of percentages thus rate the knowledge level. This study therefore sought to bring this categorization so that future studies could compare with this study. At the time of carrying out this study, few studies in Kenya had used mixed methods to capture the views of patients and healthcare workers directly and this study used this method to articulate the concerns of these participants who are the major parties involved as far as adherence is concerned.

CHAPTER THREE: MATERIALS AND METHODS

3.1 Research design

A cross-sectional study design was used in this study. This was the preferred design because it enabled data collection at a specific point in time (February- May 2022). In addition, both qualitative and quantitative approaches were employed in data collection to enable the exploration of factors influencing patient adherence to Anti-TB medication, mainly from the patients` perspective as well as the healthcare givers.

3.2 Variables

3.2.1 Independent Variables

3.2.1.1 Socio-demographic factors

The variable captured patients` background information so as to gain understanding of what their life routine is comprised of, i.e., their social life as well as livelihood. It was assessed in the following aspects: age, gender, education level, occupation, marital status and monthly income. This variable was essential as it helped understand how the social rubric of life affected patients` acceptance of TB as a disease and patients` adherence to Anti-TB Treatment. It also helped to appreciate the reasons for Anti-TB medication non-adherence

3.2.1.2 Individual factors

In this variable, the researcher was interested in identifying the lifestyle of patients, whether they were having other underlying diseases or conditions, whether they had appreciated TB as a curable disease, their perception on medication as well as how they reacted to the Anti-TB medication. The variable was assessed in terms of: alcohol consumption, HIV status, smoking, use of drugs other than Anti-TB drugs, pill burden, whether patient`s condition had improved since starting medication,

whether treated of TB before, if they experience side effects, and period they have been on treatment, whether they had a treatment supporter, stigmatization and availability of money to meet other needs apart from TB treatment. This variable was equally important since what a patient experiences at a personal level impacts a patient`s adherence to Anti-TB Treatment.

3.2.1.3 Health system factors.

This was focused on what the healthcare sector entails and how it impacts adherence to Anti-TB medication adherence. This incorporated how the TB program delivers its services, how patients interact with healthcare providers and other incentives given to motivate patients. The variable was assessed in terms of: frequency of drug stock-outs, waiting time, how friendly caregivers were, treatment length, distance to the clinic, frequency of drug refill and transport spent to pick drugs. This variable was of importance since the whole concept of access of medication is entailed in the health system, be it in terms of cost, distance or availability.

3.2.1.4 Knowledge factors

This entails what the patient knows about causes of TB, treatment length, importance of medication and symptoms of the disease . This variable is important in this study to assess how knowledge of a patient affects their adherence to Anti-TB medication. In addition, patient-centred services always ensure patients appreciate the disease by knowing more about it hence improve adherence to medication.

3.2.2 Intervening Variable

Patient`s disease condition was used as the study`s intervening variable. This was preferred since it can affect a patient`s attitude on whether to adhere to medication in the hope of getting well or defaulting if they feel they are not improving and as such become non-adherent. This variable was

measured in the following aspects: Time since diagnosis, symptom bother, deterioration, disease severity.

3.2.3 Dependent Variable

Adherence to Anti-TB treatment was the dependent variable in this research. This is an important aspect in treatment of TB considering the dynamic nature of the bacterium *Mycobacterium tuberculosis* when it comes to drug resistance. Proper adherence contributes to complete cure, minimizes chances of developing MDR-TB and improved health outcome of patients. This variable was measured in terms of whether a patient had skipped to take their medication at any given time since the previous month before they were interviewed in this study.

3.3 Study Area

Study was done in Nyatike Sub-county, Migori County with a total of seven wards, namely: North Kadem, Kanyasa, Kaler, Macalder Kanyaruanda, Got Kachola, Muhuru Ward and Kachieng Ward (Migori County Assembly, 2024). The sub-county has the largest land area, covering a vast 677 sq. Km but has the least population density in the whole County at 260 persons per sq. Km. The sub-county has a total population of 176,162 people (83989 are male while 92164 are female) with a total of 40,257 households (KNBS, 2019). The sub-county had a total of 44 health facilities at the time of conducting this study, out of which only six facilities had TB clinics (Afya360). Due to the sub-county`s varied land terrain and mineral ores, economic activities offering sources of livelihood include: farming, fishing, gold mining, livestock keeping, bee keeping, trading and tourism among others.

Nyatike is categorised as a hardship area, characterised by several challenges that make the inhabitants` life unbearable. These include: deplorable road network, frequent human-wildlife conflict, poor network coverage, high poverty levels, perennial floods, poor rainfall, barren sandy

soil, harsh climatic conditions and lack of clean drinking water among others (The National Assembly, 2024).

The researcher selected this sub-county because it contributes 21% of cases in Migori County, whose incidence rate of 209 per 100,000 population and contributes 21% of the total disease burden in the county (NTLD. 2020). The sub-county at the time of conducting this study had a total of six CCCs involved in TB care.

3.4 Study Population

This study involved all TB patients (DS-TB, MDR-TB, both new and retreated) registered on Anti-TB Treatment and attending the Comprehensive Care Clinics (CCCs) (February-May 2022) and health care workers in those clinics.

3.4.1 Inclusion Criteria

The study included only adults, therefore only those aged 18 years and above were selected. Patients who had been confirmed to be active TB cases were included in this study. In addition, they ought to have been registered on treatment for at least one month prior to their interview in this study (February-May 2022). This was to ensure the patients included in the study were those who had some experience with the drugs and had established their routine of drug consumption.

Most important, only patients who consented to take part in this study were interviewed.

3.4.2 Exclusion criteria

Patients who had completed their medication in the past two weeks prior to commencement of this study were excluded from the study so as to minimize chances of recall bias. Those patients who had been hospitalized outside the sub-county were also excluded from this study.

3.5 Sampling design

3.5.1 Sampling techniques

Census was employed to select health facilities and study participant. The researcher used a census method to sample health facilities offering TB services as well as study participants. The desired sample was 200 participants for the current study. However, there was a variation since a total of 150 participants were interviewed. The reason for this variation was as a result of low number of patients in the study area at the time of collecting the data since majority had recovered from the disease and as such were not eligible for the study.

Purposive sampling was used to sample health care providers who are involved in TB CCC service provision as key informants whereas patients were purposively sampled as Focus Group discussion participants.

3.5.2 Sample size determination

The study's sample size was determined using the hypergeometric formula by Guenther (1973):

$$n = \frac{NZ^2pq}{(E^2(N-1) + Z^2pq)}$$

Using the above formula therefore;

$$n = \frac{400(1.96^2 * 0.68 * 0.32)}{0.0025 (400-1) + (1.96^2 * 0.68 * 0.32)}$$

$$334.373 / 1.8334$$

n= 182 (Minimum sample size required)

Adjusting for spoilt forms: 10% of participants

$0.1 * 182 = 18$

n= 200

3.6 Construction of research instruments

3.6.1 Structured Questionnaires- These were developed to incorporate multiple choice and rating scale questions. Questionnaire was designed to cover all the research topics under study.

3.6.2 Focus group discussion guide- These were developed to cover key issues in the study that required in-depth information by providing qualitative data. In-depth information was guided by those issues cited by most participants as a challenge that needed further discussion from participants and healthcare providers.

3.6.3 Key informant interview guide- participants here included those providing healthcare in the clinics

3.7 Pre-Testing

It was done in Kuria West sub-county to test the clarity, adequacy and effectiveness of research instruments. The sub-county was selected because it has life patterns and economic activities similar to those in Nyatike. In addition, Kuria West is in close proximity to Nyatike but do not border each other and this was to minimize chances of interviewing a patient at Pre-Test and the actual study.

