DRIVERS OF TUBERCULOSIS TREATMENT INTERRUPTION AMONG TUBERCULOSIS PATIENTS IN MARSABIT COUNTY, KENYA, 2020

BY

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DECLARATION

Declaration by Candidate

I do hereby declare that this thesis is my original work and has not been submitted for a degree in any other examination body or any learning institution. No part of this thesis is to be reproduced without prior consent of the author and/or Moi University.

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DEDICATION

I dedicate this thesis to my lovely wife, Elizabeth Boru who had travelled this academic journey with me and encouraged me on to keep going even when there were other competing family tasks, My children(Adho, Guyo, Abudo, Adano and baby Umuro),who always provided such lively environment around me to relax when bowed down with the classwork. I thank them all for their support.

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ABSTRACT

Introduction: In 2020 ≈ 9.9 million TB cases and 1.5 million deaths were reported globally (WHO, 2020). Kenya is among top 30 high TB burden countries with an incidence of 140,000/100,000 population**.** Treatment success rate was 85.2% (target 90%) in Kenya, lost to follow up 5.7% target (<2%). Marsabit County reported 1069 cases in 2020 and a treatment success rate of 77%, lost to follow up 3%. The purpose of the study was to determine determinants of tuberculosis treatment interruption in the County.

Methods: A cross-sectional study conducted in Marsabit County. Study population was 2019 and 2020 TB patients. Data on drug susceptible TB, clinical information, and DOTS type was extracted from TB register. Data on sociodemographic information, drug side effects, infection prevention, and health care provider was collected using structured questionnaire. Sample size of 340 was obtained using Cochrane formula and adjusted for non-response of 10%. Drug sensitive TB patients list was used as sampling frame. Table of random numbers was used to obtain sample size and probability proportionate to size was used to allocate patients to Sub Counties.

Results: Of the 340 targeted respondents, 307 were recruited giving a response rate of 90.3%).There was 67 (22%) treatment interruption. Male patients had 25% interruption, age-group 55-64 years 28%, while those above 65 years had 13%. Saku Sub County had 28% treatment interruption, and North horr had 8%. Married participants reported 30% treatment interruption and widowed 1%. On multivariate analysis, long waiting time ≥ 1 hour at the clinic (AOR 6.95, CI, 2.46-19.61) was significantly associated with treatment interruption and Female sex was protective against treatment interruption (AOR 0.4, CI= 0.18-0.93).

Conclusions: Proportion of TB patients interrupting treatment is high and male sex is contributing higher proportion. Modifiable factors of male sex and long waiting time were significantly associated with treatment interruption. The County health department needs to design an intervention targeting male TB patients to reduce male treatment interruption. Expansion of TB service delivery points and early opening of clinic could help reduce waiting time hence reduction in treatment interruption.

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LIST OF ABBREVIATIONS AND ACRONYMS

TB:	Tuberculosis
HIV:	Human Immune-deficiency Virus
WHO:	World Health Organization
RHZE:	Rifampicin, Isoniazid, Pyrazinamide, Ethambutol
RH:	Rifampicin
MDRTB:	Multidrug resistant tuberculosis
DST:	Drug susceptibility testing
ART:	Anti-retroviral therapy
DOTS:	Directly observed therapy short course
IREC:	Institutional research and ethical committee

Key terminologies used

Treatment interruption: Comprised of lost to follow up which is defined as a TB patients who did not start TB treatment or whose treatment was interrupted for two or more consecutive and intermittent interruption of treatment by TB patients for shorter period of time but less than 60 days (WHO, 2013).

Drug susceptible TB: Drugs sensitive TB is defined as infection with TB bacteria that are fully susceptible to all category TB drugs including Rifampicin, Isoniazid, Pyrazinamide and Ethambutol taken as fixed drug combination (FDC) and are taken properly to provide effective treatment.

Cure: A pulmonary TB patient with bacteriologically confirmed TB at the beginning of treatment who completed the treatment as recommended by the national policy with evidence of bacteriological response and no e evidence of failure.

Treatment completed: patient who completed treatment without evidence of failure BUT with no record to show that sputum smear or culture results in the last month of treatment and on at least one previous occasion were negative, either because

Treatment success: tests were not done or because results are unavailable. The sum of cured and treatment *completed (Integrated TB Leprosy and Lung disease guideline, 202).*

TB death: A patient who died before starting treatment or during the course of treatment

Lost to follow up: A patient who did not start treatment or whose treatment was interrupted for 2 consecutive months or more.

TB Case notification or detection rate: The proportion of estimated new and relapse TB cases detected in a given year under the internationally recommended tuberculosis control strategy. The term “case detection”, as used here, means that TB is diagnosed in a patient and is reported within the national surveillance system, and then to WHO (WHO, 2020)

TB incidence rate: The estimated number of new and relapse TB cases arising in a given year, expressed as the rate per 100 000 population. All forms of TB are included, including cases in people living with HIV.

CHAPTER ONE

1.0 Introduction

1.1 Background

Tuberculosis (TB) is an airborne disease caused by *Mycobacterium tuberculosis* which is carried through the air in droplet nuclei of 1-5 microns in diameter. The droplet nuclei are generated when an infected person coughs, sneezes, sings (DNTLD-P, 2017). These infectious particles containing tubercle bacilli can remain suspended in the air and hence people get infected when they inhale them and get into the alveoli in the lungs. These bacilli can be surrounded by macrophages which are body's defense mechanism, and get killed. However, if they skip the body's defense mechanism, they can spread through the lymphatic system or blood stream to other organs where they multiply and cause TB infection (CDC, 2016). Tuberculosis can affect any part of human body except hair, nails and teeth and is divided into two types; Pulmonary TB and extra pulmonary TB. Pulmonary TB affects the lungs, and is the most common form of TB. Extra pulmonary TB on the other hand affects other parts of the body (Soumyajit Das1, 2016).

Globally an estimated 1.7 billion people are exposed to TB and therefore are at risk of developing the disease. Globally tuberculosis is the leading cause of death from a single infectious agent (Charles Sandy, Nyasha Masuka, Patrick Hazangwe, Regis C Choto, Tsitsi Mutasa-Apollo, Brilliant Nkomo, Edwin Sibanda, Owen Mugurungi, Anthony D Harries, Nicholas Siziba, 2013). As such, an estimated 9.9 million people got ill and 1.5

million died of the disease in 2020 (World health organization, 2020).The sub-Saharan Africa contributes more than 80% of TB burden. The 30 high TB burden countries, most of which are located in the sub-Saharan Africa, contribute more than 80% of TB burden. Kenya is among the 30 high TB burden Countries ranked at position 22 (WHO, 2020), with an estimated annual decline of 4% in the TB burden (Enos Masini, Sitienei Joseph, Ongango Jane, 2018). The prevalence survey conducted in 2015/2016 in Kenya estimated TB prevalence at 426 cases per 100,000 population, which translated to an incidence of 169,000 (Enos Masini, Sitienei Jposeph, Ongango Jane et al, 2018). In 2020, Kenya reported a total of 72,943 TB cases against the expected estimate of 156,000 cases, which means that 47% of the cases of TB could have been missed (DLTLD, 2020). Poor health seeking behaviour of the population, delayed diagnosis by the health care providers, poor access to health facilities in some areas among other factors could have contributed to this misses.

People with TB infection have an increased risk of progression to active TB disease. The progression from infection with tuberculosis to active disease depends on several factors, which includes infectiousness of the source case, proximity to the contact and socio-behavioral risk factors such as alcohol consumption, tobacco smoking, overcrowding. Other factors are immune-compromising conditions such as HIV infection, diabetes, malnutrition and prolonged exposure to the infection e.g. due to delayed diagnosis (Narasimhan, Padmanesan, 2013).

In 2019, Marsabit County notified a total of 739 TB cases which translated to a case notification rate of 160 cases per 100,000 population. This is a low notification when

compared with the TB prevalence and incidence in Kenya as per the prevalence survey conducted in 2015/2016, which revealed a prevalence of 426 per 100,000 population and incidence of 169,000 cases (Enos Masini, Sitienei Joseph, Ongango Jane, 2018). Marsabit County also had lower TB case notification when compared with other neighbouring counties such as Isiolo. Health facilities in Marsabit County were sparsely distributed across the vast county. The mobile nomadic population which moves with their livestock in search of water and pasture can sometimes be a driver of TB transmission as the distance from the nearest health facility may increase when they move away from the health facilities that serve them leading to poor access to healthcare. This in turn encourages continued transmission of TB since people can only come to the health facilities when they get severely ill, and continue transmitting infection. Other factors such as longer waiting time at the health facilities during the clinic days for drug refill, poor health seeking behaviour among the nomadic population can contribute to low case finding of TB in the county. (Finlay, Alyssa, 2012).

The WHO end TB strategy targets to treat properly all TB cases, reduce death due to TB by 95%, and incidence rate by 90% compared with the 2015 millennium development goals(MDGs) achievement (WHO, 2014). In Kenya TB treatment is for a period of at least six months and the regimen includes a fixed drug combination (FDC) of four drugs. These are Rifampicin, Isoniazid, Pyrazinamide and Ethambutol (RHZE). Treatment is monitored both clinically and with laboratory follow ups to ensure adherence and treatment completion and/or cure.

Treatment outcomes for TB are grouped into treatment success (Summation of bacteriologically confirmed TB patients at diagnosis who are confirmed cured through follow up sputum smear tests at month six and any other follow up sputum tests or culture and treatment complete which is defined as bacteriologically confirmed patients who do not have the required follow up sputum smear tests to confirm cure but have completed TB treatment with good clinical improvement including weight gain, as well as all the clinically diagnosed pulmonary TB cases and extra pulmonary TB cases who have successfully completed their treatment regimens with good clinical improvement including resolution of signs and symptoms of TB and weight gain following the treatment), Lost to follow up (A TB patient who did not start treatment or whose treatment have been interrupted for two or more consecutive months), TB death is defined as any Death of a TB patient from all cause while on TB treatment or before starting treatment) (National TB leprosy and lung disease, kenya, 2017). Treatment interruption was defined as failure to attend TB clinic for drug collection or clinical evaluation for at least two weeks. It included both intermittent interruptions which means interruption for less than two months, where patients continue with treatment when they return to care, and lost to follow up where patients are registered afresh when they return to care after interrupting TB treatment for more than two months (Tola et al., 2019). The other form of treatment interruption where patients miss to take their daily doses as required was not included in this study.

In 2021, Kenya recorded a treatment success rate of 85% and a cure rate of 71% among all forms of TB, (DLTLD, 2020). Though the country posted a good treatment success rate, it

did not meet the program set target for the year which was set at 90%. The low treatment success rate was contributed by the high unfavorable treatment outcomes such as death (6.3%), lost to -follow up (5.4%), relapses, and treatment failures. Marsabit County is partly occupied by pastoralist communities who practice nomadic life style and usually move from one place to another with their livestock in search of water and pasture for their livestock. This consistent movement affects their access to health care due to long distance from health facilities occasioned by their movement when they settle far away from the health facilities. There are also issues related to acceptability of modern medicine among the communities where people first seek care from traditional healers when they get sick before they finally come to the health facilities very late in the stage of the disease. This delay in seeking care leads to low case finding and continued community transmission as well as treatment interruption by the patients (John, S., 2015). In Marsabit County, a treatment success rate of 77% with only 32% cure rate was achieved against the national target of 90% (MOH, 2018). The low treatment success rate was due to: death 4% (target <2%), lost to follow up 5% (target <2%), Not evaluated 10% (target 0%) and treatment failure 1% (target 0). The data on intermittent interruption of treatment are not usually reported at the national level, but are available in the TB treatment registers at the facility levels. More than 200 patients interrupted treatment out of which lost to follow up contributed about 3% of the treatment outcome in Marsabit County in 2018. Treatment interruption is a major cause of low treatment success in Marsabit County.

