

**TUBERCULOSIS TREATMENT ADHERENCE AMONG PATIENTS
TAKING ANTI-TB DRUGS IN KILIFI COUNTY, KENYA.**

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DECLARATION

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

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I confirm that this research project has been carried out by the candidate and submitted for review with our approval as University Supervisor

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DEDICATION

I dedicate this paper to my children Ayden and Amelia, to my husband Morris, my siblings Ediga, Caro and Mercy and to my Parents Susan and Ndoli.

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ABBREVIATIONS AND ACRONYMS

AIDS	Acquired Immunodeficiency Syndrome
ART	Anti-Retroviral therapy
CDC	Centre for Disease Control
CHV	Community Health Volunteer
CIDP	County Integrated Development Plan
CNR	Case Notification Rate
DOT	Directly Observed therapy
DOTS	Directly Observed Therapy short course
HCW	Health Care Worker
HIV/AIDS	Human Immunodeficiency Virus
ICD	International classification of diseases
LTFU	Loss to Follow Up
MDR-TB	Multi-Drug Resistance TB
MOH	Ministry of Health
NLTP	National Leprosy and TB program
NTP	National TB programme
SDG	Sustainable Development Goals
TB	Tuberculosis
UNICEF	United Nations Children's Fund
WHO	World Health Organization

DEFINITIONS OF OPERATIONAL TERMS

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- Adherence** An extent to which persons behaviour, taking medication, following diet, and/or executing lifestyle changes, corresponds with agreed recommendations from health care provider
- Average adherence** Patients who scored one (1) on Morisky Medication adherence scale during time of study
- Behavioural factors** These are factors that are derived from Health Belief Model (HBM) as determinants of health behaviour that are oriented to personal beliefs or perceptions and beliefs about a particular disease or event and the way that it will be done to reduce the occurrence. These are perceptions in the health belief model that influence behaviour during treatment
- Continuation phase** This is the second phase of TB treatment for 28 weeks with isoniazid and rifampicin
- Defaulters** Patients who fail to take prescription as prescribed by Health care providers
- Full adherence** Patients who scored zero (0) on Morisky Medication adherence scale during time of study
- Individual factors** These are socio-demographic factors and level of knowledge that influences TB treatment at personal level.
- Loss to Follow-up** These are TB patients enrolled in TB care who have missed two consecutive appointments and are not accounted for.

- Poor adherence** Patients who scored two and above (>2) on Morisky Medication adherence scale during time of study
- Societal factors** These are factors that revolve around how people relate with each other and their beliefs.
- Tuberculosis** Tuberculosis is a bacterial infection that mainly affects the lungs. TB is transmittable between one person and another. TB is preventable and curable with a six-month regime medication,

ABSTRACT

Tuberculosis is a still global public health problem, despite numerous interventions in place to reduce its spread and burden among the poor. Despite TB being a treatable, curable and preventable disease, there has been very minimal decline of below 2% to TB incidence in the past years, with over 4 million cases neither diagnosed nor treated. TB has no empirical measure for treatment adherence. WHO, defines treatment adherence as either process or outcome oriented. Process oriented include the use of pill count and appointment date keeping, whilst outcome orient includes use of cure rate as a measure of success. Kilifi County has case notification rate of 189/100000 which are higher than the national standing of 154/100000. Malindi subcounty reported low treatment success rate and cure are of 68% and 68% respectively which are way below the national target of 90% cure rate, less than 5% loss to follow-up (LTFU), <5% TB deaths and 0% patients not accounted for. Further in the recent years there has been increasing loss to follow up cases of 8% in 2017, to 42% in 2018 as reported by TIBU. The study adopted a descriptive cross-sectional study to determine individual factors, behavioural factor, societal factors and health facility factors that influence TB patients into adhering to treatment in Malindi subcounty, Kilifi County. The data was collected from structured questionnaire from Morisky adherence scale and focused group discussion. The study was pretested in Kilifi County Referral Hospital-TB clinic for Validity and reliability. The findings were analysed using SPSS version 20.0, further analysed through using Odd Ratio to measure the strength of variables to treatment adherence. The findings indicated TB treatment adherence in Kilifi County was at 75% which was below the National target of 90%. Sociodemographic factors like living with family and level of knowledge on TB specifically what causes TB, who can get TB and duration of treatment were associated with TB treatment adherence. Behavioural factors of perceived severity, perceived susceptibility, Societal factors like stigma and health facility factors like patients' satisfaction were factors associated to TB treatment adherence. We recommend the Ministry of Health increase health advocacy on TB at the community to increase knowledge and reduce stigma. Secondly, Policy makers should recommend regular patient trainings on behaviour change campaigns to increase perceived severity and perceived susceptibility during treatment regime. Thirdly, refresher trainings for health care workers on service delivery to patient satisfactions

CHAPTER ONE: INTRODUCTION

1.1 Background

Tuberculosis (TB) is the leading cause of single infectious agent deaths globally surpassing malaria and human immune-deficiency virus (HIV/AIDS), those at risk being co-infected persons who are 20 to 30 times at risk of developing active TB (WHO, 2017). Despite TB being a treatable, curable and preventable disease, there has been very minimal decline of below 2% to TB incidence in the past years, with over 4 million cases neither diagnosed nor treated (WHO, 2018).

TB drugs adherence was proven to be a single factor associated with treatment outcome as evidenced through the three phase III trials of fluoroquinolone (TB research centres & British Medical Research Council) (Pranger *at, el.*, 2019). World health organization (2015) reported that poor TB treatment adherence still remains a great challenge in ending TB. TB Treatment adherence is a multifaceted and complex, hence affected by individual factors, family, organizational factors to policy. Despite there being standard international guidelines adopted by different countries in TB diagnosis, monitoring and treatment, most patients are exposed to programs that are poorly organised and monitored, hence insufficient TB care which leads to developments of drug resistant strains which hinders effective TB control (Danso *at el.*, 2015)

Tuberculosis eradication is one of the targets in Sustainable development goal (SDG) three constituted recently with the intention of addressing limitations in TB care, involving community at large other than just focusing in decentralising TB care in health facilities.

Community health volunteers (CHV) have initially been utilized in provision of primary care services and promotive and preventive health and patients who utilize CHVs are more adherent to treatment and have a high cure rate (Ong'ang'o, *at el* ,2014). Community plays a key role in TB care through new detection of new TB cases and involved in improved treatment adherence when they are empowered on TB knowledge and full implementation of community DOTS strategy (Addy *at el.*, 2019). National TB programme Kenya has policy in practice that encourages health care workers to utilize of CHVs in DOTS strategy, although has been limited implementation of these policy because of its unsustainability. Provision of incentives to CHVs plays a key role in TB management sustainability effectiveness of a community program. In the recent years, sub-Saharan Africa have a dying spirit to volunteerism because people are using their time to earn a living.

In Kenya, TB is the fifth cause of infectious death with a case notification rate of 158/100000 (WHO, 2018). It is estimated that TB cases are much higher than previously reported with approximately half of those reported missed each year (WHO, 2018). The End TB strategy 2015-2035, targeted to reduce TB incidence rates to 20% (85/100,000) by 2020 and 35% reduction of TB deaths. TB treatment for tuberculosis in Kenya is offered freely by the National TB program consisting of six (6) months in two phases of intensive phase and continuous phase. The intensive phase is the first 28 days where is patient expected to collect drugs on a weekly basis with strict supervision from clinician or health care worker, while the continuation phase, patients collect medication on monthly basis. Despite TB treatment in Kenya being free, other TB management services e.g. chest X-rays are paid, there is need also need to

maintain a balanced diet with vitamin supplementation during medication rendering TB care costly.

Kilifi county has a case notification rate of 189/100000 which is higher than the national standing (CIDP, 2018). The county adopted numerous interventions to address TB burden both from the national directive and at the county level towards achieving strategic plan 2025. Interventions adopted include use of electronic reporting system (TIBU) for routine monthly, support supervision, community TB by training and empowering CHVs on Community TB on active case finding and defaulter tracing projected to increase active TB case detection, increase treatment success rate, reduce treatment defaulter rates, TB destigmatization and community empowerment (Arshad, 2014). Undesirable treatment outcomes are attributed by poor treatment adherence which increased spread of TB, likelihood of developing MDRTB or XTB which are costly to manage. The MDR TB reported cases in the recent years are in rise and are associated with treatment interruption, low quality treatment drugs, health care workers incorrect prescriptions (WHO,2018).

1.2 Problem statement

Poor adherence to TB treatment is a major hindrance to successful fight against TB (WHO,2015, Ong'ang'o *et al.*, 2014). The most common reason for non-adherence is knowledge gap on treatment importance, disease transmission and prevention, although most people have a general idea of what TB is, which in results to poor health seeking behaviour and adherence to medication (Mondal *et al.*, 2014).

Kilifi County has a high TB case notification rate (CNR) rate of 189/100000 (TIBU, 2018) compared to national incidence at Kenya 158/100000 (WHO, 2018) despite adoption various interventions.

Lost to Follow up (LTFU) is a common cause of non-adherence to medication leading to low treatment success rates, low treatment cure rate and high LTFU cases in Malindi Subcounty, Kilifi County. Malindi subcounty reported treatment success rate of 68% and treatment cure rate of 60% (TIBU, 2018), which are way below the national target of 90%. Malindi subcounty further reported high and increasing LTFU cases of 15 (in 2016), to 8% (42) in 2017, and to 23% (87) in 2018 (TIBU). The increase in LTFU cases have been a major contributor to TB treatment non-adherence, contributing to increased new TB cases and increased development of MDR-TB which are costly to treat and manage (WHO,2015, Azizi,2018).

1.3 Justification

Kenya National TB guidelines define TB treatment success rate to be attributed by 90% cure rate, less than 5% loss to follow-up (LTFU), <5% TB deaths and 0% patients not accounted for towards achieving the End TB strategy 2035. TB treatment adherence is complex and multifaceted on its own, in order to be able to achieve the national targets of TB control, we have to be able to understand the factors that prevent patients from completing their medication and those factors that help complete their treatment. Despite numerous interventions adopted to curb adherence, the increasingly high number of loss to follow up and low treatment outcomes in the recent years is alarming. This indicates a disconnect between current TB interventions and the expected output. The purpose of these study is to determine factors influencing TB treatment adherence and be able to

suggest better approaches and interventions that address these issues to considering the sub county specific adherence needs to TB advocates and policy for better management of TB. However, other than LTFU, other factors for non-adherence in Kilifi county Kenya, have not been documented in peer review journals.