A total of 20 participants from Kuria West sub-county hospital were selected for Pre-Test. 80% adherence was found out from the Pre-Test study done in this area. Significant factors found to influence adherence at Pre-Test stage , following a bi-variate analysis included: Education, Monthly income and Distance to health facility.

The sub-county was selected because of the similarity in patient characteristics, in that most of them reside in rural areas.

3.8 Validity

The Morisky medication adherence scale (MMAS-8) was integrated as part of the questionnaire to assess adherence in this study. Knowledge assessment was adopted from the Global TB community advisory board (TBCAB) knowledge toolkit (TB Online, 2008). Knowledge categorization was adopted and modified from a peer reviewed study (Shrestha et al, 2017), in which test score more than 60% was considered to be high. This study considered a score of at least three questions correctly answered (75%) to be high.

3.9 Reliability

This was ensured by thorough refinement of the research instruments and research protocol before and after Pre-Test session to align them with the research objectives. Research assistants were well trained and involved in Pre-Testing of the research instruments.

3.10 Data collection techniques

3.10.1 Questionnaires

Interviewer-administered questionnaires were administered to patients by research assistants. Covid-19 regulations and infection control principles were strictly adhered to (Social distancing, provision of face masks to participants, sanitizing before handling questionnaires).

3.10.2 Focus group discussion (FGD)

One FGD comprising of nine members was conducted by the researcher among TB patients, based on purposive sampling (one from each facility, except for Wath Ong`er Kadem TB and Leprosy

clinic and Muhuru sub-county hospital where two participants were drawn each). This was vital in providing in-depth information on all the objectives in this study to complement the questionnaire.

3.10.3 Key informant interviews

This was conducted by the researcher to consenting health care workers providing the CCC services. A total of three key informants were interviewed.

3.11 Data Management and Analysis

3.11.1 Quantitative Data

Researcher used SPSS version 25 in data analysis. Descriptive statistics summarized data into mean, median, mode, standard deviation and other vital operations. For inferential statistics, chi-square was used to measure association of variables. For variables that were found statistically significant with chi-square, a bivariate logistic regression was done to measure the strength of association between the variables. Any statistical association with a p-value <0.05 was considered statistically significant.

3.11.2 Qualitative Data

Qualitative data analysis was undertaken using thematic framework analysis (Kothari, 2009). After identifying recurring themes, inductive codes were developed and transcriptions catalogued according to the definitions. Codes were then compiled into larger categories. Transcriptions were manually coded on the coding frame developed on the basis of Beckens theories and was informed by themes and issues emerging from the materials.

Qualitative data was analyzed with a thematic framework (Kothari, 2009). Having identified the recurring themes, codes were developed and catalogued based on the definitions. Transcriptions were generated and coded on the coding frame developed on basis of Beckens theories. Dissemination of data was in the form of summarized paragraphs

3.12 Logistical and ethical considerations

Approval of the study was granted by the Kenyatta University Graduate School. Thereafter, an application for ethical approval was made by the researcher and clearance was granted by the Kenyatta University Ethics Review Committee. A research permit was then granted upon approval by the National Commission for Science, Technology and Innovation (NACOSTI) prior to data collection. The researcher then sought Clearance from County health department before proceeding for data collection in the community. In addition, the researcher adhered to all research ethics as was outlined in the informed consent form, which was duly signed by the research participants and the researcher before commencing data collection from participants.

CHAPTER 4: RESULTS

4.0 Introduction

This study had a total of 150 participants, drawn across the sub-county and registered in various health facilities as shown in table 4.1 below.

Table 4.1: Nyatike Sub-county TB Population

Ward	Sampled Health facilities	No. of TB patients Intended for Sampling	No. of TB patients Sampled
Macalder	Macalder sub-county hospital	45	35
Muhuru	Muhuru sub-county hospital	30	20
Kachien`g	St. Camillus Mission Hospital	40	35
Got Kachola	Kadem TB and Leprosy Dispensary	50	40
	Wath Ong`er Dispensary	12	5
North Kadem	Agenga Dispensary	23	15
Total		200	150

4.1 Socio-Demographic and Individual Factors associated with adherence to anti-TB treatment characteristics

4.1.1 Socio-Demographic Characteristics

Most of the participants were male (62.7%, n=94), between the ages 31-40 years (36%, n=54). Majority of these participants` education level was primary school (n=85; 56.7%) and only 12% (n=18) had attained higher education (certificate, diploma and degree). Majority of participants were self- employed

(n=90; 60%) and married (71%; n=106) earning Ksh. 5000 or less (66%, n=99) as shown in table 4.2 below.

Table 4.2 Participants` Socio-Demographic characteristics

Characteristics	Category	Frequency (n=150)	Proportion (100%)
Gender	Male	94	62.7
	Female	56	37.3
Age	18-20 years	13	8.7
	21-30 years	22	14.7
	31-40 years	54	36.0
	41-50 years	40	26.7
	51-60 years	20	13.3
	61-70 years	0	0.0
	71-80 years	1	0.7
Level of Education	Primary	85	56.7
	Secondary	47	31.3
	Certificate	8	5.3
	Diploma	9	6.0
	Degree	1	0.7
	Occupation	Student	14
Casual jobs		36	24.0
Self-employed		90	60.0
Employed		10	6.7
Marital Status	Single	27	18.0
	Married	106	71
	Widowed	5	3
	Divorced	12	8.0

Household monthly income			
Less than 5,000	99	66.0	
5,000-10,000	36	24	
11,000-20,000	13	8.7	
21,000-30,000	1	0.7	
31,000-40,000	1	0.7	

4.1.1.1 Association between Socio-demographic characteristics and adherence to Anti-TB Treatment

When a Chi square was conducted to find out an association between adherence and socio-demographic characteristics, there was not found any association of statistical significance between the factor ($p < 0.05$) as shown in table 4.3 below.

Table 4.3: Association between adherence to Anti-TB Treatment and Socio-demographic characteristics

Characteristics	Adherence of TB Medication		Chi-square	P-value
	Non-adherent (%)	Adherent (%)		
No. of participants	n=33	n=117		
Gender			$\chi^2 = 2.249$	0.134
Male	17(18.1)	77 (81.9)	df = 1	
Female	16 (28.6)	40 (71.4)		
Age			$\chi^2 = 4.619$	0.474
18-20 years	5 (1.4)	6 (1.7)	df = 5	
21-30 years	5 (8.5)	27 (7.7)		
31-40 years	9 (16.9)	72 (20.5)		
41-50 years	11 (21.1)	86 (24.5)		

51-60 years	3 (21.1)	80 (22.8)		
71-80 years	0 (29.6)	70 (19.9)		
Education Level			$\chi^2=5.697$	0.194
Primary	14 (16.5)	71 (83.5)	df = 4	
Secondary	13 (27.7)	34 (72.3)		
Certificate	2 (25.0)	6 (75.0)		
Diploma	4 (44.4)	5 (55.6)		
Degree	0 (0.0)	1 (100.0)		
Occupation			$\chi^2=4.858$	0.182
Student	6 (42.9)	8 (57.1)	df = 3	
Casual jobs	8 (22.2)	28 (77.8)		
Self-employed	16 (17.8)	74 (82.2)		
Employed	3 (30.0)	7 (70.0)		
Marital status			$\chi^2=4.648$	0.098
Single	8 (29.6)	19 (70.4)	df = 2	
Married	20 (18.0)	91 (82.0)		
Separated	5 (41.7)	7 (58.3)		
Monthly income			$\chi^2 = 5.432$	0.212
Less than 5,000	22 (22.2)	77 (77.8)		
5,000-10,000	7 (18.9)	30 (81.1)	df = 4	
11,000-20,000	1 (11.1)	8 (88.9)		
21,000-30,000	2 (50.0)	2 (50.0)		
31,000-40,000	1 (100.0)	0 (0.0)		