This study was designed to assess the determinants of TB treatment interruption in Marsabit County.

1.2 Problem Statement

Marsabit County reported a TB treatment success rate of 77% against the national target of 90% and only 32% of them were cured. Treatment interruption is a major contributor to the low treatment success and this can impact negatively on both Country and County performance in TB control**.** Treatment interruption can lead to development of drug resistant TB, and the involved patients can eventually die from TB. Untreated TB patient continues to transmit infection in the community, hence increase in prevalence of the disease. The factors associated with treatment interruption were not known in this nomadic population, making it difficult to put in place measures to improve TB treatment outcomes, and achieve the set treatment target.

1.3 Justification

Few studies have been conducted in the pastoralist communities. However, none of this nature had been conducted in Marsabit County, to establish factors contributing to TB treatment interruption. Data on intermittent treatment interruption if known will give clear picture of true treatment interruption in the county. The knowledge of the drivers of TB treatment interruption will help the national and county TB program design interventions to improve treatment outcomes and program performance, reduce development of drug resistant TB, reduce morbidity and mortality of TB patients, and address the unique challenges associated with treatment interruption in the nomadic population.

1.4 Research question

What are the determinants of TB treatment interruption among TB patients in Marsabit County?

1.5 Objectives

1.5.1 Broad objective

To assess determinants of treatment interruption among TB patients in Marsabit county.

1.5.2 Specific objectives

1. To determine the proportion of patients in Marsabit County, whose TB treatments were interrupted?

2. To determine factors associated with the treatment interruption among TB patients in Marsabit County.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

Tuberculosis treatment is almost always curable if appropriate treatment is started early and patients adhere to this treatment. Non adherence or poor adherence to TB treatment is a serious issue when it comes TB control. This can be a major barrier to the elimination of the disease effort in any program. In a study in New York City which included 184 patients with TB, nearly half of whom were none adherent to treatment of TB, it was found that the non-adherent TB patients took much longer time to convert to smear negative as compared to the patients who were adherent to treatment (254 days in non-adherent patients and 64 days among the adherent patients). These category of patients were more likely to develop drug resistant TB including the risk of developing multidrug resistance TB. This therefore required that treatment be extended beyond the standard duration (560 days for those taking longer to convert versus 324 days those converting within the intensive phase of treatment. Treatment adherence can be particularly challenging and is affected by; long duration of treatment which takes a minimum of six months. Patients gradually start being less adherent especially if they experience clinical improvement and the signs and symptoms of TB go away or reduced. Additionally the drugs used in TB treatment have toxic effect which can lead to patients to interrupt treatment. The factor affecting treatment interruption is the cost involved in treatment of TB patients. As much as TB treatment is free of charge, there are other indirect costs such

as cost of transport to access health facilities for clinical review and drug refill. Other costs involved are cost of accessing treatment for other illnesses including the side effects due to TB drugs. Patients with TB who are coinfected with other diseases such as Human Immune-competency Virus infection (HIV), can interrupt their TB treatment due to the burden of taking too many drugs at per dose (polypharmacy) when they are on treatment for all their conditions.

The effective management of both drug susceptible and drug resistance TB depends on rapid world health organization's recommended molecular diagnostic tests (mWRDs) such as GeneXpert, as well as effective treatment regimen to kill both drug susceptible and drug resistant strains of mycobacterium tuberculosis. Culture and drug susceptibility testing is currently used as the gold standard for identification of drug resistant strains of mycobacterium tuberculosis. The DST for mycobacterium tuberculosis complex (MTBC) relies on single critical concentration of anti-mycobacterium agent which helps differentiate drug susceptible from drug resistant strains of mycobacterium tuberculosis complex. The DST is specific for each anti-tuberculosis drug used in the treatment regimen and the method used to test. The drug susceptibility testing for testing of susceptibility to anti-tuberculosis drugs serves the following purpose: They guide in the selection of chemotherapy to be used for patients, they can also be used to confirm presence of drug resistance in a patient who has failed to satisfactorily respond to the first line or second line TB treatment. Lastly they can be used for surveillance of emergence of drug resistance TB in patients who are on anti-TB treatment (WHO, 2018).

In this section we described patient from diagnosis all the way to discharge from treatment including the treatment regimen used. We highlighted best practices and difficulties encountered in the treatment process of TB patients. Key areas of focus included the main TB patient type, mainly new, relapses, and treatment after lost to follow up, treatment after failure of first line. Policies and diagnostic algorithm as available in various countries, programmatic management of TB in Kenya, TB surveillance and TB drug resistance.

2.2 Tuberculosis diagnostic algorithm, Surveillance and drug resistance

TB is a disease of global concern in both low, middle and high income countries and has become more complex due to increasing elderly populations globally as well as the rise of drug-resistant strains of mycobacterium tuberculosis (Yon Ju Ryu, M.D., 2015). In medical practice, the diagnosis of TB can be difficult, and early diagnosis of pulmonary TB continues to be challenging for clinicians. Prompt diagnosis of active pulmonary TB is a priority for TB any national TB control programs. Early detection and appropriate treatment of TB is important for two main reasons. Firstly the individual patient would be started on treatment and hence improvement in clinical signs and symptoms and eventually the patient is cured of TB. Additionally the correct diagnosis and treatment of TB is considered a major public health intervention as it helps in cutting on the transmission chain of TB in the community (Yon Ju Ryu, M.D). Furthermore, TB sometimes presents with atypical signs and symptoms and radiologic findings that cannot be distinguished from those of other lower respiratory tract disease such as community-acquired pneumonia. This similarity can result in making it difficult for clinicians to miss diagnosis of TB and instead treat patients for pneumonia which then leads to delay in the

diagnosis of TB sometimes by up to six months. The current recommendation on the diagnosis of TB in Kenya recommends that any patient presenting with any of the four cardinal symptoms of the respiratory tract be screened for TB and any presumptive TB patients be investigated promptly with the molecular world health organization recommended rapid diagnostic tests (mWRDs) such GeneXpert, Truenat etc. and started on treatment immediately. Culture and drug susceptibility tests can also be used to identify mycobacterium tuberculosis and also determine the resistance pattern of the different drug molecules. However, mycobacterial culture, which has the highest sensitivity for diagnosing and confirming active TB, takes longer period for growth and interpretation (2 to 8 weeks) and this can delay treatment in case of negative results. In some instances sputum smear microscopy can be used to diagnose TB. However, though simple and inexpensive tool to use, microscopy has low and variable sensitivity (Yon Ju Ryu M.).

The world health organization's End TB strategy of 2015-2035 which focuses on TB prevention, care and control calls for early diagnosis of TB and universal culture and susceptibility tests (DST). The strategy also outlines the important role played by laboratories in the diagnosis of TB. In order for countries to meet the End TB strategy, World Health Organization recommends the use of molecular rapid diagnostic tests for diagnosis of TB (mWRDs) in persons presenting with signs or symptoms of TB. In recent years, non-molecular and molecular diagnostic tests have been developed and recommended by the world health organization for early detection of active TB. Some of these methods can detect resistance to the mycobacteria bacilli such as rifampicin while others can only detect the bacilli but cannot detect resistance.

The diagnosis of TB is from a combination of manifestation of symptoms, clinical signs and laboratory investigations. Pulmonary TB refers to any bacteriologically-confirmed or clinically-diagnosed case of TB that involves the lung parenchyma or the tracheobronchial tree based on the revised previous standard case definitions for TB by the World Health Organization (WHO) in 2013 Additionally, all the bacteriologically confirmed TB patients should receive DST for rifampicin, and all patients with rifampicin resistance receive DST for other first line TB medicine including Isoniazid, Ethambutol and pyrazinamide if available and further DST for second line medicines including the injectables and fluoroquinolones. In this regard therefore there is need for the National TB control programs to prioritize and develop network of TB diagnostic laboratories that use the modern mWRDs, and establish effective referral systems for sample referrals, standard operating procedures (SOPs), and quality assurance processes adequate biosafety and human resource capacity. The priorities are included in the national strategic plans and well-funded to address the strategy of ending TB by 2035. While the newer molecular rapid and more sensitive diagnostic tests (GeneXpert, Truenat, the loop-mediated isothermal amplification-TB LAMP, and line probe assay-LPA) are used for early identification of drug susceptible and drug resistant mycobacterium tuberculosis complex bacteria, the use of the conventional diagnostic tools such as microscopy and culture have been retained for the purpose of monitoring of treatment of TB to ensure conversion, and cur.. These tests are also used to address the gaps in the newer approved molecular tests such as DST for other important TB drugs- like pyrazinamide, Bedaquiline, Delaminid, and testing of other respiratory specimens. The implementation of the newly approved rapid diagnostic algorithm is guided by the country specific formal evaluation and

modification to the testing algorithm and approval by the ministry of health and the national TB programs for use (Global Laboratory Initiative model TB diagnostic algorithms, 2018).

Presumptive TB cases are identified through systematic screening of people with respiratory symptoms using WHO published guidelines for systematic screening for active TB in 2013 which was later reviewed in view of new evidence for screening for active TB disease. In this regard the screening tools recommended by WHO are: chest radiography, Computer aided detection (CAD) of TB software technology, C-reactive protein.

The world health organization recommends three laboratory diagnostic algorithm including: For the initial diagnosis of all presumptive TB cases, follow up of patients on the first-line treatment, TB treatment and DRTB follow up (Europe W. H., 2017). Presumptive TB cases are subjected to two sample collections for both microscopy and GeneXpert or Truenat and culture and drug susceptibility testing (DST) (DNLTD-P, 2017). Follow up tests are done with the aim of monitoring progress of the patients on treatment, smear conversion and eventually cure. Molecular diagnostic methods such as GeneXpert and culture and DST are used to diagnose for TB from presumptive TB cases as well as identify resistance patterns. The molecular world health organization recommended rapid diagnostic tests such as GeneXpert or Truenat is used to diagnose TB as well as identify resistance patterns of rifampicin, while culture and drug susceptibility testing is used to test for others (culture DST). GeneXpert is a more sensitive diagnostic test than smear microscopy. However, the conventional microscopic methods of diagnosis are retained for the purpose of follow up of treatment monitoring. Where the GeneXpert

and smear microscopy gives negative results in a patient with symptoms of TB, chest X-rays can be done to reveal lung field changes suggestive of TB to aid in the diagnosis. The histology is performed for all presumptive extra pulmonary TB cases (DNTLD-P, 2017). Tuberculosis is classified by the site of the disease into pulmonary TB, and extra pulmonary TB. It is also classified by type of patient and type of TB into new/retreatment and drug-sensitive and drug resistant TB.