1.4 Objectives

1.4.1 Broad Objective

To investigate factors influencing TB treatment adherence among patients taking anti-TB drugs in Malindi sub-county, Kilifi County, Kenya.

1.4.2 Specific Objectives

1. To determine Individual factors influencing TB treatment adherence among TB patients taking anti-TB drugs in Kilifi County,
2. To determine behavioural factors associated with TB treatment adherence among patients taking anti-TB drugs in Kilifi County
3. To determine societal factors associated with TB treatment adherence among patients taking patients anti-TB drugs in Kilifi County

To determine health facility factors influencing TB treatment adherence among patients taking patients anti-TB drugs in Kilifi County

1.5 Research questions

1. What are individual factors influencing TB treatment adherence among TB patients taking patients anti-TB drugs in Kilifi County?
2. What are behavioural factors associated with TB treatment adherence among patients taking patients anti-TB drugs in Kilifi County?

3. What are the societal factors associated with TB treatment adherence among patients taking patients anti-TB drugs in Kilifi County?
4. What are the health facility factors influencing TB treatment adherence among patients taking patients anti-TB drugs in Kilifi County?

1.6 Significance of the study

Treatment adherence is most important factor in determining TB treatment success rate. Better understanding on factors that influences treatment adherence will aide in formulation of better interventions, strategies and policy addressing non-adherence to TB drugs. This will result in better adherence to TB treatment, leading to increased treatment success rate hence reducing TB incidences and development of MDR-TB. The study will be targeted to health care workers and TB advocates on better interventions in management of TB, towards world free from TB.

1.7 Conceptual framework

The conceptual framework adopted two theories of health belief model by IM Rosenstock (Azizi 2018) and Socioecological model by Urie Bronfenbrenner (CDC,2015). These two theories were adapted because both models have tenets that are relevant and compatible with the study objectives. Health Belief Model (HBM) has six constructs of perceived susceptibility, perceived severity, Health motivation, perceived benefits, perceived barriers, and cues for action which key in predicting and explaining behavioural alongside attitude factors during TB treatment adherence (Azizi,2018). Socioecological model was used to inform social factors influencing TB treatment adherence. Socioecological model (SEM) has five hierarchical level of individual, interpersonal, community, organization,

and policy which influences patients' decisions TB treatment adherence (CDC,2015). Individual factors, behavioural factors, societal factors and health facility factors were independent variables that influence TB treatment adherence despite intervening variables like policies in place.

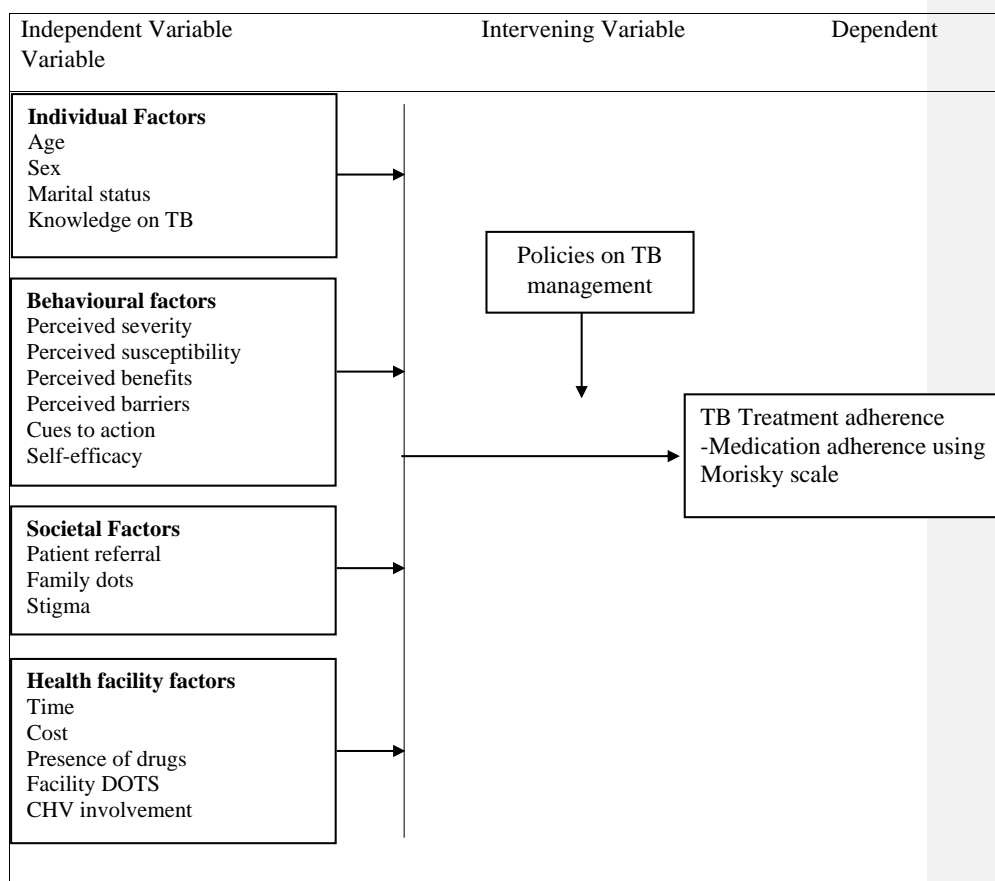


Figure 1.1. Conceptual framework

Source: Adapted and modified from literature review

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

TB treatment adherence is a single factor which determines the TB treatment outcome and success rate as highlighted in the END TB strategy 2035. The WHO-end strategy core principle is patient-centred but most TB care and prevention services are planned from top down, instead of positioning services where the TB patients actually are. TB is a good test for functional health system because of its multi-faceted approach i.e. use of laboratories, x-rays, drug supply, input from HCWs clinicians, use of health education, good follow-up by CHVs and information systems (WHO,2015).

2.2 TB treatment adherence

TB treatment adherence guarantees treatment success rates of up to 90% cure rate, through interventions like patient education and counselling, enablers and incentives, psychological interventions, and reminders. Non-adherence to TB medication reflects to low treatment success rates and emergence of MDR-TB (Mbuthia *et al.*, 2018).

Use of treatment adherence interventions like patient health education, reminders like DOTs and VOTs are interventions intended to increase TB treatment adherence (Alipanah *et al.*, 2018). A lot of resources have been channelled to Stop TB Strategy through supporting the DOTS strategy. Although the DOTS strategy has been adopted and implemented to improve TB treatment outcomes in some countries, some studies however show that poorly implemented DOTS and unmotivated TB focal persons aren't effective in improving treatment adherence

(Izudi *et al.*, 2019). However much these strategies are invested in, these services will not be sufficient if the patient is non-adherent to treatment

There are various methods used in improving TB treatment adherence among patients. Some of the approaches used to increase treatment compliance among patients include the use of Clinic-based DOT - This requires the patient to travel daily to a health facility to be given medication. It has proven to be costly and time consuming, plus there is a lack of privacy. Other methods include Home-based DOT- In this method, a patient is assigned a HCW, CHV, or family member to administer medication daily at home, Electronics bottle caps- This method is being rapidly adapted and use of short message service and/or video observed therapy.

2.3 Individual factors and TB treatment adherence

The common factors associated with TB treatment non-adherence and loss to follow up include socio-economic context, poverty, religious beliefs and distance to the health facilities (WHO, 2017). Further, Munro *et. al.*, (2006) classified factors contributing to non-adherence into social factors, health system factors and individual factors. These factors need to be addressed individually using specific interventions; for example, to address health system factors, staffs were trained on TB, which improved the quality of TB service delivery making treatment adherence one of the complicated health issues requiring multifaceted approach and a working health care system. According to Daba *et al* (2019) sociodemographic factors educational level of an individual and occupation were associated with TB treatment adherence. When one is employed, one can easily afford food, and money to commute during refills, this in return increases adherence. On contrary Mekonnen *at, al.*, (2018) suggests that being busy from

work and in and out of town increases likelihood of defaulting. During the treatment regime, food intake is key. Lack of adequate food during this time forces one to skip medication, increases drugs side effects and pill burden hence patients tend to skip leading to non-adherence (Gugsa, *et. al.*, 2017). Furthermore, WHO 2016, stated that in most of the poor households where health facilities are far, the patients prioritize food and other basic needs, rather than fare to attend hospitals to pick medications. Adequate knowledge on TB and its treatment helps patients make healthy choices hence more likely to adhere to TB treatment (Mekonnen *et. al.*, 2018). Those patients who abuse drugs, use alcohol or khat are at a higher risk to default treatment.

International classification of diseases (ICD-10), TB is classified d as either primary cause of death or a contributing factor to death. TB mortality rate is under documented because deaths occurring due to HIV-positive deaths due to TB are categories as HIV deaths. One for every three HIV/AIDs deaths is TB related (WHO, 2018). In clinical settings, when on TB treatment, there is substantial impact on reducing TB mortality by being on ART. ART reduces the death from TB by 65%, three-fifths of deaths risk are prevented during TB treatment by starting early on ARTs (Odone *et al.*, 2014). There are various models used in identifying and addressing TB treatment challenges. One is the onion model, used by WHO, which identifies probable places where a patient is likely to drop out of treatment. Another model, the care cascade model, commonly used in HIV care and recently adapted in TB care, calculates the frequency of treatment drop out along the treatment journey. The most recent model is the patient centred analysis (PPA). PPA focuses on data on the following: health care seeking behaviour and accessibility to service, gaps in

treatment, loss to follow up reasons, and improved treatment outcome interventions (Mhalu *et al*, 2019). Some studies show that presence of more than one co-morbidity during continuation phase of treatment increases TB treatment non-adherence (Mekonnen *et al*, 2018).