Fisher's exact test used when cells had expected counts less than 5

4.1.1.2 Binary regression for socio-demographic characteristics associated with adherence to anti-Tb treatment

Table 4.4 Binary regression for Socio-demographic factors

Factors	Unit	AOR	P-Value	95% Confidence Interval (CI)	
				Lower	Upper
Gender	Male	Ref			

	Female	0.190	0.831	0.911	17.771
Age	18-20 years	Ref			
	21-30 years	0.551	0.125	0.629	19.330
	31-40 years	9.476	0.365	1.210	13.119
	41-50 years	1.614	0.511	0.871	3.7290
	51-60 years	1.181	0.991	0.735	11.092
	71-80 years	0.920	0.310	0.753	1.1190
Education Level	Primary	Ref			
	Secondary	0.544	0.129	0.761	11.028
	Certificate	0.945	2.012	0.669	4.208
	Diploma	5.381	1.048	0.200	9.695
	Degree	0.256	0.246	0.067	0.979
Occupation	Student	1.098	3.068	0.374	10.754
	Casual jobs	Ref			
	Self-employed	6.982	0.779	0.995	2.110
	Employed	2.328	0.507	0.489	9.157
Marital status	Single	Ref			
	Married	0.115	1.091	1.023	18.011
	Separated	15.551	2.046	0.878	28.261
Monthly income	Less than 5,000	Ref			
	5,000-10,000	2.705	0.541	0.811	8.012
	11,000-20,000	8.920	0.199	0.753	1.119
	21,000-30,000	1.355	0.081	0.892	2.059
	31,000-40,000	5.590	2.046	0.911	2.771

4.1.2 Individual factors associated with adherence to Anti-TB Treatment

HIV status ($\chi^2 = 5.096$, $df=1$, $P=0.024$), money for other needs ($\chi^2 = 4.967$; $df=1$; $p=0.026$) (money to cater for indirect costs) and use of other non-TB drugs ($\chi^2 = 4.371$; $df=1$; $P= 0.039$) (drugs to treat other conditions/ diseases, notably diabetes, malaria and hypertension were the most mentioned) were found to be of statistical significance following a chi-square operation on the individual factors as shown in table 4.5 below.

Table 4.5: Chi-square test of individual factors affecting adherence to Anti-TB Treatment

Characteristics	Adherence of TB Medication		Chi-square	P-value
	Non-adherent n (%) [*]	Adherent n (%) [*]		
No. of participants	n=33	n=117		
Alcohol consumption			$\chi^2=0.036$	0.826
Yes	9(23.1)	30 (76.9)	df = 1	
No	24 (21.6)	87 (78.4)		
Smoking			$\chi^2=0.444$	0.686
Yes	1 (12.5)	7 (87.5)	df = 1	
No	32 (22.5)	110 (77.5)		
Use of other non-TB drugs			$\chi^2=4.371$	0.039
Yes	6 (12.0)	44 (88.0)	df = 1	
No	27 (27.0)	73 (73.0)		
Pill Burden			$\chi^2=4.858$	0.182
Yes	10 (27.0)	27 (73.0)	df = 3	
No	23 (20.4)	28 (79.6)		
Conditions improved			$\chi^2=2.811$	0.094
Yes	29 (20.6)	112 (79.4)	df = 1	
No	4 (44.4)	5 (55.6)		
Prior TB treatment			$\chi^2=0.017$	0.896
Yes	12 (21.4)	44 (78.6)	df = 1	
No	21 (22.3)	73 (77.7)		
Side effects			$\chi^2=0.373$	0.541
Yes	13 (19.4)	54 (80.6)	df=1	
No	15 (23.80)	48 (76.2)		
Didn't respond				

Characteristics	Adherence of TB Medication			
	Non-adherent n (%) %)*	Adherent n (%) %)*	Chi-square	P-value
No. of participants	n=33	n=117		
Treatment period				
Less than 6 months	29 (21.0)	109 (79.0)	$\chi^2=0.976$	0.299
>6 months	4 (33.3)	8 (66.7)	df=1	
HIV status			$\chi^2=5.096$	0.024
Negative	25 (28.4)	63 (71.6)	df = 1	
Positive	8 (12.9)	54 (87.1)		
Treatment supporter				
Yes	23 (19.8)	93 (80.2)	$\chi^2=1.407$	0.246
No	10 (29.4)	24 (70.6)	df=1	
Appreciated by others				
Yes	22 (19.1)	93 (80.9)	$\chi^2=2.365$	0.124
No	11 (31.4)	24 (68.6)	df=1	
Money for other needs				
Yes	10 (38.5)	16 (61.5)	$\chi^2=4.967$	0.026
No	23 (18.5)	101 (81.5)	df=1	

***P-value is statistically significant at ($\alpha<0.05$), df=degree of freedom) | Fisher's exact test used when cells had expected counts less than 5**

4.1.2.1 Binary regression for Individual Factors

When a binary regression was done, factors found to be statistically significant were: HIV status (AOR1.152; 95%CI: 0.408-3.691, p=0.029), money for other needs (AOR2.363; 95%CI: 0.934-5.981, p= 0.007) and use of other non-TB drugs (AOR 0.418; 95%CI: 0.157-1.109, p=0.008) as shown in table 4.6 below.

Table 4.6 showing Binary regression for Individual Factors

Factors	Unit	AOR	P-Value	95% Confidence Interval (CI)	
				Lower	Upper
Alcohol consumption	Yes	Ref			
	No	6.115	1.846	1.023	9.011
Smoking	Yes	Ref			
	No	0.374	1.209	1.012	8.139
Use of other non-TB drugs	Yes	0.418	0.008	0.157	1.109
	No	Ref			
Pill Burden	Yes	0.775	4.982	1.091	19.234
	No	Ref			
Conditions improved	Yes	7.302	0.579	0.263	6.692
	No	Ref			
Prior TB treatment	Yes	0.613	1.025	0.011	1.309
	No	Ref			
Side effects	Yes	Ref			
	No	5.123	0.926	1.009	23.379
	Didn't respond	0.902	3.098	1.221	2.985
Treatment period	Less than 6 months	Ref			
	>6 months	0.281	0.439	0.735	1.938
HIV status	Negative	Ref			
	Positive	1.152	0.029	0.408	3.691
Treatment supporter	Yes	0.525	0.219	1.439	7.092
	No	Ref			
Appreciated by others	Yes	6.28	1.920	0.753	3.128
	No	Ref			
Money for other needs	Yes	2.363	0.007	0.934	5.981

4.1.2.2 Qualitative analysis results for Individual factors associated with adherence to anti-TB treatment

The following were responses from participants taking part in FGD and KII interviews on in regard to individual factors affecting their adherence to anti-TB treatment

An enquiry from patients if they could afford to cater for needs related to TB treatment yielded the following results:

Respondent 3: I usually spend up to Ksh. 300 to and from the facility while picking up my drugs . if only other facilities were equipped to offer the TB services which are nearer then it would be at least.

Respondent 7: while undergoing treatment, porridge made of millet and sorghum is a necessity and mostly I lack money to acquire the porridge.

On matters regarding peer-to-peer groups, participants reported thus:

Respondent 9: that has not been the case here but it would be a nice thing if it were initiated here.

Key informants attested to sentiments made by FGD respondents save for one whose facility had functional groups:

Respondent 1: we meet at the beginning of every month and end month

Respondent 2: there are no patient support groups as is the case for HIV because the programme donor does not fund it, although we had it before Covid-19 struck.