Diagnostic methods

a). Radiologic study

Any patient who presents with a cough of any duration or with unexplained fever, night sweats and/or weight loss should be evaluated for TB. Chest X-ray which is the primary radiologic evaluation method of people presumed to have pulmonary TB. Radiological presentation of TB may vary but in many cases is quite characteristic. Radiology may also provide essential information for management and follow-up of pulmonary TB patients. It is a valuable tool for monitoring complications of pulmonary TB. However, Chest X-ray is not specific and therefore cannot be used to confirm the diagnosis of pulmonary TB. Sometime Chest X-ray may appear normal even when the disease is present. Since it cannot be used to confirm TB diagnosis, it is always necessary to follow it up with a confirmatory diagnosis using laboratory methods for example sputum smear microscopy or molecular tests. Many of the atypical manifestations of pulmonary TB are actually usual manifestations of primary disease. Post-primary TB in adults which usually typically develops in people with sufficient immunity which clears and heals caseation granulomas from the primary TB and is typically restricted to the upper lobes of the lung with no evidence of infection in any other part of the body. It manifests as a heterogeneous, often

cavitary opacity in the apical and posterior segments of the upper lobes and the superior segments of the lower lobes. Lymphadenopathy is a rare presentation in post primary TB. Cavitation is the most common presentation on chest X-ray of post-primary TB and appears in about half of all TB patients. Patchy, poorly defined consolidation in the apical and posterior segments of the upper lobes and in the superior segment of the lower lobe is also commonly observed. However, chest X-ray cannot be used to assess accurately post-primary TB disease activity. However, this can be done when combined with laboratory follow up results. For example, radiographic stability for 6 months and negative sputum cultures can be used as indicator of inactive disease (Yon Ju Ryu M. , 2015). The other radiologic feature of a Post-primary TB is that it usually heals with parenchymal scarring and nodules. An important task for radiology is to determine whether these residual findings are indicative of active disease. This is a limitation for the use chest X-ray, since it can only establish that a lesion is stable, and stable lesions can contain active bacilli. Chest computed tomography (CT) is generally required to detect fine lesions that can be overlooked on chest X-ray, to define equivocal lesions, or to evaluate complications. Chest CT is an effective diagnostic method when plain films are normal or inconclusive, and it provides valuable information for managing the illness. Chest CT can add valuable information for detecting bacterial activity. Branching opacities, cavitation, or consolidation are clear signs of active TB, but active disease must be confirmed by analyzing sputum for the presence of bacilli .Tree in-in-bud pattern is a significant radiologic finding in chest CT. It consists of multiple branching linear structures that represent bronchogenic dissemination of disease with caseating necrosis in the respiratory and terminal bronchioles. These branching opacities have a lobar or segmental distribution

and are considered reliable markers of activity. Tree-in-bud opacities are also seen in other infections, but when visualized in combination with cavitation or nodular opacities in the upper and posterior lung segments, and in the appropriate clinical setting, a specific diagnosis of pulmonary TB can be established. While chest CT is useful for clarifying confusing findings, it has not been conclusively shown to have a significant impact on patient management, therefore microbiological identification of TB by culture should follow this test.

b). Acid fast bacilli smear microscopy and culture

For the diagnosis of pulmonary TB, sputum sample is commonly used for laboratory testing, where direct sputum smear microscopy is the most widely used method for the diagnosis of pulmonary TB. Smear microscopy is widely available in most primary health-care laboratories at the peripheral health facility level. Smear microscopy may, however, be costly and inconvenient for patients, who must make multiple visits to health facilities and submit multiple sputum specimens over several days. For a sputum smear microscopy diagnosis, patients are required to make several visits to the health facilities for sputum sample collection (spot, morning and spot samples) which makes expensive for the patients due to expenses incurred in the process of accessing the facilities including the transport cost. Fortunately, good-quality microscopy of two consecutive sputum specimens has been shown to correctly identify the most (95%–98%) of smear-positive TB patients (Yon Ju Ryu, M.D., 2015). The WHO policy recommendation on the diagnosis of TB using microscopy recommends a reduction in the number of specimens examined to detect mycobacterium tuberculosis from three to two in settings where appropriate external quality assurance and documented high quality microscopy is

practiced and adhered to. In addition, the WHO recommends that countries that have successfully implemented current WHO recommendations for a two-specimen AFB microscopy strategy to detect TB can consider switching to same-day diagnosis and treatment initiation, especially in settings where patients are likely to default from the diagnostic process. The Kenya guideline for TB, Leprosy and Lung Disease recommends that presumptive TB patients should have multiple sputum samples, at least two, and allows first sputum sample for front-loaded or same-day microscopy. Conventional smear microscopy of Ziehl-Neelsen–stained smears prepared directly from sputum specimens is the most widely available test for diagnosing TB in resource-limited settings. This method is highly specific but has varied sensitivity level ranging between 20% to 80%. Fluorescence microscopy is more sensitive (10%) than the Ziehl-Neelsen and takes less time, but it has some limitation including the high cost of mercury vapor light sources, the high cost of regular maintenance, and the fact that dark room is required for its use. To cover for some of these limitations, light-emitting diodes (LED) have been developed to offer fluorescence microscopy without the associated costs. The efficacy of LED microscopy was assessed by the WHO and evaluated by standards appropriate for the accuracy and the effect of new TB diagnostics on both patients and public health. The accuracy of LED microscopy was equivalent to that of international reference standards. It was found to be more sensitive than conventional Ziehl-Neelsen microscopy with qualitative, operational, and cost advantages over both conventional fluorescence and Ziehl-Neelsen microscopy. It was based on these findings that the WHO recommends conventional fluorescence microscopy to replace LED microscopy and that LED microscopy be phased in as an alternative for conventional Ziehl-Neelsen light

microscopy. The direct smear microscopy technique, although specific, has low and variable sensitivity. It cannot also be used to identify drug-resistant strains of mycobacterium tuberculosis. It is therefore required that clinicians obtain the diagnosis of TB as well as establish the resistance patterns for the various molecules of TB medicines using mWRDs such as GeneXpert and or culture and DST whenever possible.

Mycobacterium tuberculosis culture is mainly done on solid media, the Lowenstein Jensen slope, or in broth media. The culture method from microscopy-positive material is usually a slow process taking between 2–4 weeks and for microscopy-negative material from 4–8 weeks. TO shorten this long duration Therefore, liquid media is used as the mycobacteriology method of choice for initial isolation, since it is significantly faster taking between 10 and 14 days. It is also better for isolation, compared to the solid media. Using this method, the delay may be reduced to as little as 10 days compared to 4–6 weeks with conventional solid media. The liquid systems are more sensitive in detecting mycobacteria and increases the yield by up to 10% over solid media. With increased sensitivity and reduced delays, liquid systems may contribute significantly to improved patient management in terms of early detection of resistant strains. However, the liquid systems have some limitation. This include being more prone to contamination by other microorganisms, failure of specimen to yield results due to contamination. For example in experienced laboratories, approximately 5%–10% of specimens fail to yield results. Procedures to prevent cross-contamination (due to carryover of bacilli from positive to negative specimens) should also be strictly followed, especially where increased numbers of positive specimens are processed in high-incidence countries. Solid media are made of agar, egg, and malachite green to limit the growth of remaining contaminants

(Lowenstein, Stonebrink, or Ogawa medium). Liquid culture and DST systems are more complex and sensitive than solid culture and DST media. Increased bacterial contamination and an increased frequency of nontuberculous mycobacterial (NTM) isolation must be addressed. Several manufacturers in the effort to differentiate Mycobacterium tuberculosis complex and Nontuberculous mycobacterium have come up with rapid tools that can automatically detect Mycobacterium tuberculosis growth in the laboratory, this include Bactec "Mycobacterial Growth Indicator Tube 960" (MGIT 960; Becton-Dickinson, Sparks, MD, USA) and the MB/Bact Alert 10 3D (Biomérieux, Durham, NC, USA). The automated tools for liquid culture however, have some disadvantages in that they are expensive, they do not give rapid mycobacterial species' identification, and they do not identify contaminated or mixed cultures. In contrast, cultures on solid media provide all of this information with a simple observation of colonies. The current guideline recommends that all specimens cultured on liquid media also be inoculated on solid media to ensure purity and provide sufficient strength for the diagnosis.

c). Molecular methods

Nucleic acid amplification testing (NAA)

These are reliable tests which helps increase the specificity of diagnosis of TB. However, the sensitivity of the test is too low and it's not easy to rule out the disease, especially in smear-negative or paucibacillary disease like in children where clinical diagnosis on the basis of clinical presentation and radiological findings are critical for the diagnosis of TB Compared with AFB smear microscopy. The advantage of NAA testing is that it has greater positive predictive value (PPV) (>95%) with AFB smear-positive specimens in

settings in which NTMs are common and it has ability to rapidly confirm the presence of Mycobacterium tuberculosis in 50%–80% of AFB smear-negative, culture-positive specimens. Compared with culture, NAA tests can detect the presence of Mycobacterium tuberculosis bacteria in a specimen weeks before culture for 80%–90% of patients presumed to have pulmonary TB whose TB is ultimately confirmed by culture. Although NAA testing is recommended to perform the initial diagnosis of persons presumed to have TB, the currently available NAA tests should not be ordered routinely when the clinical suspicion of TB is low because the PPV of the NAA test is less than 50% for such cases. The United States' Centers for Disease Control and Prevention (CDC) recommends that NAA testing should be performed on at least one respiratory specimen using a Food and Drug Administration (FDA)–approved test from each patient that has signs and symptoms of pulmonary TB for whom a diagnosis of TB is being considered but has not yet been established and for whom the test result would alter case management or TB control activities such as contact investigations. A single negative NAA test result cannot be used as a definitive result to exclude TB, especially when clinical suspicion of TB is moderate to high. Rather, a negative NAA test result should be used as additional information in making clinical decisions, to expedite testing for an alternative diagnosis, or to prevent unnecessary TB treatment.

Line probe assay

Conventional methods for mycobacteriological culture, identification of a Mycobacterium tuberculosis complex and DST are slow and cumbersome, therefore, rapid DST of isoniazid and rifampicin or of rifampicin alone using molecular technologies is recommended over conventional testing in sputum smear-positive or culture proven cases

at risk of multi-drug resistant DRTB, such as previously-treated patients. Line probe assay (LPA) has been widely available for the purpose of rapid DST. This is a type of molecular assay that can allow specific gene markers associated with rifampicin resistance alone or in combination with isoniazid to be detected. Resistance to isoniazid occurs primarily due to mutations in katG, followed by mutations at the InhA active site (20%–35%) and in the promoter region of ahpC. Mutations in the rpoB region are found in about 96% of rifampicin -resistant Mycobacterium tuberculosis isolates. According to systematic reviews and meta-analyses to evaluate assay performance, results that compared conventional DST methods showed that LPA are highly sensitive (≥97%) and specific (≥99%) for detecting rifampicin resistance, alone or in combination with isoniazid (sensitivity ≥90%; specificity ≥99%), in Mycobacterium tuberculosis isolates and in smear-positive sputum specimens. However, LPA cannot replace conventional culture with DST, and mycobacteriological culture for smear negative specimens with DST because second-line anti-TB drugs are still required (WHO, 2022).