2.4 Behavioural factors and TB treatment adherence

Behavioural factors are better defined by Health Belief Model (HBM) when assessing behavioural compliance to TB medication. There are various studies related to long term disease therapy like hypertension, HIV and diabetes where behaviour of patients taking medication is influenced by HBM. HBM is influenced by perception on information that one has, possibility that one will be obedient to specific actions depending on his/her beliefs, individuals' perception on diseases threat and considering its benefits (Kurniasih *et al*, 2019). Individuals' behaviours are influenced by specific attitude and not just general attitude towards something. Further, behaviours are not only influenced by attitude, but also by beliefs which are one's perception. Finally, specific attitudes and beliefs towards a behaviour makes one behave in a certain way. Positive health behaviour will be formed by directing positive beliefs. Increasing perceptions on susceptibility and severity, perceived benefits and self-efficacy, and reduce perceptions on barriers increases patients' confidence towards adherence to medication. Perceived barrier over and perceived benefits directly associated with non-adherence, cue to action and psychological distress influence non adherence mediated through perceived barriers and benefits (Tole *et al*, 2017). Further, other studies have shown that perceived risk and perceived wellness by a patient on treatment adherence were associated with TB treatment adherence (Sahile *et al*, 2018)

2.5 Societal factors and TB treatment adherence

Stigma is defined as a process on which an individual is devalued to a specific condition. This situation hence marginalizes an individual, excluding one from most social norm due to their condition. One of the main factors that affects patient's capability to adhere to treatment is stigma related to social stigma, fear, patients' beliefs in traditional healing, and discrimination (Gugsa, *et. al.*, 2017).

Patients with supportive partner have a higher treatment adherence than those with unsupportive partners or no partners at all which may remove additional barriers (Rintamaki *et. al.*, 2019, Gebreweld *et al*, 2018).

2.6 Health facility factors and TB treatment adherence

Health facility factors focuses on the amount of money used for monthly visits, time taken to receive service, availability of drugs, Facility DOTS and CHV involvement and patients' satisfaction. Patients with poor patient health provider relationship, Poor communications between health care workers and unavailability of health care services, prolonged time awaiting health care service at the health facility are more likely to default treatment (Mekonnen *at, al.*, 2018, Gube *et, al.*, 2017). Interventions like decentralization of TB refill centres to local and closer health facilities reduces hustle during refill and transportation cost increases TB adherence (Woimo *et, al.*, 2017 & Gube *et, al.*, 2017)

During treatment, patients are expected to be provided with health information at each refill. Provision of adequate and continues knowledge on TB and importance of adherence increases the likelihood of treatment adherence (Woimo *et, al.*, 2017).

Community health education and small transport reimbursements addressed personal barriers. However, there were few interventions were focused on the social and family aspect of this disease (e.g. they could use of CHVs to advocate for TB control, but did not). Treatment side effects, loss of work of income during the medication regime and lack of social support are barriers associated with TB treatment adherence (Gebreweld *et al.*, 2018).

2.7 Challenges in TB treatment

TB treatment takes a minimum of six months to complete medication and this is categorized as a long-term treatment arrangement. If patient's fail to adhere to these treatment guidelines or fail to understand the importance completing treatment even when they feel cured, they end up not adhering to treatment (Gebreweld *et al.*,2018).

Missing TB cases is also a major setback in TB treatment. The TB missed cases are all important because they play key factor continued TB transmission to the community. Missing TB patients' cases can be categorized into three main groups: those who have not sought care, those who delayed seeking care, and those who sought care and did not receive a diagnostic result or treatment (Hanson *et al.*, 2017). Patients may not seek acceptable medical care if there are no severe symptoms but instead most patients choose to seek non-medical forms of treatment like herbalist and witchdoctors during the early onset of the disease (Mbuthia *et al.*, 2017). Mbuthia further stated that there is need to decentralize TB services to the lowest level of Health care to improve on service accessibility.

They may delay treatment because of finances or barriers in accessing care. Some may seek care from a private facility and might have not received diagnostic

results or are not captured under the national TB program. Patients receiving treatment from private sector are prone to inappropriate TB testing or treatment and those that start are prone to incomplete treatment (WHO, 2015).

CHAPTER THREE: MATERIALS AND METHODS

3.1 Research design

The study adopted a cross-sectional study design. The study was carried at a given point in time where questionnaires were administered to TB patients taking anti TB drugs in Malindi subcounty, Kilifi County

3.2 Study Variables

Adherence is defined as compliance to treatment. TB treatment adherence as a dependent variable and Individual factors, behavioural, societal and Health facility factors as independent variable. Structured standardized questionnaire was administered to TB patients, and Focused group discussions

3.2.1 Dependent variable

The dependent variable is TB treatment adherence. There are no standard criteria of defining adherence in TB management, hence after extensive literature review non-adherence can be defined as cases that are $\geq 10\%$ of the total prescribed medication both during the intensive and continuation phase. Adherence can be measured using two ways, either process-oriented i.e. appointment keeping and pill counts or outcome oriented i.e. using cure rate as indicator (WHO, 2019). Administering a standard questionnaire and counter checking appointment keeping will be used to measure adherence.

3.2.2 Independent Variable

Individual factors- These include age, sex, level of education, marital status, household income co-morbidities HIV status, and Knowledge on treatment adherence

Behavioural factors- perceived susceptibility, perceived severity, perceived barriers, perceived benefits, cues to action and self-efficacy

Societal factors- questions related to stigma, Patient referral, Family dots

Health facility factors- Time, Cost, Presence of drugs, Facility DOTS and CHV involvement

3.3 Study area

The study was carried out in Kilifi County is vast area with approximately 12246KM², approximately 1.4 million people and poverty index of 68% (projected census 2009). The County is located at the Kenyan coastal line, hence most likely hit hard an alteration of global weather patterns due to increasing temperatures and storm activity called climatic change. The county experience unpredictable change in weather patterns, accompanied by natural disasters like frequent flooding in Magarini subcounty, Ganze and drought (Kilifi, CIDP).

The county one referral hospital, has eight level 4 public hospitals, 20 level 3 public health Centres, 197 level 2 public dispensaries, one mission hospital, two private hospitals, one armed forces hospital, five private nursing homes and 107 private clinics (Kilifi, CIDP,2013-2017,). Kilifi referral hospital hosts KEMRI that is involved in various health research activities.

The specific sites where the study was carried out was in Malindi subcounty. Malindi subcounty have both the Urban setup which is Malindi town, peri-urban and rural areas. In the urban setup, most dwellings are made of concrete and iron sheet shelter, whilst in most homes in the rural setup are semipermanent and mud housing either papyrus thatched or iron sheets. The rural area is also characterized by strong Mijikenda cultural practices and a common one is

consulting a witchdoctor and or traditional medication as first line of treatment.

(Map of study area, Appendix VII)

3.4 Study population

Study Population included all the TB patients registered in TB4 register attending clinics at Malindi subcounty.

3.4.1. Inclusion criteria

The inclusion criteria are the all-TB patients taking anti-TB treatment drugs, either in the intensive or continuation phase, enrolled in the past six months, be aged above 18 years and consented to participate in the study

3.4.2. Exclusion criteria

TB patients who were critically ill at the time of study, patients who are unable to hear or speak and those that have declined to participate in the study

3.5 Sampling Techniques and Sample Size

3.5.1. Sampling Techniques

The study used both probability and nonprobability sampling technique. Non probability technique of purposive sampling technique was used to select 8 facilities with high number of registered TB patients contributing to 448 patients (99.5%) of the total TB patients in Malindi subcounty. Systemic random sampling was then be used to select patients who will participate in the study. After a random start, systemic random sampling was used to select a fixed interval of K^{th} of 2 throughout the study. The table below shows the distribution of the sample across the facilities.

Table 3.1 Proportions of Patients Sampled Per Facility

Name of the Facility	No. of patients	Proportion	No of Patients selected
Malindi District Hospital	282	0.6295	148
Tawfiq Muslim Hospital	43	0.0960	23
David Kariuki Medical Centre	37	0.0826	19
Municipal Health Centre	36	0.0804	19
The Omar project	17	0.0379	9
Ganda Dispensary	12	0.0268	6
Jambo Clinic	11	0.0246	6
Malindi Care Services Limited	10	0.0223	5
Total	448		235

3.5.2. Sample size determination

The Sample size was determined using Fischer *et al* (2003) formula when the sample size is less than 10,000.

$$Z^2pq / d^2 n =$$

Where

n = minimum sample size

Z = Standard score corresponding to a given confidence level. Confidence Level or 5% level of significance ($\alpha = 0.05$), Z = 1.96.

P = Prevalence of TB adherence (0.42) q = (1 – p) or percentage of failure which is (1-0.42)

d = Precision limit or proportion of sampling error which is usually 5% (0.05) confidence limit

$$N = \frac{(1.96)^2(0.42)(0.58)}{(0.05)^2} = 375$$

Then use of finite correction formula for population less than 10,000.

$$nf = n / (1 + n/N) \quad nf$$

$$= 375 / (1 + 375/493)$$

$$= 213$$

The sample size is 213, but was increased by 10% to cover for any incomplete interviews which gives a total of 235

3.6 Data Collection instruments

Data was collected using both primary and secondary data collection tools. Structured questionnaires (Appendix 11) and ocused group discussions guide (Appendix 111) were used to collect primary data.. Secondary data was reviewed from the TB management register (TB 4) at the respective health facilities and patients' appointment cards and TIBU system.

3.7. Validity and Reliability

3.7.1. Validity

Pretesting of the questionnaires was carried out at the TB clinic, Kilifi referral hospital in Kilifi North Subcounty. The TB clinic was chosen for pretesting because it has high number of registered TB patients. Twenty-three respondents (10%) of the sample size were used for pretesting. The feedback from the pretest

sample was used to modify research questions to answer objectives of the study promptly.

Further, TB experts in TB management were consulted at the County level and in-cooperated it with supervisors' guidance and feedback.

3.7.2. Reliability

Standard questionnaire from Morisky medication adherence scale 4-item (MMAS-4) (cite the source) was used. Those who scored 0 were scored to have high adherence, score between 1 as medium adherence and score more than 2-3 are scored as to have poor adherence to TB treatment. The dependent variable treatment adherence, Cronbach's alpha of 0.78 was achieved which was acceptable (Mugenda Mugenda 1999).