Respondent 3: currently, peer-to-peer counseling is not available in this facility.

When asked about stigmatization for TB patients, FGD participants said:

Respondent 1: in this community, TB is just a disease like any other diseases as such there are no stigma incidences. However, a few believe TB and HIV is 'chira' (curse).

The response was alluded to by the other participants except respondent 5.

Respondent 5: I was almost being divorced for contracting the disease because as a woman who doesn't practice gold mining, chances were I got it from promiscuity.

4.2 Health system factors associated with adherence to Anti-TB Treatment

An association was not found between health system factors and adherence to treatment as shown in table 4.7 below

Table 4.7: Chi-square test showing association between health system factors and adherence to Anti-TB Treatment

Characteristics	Adherence of TB Medication		Chi-square	P-value
	Non adhere %)*	Adherent n (%)*		
No. of participants	n=33	n=117		
Drug stock-outs				
Agree	2 (13.3)	13 (86.7)	$\chi^2=0.730$	0.393
Disagree	31 (23.0)	104 (77.0)	df=1	
Long waiting time				
Agree	7 (35.0)	13 (65.0)	$\chi^2=2.273$	0.132
Disagree	25 (20.0)	104 (80.0)	df=1	
Friendly caregivers				
Agree	29 (22.1)	102 (77.9)	$\chi^2=0.011$	0.915
Disagree	4 (21.1)	15 (78.9)	df=1	
Lengthy treatment				
Agree	11 (26.8)	30 (73.2)	$\chi^2=0.767$	0.381
Disagree	22 (20.2)	87 (79.8)	df=1	
Clinic distance				
1-5 km	12 (12.2)	42 (77.8)	$\chi^2=0.002$	0.961
>5 km	21 (21.9)	75 (78.1)	df=1	

Drug refill period					
Weekly	1 (20.0)	4 (80.0)	$\chi^2 = 3.996$	0.334	
2 weeks	3 (15.8)	16 (84.2)	df=3		
Monthly	28 (22.4)	97 (77.6)			
2 months	1 (100.0)	0 (0.0)			
Waiting time					
<30 minutes	25 (20.7)	96 (79.3)	$\chi^2 = 3.344$	0.316	
30-45 min	5 (25.0)	15 (75.0)	df=3		
45-60 min	3 (50.0)	3 (50.0)			
1 hour	0 (0.0)	3 (100.0)			
Transport cost (ksh)					
1-500	32 (22.2)	112 (77.8)	$\chi^2 = 0.979$	0.781	
501-1000	0 (0.0)	3 (100.0)	df=2		
Above 1000	1 (3.3)	2 (66.7)			

***P-value is statistically significant ($\alpha < 0.05$), df=degree of freedom) | Fisher's exact test used when cells had expected counts less than 5**

4.2.1 Binary regression on health system factors affecting adherence to Anti-TB treatment

To further ascertain strength of relationship between health system factors and Anti-TB treatment adherence, a binary regression was done on the factors. None of the factors were associated ($p < 0.05$) as shown in table 4.8 below.

Table 4.8: Table showing Binary regression on Health system factors associated with adherence to Anti-TB treatment

Factor	Unit	AOR	P-value	95% Confidence Interval	
				Lower	Upper
Drug stock-outs	Agree	0.194	0.128	0.871	9.729
	Disagree	Ref			
Long waiting time	Agree	0.782	2.818	0.932	1.197
	Disagree	Ref			
Friendly caregivers	Agree	2.828	1.245	0.198	5.243
	Disagree	Ref			
Lengthy	Agree	3.760	0.953	1.219	4.214

treatment	Disagree	Ref			
Clinic distance	1-5 km	Ref			
	>5 km	0.390	1.295	0.829	1.684
Drug refill period	Weekly	1.383	0.387	0.102	16.503
	2 weeks	Ref			
	Monthly	0.518	3.679	0.211	3.936
	2 months	0.443	0.356	1.933	5.723
Waiting time	<30 minutes	9.928	2.985	0.219	1.918
	30-45 min	Ref			
	45-60 min	0.280	0.937	4.993	16.055
	1 hour	0.875	0.187	0.489	2.937
Transport cost (ksh)	1-500	Ref			
	501-1000	0.856	3.845	8.226	19.437
	Above 1000				

FGD participants reported the following on matters pertaining adherence and health system factors:

Drug stock-out was not common except for pyridoxine drugs:

Respondent 2: there are drugs in the clinic every time we come for refill although the small white pills (pyridoxine) are usually not available. For instance today we were not able to get those drugs and as such we have to go buy in the chemist, a dose usually going at Ksh. 200

Key informants were also in agreement to what the FGD reported:

Key informants also alluded to the fact that there has been drug stock-out, although it is not for the main Anti-TB drugs, as reported:

Respondent 1: we have never had anti-TB drugs out of stock but for the preventive therapy and pyridoxine, it usually happens.

Respondent 2: not frequent as such unless it happens at the subcounty level. The last time pyridoxine lacked, it was reported countrywide and not our facility alone.

Respondent 3: that is not common here because we make arrangements in time

On matters affordability of pyridoxine drugs, the participants had this to say:

Respondent 1: I mostly cannot afford to buy the pills since I have been laid off from work

An enquiry was made to find out whether patients received nutritional supplements and they reported thus:

Respondent 4:that is not the case here. While I was receiving treatment in Bondo, it happened I got very weak and was given supplement in form of porridge flour which I took and in a month`s time, I had regained.

Respondent 6: when you are initiated on treatment, you are also given vitamin supplements to boost your appetite and immunity.

Respondent 7:at initiation, I weighed 51kg and experienced difficulties in walking long disances. With the help of vitamin supplements, I weighed 60kg in a month`s time and even walking for long distance was never an issue again.

Key informants also reported a few challenges in the course of their duty dispensation:

Respondent 1: there has been a pyridoxine stock-out for a while now. Sometimes I get a client who truly needs the TB ;preventive therapy but since they are not available, I fail to administer them. It also becomes a challenge when each and every time we ask patients to go buy the pyridoxine drugs since they claim it is us who take those drugs and sell to them in return.

We usually lack nutritional supplements which sometimes become a challenge when we get a patient whose BMI is 12 and for sure they cant afford the foods we advise them to go and buy because of financial constraints.

Respondent 2: inadequate personnel. We usually don't get financial aid from the government.

The available personnel are not updated on the changes in good time from the TB program.

There is need for channeling of funds from the government to support peer-to-peer groups.

There is need for increment of test centres so as to reduce time taken to access the centres especially the GeneXpert since they are not many in the county.

If there can be a facilitation finance wise to enable contacting of patients not showing up on clinic days and also the non-adherent patients, it will be of benefit to us.

4.2.2 Hypothesis test

There is no association between socio-demographic, individual and health system factors and patient adherence to anti-tuberculosis treatment among tuberculosis patients in Nyatike, Migori County_

Reject hypothesis

4.3 Level of knowledge of patients on tuberculosis and its association with adherence to anti-tuberculosis treatment

The knowledge level on TB among the participants was determined by computing the results of four questions i.e. what causes TB, what are the signs and symptoms of TB, the length of treatment period and importance of taking medication as prescribed. The four questions were chosen because they give more light on possibilities of a patient appreciating their condition and likely to adhere to treatment.

Out of the four questions, 6.7% (n=10) had one correct response while 23.3% (n=35) had 2 correct responses. Majority of the participants, 62.7% (n=94) had 3 correct responses and only 7.3% (n=11) had 4 correct responses as shown in Table 4.9 below.