Xpert MTB/RIF

The Xpert MTB/RIF assay is a novel, rapid, automated, and cartridge-based NAA test that can detect TB along with rifampicin resistance directly from sputum within 2 hours of collection (WHO, 2013). The GeneXpert cartridges are pre-loaded with all of the necessary reagents for sample processing, DNA extraction, amplification, and laser detection of the amplified rpoB gene target. The GeneXpert cartridges are pre-loaded with all of the necessary reagents for sample processing, DNA extraction, amplification, and laser detection of the amplified rpoB gene target. One of the advantages of the Xpert MTB/RIF method is the fact that it can be accurately administrated with minimal hands-on

technical time. It has fairly high sensitivity and specificity for TB detection The Xpert MTB/RIF test is a valuable, highly sensitive, and specific new tool for early TB detection and for determining rifampicin resistance. While it should be noted that mono-resistance to rifampicin is found in approximately 5% of rifampicin-resistant strains, a high proportion of rifampicin resistance is associated with concurrent resistance to isoniazid (~95%). Thus, detecting resistance to rifampicin can be used as a marker for MDR-TB with a high level of accuracy (Karin Weyer et al, 2012). In a study of the performance of Xpert MTB/RIF, among 561 culture-positive patients (561/1730), a single, direct Xpert MTB/RIF test identified 98.2% (551 out of 561) of the sputum smear-positive TB cases and 72.5% (124 out of 171) of those with sputum smear-negative TB. The test was specific in 604 of 609 patients (99.2%) not affected by TB. A second Xpert MTB/RIF test among patients with sputum smear-negative, culture-positive TB increased detection sensitivity by 12.6% and a third by 5.1%, to reach 90.2%. When compared to phenotypic DST, the Xpert MTB/RIF assay correctly identified 97.6% (200 out of 205) of patients harboring rifampicin-resistant strains and 98.1% (504 out of 514) of those with rifampicin-susceptible strains (Catharina C. Boehme et al, 2011).

2.3 Tuberculosis care and treatment

The history of TB treatment dates back to 1940s when treatment was done using streptomycin and P- amino salicylic acid up to 1980 when the current drug of isoniazid, rifampicin, pyrazinamide and ethambutol were initiated. Currently fixed drug combination of four drugs (Rifampicin, Isoniazid, Pyrazinamide and Ethambutol, RHZE) are recommended for use in the intensive phase and rifampicin and Isoniazid (RH) in the continuation phase in Kenya (DNLTD-P, 2017).The objectives of TB treatment is to cure

individual patient, decrease the disease transmission and prevent development of drug resistant TB (CDC, 2016). The guidelines recommend use of case management interventions and directly observed therapy short course DOTS) using fixed drug combination to treat TB to minimize non-adherence to treatment and drug resistance of TB. In Kenya TB management structure is run by the division of national TB leprosy and lung disease (DNTLD-P). The same structure is cascaded to counties and sub-counties. Program officers and county and sub county coordinators play the role of carrying out program activities at the national and county levels respectively.

2.4 Reasons TB patients fail to adhere to treatment

There are several factors that can lead to TB patients interrupting their treatment. Several studies have shown factors such as type of TB, type of patients, sex of patient, type of DOTS, previous history of TB, drug-related side/adverse effects, long distance to the health facility, long average waiting time at the facility to collect drugs, HIV and nutritional status of the patient, use of alcohol and herbal medication can all affect level of adherence to TB treatment.

A cross-sectional study conducted in Nandi County of Kenya in 2015 by Wanyonyi et al on factors associated with treatment interruption found that 31% of all TB patients interrupted their treatment. The study found that factors such as use of herbal medication, presence of drug side effect during treatment, inadequate knowledge of TB disease transmission, average waiting time of more than one-hour at the health facility, and low monthly income of less than kshs. 10,000 contributed to high proportion of treatment interruption among TB patients in Nandi County. On the other hand, being accompanied

to the treatment health facility by a relative, having knowledge of diagnosis before initiation of treatment, distance of less than 10km from the health facility were found to be associated with decreased treatment interruption (Wanyonyi, Alfred Wandeba, 2015). This study was conducted in a more sedentary community of Nandi with a slightly different lifestyle as compared to the largely pastoralist community of Marsabit county. This will therefore bring out similarities and differences in factors associated with treatment interruptions among these communities. There is also difference in level of formal education between these two counties which might have influence on the level of treatment interruption.

A prospective cohort study which was conducted in Kenya by Jepchumba V. Karanja S and Amukoye E. and others on timing and determinants of tuberculosis treatment interruption in Nairobi Kenya looked at estimated median time to treatment interruption, associated factors and overall predictors of non-adherence to TB treatment. This study observed that 6.5% of the TB patients interrupted treatment. Patients in private health facilities and public health facilities with adequate number of healthcare workers where directly observed therapy (DOTS) by healthcare workers can be done had less odds of interrupting treatment compared with those with in public health facilities with inadequate healthcare workers. Treatment interruption was also found to be higher among the patients who had attained secondary level of education (Jepchumba, Violet, 2017). This was a prospective cohort study and it had largely similar findings as the above cross-sectional studies. However, higher level of education is expected to be associated with less treatment interruption since the patients are more knowledgeable and understand the risk of TB disease transmission and consequences of non-adherence to treatment. Availability

of DOTS also seem to increase adherence to treatment. Other studies that had similar findings on factors associated with TB treatment interruption include a study in India on assessment of treatment interruption among pulmonary TB patients which made an assessment of treatment adherence among pulmonary TB patients admitted to the hospital and with previous history of treatment with anti-TB drugs for 1- month or more from any source and who returns to treatment after not taking TB drugs for 2 months or more. The study found that 62% of the patients interrupted treatment only once, 55.34% of which interrupted during the continuation phase (3-4months) of treatment. There were various reasons given for interruption of treatment. This included patient feeling well after initial phase of treatment (29.53%), due to side effects of the drugs (16%), Lack of money for transport to attend clinic (8.29%). Other factors that were associated with treatment interruptions found by this study were age between 30 and 60 years, male gender, lack of or low level of education, low level of income (daily wage labour), being married (Gorityala, Satya Bhgath, 2015). The author of the study concluded that treatment interruptions can be improved through strengthening of direct supervision (DOTS), patient counseling before initiation of treatment, and retrieval of treatment interrupters. Factors associated with treatment interruptions can be divided into patient factors, health worker related factors and health system related factors. Adherence to treatment can be affected by any of the factors.

Another study conducted in Kenya by E. Masini et al considered patient-related factors that contributed to treatment interruptions among TB patients. This study looked at survival analysis to identify risk factors associated with TB treatment interruption among new and previously treated TB patients in Kenya. The study found that treatment

interruption among new TB patients was 4.5% while previously treated patients had a treatment interruption of 8.5%. Patients with previous history of lost to follow up were found to be at higher independent risk for treatment interruption (19.7%). Other factors related to increased risk of treatment interruption were; being HIV-positive especially if not yet initiated on anti-retroviral therapy (ART) compared with those on ART or HIV-negative patients, and a history of previous TB (Relapse). Male gender (5.4%) compared with female (3.7%) as well as malnutrition were also found to contribute to treatment interruption. Targeted interventions to patients during intensive phase of treatment, previously treated patients and integration of TB/HIV services were recommended by this study (Masini, Enos O., 2016). However, the study did not consider age as a factor for treatment interruption.

Service provider level risk factors combined with patient level risk factors are significantly associated with TB treatment interruption as found by a case control study which was conducted by Finlay and Alysa in 2012 in south Africa to assess patient level and provider level risk factors associated with treatment interruption among TB patients. It was found in this study that 22% of patients who were initially classified as lost to follow up actually died in the first two months of stopping treatment, hence were misclassified as lost to follow up. Poor healthcare worker attitude and change of residence during TB treatment period were mentioned by both new and previously treated patients as reasons for treatment interruption. Additional reasons for treatment interruption among new patients included not receiving adequate counseling during TB treatment, lack of formal education, feeling ashamed to have TB (stigma), drinking of any alcohol during TB treatment, seeking care of a traditional healer during TB treatment. Factors leading to

treatment interruption among previously treated TB patients were previous history of lost to follow up, not feeling better on TB treatment (Finlay, Alyssa, 2012). In this study only 26% of patients who were lost to follow up were traced and interviewed by the study team, this therefore might have affected validity and power of the study.

From the literature review it's evident that treatment interruption can lead to more complications of TB disease including severe disease, development of drug resistant TB, or even death. Treatment interruption is associated with several factors. These factors can be patient-related factors such as going to traditional healers, history of previous lost to follow up and previous history of TB treatment, side effects of the drugs, feeling better on treatment or lack of improvement on TB treatment, stigma, male gender, low level of education, lack of money to attend the clinic. It can also be healthcare provider factors e.g. lack of adequate counseling and pre-treatment patient education, poor healthcare worker attitude towards TB patients. Health system related factors can also be attributed to treatment interruption these are distance to the nearest health facility, longer waiting time at the health facility to access services. Studies have found that up to 60% of TB patients interrupt treatment in some instances hence risking related complications and increased TB mortality.

Minimizing TB treatment interruption is important if we are to reduce TB related deaths and risk of developing drug resistance among TB patients in Kenya. Studies have proposed strategies to reduce treatment interruption. Pre-treatment patient education and counseling, early identification of patients who are at risk of interrupting treatment and instituting measures to prevent treatment interruption such DOTS by healthcare worker can help prevent treatment interruption. Most of the studies focused on urban settlements

but few had looked at pastoralist populations where access to healthcare is poor with distance to health facilities as far as 50km. Pastoralist communities move from one place to another with their livestock and this further affects access to health care in a unique way. Low level of education among the pastoralist communities is a contributing factor to treatment interruption. Our study will therefore help identify factors associated with treatment interruption among the agro-pastoralist population of Marsabit County as well as determine period from initiation of treatment and treatment interruption and recommend ways of preventing or reducing treatment interruption.