Table 3.2: Cronbach's Alpha Reliability test

Variable	Cronbach's Alpha
Morisky adherence scale	0.78
Behavioural factors	0.644
Societal factors	0.701
Health facility factors	0.687

3.8. Data Collection Techniques

Primary data- research assistants were trained on data collection tools i.e. questionnaires. They were asked to pre-test the questionnaire to on the nearing Kilifi Referral Hospital before actual data collection to ensure that the questions were understood and answer the objectives as intended. Five focused group discussions were conducted using a structured FGD guide to collect qualitative data. TB registers and health documents were also reviewed.

3.9 Data analysis

TB treatment adherence status was determined using Morisky scale. TB5 patient cards were used to complement the findings. Data from Morisky scale was administered to the respondents consisted of seven questions. For every No and correct respond was scored 0 and for every Yes and wrong respond was scored 1. Sum of all the answers from the patients was analysed. Those patients whose responses scored 0 are considered full adherent, 1-2 were considered averagely adherent to treatment, whilst those who scored 3 and above were considered to have Poor adherence to TB treatment.

Table 0.3: 4-item Morisky Medication Adherence Scale- (MMAS-4)

4-item Morisky Medication Adherence Scale- MMAS-4	
1)	Do you sometimes forget to take your TB medication?
2)	In the last two weeks, was there any day when you did not take your TB medication?
3)	Have you ever stopped taking your medications or decreased the dose without first warning your doctor because you felt worse when you took them?
4)	When you travel or leave the house, do you sometimes forget to take your medications?

TB5 Patient's card was also used to assess adherence. Patient's card showed specific dates for drug refill monthly and signed by a doctor. For the adherent group, the patients have consistently collected their medication during their appointment dates. Patient appointment cards (Complete for 100%, satisfactory between $\geq 80\% < 100\%$ and unsatisfactory $< 80\%$). The data from patients' card (TB5) was used to validate responses from Morisky scale.

Focused group discussions were tape recorded and transcribed for analysis from which thematic analysis were used to identify the themes. The questionnaires were coded using MS Excel then be analysed using SPSS version.20.0. Descriptive analysis and inferential statistics were used. Multiple logistic regression was used to identify factors associated with TB treatment adherence and further backward regression analysis to identify the confounders

3.10 Logistical and Ethical consideration

Clearance and approval from Kenyatta University, Kenyatta university ethics and review committee (Appendix VI). Ethical clearance and research permit from national commission for science and technology (NACOSTI) (Appendix V). Approval from Kilifi County government (Appendix VI). Informed Oral and written consents were sought from the study participants (Appendix 1). To ensure privacy and confidentiality, study participants were coded to secure their identity.

CHAPTER FOUR: RESULTS

4.1 Introduction

This chapter presents results with their order of presentation corresponding to the order of the research objectives. The results include socio-demographic information of the respondents; TB treatment adherence , individual factors , behavioral factors and health facility factors.

Two hundred and thirty (230) patients were interviewed corresponding to 98% of the sample. size of 235 during the month of October 2020.

4.2 Socio-Demographic Characteristics of the Respondents

Table 4.1 presents socio-demographic characteristics of the respondents. out of 230respondents, , 57% (130) were male and 43% (100) were female. The study subjects had a mean and median age of 36 years and 34 years respectively with a standard deviation of 16. Majority of those interviewed ages range between 18 to 27 years at 70 (31%). Eighty-two (82%) of the population live with their families.

Table 4.1: Socio-demographic Characteristics of the Respondents

Variable	Frequency	Percentages
Sex		
Male	130	57%
Female	100	43%
Age group		
18-27	70	31%
28-37	65	28%
38-47	55	24%
48-57	16	7%
above 58	24	10%
Marital status		
Married	109	47%
Single	97	42%
Divorced/widowed	24	11%
Level of Education		
No formal education	38	17%
Primary	113	49%
Secondary	64	28%

College/University	15	6%
Occupation		
Employed	35	15%
Self employed	90	39%
Unemployed	105	46%
Amount of money used for food daily		
0-200	82	36%
201-400	111	48%
401-600	31	13%
601-above	6	3%
Live with Family		
Yes	189	82%
No	41	18%

4.3. TB treatment adherence

Seven item questions from modified from Morisky medication scale of adherence were asked to assess TB treatment adherence among patients taking anti-TB drugs (Table 3.3). Morisky Medication adherence scale (MMAS) has adherence scale of 0. every correct response scores 0 and 1 for incorrect response and were reported as follows in table 4.2.

Table 4.2. Response rate from Morisky medication adherence scale

	Morisky medication scale of adherence	Frequency	Percentage
1	Have you ever forgotten to take your drugs? Yes No	25 205	11% 89%
2	In the past two weeks, were there days you did not take your medicine? Yes No	19 211	8% 92%
3	Did you forget to take your drugs yesterday? Yes No	4 226	2% 98%
4	Are there times when you didn't take your medicines and didn't tell anyone because you felt worse after taking them? Yes No	27 203	12% 88%
5	Have you ever travelled and forgot your medicines home, hence didn't take the medicine? Yes No	7 223	3% 97%
6	When you feel you are much better health wise, do you sometimes stop taking your medicines? Yes No	12 218	5% 95%
7	How often do you forget taking your medicines? Rarely Sometimes Always	22 158 50	9% 69% 22%

From the response table 4.2, the responses are further categorized to full adherence, moderate adherence and poor adherence. From the respondents 172 (75%) had a

scored 0 (100%) full adherence to TB medication, 45 (20%) responded to have scored between 1-2, categorized as average treatment adherence while those who scored more than 3 are categorized to have poor TB treatment adherence. Further, adherent level was at **172 (75%)**, while **58 (25%)** were non-adherent to TB treatment.

Table 4.3: TB treatment adherence

Variable	Frequency	Percentage
Adherence to TB treatment		
Full adherence	172	75%
Average adherence	45	20%
Poor adherence	13	5%
Adherence to TB treatment		
Adherent	172	75%
Non-adherent	58	25%

“Common reasons for not adhering to treatment include: lack of social support, feeling of being cured and ignorance, forgetting to take medication, medication side effects of TB drugs, limited knowledge on treatment adherence, Refusal to seek care, belief its witchcraft, no time on their routine work until they are very ill, not knowing a lot about TB, Negligence from caregivers and uncaring caregiver, stigma from friends and family, feel healthier, hopelessness, Neglect, Drugs make you have a lot of energy, and laziness in refill ” FGD

Strategies that could be used to increase TB treatment adherence: Train their caregivers on TB care, take medications at hospital especially those defaulting, Home visits by health care workers, Close monitoring by caregivers, support from family DOTS, Follow up from CHVs, decentralize medication collection sites to nearest dispensaries, defaulters be traced and followed, isolation of defaulters, collective approach from village elder and family DOTS” FGD.

4.4 Individual factors influencing TB treatment adherence

4.4.1 Relationship between Socio-demographic factors and TB treatment adherence

Table 4.4 summarizes the relationship between socio-demographic factors and TB treatment adherence. From the findings, 53% (92) of males were adherent to TB treatment and 47% (80) of the women were adherent. Fifty one percent (87) of those who were married were adhering to treatment while 49% (85) of either single, divorced and or widowed were also adhering to treatment. The highest adherence was in range 28-37 years at 49%. Occupationally 54% (93) of Employed were adherent to treatment. Level of education, 116 (57%) of the respondents had primary education or none.

Of the respondents who lived with their families, 87% (150) were adherent to TB treatment. Those living with Family were three times more likely to adhere to treatment than those living alone. There was a significant statistical association between living with family (OR =3.01; CI: 1.45-6.25, P=0.003) and TB treatment adherence.

Sex, age-group, marital status, Level of education, Occupation, and amount used for food daily had no statistical significance to TB treatment adherence.

Table 4.4: Relationship between Socio-demographic factors and TB treatment adherence

Variable.	Treatment outcome		Odds Ratio (CI 95%)	P-value
	Adherent N (%)	Non- adherent N (%)		
Sex				
Male	92 (53%)	38 (66%)	0.588 (0.315-1.1)	0.097
Female	80 (47%)	20 (34%)		
Marital status				
Married	87 (51%)	22 (9%)	0.707 (0.366-1.354)	0.294
Single/Divorced/widowed	85 (49%)	36 (16%)		
Age Group (years)				
18-27	60 (35%)	21 (36%)	0.848 (0.585-1.228)	0.382
28-37	85 (49%)	25 (43%)		
38-47	10 (6%)	7 (12%)		
48 and above	17 (10%)	5 (9%)		
Occupation				
Employed/self employed	93(54%)	33 (57%)	1.081 (0.563-2.076)	0.815
Non-employed	79 (46%)	25 (43%)		
Level of Education				
None/Primary	116(67%)	35 (60%)	0.735 (0.397-1.359)	0.326
Secondary/college	56(33%)	23 (40%)		
Amount of money used for food daily				
0-200	62 (36%)	20 (34%)	0.934 (0.5-1.744)	0.830
201-400 and above	110 (64%)	38 (66%)		
Do you live with your Family?				
Yes	150 (87%)	39 (67%)	3.01 (1.45-6.25)	0.003
No	22 (13%)	19 (33%)		

4.4.2 Relationship between level of Knowledge on TB treatment and TB treatment adherence.

Knowledge on TB showed that 46% of the respondents were able to state that TB is caused by a bacterium. 21% and 19% of the respondents believed that TB is caused by Smoking/alcohol and Heavy work respectively. Majority of 97% the population

were able to agree that TB is transmittable from one person to another and 83% through infectious cough, 93% were able to mention at least one symptom of TB.

Table 4.5 presents the relationship between knowledge on TB treatment and TB treatment adherence. The respondents who know what causes TB are three times more likely to adhere to TB treatment, while those who know who can get TB are five times more likely to adhere to treatment. There was a significant association between what causes TB (OR=3.139; CI: 1.564-6.297, P= <0.0001) and who can get TB (OR=5.465, CI: 1.507-19.818, P= 0.010) were specific variables that are associated with TB treatment adherence.