Table 4.9 Level of patient Knowledge on importance of adherence to treatment

Knowledge score	Frequency	Percent
1 correct response	10	6.7
2 correct responses	35	23.3
3 correct responses	94	62.7
4 correct responses	11	7.3
Total	150	100.0

4.3.1 Categorization of patient knowledge on importance of adherence to treatment

Persons who correctly answered at most two questions were considered to have low knowledge level while those answering at least three questions correctly were considered to have high knowledge level as shown in Table 4.10 below.

Table 4.10: Table showing knowledge level of participants on the importance of adherence to treatment

Knowledge levels	Frequency	Percent
Low knowledge (Two questions)	45	30.0
High knowledge (At least 3 questions)	105	70.0
Total	150	100.0

4.3.2 Association between adherence to Anti-TB Treatment and Knowledge level

There was an association between knowledge level and adherence to Anti-TB Treatment ($\chi^2 = 14.275$, $df=3$, $P= 0.003$). Participants with the three correct responses recorded the highest percentage of adherence to TB medication (86.2%) whereas respondents with one correct response had the lowest level of adherence (40%) as shown in Table 4.11 below.

Table 4.11: Table showing Association between adherence to Anti-TB Treatment and Knowledge level

Knowledge level	Adherence of TB Medication		Chi-square	P value
	Non-Adherent (%)	Adherent (%)		
Knowledge Scores	n=33	n=117		
			$\chi^2=14.275$	0.003*
One correct response	6 (60.0)	4 (40.0)	df = 3	
Two correct responses	10 (28.6)	25 (71.4)		
Three correct responses	13 (13.8)	81 (86.2)		
Four correct responses	4 (36.4)	7 (63.6)		

***P-value is statistically significant ($\alpha < 0.05$), df=degree of freedom| Fisher's exact test used when cells have expected count less than 5**

The researcher interviewed the participants to ascertain the cause of TB from them. They reported as follows:

Respondent 2: Mining of gold is the main cause of TB. Whenever one goes to the mines, they are exposed to the dust from the rocks and one is likely to contract the disease. The situation is worsened by insufficient food.

The response was alluded to by the other participants.

Respondent 4: when one becomes promiscuous, he/she is likely to suffer from the disease.

4.3.3 Regression analysis for knowledge as a factor associated with adherence to Anti-TB Treatment

Odds ratio showed that respondents who had high level of knowledge were more likely (OR2.856) to be adherent to treatment (OR: 2.856; 95%CI: 1.282-6.365; P= 0.01) than those with low level of knowledge as shown in table 4.12 below.

Table 4.12: Odds Ratio on participants` knowledge and likelihood of adherence

Characteristics	Odds Ratio (OR)	95% CI		P value
		Lower	Upper	
Knowledge level				
High Knowledge level	2.856	1.282	6.365	0.010
Constant	1			

4.3.3 Hypothesis testing

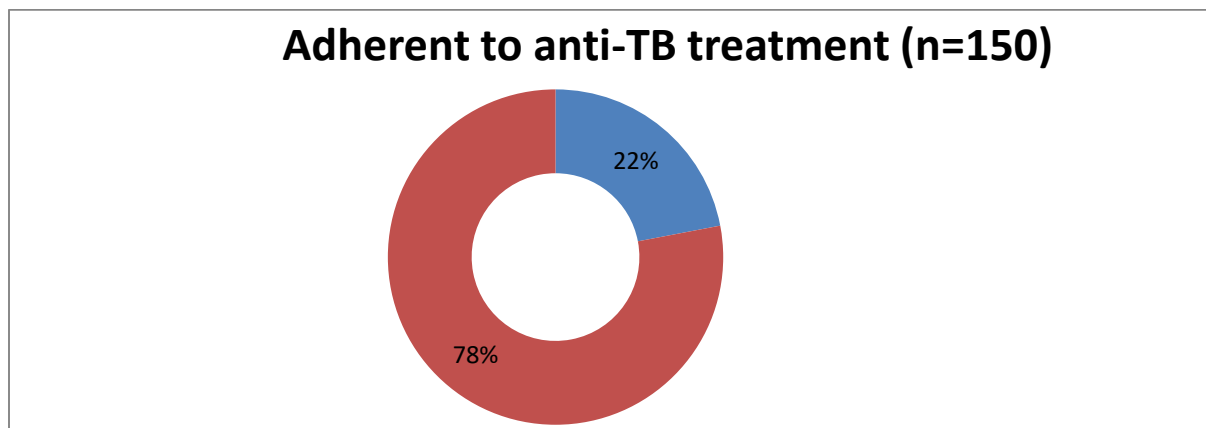
Null Hypothesis: Level of knowledge on importance of adherence among TB patients in Migori County is not associated with adherence to Anti-TB Treatment_ Reject

4.4 Prevalence of Adherence to Anti-TB Treatment

4.4.1 Missed to take medication

When respondents were asked whether they missed to take TB medication, 78.0% (n=117) stated no while 22.0% (n=33) stated yes as shown in Fig. 4.1 below.

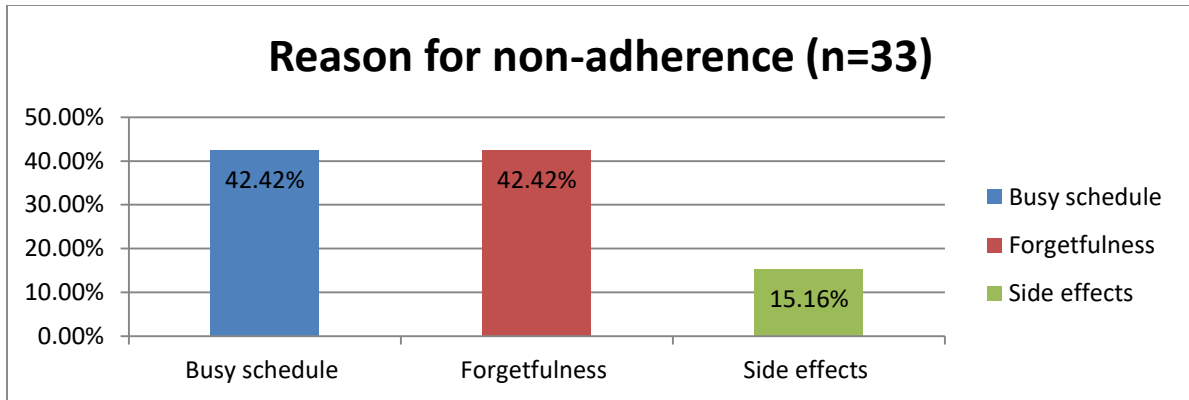
Fig. 4. 1: Pie-chart showing rate of adherence to treatment



4.4.2 Reasons for non-adherence

When asked the reason for being non-adherent, forgetfulness, busy schedule and side effects were the only reasons cited by the participants. Busy schedule and forgetfulness were the most cited reasons (42% each) while 15.16% attributed it to side effects as shown in Fig. 4.2 below.

Fig. 4.2: Graph showing reasons for non-adherence



CHAPTER FIVE: DISCUSSION

5.0 Introduction

It is no doubt that adherence to anti-tuberculosis treatment is very key as far as cure from the disease is concerned. Much has been done as far as Tuberculosis eradication is concerned and records show that complete eradication of the disease is possible (WHO, 2018). With the current short-course treatment and availability of BCG vaccine, the disease can be partially prevented, with more efforts being called upon, especially from developing countries to intensify the DOTS strategy and more efforts on active case finding as the key to detection and subsequent treatment of the disease (WHO 2018). It is for this reason this research was conducted to identify factors associated with adherence to Anti-TB treatment in Migori County so as to inform the healthcare providers on what needs to be strengthened to improve on its health care delivery.