Conceptual framework

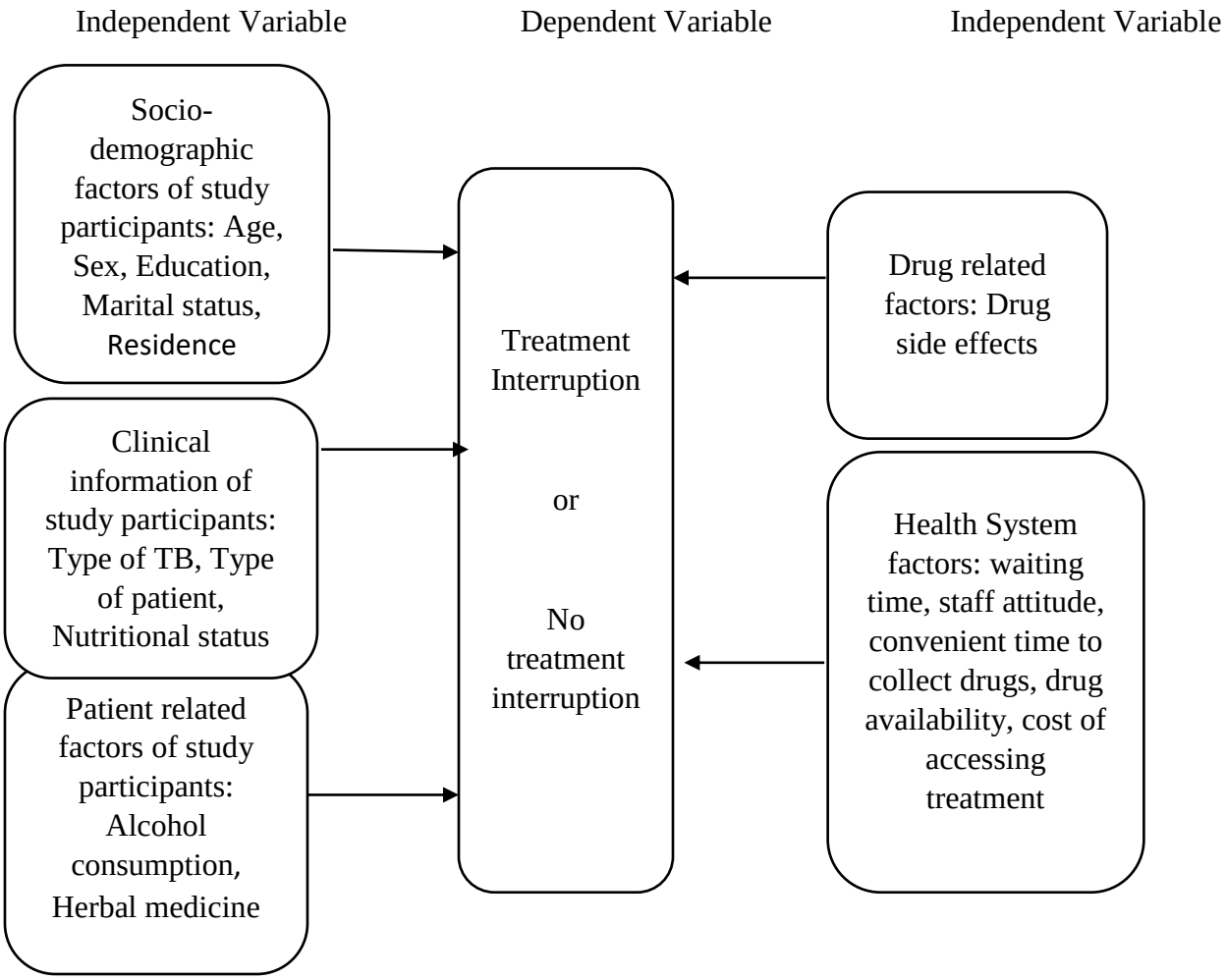

Figure 2.1: Conceptual framework

The conceptual framework for the study has two variables which are dependent and independent variables. The independent variables such as the socio-demographic, clinical information of the study participants, patient related factors and the health system and health care provider related factors determine the outcome or dependent variables which is either treatment interruption or no treatment interruption. This conceptual framework is a snapshot of interaction between the independent and dependent variables.

CHAPTER THREE

RESEARCH METHODOLOGY

3.0 Introduction

3.1 Study Area

The study was conducted in all the 4 sub-counties of Marsabit County namely North Horr, Laisamis, Saku, and Moyale which are also known as TB control zones. Marsabit County is located in Northern Kenya. It has a total surface area of 70,961.2 KM^2 and a population of 459,785 persons (Kenya national bureau of statistics, 2019) with the male population of 243,548 (53%). The county borders Turkana County to the west, Samburu and Isiolo Counties to the south and Wajir County to the east. It also has an international border with Ethiopia to the north. Majority of the population of Marsabit County practices pastoralism way of life where they seasonally move from one place to another in search of water and pasture for their livestock. This episodic migration of the nomadic population leads to poor access to health care among the pastoralist community (Abdi A. Gele, Mette sagbakken et al, 2010) hence potentially encouraging treatment interruption by TB patients. The county is also sparsely populated with a population density of 11 people per square kilometer (County integrated development plan 2018-2020). The county is served by 104 health facilities; 4 level 4 hospitals including county referral hospital, 25 health centers, and 80 dispensaries. There are 75 TB treatment facilities, 23 out of which provide TB diagnostic services which are distributed across all the 4 sub counties.

The leading causes of morbidity and mortality in Marsabit County were respiratory tract infections, diarrheal diseases, pneumonia, and skin diseases. The county has a total

fertility rate of 5 children per woman (Kenya 3.9) and an HIV prevalence of 1.4% (National AIDS and STI Control programme, 2018).

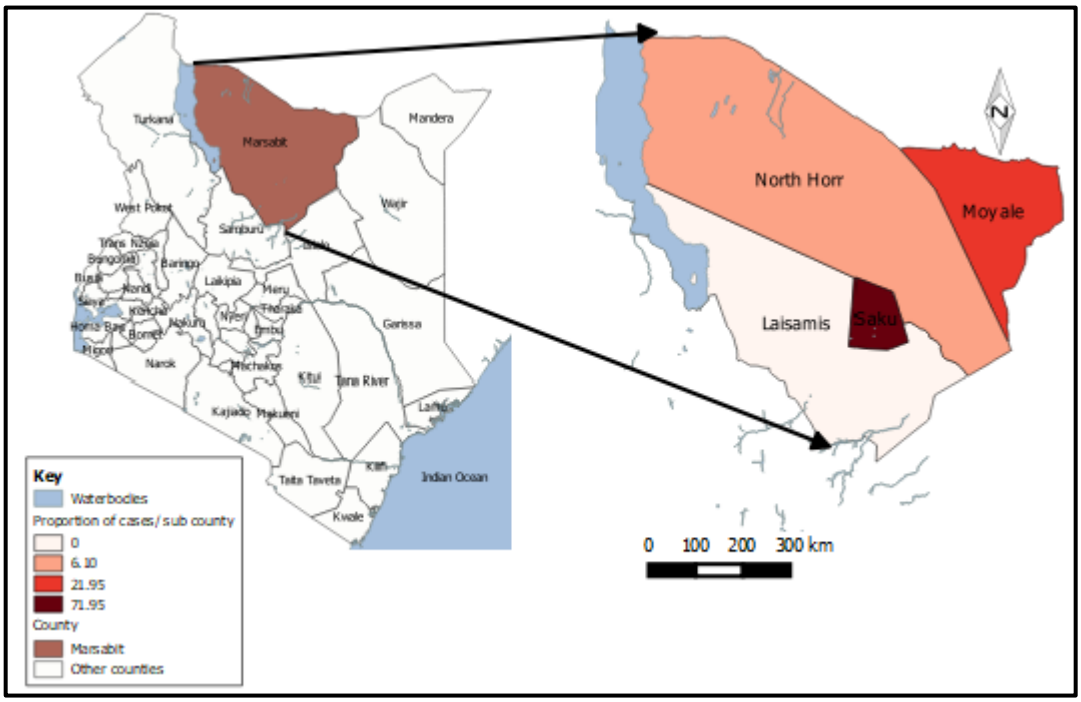

Figure 3.1: Map of Kenya showing location of Marsabit county and study areas

3.2 Study design

This was a community based cross-sectional study, conducted from May 2021 to October 2021.It involved retrospective review of drug susceptible TB data in the sub-county TB treatment registers for the patients diagnosed and started on treatment between 1st of January 2019 to 31st of December 2020,as well as collection of patient data using standard questionnaire.

3.3 Study population

The study population was all drug-susceptible TB patients above 14 years of age. Drug susceptible TB was defined as infection with TB bacteria that are fully susceptible to all the category I TB drugs including rifampicin, isoniazid, Pyrazinamide and Ethambutol in a fixed drug combination (FDC) and are taken to provide effective TB treatment.

3.4 Inclusion criteria

1. Drug susceptible pulmonary and extra pulmonary TB patients in the TB treatment registers who are more than 14 years of age and started on treatment between January 2019 and December 2020 in the selected Marsabit county health facilities.

3.5 Exclusion criteria

1. Drug susceptible pulmonary and extra pulmonary TB patients whose data on socio-demographic and clinical information were missing in the register since incomplete data will not give the required information for the sturdy

2. Those whose record indicate transfer out of Marsabit County.

3.6 Sample size determination

The sample size was determined using the Cochrane formula (1977) (Yılmaz, n.d.) With the following assumptions.

$n_o = Z^2pq/e^2$

Assumptions:

- Z is the 95% confidence interval;
- P is the expected incidence of tuberculosis in Marsabit county-. Expected incidence was estimated at 0.33 from a study in Nandi on factors associated with treatment interruption (A. Wanyonyi, P. Wanjala, J. Githuku et al, 2015) , and q=1-p, n_0 is the sample size. e is the precision
- Z - 95% confidence intervals 1.96,
- e -Acceptable margin of error =0.05,

$1.96^2(0.33(0.67)/0.05^2) = 339.75= 340$

Non-response of 10% was adjusted: n/1-0.1=340/1-0.1= 340/0.9=377

3.7 Probability proportional to size

The sample size was proportionately distributed based on the proportion of cases contributed by each sub county**.** This was achieved by obtaining the proportion by each county which was calculated by dividing the number of TB cases in each sub county by the total county TB cases. The sample size by each sub county was then obtained by multiplying the proportion by the total sample size (table1 below).

Table3.1: Sample size allocation by sub county, Marsabit County, 2020

Sub county	TB 4 register* 2019-2020)	Proportion (sub county TB cases/Total County TB cases)	Sample size (Sub county proportion X Total Sample size)
Moyale	558	0.52	177
Saku	334	0.31	106
North Horr	70	0.07	22
Laisamis	107	0.1	34
Total	1069		340

*****TB 4 Register- Sub county TB coordinator's register, this register is updated with TB data from the health facilities monthly before it is reported on TIBU

3.8 Sampling Method

Random sampling was used to identify potential study participants in every sub county using the sub county TB treatment register for 2019 and 2020 as a sampling frame. Table of random numbers was used to generate the participants from a sampling frame (TB register) of each sub-county**.** The study participants identified in the TB registers were contacted using the mobile number provided in the treatment registers. However, for those whose contacts were not provided i used local leaders such as chiefs and assistant chiefs of the area as well as the village elders and the community health volunteer. Study participants who were not traced using any of the above methods were replaced using randomization method and replacement was done up to three times. Randomization was done using those in the treatment registers and were not selected into the study before. The TB patients who were in the TB treatment registers were listed numerically and required number was selected using the table of random numbers.

There were a total of 1779 records of TB patients in the register who were initiated on treatment between January 2019 to December 2020 in Marsabit County health facilities. Of these 364 patients were excluded; 193 were children 14 years and while 79 patients died in the course of TB treatment, 92 were transferred out to another county to continue treatment. A total of 340 study participants were selected through random sampling from the remaining 1415 patients to participate in the study. During data collection, out of the 340 selected participants, 22 were reported to have died after treatment completion from other causes. Twenty-eight (28) of them declined to be interviewed while 20 were not traced (Fig 3.1 below).