Table 4.5: Relationship between level of Knowledge on TB treatment and TB treatment adherence

Variable.	Medication outcome		Odds Ratio (CI 95%)	P-value
	Adherent N (%)	Non-adherent N (%)		
What causes TB Bacterium Virus/Smoking and/or alcohol/ Others (Heavy work)	90 (52%) 82 (48%)	15 (26%) 43 (74%)	3.185 (1.646- 6.162)	0.001
Is TB transmittable from one person to another person? Yes No	167(97%) 5 (3%)	55(95%) 3 (5%)	1.055 (0.765- 1.455)	0.746
How is TB transmitted from an infected person? Through infectious cough and sneezing droplets Don't know	147 (85%) 25 (15%)	45 (76%) 13 (24%)	0.704 (0.458-1.084)	0.111
In your opinion, who can get TB? Anybody Others (only alcoholic people/poor people/drug users/HIV patients/Others)	166 (96%) 6 (4%)	49 (84%) 9 (16%)	0.689 (0.502- 0.948)	0.022
How do you think TB can be treated?			0.938	0.485

Anti-TB drugs	161(94%)	52 (90%)	(0.783-1.123)	
Others inclusive traditional medicine	11 (6%)	6 (10%)		
The duration of completing treatment?				
6 months	157 (91%)	57(99%)	1.514 (0.807-2.837)	0.196
Others (8,12, I don't know.)	15 (9%)	1 (1%)		

Further knowledge was assessed in summary. For each correct answer it was scored 1, and 0 for a wrong response (Table 4.6). The highest score being 6, those who scored 6 had good knowledge on TB, those who scored between 3-5 had average knowledge, while those scored 2 and below are categorized as have poor knowledge.

Those who had high level of knowledge were four times more likely to adhere to TB treatment. Level of knowledge has a significant statistical association with TB treatment adherence (OR; 4.078, CI: 2.039-8.154, P=0.001)

Table 4.6. Summary of level of Knowledge on TB and TB treatment adherence

Variable.	Treatment outcome		Odds Ratio (CI 95%)	df	P-value
	Adherent N (%)	Non-adherent N (%)			
Knowledge on TB					
Low	3 (2%)	3 (5%)	4.078 (2.039-8.154)	1	<0.001
Average	90 (52%)	46 (79%)			
High	79 (45%)	9 (16%)			

Of the respondents, 113 (49%) are HIV negative and 45 (20%) are HIV positive with the rest don't know their status.

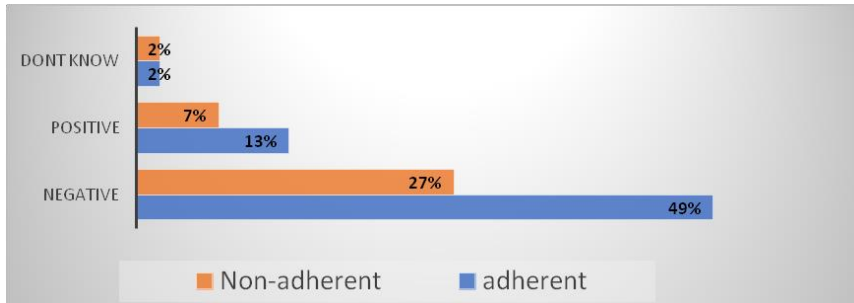


Figure 4.1. HIV status and TB treatment adherence

“TB is caused by Bacteria that affects the lungs. It is transmitted from one person to another through cough. Signs and symptoms include Cough more than 2 weeks, shortness of breath, tiredness, body and joint pains, coughing blood, chest pains, headaches. Some misconceptions around TB include: it being caused by heavy work, Alcohol use, tobacco use/smoking, its hereditary/Follows certain lineages, one must be HIV positive to have TB, sign of witchcraft” FGD

4.5 Behavioural factors influencing TB treatment adherence

Perceived severity, Perceived susceptibility, Perceived barriers, perceived benefits, cues to action and self-efficacy were used to assess behavioural factors related to TB treatment adherence (Table 4.7). For perceived severity, 191 (83%) of the respondents agree that not adhering to treatment makes ones very sick, 156 (68%) have very high perceived chances of contracting TB after not adhering.

Table 4.7. Behavioural factors influencing TB treatment adherence

Variable	Frequency	Percentage
Perceived Severity		
To what extend do you think not adhering to TB treatment affects your life?		
Make you very sick/affect you very much	191	83%
Might affect you/ affect somehow	37	16%
I don't think it will affect	2	1%

How would not adhering/ completing your TB treatment affect life of your family and community?	94	41%
Make them very sick/affect very much	133	58%
Might make them sick/ affect somehow	3	1%
I don't think it will affect them		
Perceived Susceptibility		
What are your perceived chances of contracting TB after not adhering to treatment?	156	68%
Very High	61	26%
High	9	4%
Moderate	2	1%
Low	2	1%
Very Low		
What is the possibility of protecting yourself from other forms of TB by adhering to treatment?	111	48%
Very High	52	23%
High	15	7%
Moderate	3	1%
Low	49	21%
Very Low		
Perceived Barriers		
Have you ever had anyone talking ill about people with TB?	99	43%
Never	45	20%
Rarely	77	33%
Sometimes	7	3%
Often	2	1%
Always		
Have you ever had or seen people with TB being sent away or treated badly?		
Never	140	61%
Rarely	33	15%
Sometimes	51	22%
Often	5	2%
Always	1	0%
Perceived Benefits		
If I take my TB medications daily, I will reduce risk of TB recurrence and developing MDR TB.		
Strongly Agree	123	53%
Agree	46	20%
Neutral	6	3%
Disagree	38	17%
Strongly disagree	19	7%
Cues to Action		

How ready are you to adhere to TB treatment?		
Yes very ready	211	92%
Somewhat ready	17	7%
Not ready	2	1%
Do you know someone who had TB, adhered to treatment, completed treatment and is now healed?		
Yes	201	87%
Sometimes	10	4%
No	19	8%
Self-Efficacy		
There is no much I can do to prevent TB, If it's going to happen then it will happen no matter what I do?		
Never	129	56%
Sometimes	71	31%
Always	30	13%

4.5.1 Perceived severity

The responses were scored 2, 1 and 0 for Make you very sick, might affect you and I don't think respectively. Data was further computed between the two questions, and the highest score was given a 4 which represented high perception on severity, 2-3 representing moderate and lowest score at 0-1 representing low perception on severity. 41% of the respondents had high perception, with majority of the population having moderate perception on severity of not adhering/ completing your TB treatment affect their life of your family and community. (Refer Table 4.7).

Table 4.8. Summary of Perceived Severity

Category		Frequencies	percentages
Perceived severity	High	94	41%
	Moderate	133	58%
	Low	3	1%

4.5.2 Perceived Susceptibility

Each question was scored in a Likert scale of Very high, high, moderate, low and very low, where very high and high were scored as 2, moderate scored as 1 and low and very low given a score of 0. Data was computed from the two questions where the

highest score was 4 and lowest 0. High perception on susceptibility was scored as 4, moderate perception at 2-3 and low perception on susceptibility as 0-1. The findings showed that the respondents had a high perceived susceptibility at 68% of possibility of protecting yourself by adhering to treatment and perceived chances of contracting TB after not adhering to treatment. (Refer Table 4.7).

Table 4.9: Summary of perceived susceptibility

Category		Frequencies	percentages
Perceived Susceptibility	Low	2	1%
	Moderate	72	31%
	High	156	68%

4.5.3 Perceived Barriers

Each question was scored as never, rarely, sometimes, often and always. Where Never and rarely were considered not a barrier to TB treatment adherence and scored as 2, sometimes was moderately considered as a barrier scored as 1 and low and often and always considered a barrier given a score of 0. Data was computed from the two questions where the highest score was 4 and lowest 0. High perceived barrier was scored as 4, sometimes as moderate perception at 2-3 and never range 0-1. The findings indicated that the respondents at 54% have never 45% sometimes heard anyone talking ill about people with TB or had or seen people with TB being sent away or treated badly perceived as barrier towards treatment adherence, perceive barriers as a factor. (Table 4.7).

Table 4.10. Summary of Perceived Barriers

Category		Frequencies	percentages
Perceived Barriers	Always	3	1%
	Sometimes	103	45%
	Never	124	54%

4.5.4 Perceived Benefits

The response was categorised as strongly disagree and disagree as 0, Neutral as 1 and agree and strongly agree as 2. 73% of the population agree that if take my TB medications daily, I will reduce risk of TB recurrence and developing MDR TB, 24% had moderate perception.

Table 4.11. Summary of Perceived Benefits

Category		Frequencies	percentages
Perceived Benefits	Agree	168	73%
	Neutral	6	3%
	Disagree	55	24%

4.5.4 Cues to action

Each question was scored from a scale of yes, sometimes and No. Yes, was scored 2, sometimes 1 and No 0. Data was computed from the two questions where the highest score given was 4 and lowest 0. Readiness to take action was scored at 4, moderate at 2-3 and No readiness at 0-1. 84% of the respondents were ready to take action regarding their health during and after treatment. (Refer Table 4.12).

Table 4.12. Summary of Cues to Action

Category		Frequencies	percentages
cue to action	Yes	193	84%
	Neutral	34	15%
	No	3	1%

4.5.5 Self- Efficacy

The response was categorised as never, sometimes always where never was scored 3, sometimes 2 and always as 1. 56% of the respondents were ready to take charge in prevention of TB, 31% were moderately self-efficient in TB control while 13% were not. (Refer Table 4.7).

Table 4.13. Summary of Self -Efficacy

Category		Frequencies	percentages
Self-efficacy	always	30	13%
	sometimes	71	31%
	never	129	56%

Respondents who perceive severity of the disease as harmful are twice more likely to adhere to TB treatment. Perceived severity OR=2.186, CI: 1.088-4.393, P=0.028) and perceived susceptibility (OR=0.477, CI: 0.303-0.752, P=0.001) are variables that are significantly associated with TB treatment adherence.