5.1 Discussion

Socio-demographic factors influence health outcomes and have been part of TB studies as they equally play a role, contributed by societal inclinations such as gender and socio-economic backgrounds majorly the income and occupation of an individual. Gender has been found to influence patients` adherence to anti-TB treatment, men being slow in health-seeking partly because of the male masculinity which dictates that men are the security of the family and only seek help as the last resort (Mthembu, 2015). In this study though, gender was not a significant factor influencing adherence but contrary results have been found by other researchers where gender was a significant factor. One study in Tanzania found female gender to adhere more than the male counterpart (Mkopi *et al*, 2012) whereas in Kenya and Ghana, male were found to be less adherent compared to the female, attributed to poor health-seeking behavior among men and the mobile nature of men (Kimani *et al*, 2021, Dogah *et al*, 2021). Young age was also a factor influencing adherence as found out by one study in Botswana (Gust *et al*, 2011) whereas in Nigeria, adherence decreased with

increase in a participant's age and as such the aged were less adherent to treatment (Ifibunandu & Ukwaja 2012). In this study however, age was not a significant factor influencing adherence.

Marital status was not associated with adherence to treatment in this study and was consistent to findings by another Kenya-based study (Chebet *et al*, 2022). However, in Ethiopia, the married participants were found to be more adherent compared to the unmarried counterparts (Tola *et al*, 2017). In China, although the married participants were found to adhere more than those not married, it was also realized that those under DOTS monitored by a healthcare provider were more adherent than being under a family member thus necessitating further research to evaluate the effectiveness of the role played by family members under DOTS (Fang *et al*, 2019).

Socio-economic status is also a strong predictor as far as adherence is concerned especially the low-income classes (Tola *et al*, 2015). This association was not found in this study to be statistically significant. However, qualitative results evidently showed the struggles patients had to endure ranging from buying nutritious food, high transport cost to the clinic which was a far distance for most patients coupled with poor transport network and sometimes having to buy pyridoxine drugs from out of pocket when these drugs were out of stock at the clinic. Low monthly income was reported in another study in Kenya to significantly impact patient non-adherence to anti-TB treatment (Wanyonyi *et al*, 2017).

Participants' occupation was equally not found to be associated with adherence in this study as was the case in another study in Kenya (Wanyonyi *et al*, 2017). In Morocco however, patients found to be non-adherent cited their occupation which demanded their presence at the work else they would earn a lower pay hence opting to delay to refill their medication (Tachfouti *et al*, 2013). Previous studies reviewed in this paper in Kenya as well as the current study have not found education to be

of statistical significance as far as adherence is concerned. In Pakistan, participants with low education level were associated to lost-to-follow-up and further complicated the situation by giving wrong address hence becoming hard to reach them. Poor adherence was also reported to be connected with low education level in Peru (Lackey *et al*, 2015), therefore raising the need for healthcare workers to discuss and come to an agreement with patients on matters adherence.

People have different characteristics, conditions and needs in as much as they are suffering from TB, underscoring the need to address this disease from all fronts because it affects anyone. Being HIV positive became a protective factor in this study, as they had more chances of being adherent compared to those who were HIV negative (AOR 1.152). The findings are consistent with the nationwide survey on adherence in Kenya conducted by the TB program where it was found that HIV positive was a contributing factor to adherence (NTLD, 2018). On the contrary, a study done in Nairobi found that participants who were HIV positive were prone to default from treatment contributed by Attendance of separate clinics, thereby increasing the transport cost as well as the side effects resulting from the drugs. In the study area, as informed by key informants, HIV patients were organized in peer groups, meeting twice a month with the healthcare givers to offer them moral support, self-care and experiential knowledge. Peer groups have been found to be one of the effective strategies for management of HIV patients (Doull *et al*, 2017). This could have had a far reaching effect in improving the adherence levels of these patients while undergoing TB treatment.

Smoking and alcohol consumption are discouraged habits for people undergoing TB treatment but several studies have found these habits persistent despite the dangers they pose to the patient. In the current study, an association was not found in regards to smoking and drinking alcohol and adherence to treatment although such association was found in other studies. Patients in Baringo, Kenya, mentioned alcoholism one of the factors for their non-adherence (Obwoye *et al*, 2021)

whereas in Peru smoking was found to hinder adherence to anti-TB treatment among the patients (Lackey *et al*, 2015). Alcohol and smoking contribute to adverse drug reactions, increased chances of failure in treatment and prolonged negative sputum conversion (Ma *et al*, 2019), therefore this should be a clarion call for health workers to discourage this habit among patients.

Using other drugs alongside anti-TB drugs was a contributing factor to non-adherence in this study. Apart from HIV, when asked whether they used other drugs alongside anti-TB, patients also cited hypertension, diabetes, fever and malaria drugs. A possible reason for reduced adherence was not deduced since those claiming to use these drugs said they took them at different times. However, other studies that encountered co-morbidity and were associated with non-adherence, pill burden (Boru *et al*, 2017; Aibana *et al*, 2020) was cited as a reason.

Tuberculosis drugs are given at no cost in Kenya but lacking money to cater for other needs was found to significantly affect the adherence of patients in this study. This included meeting other TB related costs such as nutritious food, transport to the clinic, purchasing of pyridoxine drugs (when out of stock, patients were asked to buy them off-the-pocket) among others. This could have an effect because most participants were earning less than Ksh. 10,000 a month (90% of participants) and the average cost of transport to the clinic was Ksh. 400. The study area is vast, coupled with poor road network and few clinics offering anti-TB services. Similar concerns were aired in an Ethiopian-based study (Tola *et al*, 2015), as well as in Kenya (Wanyonyi *et al*, 2017).

Stigma is a major problem derailing the efforts to combat TB as has been reported in a Tanzania-based study (Msoka *et al*, 2021). In this study, most patients confessed they were not rejected but received relevant support from family members and appreciated by the community, and would go for drug re-fill without shame. However, one participant in a qualitative study reported to face

rejection from her husband, where she was alleged to have contacted the disease as a result of promiscuity. This factor though was not of statistical significance in the current study was found out to contribute to default in another Kenyan study (Muture *et al*, 2011) hence there is a need to conduct public education on TB disease.

A treatment supporter is an essential pillar among TB patients while undergoing treatment because the duration is long. This lengthy treatment though not found to be of statistical significance in the current study, it has been associated with treatment default in other similar studies (Gebreweld *et al*, 2018). Supports therefore come in handy to give moral support as well as foster the DOTS strategy. Most patients said they had a treatment supporter, in addition to the CHVs and healthcare providers and though it was not significantly associated with adherence, it played a major role to enhance treatment adherence. The effect of social support has been recognized in other studies in Kenya (Chebet *et al*, 2022), Zimbabwe (Zarova *et al*, 2018) and Pakistan (Saleem *et al*, 2018).

Side effects were reported in this study, such as skin rash, loss of appetite, nausea and vomiting from patients. This was reported as factor contributing to non-adherence by 15.16% of patients but it did not have significant association with treatment adherence. Past studies however, have reported side effects as a contributor to treatment default such as in Nairobi, Kenya and Ethiopia (Muture *et al*, 2011; Tesfahuneygn *et al*, 2015).

When patients are initiated on treatment, the TB symptoms disappear within two weeks of medication and negative sputum conversion within 4 months of medication (NTLP, 2021). This relief can make patients feel they have recovered from the disease and stop taking their medication. Feeling better did not influence participants` adherence in the current study but has been a reason for

treatment defaulting in other studies in Kenya, such as Kisumu (Ayisi *et al*, 2011), Baringo (Obwoye *et al*, 2021) and Nairobi (Muture *et al*, 2011).