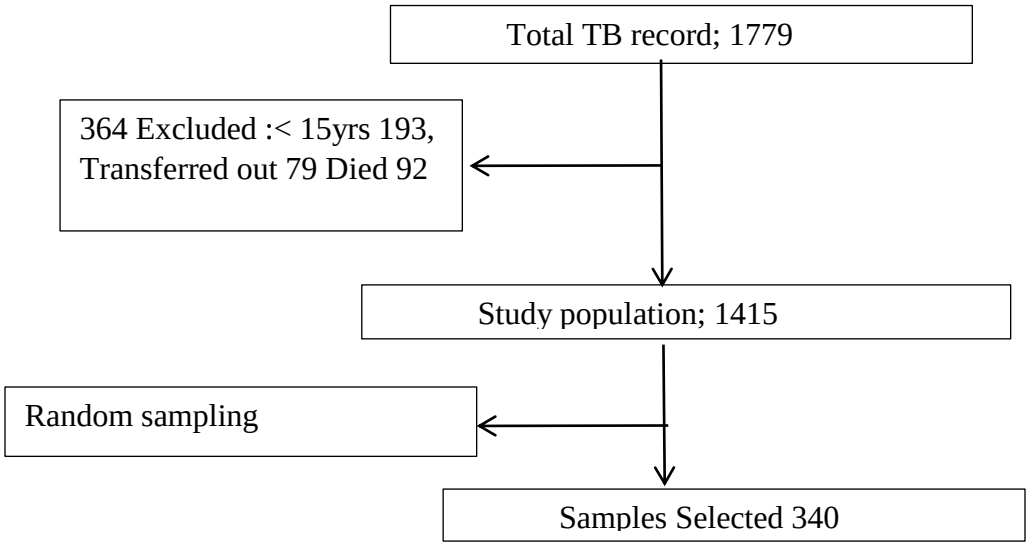

Figure 3.2: Flow chart showing study participants recruitment, Marsabit County, 2020

3.8 Data collection

3.8.1 Proportion of patients whose TB treatments were interrupted

Data was collected using standard checklist and semi-structured questionnaire**.** This questionnaire was translated into Borana local language which was the most commonly spoken language in the area. Research assistants were recruited and trained on the objective of the study and data collection. After identifying the participants from the registers they were contacted using the telephone numbers indicated in the register to locate them and the research assistants travelled to where the participants were and administered the questionnaire. For the study participants who understand English the questionnaire was directly read out to them, while for those who could not read and write, it was read to them in the Borana language if that is the local language they understand. For those that do not speak any of the languages, the data collectors used translators to translate for them into their own local languages. The questionnaire was piloted in the neighboring Isiolo County and the findings were used to adjust them appropriately before implementing them in the study area.

3.8.2 Factors associated with the treatment interruption among TB patients

The following data were abstracted from the TB register using a standard checklist;

1. TB patient clinical information which included the Type of TB, Type of patient, Nutritional status of the patient, HIV status of the patient

2. Type of DOTS supporter,

The data on; 1. Data on sociodemographic which included sex, age, residence

2. Behavioral factors such as alcohol consumption, herbal medicine
3. Medicine related factors such as drug-related side effects
4. Patient related factors including knowledge about TB transmission and infection prevention

   Health system and health care provider factors for were collected using structured questionnaire administered to the selected study participants. These factors were health care provider attitude towards the patients, Waiting time at the health facility during the clinic visit, distance of the health facility from the settlement, consistent availability of medicine in the health facility, Preferred clinic visiting time.

3.9 Data analysis

Data analysis was done using Epi info version 7. Continuous variables were analyzed using measures of central tendency and dispersion (means, and standard deviation, median, and interquartile range) while categorical variables were summarized using frequency and proportion. Measures of association (odds ratio) and confidence intervals were calculated to assess factors associated with treatment interruption. P value of ≤ 0.05 was considered statistically significant. Multivariate analysis was done for variables with P value ≤ 0.2 to identify factors independent associated with TB treatment interruption.

Results were presented in tables, and graphs.

3.10 Ethical consideration

To ensure confidentiality i used patient registration numbers as unique numbers instead of patient names. Ethical approval was granted by the Institutional Research and ethical

committee (IREC), Ref. IREC/2021/87, approval no. 0003927. Authority to conduct the study was given by the county government of Marsabit department of health. The consent from the study participants was sought either in writing or verbal. Consent by the study participants was signed on site prior to the interview. Children below the age of 18 years were included in the study after they had given assent and their parents or guardians consented on their behalf. Other vulnerable groups that were included in the study included pregnant women and the participants who might be in prison during the study period. However, this study did not pose any risk at all to this group.

The study participants were assured of their rights to voluntarily participate in the study and that they could opt out of the study at any stage of the interview. That the information given by them was to be used only for the purpose of the study. The contact details of the researchers were availed to them in case they needed more information in the course of the study.

3.11 Dissemination of the Findings

The findings of the study will be presented to the National TB Program (NTP), Field Epidemiology and Laboratory training program (FELTP), Marsabit County health management team. I will also prepare a manuscript of the findings for publication in a peer reviewed journal.

CHAPTER FOUR

DATA PRESENTATION, ANALYSIS AND INTERPRETETION OF THE FINDINGS

4.0 Results

4.1 Proportion of patients whose TB treatments were interrupted

4.1.1 Socio-demographic characteristics of the study participants (n=307)

Of the targeted 340 study respondents, data from 307 were analyzed which gave about 90% participants response rate.

There was a total of 102 (36%) females who participated in the study. When analyzed by age group, 94 (31%) of the study participants were aged between 15-24 years and 23 (7%) were in the elderly age group of >65 years. Moyale sub-county contributed 159 (52%) of the study participants while North horr 25 (8%). Saku and Laisamis sub counties, contributed 90(29%) and 29 (11) participants respectively.

Overall, about 67 (22%) of the study participants interrupted their TB treatment. Among the study participants who interrupted treatment, 59 of them (88%) were those who interrupted their TB treatment for less than two months (intermittent treatment interruption). There were less female study participants who interrupted TB treatment as compared to the males (25%). The 55–64-year-old age group had highest proportion (28% interrupting their TB treatment while only 13% of the elderly age group of above 65 years interrupted. The age-group 25-34, 35-44, and 44-54 years old had a treatment interruption of 24% each. The study participants from Saku Sub County had highest reported proportion of TB treatment interruption (28%) and only 8% of the study participants from

North horr Sub County had their treatment interrupted. Of the interviewed participants, 185 (60%) were married, while minority 10 (3%) were separated. Treatment interruption was highest (30%) among those whose marital status was reported as separated, but lowest for those who were widowed (1%). On level of education, 138 (45%) of the participants did not have any formal education, 62 (20%) had primary complete, 37 (12%) secondary complete and 16 (5%) had tertiary education. Those with primary level of education had the highest proportion (29%) of treatment interruption and only 6% of those with tertiary level of education interrupted treatment. When asked about availability of food, the participants said it was always available to take with medicine 218 (71%) or available most of the time 34 (11%). The rest 55 (18%) said food was not available. The participants who said they had food not always available had highest proportion of treatment interruption (25%). Majority of the participants reported that they neither smoked 281 (92%) nor took alcohol 286 (93%) in the six months prior to TB diagnosis. Those who had history of taking alcohol six months prior to treatment initiation had highest proportion (25%) of treatment interrupted as compared to those who did not take alcohol. However, those who did not smoke cigarette had treatment interruption of 22%. The youngest participant was 15 years old and the oldest 82 years (Ref table 2 below).

Table4.2: Sociodemographic characteristics of the Study participants

Variable	Characteristics	Overall		Interrupted treatment			
				Yes		No	
		No.	%	No.	%	no	%
Sex	Male	195	64	48	25	147	75
	Female	112	36	19	17	93	83
Age group	15-24	94	31	17	18	77	82
	25-34	83	27	20	24	63	76
	35-44	50	16	12	24	38	76
	45-54	25	8	6	24	19	76
	55-64	32	10	9	28	23	72
	>65	23	7	3	13	20	87
Sub county of Residence	Moyale	159	52	33	21	126	79
	North Horr	25	8	2	8	23	92
	Saku	90	29	25	28	65	72
	Laisamis	33	11	7	21	26	79
Marital status	Married	185	60	45	24	140	76
	Single	92	30	17	18	75	82
	Widowed	20	7	2	1	18	99
	Separated	10	3	3	30	7	70
Education level	None	138	45	34	25	104	75
	Primary complete	62	20	18	29	44	71
	Primary incomplete	38	12	6	16	32	84
	Secondary complete	37	12	6	16	31	84
	Secondary incomplete	16	5	2	13	14	87
	Tertiary	16	5	1	6	15	94
Availability of food	Always available to take with medicines	218	71	50	23	168	77
	Not always available	55	18	13	24	42	76
	Available most of the time	34	11	4	12	30	88
Alcohol Consumption (in the last 6 months)	Yes	20	7	5	25	15	75
	No	286	93	62	22	224	78
	Cannot remember	1	0	0	0	1	100%
Cigarette smoking (in the last 6 months)	Yes	26	8	5	19	21	81%
	No	281	92	62	22	219	78%

4.1.2 Clinical characteristics of the study participants

Of the total 307 study participants 280 (91%) of them were treated for pulmonary TB, 274 (89%) were new TB patients. Pulmonary (PTB) and extra pulmonary TB (EPTB) patients had equal proportion of treatment interruption rate (22%) with an odds ratio (OR) of 1.23 (PTB ref) at a P value of 0.75. Treatment interruption rate among the newly diagnosed TB patients was 23% (ref) compared with the previously treated TB patients which was 15% and 0.47 OR and a P value of 0.44 which was also statistically not significant. On the nutritional status of the study participants, 204 (67%) study respondents had moderate to severe malnutrition while only 82 (27%) had normal nutritional status. More than 40% of the TB patients with severe and moderate malnutrition interrupted their TB treatment with an OR of 1.32 and a statistically not significant P value of 0.52 among the moderately malnourished TB patients. When the data on the HIV testing of the study respondents were extracted from the register and analyzed, it was found that a total of 297 (97%) study participants were tested for HIV, and 27 (9%) of them tested HIV positive. Though not statistically significant (P value 0.83), About 23% of the HIV negative study participants reported that they interrupted their TB treatment, while almost equal proportion (22%) of those who were HIV positive said they interrupted TB treatment. On the directly observed therapy (DOTS), 294 (96%) of the respondents reported that they were observed on treatment by their family members, 10 (3%) by health care workers (HCWs) and 3 (1%) by community health volunteers (CHVs). Treatment interruption rate was 33% among those observed by the CHVs (P value, 0.39) compared to 22% and 20% for those who were observed by the family members with a P value of 0.52 and HCWs respectively (Ref). However, none of these findings were statistically significant.