Table 4.14. Relationship between behavioural factors and TB treatment adherence

Variable.	Medication outcome		Odds Ratio (CI 95%)	P-value
	Adherent N (%)	Non-adherent N (%)		
Perceived severity				
High	65 (38%)	13(22%)	2.186(1.088-4.393)	0.028
Moderate	106 (62%)	44 (76%)		
Low	1 (0%)	1 (2%)		
Perceived Susceptibility				
High	107 (62%)	48 (83%)	0.477 (0.303-0.752)	0.001
Moderate	63 (37%)	9(15%)		
Low	2(1%)	1 (2%)		
Perceived Barriers				
Always	2(1%)	1 (2%)	0.937 (0.525-1.674)	0.826
Sometimes	79 (46%)	24 (41%)		
Never	91 (53%)	33(57%)		
Perceived Benefits				
Agree	131 (76%)	38 (66%)	1.301 (0.932-1.814)	0.122
Neutral	4 (3%)	2 (3%)		
Disagree	37 (21%)	18 (31%)		
cue to action				
Yes	148 (86%)	45 (78%)	1.328 (0.902-1.954)	0.151
Neutral	23 (14%)	11 (19%)		
No	1 (0%)	2 (3%)		
Self-efficacy				
Always	25 (14%)	5 (9%)	1.298 (0.817-2.062)	0.27
Sometimes	46 (27%)	25 (43%)		
Never	101 (59%)	28 (48%)		

“Behavioural factors like not understanding the advantages of adhering to treatment, ignorance during treatment period, perceived severity is associated with treatment adherence” FGD

4.6 Societal factors associated with TB treatment adherence

4.6.1 Relationship between patient family history and TB treatment adherence

Fifty one percent of the respondents had, had their family members ever been diagnosed with TB were adhering to TB treatment. This factor was not statistically significant factor in TB treatment adherence.

Table 4.15. Relationship between patient family history and TB treatment adherence

Factors	Treatment outcome		Odds Ratio (CI 95%)	df	P value
	Adherent	Non adherent			
Has anyone in your household or family ever had TB?			1.022 (0.575-1.818)	1	0.941
Yes	87 (51%)	31(53%)			
No	85 (49%)	27(47%)			

4.6.2 Patients' referral to seek TB Care

Approximately 36% of the respondents were referred by Family /friend and 36% self-referral to seek appropriate diagnosis and medication for TB.

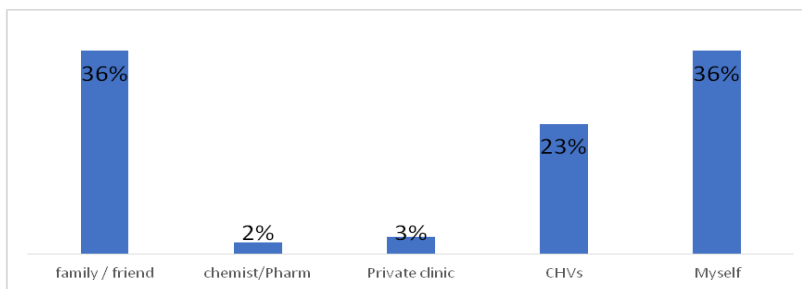


Figure 4.2: Patient's referral in seeking TB care

4.6.3 Relationship between Stigma related factors associated with TB treatment adherence

Six variables were used to assess stigma. Supportive family DOTS (OR; 1.737, CI: 1.057-2.854, P=0.028) and skipping treatment while others were around (OR; 2.407, C.I: 1.407-4.117, P=0.001) are specific variables associated with TB treatment adherence.

Table 4.16 Relationship between Stigma related factors associated with TB treatment adherence

Variable.	Medication outcome		Odds Ratio (CI 95%)	P-value
	Adherent N (%)	Non- adherent N (%)		
How supportive is your family members/Family DOTs on you taking your TB medicines?			1.737 (1.057-2.854)	0.028
Never	21(12%)	19(33%)		
Sometimes	139(81%)	26(45%)		
Always	12 (7%)	13 (22%)		
Do you feel that family members /neighbours feel free to share utensils e.g. plates, spoon and basins if they know/find out you have TB?			1.346(0.752-2.407)	0.317
Not at all free	22(13%)	19(33%)		
Somewhat free	123(72%)	19(33%)		
Very Free	27 (15%)	20(34%)		
Did you think that community members will shake hands freely with you if they found out you have TB?			1.413 (0.779-2.565)	0.255
Never	33(19%)	31(53%)		
Sometimes	108(63%)	16(28%)		
Always	31(18%)	11(19%)		
Would you still remain friends if you found out that your friends have been diagnosed with TB?			1.029 (0.518-2.046)	0.934
Never	27(15%)	26(45%)		
Sometimes	136(79%)	30(52%)		
Always	9(5%)	2(3%)		
Have you ever skipped a treatment because others were around?			2.407(1.407-4.117)	0.001
Always	21(12%)	25(43%)		
Sometimes	142(83%)	25 (43%)		
Never	9(5%)	8(14%)		
Do you know of family members or any other persons sacked by their employers because they discovered that they have TB?			1.057 (0.649-1.723)	0.823
Yes	37(22%)	15(26%)		
No	121(70%)	30(52%)		
Don't Know	14(8%)	13(22%)		

To summarize each question was scored from a scale of Never, sometimes and always. The stigma related questions were decoded as never scored 0, sometimes 1 and always as 2. Data was computed from the four questions where the highest score was 8 and lowest 0. High stigma was scored of 6-8, moderate stigma at 3-5 and low stigma at 0-2. 54% of the respondents did not feel rejected or avoided by their family members and neighbour after being diagnosed with TB. 23% of the population also agree that they have at one point been dismissed from their work because they had TB or know someone who was. Patients who face low stigma are twice more likely to adhere to TB treatment. There was a significant statistical association between stigma related factors and TB treatment adherence (OR; 2.979, CI: 1.955-4.536), P=0.000)

Table 4.17. Summary of stigma related factors and TB treatment adherence

Factors	Treatment outcome		Odds Ratio (CI 95%)	P value
	Adherent	Non adherent		
Stigma related factors				
High	17 (10%)	17 (29%)	2.979 (1.955-4.536)	0.000
Medium	44 (26%)	27 (47%)		
Low	111(64%)	14 (24%)		

“Societal factors like not being accepted by family and friends, fear of being re-infected or infecting others, don’t share utensils, seclusion of patients, believe its caused by witchcraft, no support from home, some churches don’t believe in taking medication, living with TB patients causes stigma to as caregivers causes patients not to adhere” FGD

4.7 Health facility factors influencing TB treatment adherence

4.7.1 Cost and Time as factors influencing TB treatment adherence

The cost to and from hospital and time taken during routine refill were assessed. Amount spent to and from hospital was a mean of 145 KSH with majority paying

range of 0-100 KSH at 93%. This showed a significant association between cost with TB treatment adherence.

The patients spent an average of 20 minutes to refill their medication at health facilities with 96% of them spending between 0-20 minutes. Both times spent at the facility awaiting refill and cost of distance were not statistically significant associated with TB treatment adherence.

Table 4.18. Relationship between Cost and Time and TB adherence

Variable	Treatment outcome		Odds Ratio (CI 95%)	P value
	Adherent	Non adherent		
Cost to and from Hospital in KSH				0.304
0-100	104(60%)	39(67%)	1.226 (0.831-1.809)	
101-200	44(26%)	15(26%)		
201-300	15(9%)	1(2%)		
301-400	9(5%)	3(5%)		
During the last visit, how long did it take before being attended to?			1.264 (0.737-2.169)	0.395
0-20 mins	112(65%)	44(76%)		
21-40 mins	53(31%)	12(21%)		
41-60 mins	6(3%)	0 (0%)		
61 mins above	1(1%)	2(3%)		

4.7.2 Drugs availability and Cost

Ninety eight percent (225) of the respondents were actually given medication free of charge at the government facilities, with 97% acknowledging they get medication during their monthly visits.

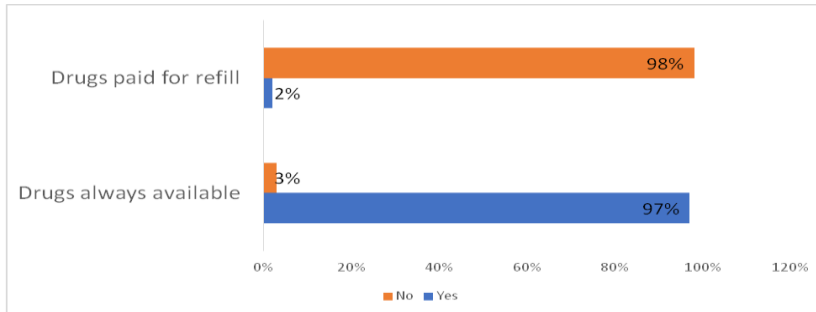


Figure 4.3. Drug availability and cost during refill

4.7.3 Patient satisfaction as factor influencing TB treatment adherence

Forty six percent (105) of the respondents were extensively explained about their illness at the health facility. Seventy six percent (175) were very satisfied with the way health personnel explained the need to adhere to treatment.

Table. 4.19: Patient satisfaction related factors

Institutional factors cont.		Frequency	Percentages
Were you explained about your illness at the health facility?	Not at all explained	25	11%
	Moderately explained	100	43%
	Extensively explained	105	46%
Did the health facility personnel explain the need for treatment adherence to your satisfaction?	Not at all satisfied	11	5%
	Moderately satisfied	44	19%
	Very satisfied	175	76%

Two questions to assess the patient's satisfaction after being diagnosed and counselled on matters TB. Each question was scored from a scale from of low to high. Not at all explained and not at all satisfied were coded as low, Moderate as medium and High for Extensively explained and satisfied. The questions were decoded as scored 0 for low to 2 for high and computed with highest score being 4 and lowest

score be 0. 48% of the findings indicated that adherent patients were explained on their diagnosis and treatment to their satisfaction, with 22% not at all explained nor satisfied by the services. Patient satisfaction has a significant statistical difference associated with TB treatment adherence (OR; 1.824, CI: 1.257-2.647), P=0.002).

Table 4.20. Patient Satisfaction Factors Influencing TB Treatment Adherence

Patient's satisfaction Variable	TB treatment		Odds Ratio (CI 95%)	P value
	Adherence	Non-adherent		
High	83 (48%)	15 (26%)	1.824 (1.257-2.647)	0.002
Medium	51 (30%)	20 (34%)		
Low	38 (22%)	23 (40%)		

4.7.4 Enrolment to TB support groups and TB treatment adherence.

Six percent (5) of the patients are enrolled in TB support groups. With 54% (93) of the adherent category been visited by CHVs on matters TB. Enrolment of TB patients to support groups has a significant statistical difference associated with TB treatment adherence (OR; 0.353, CI: 0.438-1.538), P=0.031).