Health system has its share in influencing adherence among patients, majorly based on the distance and policies guiding healthcare delivery. Transport cost incurred by patients when going to the clinic for checkup and drug refill can discourage patients and be a contributing factor to treatment default, especially when they go for long distances spending more to access the clinic. This was not found to have a statistical significance in the study but has been associated with adherence in Ethiopia (Nezenega *et al*, 2020) and Ghana (Appiah *et al*, 2023). Transport cost is usually compounded by long distances and frequent drug refill period especially for patients in the intensive phase who have to be closely monitored by the healthcare providers hence required to visit the clinic regularly. All of these factors were not found to influence patient adherence. However in Uganda (Elbireer, *et al*, 2011) and Nigeria (Ifebunandu *et al*, 2012), long distance was found to impact patient adherence to medication.

Participants in this study had a good rapport with their healthcare givers attributed to the peer groups among HIV patients and the experience of the caregivers in dealing with TB patients who have learned this soft skill over time. This was therefore not reported as a point of concern among patients but rather praised them for the support they get. In India (Roy *et al*, 2015) and Nairobi Kenya (Muture *et al*, 2011), this was reported to be of negative influence as far as patient adherence is concerned. Patients also did not report long waiting time, most of them served in less than 30 minute and left. This was consistent with findings from Kilifi Kenya (Chebet *et al*, 2022) but in Nandi, Kenya, patients were more likely to default when they waited for more than one hour (Wanyonyi *et al*, 2017). Drug stock-out is a rare phenomenon and has not been reported in Kenya for a very long

time as was reported by key informants during the interviews but was a reason for non-adherence in Uganda (Elbireer, *et al*, 2011).

Adhering to anti-TB treatment plays a major role towards realizing the WHO goal of ending TB by 2035, WHO recommending at least 90% adherence for the disease to be successfully cured in an individual (Awofeso, 2008). Adherence is also important because it minimizes chances of disease relapse, development of MDR-TB, complete cure from the disease; prevent undesirable disease outcomes such as death and disability among others (NTLP, 2021). Adherence levels in most studies however, have not met the minimum threshold of 90%, which calls for concerted efforts from all sectors to combat the disease and maintain high adherence levels. Some studies however, have met these standards. Among those studies include one in Tanzania where patients adherence was 91% (Mkopi *et al*, 2012). In Gondar region of Ethiopia, a study found 90.5% adherence among patients whereas in northwest Ethiopia, 90% adherence was found. Gebremariam *et al*, 2021; Valencia *et al*, 2017).

The study established a prevalence of 78% among participants on anti-TB treatment, types of patients included those on re-treatment and first time, drug sensitive and drug resistant. The rate was the same as reported in Ethiopia, with 78% adherence (Mekonnen & Azagew, 2018) but lower than 86% reported in Sudan and 83.3% found in Nairobi (Muture *et al*, 2011). The prevalence however was higher than the national average (75%) that was reported after a survey comprising fifteen Kenyan Counties (NTLP, 2018). The rate was also higher than that found in Nandi at 69% and 54% reported in Baringo (Wanyonyi *et al*, 2017; Obwoye *et al*, 2021).

Knowledge is important in the fight against TB because empowered population will detect symptoms and seek health services early enough thereby preventing spread of the disease to other

people and reduce stigmatization in the community. In Kenya, the TB program (NTLD) has made calls on Kenya institute of curriculum development (KICD) to increase TB information in primary and secondary levels of education which will in turn help to enlighten the masses in the country (CHS, 2015). This is essential because college students have been found to have low levels of TB awareness at 81.6% hence there is need to empower students with this knowledge. An intervention targeting to increase knowledge among students improved students` knowledge from 65.22% at baseline to 86.83% at the end of the project (Panaligan & Guiang, 2012), a clear indication this will not be a vain intervention.

In the current study, knowledge level was assessed and found to be 70%. The remaining 30% only managed to answer half of the questions and failed the other half. Of the questions used to test patient knowledge, the cause of TB was least known while being attributed to dust, gold mining and promiscuity with only 8% correctly linking it to some form of bacteria. There was an association knowledge and treatment adherence in the current study, patients with high knowledge on TB being 2.86 times (OR: 2.856; 95% CI: 1.282, 6.365), $P= 0.05$) more likely to adhere to treatment than those with low level on the disease. The knowledge score found in this study was higher than 44.2% found in Tanzania (Kazaurav & Kamazima, 2021), 55.3% in Saudi Arabia (Anaam *et al*, 2023) and 61.9% in Uganda (Ogwok *et al*, 2022). The knowledge level was also lower than was found among patients in Nyeri, Kenya (Mukundi 2015). Several other studies have also found association between knowledge patient adherence to treatment as was the case in this study. A study in Ghana reported higher adherence levels among high-knowledged participants (Dogah, *et al*, 2021) same as was reported in Ethiopia (Gashu *et al*, 2021), Kilifi (Chebet *et al*, 2022) and Nandi Counties in Kenya (Obwoye *et al*, 2021).

5.2 Conclusion

There were no association between socio-demographic factors and treatment adherence in the current study as well as the health-system related factors. Significant factors in the current study included: lacking money to cater for other needs, taking other drugs apart from anti-TB drugs and being HIV positive. The pyridoxine drug stock-out is a challenge patients are facing as they have to purchase it out-of-pocket whenever it is not available in the clinic during drug refill. Lack of regular update of healthcare providers working in the faith-based health facilities in the sub-county is also a challenge to the healthcare providers as they are not kept a breast with changes in the program on time as far as

Tb management is concerned. The study found TB prevalence to be 78%, higher than the national average of 75%. This level is still lower than the 90% recommended by WHO hence there is still need for more efforts to ensure adherence is maintained by patients across the continuum of care for achievement of disease cure. In the study, knowledge level of patients to be high at 70% as most of the patients were able to correctly answer more than half of the questions correctly, although the causative agent of the disease was not correctly identified but was only linked to the risk factors, mainly mining and dust exposure. Stigmatization levels were found to be low in the community of the study area as was reported by most patients.

5.3 Recommendations

5.3.1 Recommendations for the study

- i. Health facilities should organize and come up with functional peer to peer groups for TB patients to promote adherence among the patients

- ii. Health facility TB caregivers should fully incorporate community health practitioners in promoting the DOTS in the community
- iii. The healthcare team involved in tuberculosis management in the sub-county in liaison with the public health team should conduct health education in the community on TB disease to raise awareness of the disease
- iv. The TB healthcare providers in the facilities should liaise with the nutrition and dietetics department to give nutritional counseling to TB patients to minimize cases of malnutrition

5.3.2 Recommendations for further studies

- i. The current study excluded children under the age of 18 years hence the need to conduct this study to find what factors affect their adherence and find out their adherence level to anti-TB treatment
- ii. Study assessing knowledge in other parts of the County should be conducted, computing the knowledge levels to find out how they compare with that of Nyatike because such studies were scarce in the country hence an appropriate comparison was limited
- iii. The study did not find an association between socio-demographic and health system factors with adherence to anti-TB treatment in Nyatike and as such a study should be conducted in the study area in future to find out whether there is an association of these factors with adherence to anti-TB treatment