Table4.3: Clinical characteristics of the Study participants

Variable	Characteristics	Overall		Interrupted treatment					
				Yes		No		AOR	Pvalue
		N o	%	no.	%	no.	%		
Type of TB	Pulmonary	280	91	61	22	219	78	Ref	
	Extra pulmonary	27	9	6	22	21	78	1.23	0.75
Type of Patient	New	274	89	62	23	212	77		
	Previously treated	33	10	5	15	28	85	0.47	0.44
Nutritional status	Severely Malnourished	113	37	22	19	91	81	Ref	
	Moderately Malnourished	91	30	23	25	68	75	1.32	0.52
	Normal	82	27	18	22	64	78	1.16	0.67
	Overweight	9	3	2	22	7	78	1.18	0.84
	Obese	1	0	1	100	0	0	1.00	
	Not Evaluated	11	4	1	10	10	90	0.41	0.41
HIV Status	HIV+	19	6	4	21	15	79	Ref	
	HIV-	278	91	62	22	216	78	0.81	0.83
	HIV test Not done	10	3	1	10	9	90	0.42	0.46
Type of DOTS support	HCW	10	3	2	20	8	80	Ref	
	Family member	294	96%	64	22%	230	78%	0.48	0.52
	CHV	3	1%	1	33%	2	67%	0.26	0.39

4.1.3 Knowledge on TB clinical symptoms by the study participants

The study respondents were asked if they know the clinical symptoms of TB. The responses were based on the three (3) of the four (4) major symptoms of TB as well as chest pain. The symptoms are cough, drenching night sweats and unintentional weight loss. The responses were then tabulated (table 4 below) and proportion of TB treatment interruption determined. Of the study respondents, 303 (99%) participants said that TB presents with a cough, 253 (82%) said it presents with night sweat, and a further 274

(89%) said it presents with weight loss and 297 (97%) of them reported that chest pain is a symptom of TB. When i analyzed TB treatment interruption according to the reported knowledge of TB symptoms among the respondents, 21% each of those who said TB presents with a cough, night sweat and weight loss and chest pain had their treatment interrupted. The study participants who did not have knowledge of cough as a symptom of TB had high odds of treatment interruption (OR, 1.02) as compared to those who reported that TB presents with a cough (P value, 0.43). The respondents who did not report night sweats as a symptom for TB had 1.44 times higher odds of interrupting their treatment as compared to those who knew TB presents with night sweats as a symptom (P value, 0.53). Study participants who did not report that weight loss was a symptom of TB, had interrupted treatment more than those who said weight loss is a TB symptom (OR,0.82, P value, 0.77) and for those who did not report chest pain as a symptom for TB, they had 5.13 odds of interrupting their TB treatment (P value, 0.11).

Table 4.4: Knowledge on TB clinical symptoms by the study participants, Marsabit, 2020

Variable	Characteristics	Overall		Interrupted treatment				OR	P Value
				Yes		No			
		No.	%	no.	%	no.	%		
Cough	Yes	303	99	67	21	236	79		
	No	4	1	0	0	4	100	1.02	0.43
Night sweat	Yes	253	82	52	21	201	79	Ref	
	No	54	18	15	28	39	72	1.44	0.53
Weight loss	Yes	274	89	57	21	217	79	Ref	
	No	33	11	10	30	23	70	0.82	0.77
Chest pain	Yes	297	97	63	21	234	79		
	No	10	3	4	40	6	60	5.13	0.11

4.1.4 Health system related characteristics of the study participants

Health system related factors are crucial and play key role in quality of care for TB patients. These factors include HCWs and their attitude in terms of how friendly they related to the TB patients. The study participants were asked to rate how the HCWs related to them during the period of their TB treatment. The participants were asked to say whether HCWS were very friendly, Friendly, or indifferent. They were also asked to state the most convenient time for them to collect their TB medicine during the official working hours of the health facility where they went for their treatment. The other important health system related factor asked was the waiting time at the health facility when they came to collect their TB medicine as well have clinical evaluations done. The respondents reported that the most convenient time for their TB drug collection was between 8:00 am and 5:00pm 267 (87%).When asked how long they waited at the TB clinic for drug collection and clinical evaluation, 260 (85%) of them said they waited for less than one hour. When asked about the staff attitude, 233 (76%) of them reported that the staff attitude was very friendly while only 3 (1%) of the respondents said the staff attitude was indifferent. Of

those who said the most convenient time to collect their TB medicines was between 8am and 5 pm, 21% of them interrupted their TB treatment, while 30% of those whose convenient time was before 8am interrupted their treatment. The odds of treatment interruption among the patients whose convenient time for drug collection was between 8.00 am and 5.00pm, was 0.53 (P value 0.26).). Among those respondents who reported that they waited for less than one hour at the TB clinic to collect their medicines, 18% of them had their TB treatment interrupted as compared with those who waited for one to two hours at the clinic. These patients had higher odds of treatment interruption (OR, 6.95) as compared to the reference group with a statistically significant P value of 0.00.

Those who reported that the TB clinic staff at attitude was indifferent had interrupted their TB treatment 33% of the time with an OR of 1.06, as compared with those who said the staff attitude was very friendly whose TB treatment interruption rate was 21%. However, this was not statistically significant (P value, 0.92.

Table 4.5: Health system related characteristics of the study participants, Marsabit, 2020

Variable	Characteristics	Overall		Interrupted treatment				OR	P Value
				Yes		No			
		no	%	no	%	No	%		
Convenient time to collect medicine	[8am]	40	13	12	30	28	70	Ref	
	[8am- 5pm]	267	87	55	21	212	79	0.53	0.26
Waiting time at TB clinic	[<1 hr.]	260	85	45	17	215	83	Ref	
	[1-2 hrs.]	47	15	22	47	25	53	6.95	0.00
HCW attitude	Very friendly	233	76	50	21	183	79	Ref	
	Friendly	71	23	16	23	55	77	1.06	0.92
	Indifferent	3	1	1	33	2	67	1.96	0.68

4.1.5 Cost incurred on travels when seeking TB treatment

In Kenya TB treatment is offered free of charge in all public and faith based health facilities (Annual DLTLDP report, 2020). However, there are other indirect costs associated with TB treatment. One of such cost is the transport to travel to the health facility for treatment. When asked how much they spent to access the TB clinic for treatment, 33% of the study participants said they walked to the clinic and therefore there was no cost incurred. Another 22% of them said they paid less than kes.50, while 21% said they spent more than kes.200. Of the remaining participants, 20% spent kes.50-100, and 19% of them said they spent kes.100 200. The proportion of treatment interruption based on the cost incurred to access TB treatment, ranged between 10%-27%. Treatment interruption was highest among those who paid higher amount of money (more than kes.200) to travel for the treatment where about 27% of the respondents interrupted their TB treatment. Those who paid less than kes.50 had the lowest proportion interrupting treatment (10%) while those who reported that they lived just few kilometers for the health facilities and therefore, walked to the health facility to access their TB treatment, and hence did not incur any travel expense, had a treatment interruption rate of 22%. The proportion of TB patients interrupting treatment increased with the increase in cost of travel to the health facility for treatment.

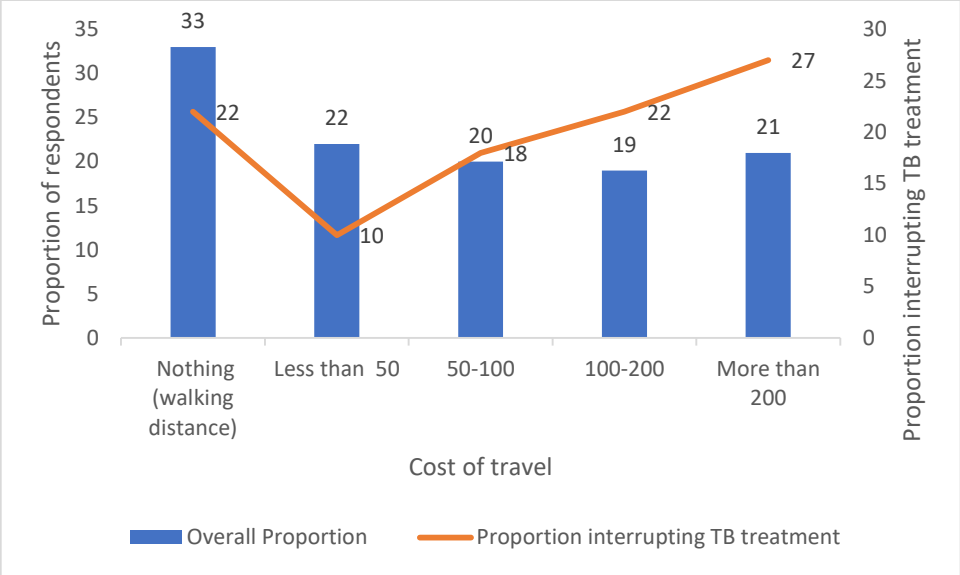

Figure 4.4: Cost incurred on travels when seeking TB treatment

4.1.6 Distance covered while seeking TB Treatment by the Study Participants

The study participants were asked what distance they traveled to access TB treatment, and 135 (44%) of them said they travelled less than 5km, 65 (21%) said they covered a distance of 5-10km while 28 (9%) respondents covered 11-15km, 22 (7%) travelled 15-20km and the remaining 57 (19%) travelled for more than 20kms to access TB treatment. The study participants who said they travelled less than 5km to access treatment, had 25% TB treatment interruption. Those who travelled between5-10km had 29% treatment interruption rate. The participants who reported travelling between 11km and 15km, had 11% of them interrupting TB treatment, those who travelled between15-20km had 9%, while the participants who reported to have travelled for more than 20km had 16% interruption rate.

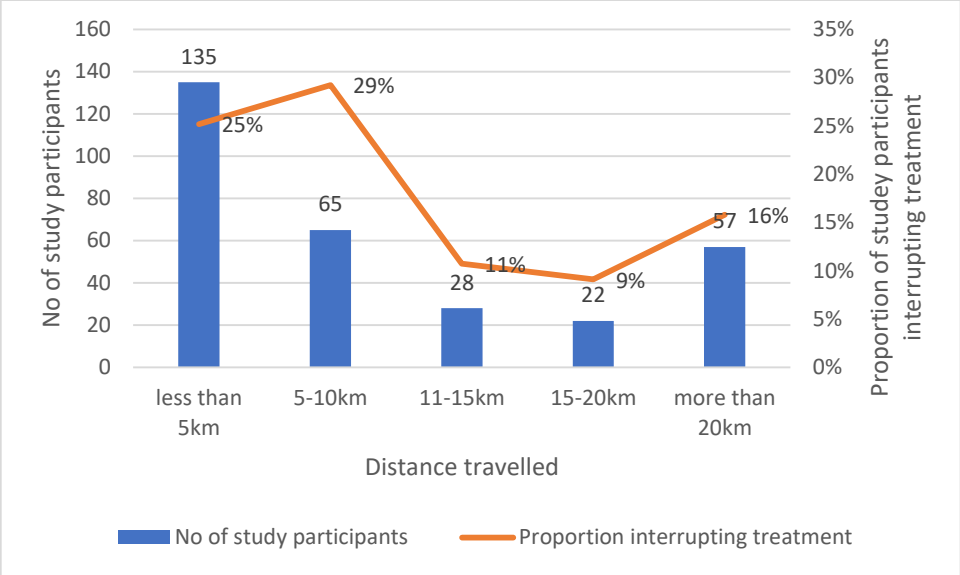

Figure 4.3: Distance covered while seeking TB Treatment by the Study Participants

4.1.7 Stigma and social discrimination among the study participants

On stigma and discrimination, 285(93%) lived with their family, 15(5%) lived alone. The TB treatment interruption proportion among those who said they lived with their family was 22%, while those who lived alone had treatment interruption was 33%. The number of household members ranged between 1-6 persons in 256 (83%) of the participants, and 132(10%) lived with more than 6 people in the household. Treatment interruption was higher among those who said they lived with up to three people in the house (27%). The participants lived in the current location for more than 12 months, 274(89%), and 26 (8%) 3-12 months. Those study participants who said they lived in the current dwelling for between 3-12 months had highest proportion of treatment interruption (42%), while those who lived in the current dwelling for at least 12 months had lowest treatment interruption of 1%. When they were initiated on TB treatment, 302 (98%) participants said they

informed their family that they were on TB treatment and those who did not inform their family about them being on TB treatment had higher treatment interruption (60%).