Table 4.21. Enrolment to TB Support Groups as Factor Associated with TB Treatment Adherence

Variable	TB treatment		Odds Ratio (CI 95%)	P value
	Adherence	Non-adherent		
Are you in any TB treatment support groups following up on TB treatment adherence?			0.353 (0.137-0.911)	0.031
Yes	2(1%)	3(5%)		
No	170(99%)	55(95%)		
Has a community health volunteer ever visited you at home on matters of TB?			0.839 (0.438-1.538)	0.571
Yes	93 (54%)	28 (48%)		
No	79 (46%)	30 (52%)		

“Health facility factors like Rude health care professionals, Long distance, long and difficulty in diagnosing. language barrier to explain, no medicines always especially those for reducing side effects, CHVs don’t visit all homes with patients, only visit PTB positive patients are associated with patients not adhering to TB treatment”
FGD

CHAPTER FIVE: DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1 Discussion

5.1.1 TB treatment adherence

The study found out that TB treatment adherence during medication is still a great challenge in Kilifi County. Adherence to TB medication being a complex matter require a multifaceted technique since its influenced by different factors ranging from individual factors to external factors like social relationship. This study used Morisky medication adherence scale to determine TB treatment adherence levels, and the study findings showed that 75% were adhering to TB treatment. These findings were way below the national target and End TB Strategy 2025 targets of, 90% treatment coverage, 90% active case finding and 90% treatment success rate. This study is in line with studies done in South Ethiopia and Northwest Ethiopia. However, other counties in Kenya like Homabay reported higher adherence levels of 92%. Also Khartoum (86%), Northwest Ethiopia (86%), South Ethiopia reported high adherence level.

Some of the common reason for not adhering to treatment include lack of social support, feeling of being cured and ignorance, forgetting to take medication and being far from home, alcoholism and other medication side effects of TB drugs. This agrees with studies done in Northwest Ethiopia, South Ethiopia, Uganda, (Gebreweld *et al.*, 2018, Zegeye *et al.*, 2018). Shorter and simple drugs regime are being discussed to improve adherence and disease control.

5.1.2 Individual factors influencing TB treatment adherence

Individual factors included the socio-demographic data and Level of knowledge on TB. The study findings indicated that there are more men than women who are affected by TB. Similar to studies by WHO, 2017, suggested that men are more likely to be affected by TB compared to women. There are reports that indicate men are 1.6 times more at risk of contracting TB than women globally, this is because of biological differences of TB in access to healthcare facilities and risk factors associated with TB like occupation (Okethwangu *et al.*, 2019 and Marcoa *et al.*, 2018)..

The findings indicated that the most affected group is the age-productive group of 18-40 years at 71%. This agrees with studies of WHO, 2019 which states that TB affects the most productive age. Others studies by END-TB strategy report (2019) and CDC report (2019), agree that the TB affects the productive due to high exposure to risk factors and behavioural factors.

The study indicated that Patients who live with their families are 3 times more likely to adhere to TB medication during the treatment period. Patients who have family support during his/her treatment period are cared for and reminded of their medication. This is in line with studies done by Okethwangu *et al.*, (2019) and Mekonnen *et al.*, (2018), that factors like living with family provides moral support to patients during treatment, reduces stigma hence encourages the patient to be more adherent.

Level of knowledge was a factor that significantly associated with TB treatment adherence. Patients understanding on what causes TB, duration of treatment and transmission are the were significant factors affecting TB treatment adherence (WHO

2019, Gebreweld *et al.*, 2018). WHO further states that although we may put resources on other factors related to TB adherence, without correct knowledge on treatment adherence of the same we haven't done any (WHO 2018).

From the study individual factors identified to be associated with TB treatment adherence include living with the family and level of knowledge. However, findings from the study are similar to results in African countries of Uganda, Sudan and Ethiopia (Okethwangu *et al.*, 2019, Ali *et al.*, 2016, Zegeye *et al.*, 2019, Woimo *et al.*, 2017), agree that other than living with family and level of knowledge, factors like sex, marital status, occupation, level of education and amount of money used for food daily are associated with TB treatment adherence which are contrary to my study.

5.1.3 Behavioural factors influencing TB treatment adherence

Health belief model is commonly used to describe and explain health behaviours factors that are resulted from personal beliefs and or perceptions in ways that and be done to reduce its occurrence or event. The model is influenced by individual perception in obedient towards taking action to reduce threats and considering benefits over loses.

Findings indicated that perceived severity and perceived susceptibility are factors associated with TB treatment adherence. This agree with studies from Ika *et al.*, 2020, Notoatmojo *et al.*, 2014, stating that Patients' beliefs on perceived susceptibility, perceived severity, perceived barriers, perceived benefits, cues to action and self-efficacy are influenced by knowledge, attitude and practices towards adhering to TB medication.

Patients' belief about the disease using health belief model like perceived cure and barriers influence TB treatment adherence (Zakariya *et al.*, 2020, Sahile *et al.*, 2018).

Further Tole *et al* (2017) stated that perceived barriers and perceived benefits are factors that significantly influence TB medication like. Cues to action and self-efficacy are factors that indirectly influence adherence to TB medication (Tole *et al.*, 2017).

5.1.4 Societal Factors Influencing TB Treatment Adherence

From the findings, societal factor related to stigma is associated with TB treatment adherence. Social support from families, neighbours during their treatment regime in taking their medication, financial assistance and food influence TB treatment adherence to medication according to Zakariyas *et al.*,2020, Mindachew *et al.*, 2014, Eticha *et al.*,2014, Murkeji *et al.*, 2018,). This means experienced stigma and perceived stigma and social stigma leads to patients defaulting to treatment. Further, Patients who reported to have or seen someone lose job because of TB are more likely to hide their TB status increasing their defaulting chances (Gebreweld *et al.*, 2018) .

Factors like living with family provides moral support to patients, reduces stigma hence encourages the patient to be more adherent. The relationship between healthcare worker and Patient satisfaction as a factor in TB treatment adherence. Patients who are satisfied with the way they are being treated at health facilities are more likely to continue adhering to treatment

5.1.5 Health facility factors influencing TB treatment adherence

From the results, Health facility factors like patient satisfaction and whether a patient is enrolled on TB support groups were significantly associated with TB treatment adherence. This agrees with studies from Nazenega *et al.*,(2011), stating that Patient satisfaction at the health facility in terms of service provision positively influences adherence to treatment. This study was contrary to studies of Distefano *et al.*, (2016),

and Gube *et al.*, (2018) stating that other than patient satisfaction, other factors like drug stock outs, cost, long waiting time during refill and poor relationship with health care workers are factors associated with TB treatment adherence.

CHV involvement in TB treatment adherence was not a significant factor in this study contrary to other studies in Kenya, (Abongo *et al.*, 2020) agree that involvement of CHVs in TB care increases TB treatment adherence and early diagnosis of TB. Further, involvement of community health volunteers (CHVs) play a key role in TB care including active case finding, contact tracing and screening and defaulter tracing all under community TB under community TB strategies.

Family support reduces patients feel of stigma. Community and patients' knowledge on what causes TB, how it is transmitted and signs and symptoms are key in improving TB treatment outcomes. Increase in knowledge will influence behavioural factors as explained by health belief model which further influences personal perceptions on the need to adhere to treatment. Increase knowledge and active TB support groups influences stigma and societal support during treatment regime. Patients' perception and satisfaction while receiving TB care is important in providing moral support.

5.2 Conclusion

The study made the following conclusions: Individual factors (patients living with family and level of knowledge on TB) and TB treatment adherence were statistically significant. This implies that encouraging patients to live with families and advocacy on TB to increase knowledge of patients in Malindi Subcounty improves TB treatment adherence.

Behavioural factors: The study also concludes that high perceived severity and perceived susceptibility to TB treatment is significant to TB treatment adherence.

Societal Factors: Reduced stigma at the society on TB treatment is statistically significant in TB treatment adherence.

Health facility factors: Overall patient satisfaction on service delivery by the health care worker is statistically significant to TB treatment adherence.

5.3 Recommendation

5.3.1. Recommendations from the Study

- We recommend the Ministry of Health increase health advocacy on TB at the community to increase knowledge and reduce stigma.
- Policy makers should recommend regular patient trainings on behaviour change campaigns to increase perceived severity and perceived susceptibility during treatment regime.
- Refresher trainings for health care workers on service delivery to patient satisfactions

5.3.2. Recommendations for further research

- Further studies- new interventions and use of new technological models like mobile phones short messaging service or video services, being implemented to increase TB treatment adherence in Kilifi County

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APPENDICES

APPENDIX 1: INFORMED CONSENT

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My name is Nancy August Chebet, a Masters student from Kenyatta University. I am conducting a study entitled “TB treatment adherence among patients taking anti-TB drugs in Malindi Subcounty, Kilifi County”. The information from the study will be used to determine factors influencing TB treatment adherence and be able to suggest better approaches, interventions and policy for better management of TB.

Participation in this study will require that I ask you some questions related to how you have been taking your anti-TB medications.

Voluntarism

You have the right to refuse participation in this study. You will get the same services and care whether you agree to join the study or not and your decision will not change the care you will receive. Please remember the participation in this study is voluntarily. You may ask questions related to the study at any time.

You may refuse to respond to any questions and you may stop an interview at any time. You may also stop being in the study at any time without any consequences to the services you receive here or any other organization now or in the future

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. You may also stop the interview at any time. The interview may add approximately half an hour to the time you wait after you receive your routine services. Risks of the study include risk of contracting and or spreading TB infection and or Covid 19 during data collection period. To address this risk, research assistants will be tested for corona virus and advised to strictly observe ministry of health preventive guidelines including wearing of masks, keeping one-meter distance during interview and use alcohol-based sanitizer at all times during data collection period.

Physical abuse from the patients during interview. In case of hostility from the patient’s, the research assistant is advised to immediately retreat from the interview and report the matter.

Benefits

If you participate in this study you will help us to learn how to address immediate shortcomings towards adhering to treatment among patients and suggest better

approaches. The study will have no monetary rewards of kind to individual participants, instead the findings will be beneficial to TB patients and community as it will address their immediate factors influencing towards adhering to treatment and suggest better approaches as a whole. TB program managers will also use the findings to propose better approaches to be implemented at the subcounty towards improving treatment adherence among TB patients. Further, the information will be used by County coordinators and TB advocates to map different approaches to improve adherence from the county level to policy level.