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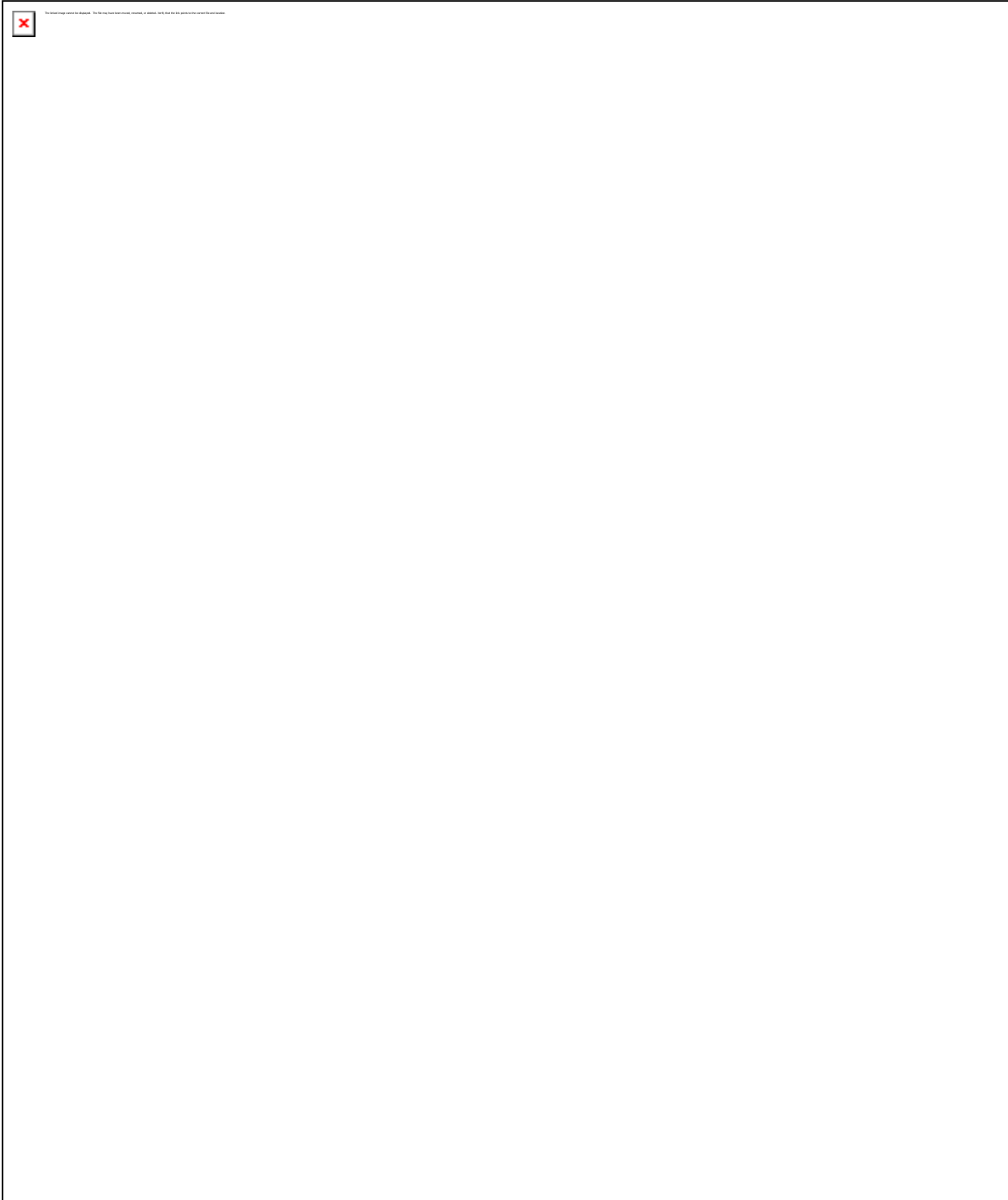
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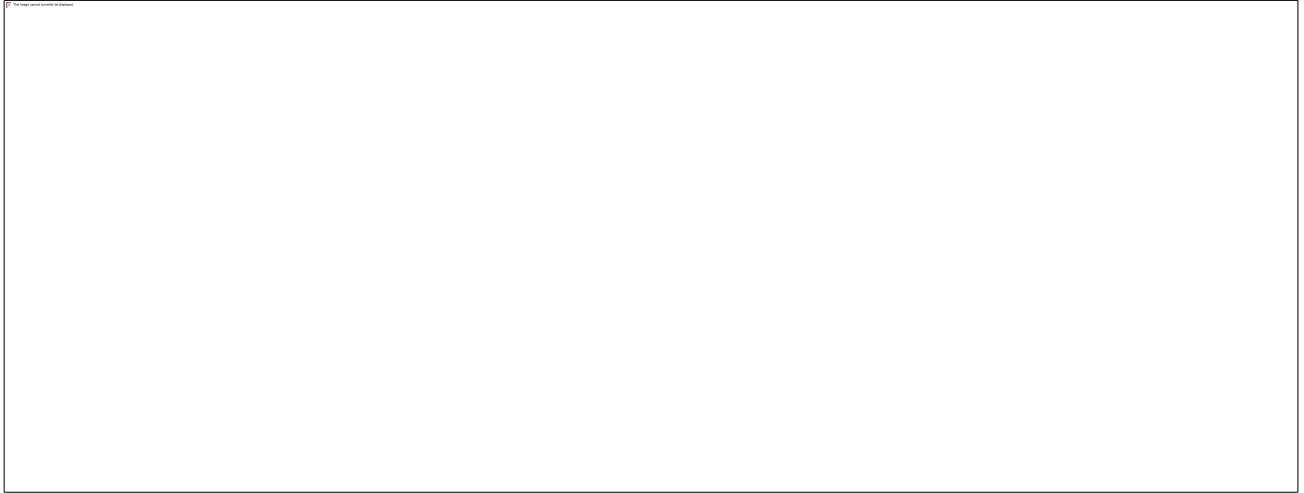
APPENDICES

Appendix II: Research Permit





Appendix III: Map Of Study Area



Appendix IV: Informed Consent Form

**KENYATTA UNIVERSITY
OFFICE OF THE CHAIRMAN ETHICS REVIEW COMMITTEE**

My name is **Babere Patrick Kerata**. I am a Masters student from Kenyatta University. I am conducting a study titled "**Adherence To Anti-Tuberculosis Treatment Among Patients Attending TB Clinics In Migori County, Kenya**". The information will be used for academic purposes as well as the ministry of health to improve provision of TB services to minimize non-adherence.

Procedures to be followed

Participation in this study will require that I ask you some questions and record the information you provide in a questionnaire.

Voluntarism

Your participation is voluntary and you have the right to refuse participation in this study. You will receive the same services and care whether you agree to join the study or not and your decision will not affect the care you will receive. You may refuse to respond to any questions or stop an interview at any time.

Discomforts and Risks

Some of the questions you will be asked are on intimate subject and may be embarrassing or make you uncomfortable. If this happens, you may refuse to answer these questions if you so choose.

Benefits

If you participate in this study you will help us to learn how to provide effective services to improve Adherence To Anti-Tuberculosis Treatment

Reward

There are no rewards or any payment to you if you participate.

Confidentiality

Your name will not be recorded on the questionnaire. The questionnaires will be kept in a locked cabinet for safe keeping. Everything will be kept private and only shared with the study team.

Contact Information

If you have questions about the study call **Mr. Patrick Babere** (investigator) 0706857514 or **Dr. Rosebella Iseme** 0706267212.

However, if you have questions about your rights as a study participant: You may contact the Kenyatta University Ethical Review Committee Secretariat on chairman.kuerc@ku.ac.ke.

Participant's statement

The above information regarding my participation in the study is clear to me and my participation is completely voluntary. The study has been explained to me and I have been given a chance to ask questions and my questions have been answered to my satisfaction. I understand that my records will be kept private and that I can withdraw from the study at any time.

Name of Participant.....
Signature or Thumbprint Date

Investigators statement

I, the undersigned, have explained to the volunteer in a language s/he understands, the procedures followed in the study and the risks and benefits involved

Name of Interviewer

Signature Date