Reward

The study participation is free and there will not any kind of payment

Confidentiality

The interviews and examinations will be conducted in a private setting within the clinic. 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 My Supervisor Dr. Joyce Kirui, Phone: 0710988103.

However, if you have questions about your rights as a study participant: You may contact 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. 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. My participation in this study is entirely voluntary. I understand that my records will be kept private and that I can leave the study at any time. I understand that I will still get the same care and medical treatment whether I decide to leave the study or not and my decision will not change the care that I will receive from the clinic or that I will get from any other clinic at any other 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 to be followed in the study and the risks and benefits involved

Name of Interviewer: _____

Signature _____ Date _____

APPENDIX 11: QUESTIONNAIRE FOR TB PATIENTS

Questionnaire No.....

TB Reg. no. Type of TB.....

A. Individual Factors

I. Sociodemographic factors

1. Sex

1. Male

2. Female

2. Age in years _____

3. Marital status

1. Married

2. Single

3. Divorced

4. Widowed

4. Level of Education

1. No formal education

2. Primary

3. Secondary

4. College/University

5. Occupation

1. Employed

2. Self employed

3. Unemployed

6. Approximate amounts of money used on food daily (KSH)

7. a. Do you live with your family?

1. Yes

2. No

b. How many children under the age of five live in your household? _____

II. TB level of knowledge

Interviewer note: do not read out the options.

8. What causes TB?

1. Bacterium

2. Virus

3. Witchcraft/Curse

4. Smoking and/or alcohol

5. Others
(Specify _____)

9. Is TB transmittable from one person to another person?

1. Yes

2. No

10. How is TB transmitted from an infected person?

1. Through infectious cough and sneezing droplet

2. Don't know

3. Others
(specify _____)

11. What are signs and symptoms of TB?

1. Cough more than 2 weeks

2. Pain in the Chest

3. Coughing up blood

4. Loss of appetite

5. Shortness of breath

6. Fever and night sweats

7. Other
(specify _____)

12. In your opinion, who can get TB?

1. Anybody

2. Only alcoholic people

3. Poor people

4. Only people living with HIV/AIDS

5. Only drug users

6. Other
(specify _____)

13. How do you think TB can be treated?

1. Antibiotics

2. Anti-TB drugs

3. Traditional medicine

4. Recovery by itself

5. Other
(specify _____)

14. The duration of completing treatment?

1. 6 months

2. 8 months

3. 12 months

4. I don't know

5. Other
(specify _____)

15. What's your HIV Status

1. Negative

2. Positive

3. Don't know

B. Behavioural factors

a. Perceived Severity

1. To what extent do you think not adhering to TB treatment affects your life?

Make you very sick

Might affect

I don't think so

2. How would not adhering/ completing your TB treatment affect life of your family and community?

Make them very sick Might affect I don't think so

b. Perceived Susceptibility

3. What are your perceived chances of contracting TB after not adhering to treatment?

Very high High Moderate Low Very
Low

4. What is the possibility of protecting yourself by adhering to treatment?

Very high High Moderate Low Very
Low

c. Perceived Barriers

5. Have you ever had anyone talking ill about people with TB?

Never Rarely Sometimes Often
Always

6. Have you ever had or seen people with TB being sent away or treated badly?

Never Rarely Sometimes Often
Always

d. Perceived Benefits

7. If I take my TB medications daily, I will reduce risk of TB recurrence and developing MDR TB.

Strongly disagree Disagree Neutral Agree
Strongly agree

e. Cues to action

8. How ready are you to adhere to TB treatment?

Yes Sometimes No

9. Do you know someone who had TB, adhered to treatment, completed treatment and is now healed?

Yes Sometimes No

f. Self- Efficacy

10. There is no much I can do to prevent TB, If it's going to happen then it will happen no matter what I do?

Never Sometimes Always

C. Societal and Stigma related Factors

1. Has anyone in your household or family ever had TB?

1. Yes

2. No

2. Who asked you to seek appropriate TB treatment?

1. Family/friend

2. Chemist

3. Private clinic

4. Community health volunteers

5. Myself

3. How supportive is your family members/Family DOTs on you taking your TB medicines?

Never Sometimes Always

4. Do you feel that family members /neighbours feel free to share utensils e.g. plates, spoon and basins if they know/find out you have TB?

Not at all free Somewhat free Very free

5. Did you think that community members will shake hands freely with you if they found out you have TB?

Never Sometimes Always

6. Would you still remain friends if you found out that your friends have been diagnosed with TB?

Never Sometimes Always

7. Have you ever skipped a treatment because others were around? Never

Sometimes Always

8. Do you know of family members or any other persons sacked by their employers because they discovered that they have TB? 1. Yes

2. No

3. Don't know

9. Do you know any TB treatment support groups following up on TB treatment adherence?

- 1. Yes
- 2. No
- 3. Don't know

If Yes, which one?.....

10. Have you ever heard of laws governing non-adherence/defaulting?

- 1. Yes
- 2. No

If Yes, please explain.....

C. Health facility factors

1. How much fare did you use to and from the facility?.....
2. During the last visit, how long did it take before being attended to?
.....(mins)
3. Were drugs available each time you visited the facility?
 - 1. Yes
 - 2. No
4. Each time you visit health facility, have you ever been asked to pay for TB drugs? 1. Yes 2. No **b** If YES, where?
 - 1. Government Hospitals
 - 2. Mission hospitals
 - 3. Others (Specify).....
5. Were you explained about your illness at the health facility?
Not at all explained Moderately explained Extensively explained
6. Did the health facility personnel explain the need for treatment adherence to your satisfaction?
Not at all satisfied Moderately satisfied Very Satisfied
7. Has a community health volunteer ever visited you at home on matters of TB?
 - 1. Yes

2. No

b. If yes, what did he/she say?

.....

8. Do you agree to isolation of TB patients?

Strongly disagree Moderately agree Strongly Agree

9. Do you know of any functional Manyatta/Isolation centres for TB patients?

1. Yes

2. No

b. If yes, name one.....

10. Have you ever been confined in a Manyatta?

1. Yes

2. No

b. If yes, why?..... If yes, why?.....

11. In your opinion, why do TB patients fail to adhere to treatment?

.....

D. Treatment Adherence Using Morisky Scale

Morisky scale of adherence		YES	NO
1	Have you ever forgotten to take your drugs?		
2	In the past two weeks, were there days you did not take your medicine? If Yes, which days.....		
3	Did you take your drugs yesterday?		
4	Are there times when you didn't take your medicines and didn't tell anyone because you felt worse after taking them?		
5	Have you ever travelled and forgot your medicines home, hence didn't take the medicine?		

6	When you feel you are much better health wise, do you sometimes stop taking your medicines?		
7	How often do you forget taking your medicines?		
	Rarely <input type="checkbox"/> Sometimes <input type="checkbox"/>		
	Always <input type="checkbox"/>		

APPENDIX 111: FGD GUIDE

Questions

1. What are some of the misconceptions around TB?
2. What are some of individual factors that prevent people from adhering from TB treatment?
3. What are the societal factors that influence TB?
4. What are some of Health facility factors that prevent individuals from adhering to TB treatment?
5. What's the role of community health volunteers in TB care?
6. What do you think about the laws governing treatment non-adherence?
7. In your opinion, what are the top reasons that patients do not adhere to TB treatment??
8. What could be possible strategies that could be used to increase TB treatment adherence?

**APPENDIX IV: KENYATTA UNIVERSITY ETHICAL REVIEW
COMMITTEE APPROVAL**



Kenyatta University
P.o Box 43844-00100 Nairobi-Kenya

REF: KU/ERC/APPROVAL/VOLI/I

Date: 21st September, 2020

Nancy Chebet
P.o Box 43844-001 OO
NAIROBI

Dear Ms. Chebet,

**APPLICATION NUMBER: PKU/2122/11266 TUDERCULOSIS TREATMENT
ADHERERANCE TAKING ANTI-TB DRUGS IN KILIFI COUNTY, KENYA**

This is to inform you that KENYATTA UNIVERSITY ETHICS REVIEW COMMITTEE has reviewed and approved your above research proposal. Your application approval number is PKU/2122/11266. The approval period is 21st September, 2020 — 21st September, 2021.

This approval is subject to compliance with the following requirements;

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



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

Yours sincerely

Prof. Judith Kimiywe

CHAIRPERSON- KENYATTA UNIVERSITY ETHICS REVIEW COMMITTEE.

APPENDIX VI: KILIFI COUNTY APPROVAL

COUNTY GOVERNMENT OF KILIFI

DEPARTMENT OF HEALTH
When Replying quote P. O. Box 9-
Email: chmtkilifi@gmail.com
REF: DOH/KLFIRESWVOL.1121



SERVICES
80108

Date: 7th October 2020

OFFICE OF THE COUNTY DIRECTOR


Nancy August Chebet
Student Reg No. (0142/26861/2018)
Kenyatta University,
NAIROBI, KENYA.


RE: DEPARTMENTAL AUTHORIZATION TO CARRY OUT
RESEARCH IN KILIFI COUNTY

The Kilifi County Department of Health Services is in receipt of your request to conduct a study titled, "Tuberculosis treatment adherence among patients taking anti-tb drugs in kilifi county, Kenya." The department is in receipt of the protocol and ethical and scientific approval from Kenyatta University Ethics Review Committee Ref: PKU/2122/11266 and NACOSTI Ref: NACOSTI/P/20/5926.

The Department is pleased to grant you authorization to conduct your study within Magarini and Malindi Sub Counties in line with the ethical considerations stipulated in the approved study protocol, the county guidelines on the conduct of research in Kilifi County during COVID-19, and within the expiry date of your ERC approval September 21st, 2021. It is required that you engage the County TB Coordinator, and the Sub County and hospital administration prior to commencing data collection.

Upon completion of the study, you are required to share your study findings, and recommendations with the County Director, Department of Health Services, Kilifi County.


Dr. David Mulewa
Director of Medical Services - Kilifi County



c.c

- CECM-Health Services
- Chief Officer Public Health

APPENDIX VII: MAP OF KILIFI COUNTY