Table4.6: Stigma and social discrimination among the study participants

Variable	Characteristics	Overall		Interrupted treatment			
				Yes		No	
		no	%	No	%	no	%
Who do you live with	Family	285	93%	62	22%	223	78%
	Friends	5	2%	0	0%	5	100%
	Alone	15	5%	5	33%	10	67%
	Other	2	1%	0	0%	2	100%
How many other people live with you	None	19	6%	4	21%	15	79%
	1-3	132	43%	35	27%	97	73%
	4-6	124	40%	23	19%	101	81%
	>6	32	10%	5	16%	27	84%
Duration in current dwelling	(12 months)	7	2%	1	1%	6	99%
	(3-12 months)	26	8%	11	42%	15	58%
	(>12 months)	274	89%	55	20%	219	80%
Inform family members you were on TB treatment	Yes	302	98%	64	21%	238	79%
	No	5	2%	3	60%	2	40%

4.1.8 Disease and Medicine Related factors

Of the total study participants, 297 (97%) said TB treatment is taken for 6 months and stopped, while 10 (3%) of the participants said that the treatment is taken until one feels better and then stopped. Of the study participants who said the treatment is taken for 6 months, 22% interrupted their treatment. Half (50%) of those who said treatment is taken until one feels better, interrupted treatment. When the study participants were asked

duration on treatment before feeling better, 74% said they felt better in less than one month, 25% in 2-4 months, 1% in 5-6 months, and 1% said did not feel better on treatment. Among those who said they felt better on treatment within 5-6 months, 67% interrupted their treatment while 50% of those who did not feel better on treatment interrupted. Those that felt better on treatment within the first two months had least treatment interruption (26%).The study participants were asked if they completed their TB treatment, and 252 (82%) of them reported that they completed. Some of the study participants (5%) were also on other drugs while they were on TB treatment where 13 (81%) of them were on ART, 1 (6%) on anti- hypertensive treatment and 2 (13%) on other drugs. Of those on other drugs 33% who were on highly active antiretroviral (HAART), interrupted treatment while none of those on antihypertensive and other drugs interrupted their TB treatment. To the question whether they experienced drug side effect, 111 (36%) study participants reported that they experienced side effects, the type of side effect experienced were skin rashes 36 (12%), diarrhea and vomiting 33 (11%), painful limbs 32 (10), headache and dizziness 19 (6%). Other side effects were numb feet or hands 12 (4%), yellowness of the eye 5 (5%). Up to 50% of those who said TB treatment is taken until one feel better and then stopped, interrupted their treatment compared to those who said treatment is taken for six months. Treatment interruption was highest (67%) among those who said they felt better in 5-6 months of TB treatment. Half of those who did not feel better on treatment interrupted their treatment. Only 19% of the study participants who felt better in the first two months of TB treatment interrupted. Those who completed their treatment said they interrupted about 16% of the time, while those who said they did not complete treatment interrupted 47%. Out of the 16 study participants who were on

other drugs, 3 (16%) interrupted treatment and 22% of those not on other drugs interrupted. Out of the 13 (81%) on HAART, 33% interrupted TB treatment and none of those who were on antihypertensive drugs or other drugs had interrupted. The common side effects among those who interrupted treatment were yellow eyes (60%), skin rashes (53%), headaches and dizziness (37%), numb feet or hands (25%) and painful limbs (22%).

Table 4.7: Disease and Medicine Related factors among the study participants

Variable	Characteristics	Overall		Interrupted treatment			
				Yes		No	
		no	%	No	%	no	%
TB Treatment duration	6 months	297	97	66	22	231	78
	One feels better then stop on your own	10	3	5	50	5	50
Duration to feeling better(months)	[<2]	226	74	44	19	182	81
	[2-4]	76	25	20	26	56	74
	[5-6]	3	1	2	67	1	33
	[Did not feel better]	2	1	1	50	1	50
Treatment completion	Yes	252	82	41	16	211	84
	No	55	18	26	47	29	53
Patient on other drugs	Yes	16	5	3	19	13	81
	No	291	95	64	22	227	88
Other drugs (n = 16)	HAART	13	81	3	33	10	87
	Anti-hypertensive	1	6	0	0	1	100
	Other	2	13	0	0	2	100
Experienced Side effect	Experienced side effect	111	36	27	24	84	76
	Not experienced side effect	196	64	40	20	156	80
Side effect experienced (n = 111)	Diarrhea & Vomiting	33	30	5	15	28	25
	Headaches and dizziness	19	17	7	37	12	63
	Skin rashes	36	32	19	53	17	47
	Numb feet or hands	12	11	3	25	9	75
	Yellow eyes	5	5	3	60	2	40
	Painful limbs	32	29	9	22	23	78
	Other	14	13	2	14	12	86

4.1.9 Characterizing treatment interruption among the study participants

The participants were asked if they ever interrupted treatment, how many times they interrupted and the reason for treatment interruption. Sixty-seven of them (22%) said they ever interrupted treatment, 240(58%) said they interrupted less than two times, 23 (34%)

two to four times and, five (7%) patients said they interrupted more than four times in the course of their TB treatment.

Table 4.8: Proportion of study participants interrupting TB treatment

Variable	Characteristics	No	%
Treatment interruption	Yes	67	22%
	No	240	78%
Frequency of treatment interruption (n = 67)	[< 2]	39	58%
	[2-4]	23	34%
	[> 4]	5	7%

4.1.10 Reasons for treatment interruption (n=67)

When the study respondents were asked the reasons that led them for their interrupting treatment, 52% reported that they stopped treatment because they felt well, 36% due to side effect, 13% due to distance from the health facility, while 12% each due to cost of travel and other reasons.

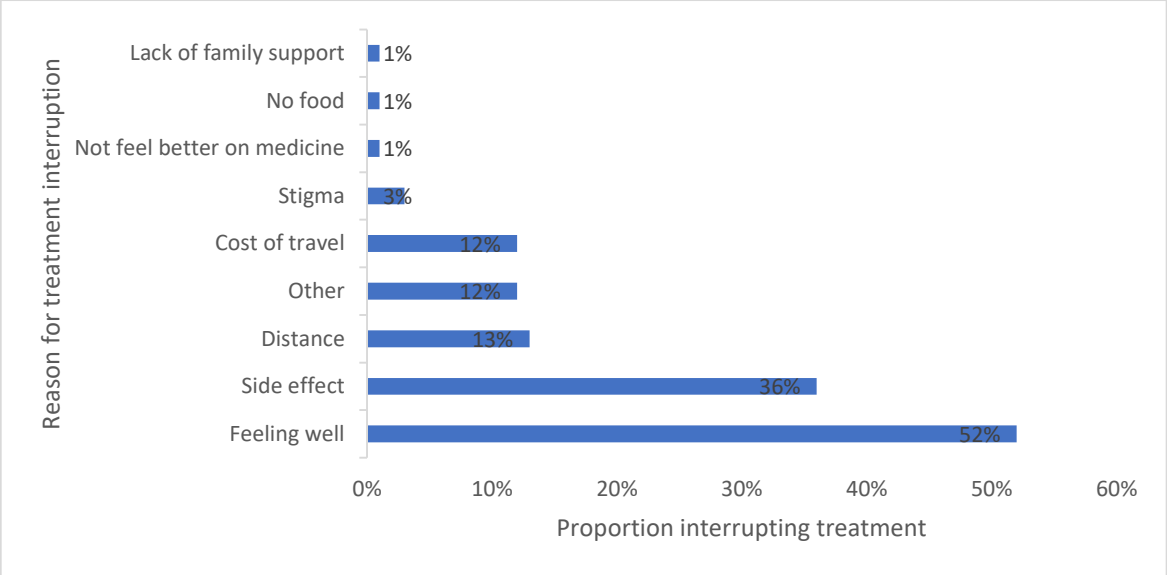

Figure 4.9: Reasons for treatment interruption

4.1.11 Opinion on what can help patients complete TB treatment

The study participants were asked what in their opinion can help TB patients complete their treatment and, 84(28%) said the desire to get cured of TB can help them complete treatment, 64 (22%) health education by health care providers, 28 (9%) said that having knowledge on TB, will help in treatment adherence. Other responses were, availability of food, distance from the health facility, family support, feeling better on treatment, and pretreatment patient counseling.

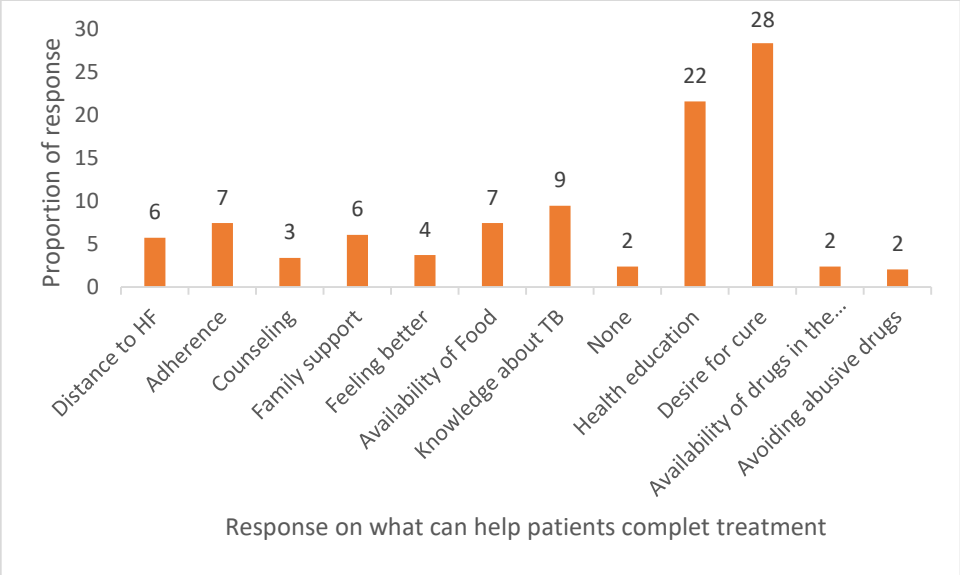

Figure 4.10: Opinion on what can help patients complete TB treatment

4.2 Factors associated with the treatment interruption among TB patients

4.2.1 *Bivariate and Multivariate analysis of the likelihood of treatment interruption among the TB patients in the selected demographic, clinical, and health system related characteristics*

The variables were analyzed at bivariate level to determine the factors associated with treatment interruption (odds ratio) and all the variables with p-value of ≤ 0.2 were analyzed at multivariate level using logistic regression to determine factors independently associated with TB treatment interruption. At the bivariate level only long waiting time of more than one hour at the TB clinic for review and drug collection was significantly associated with TB treatment interruption (P-value-0.00). However, when analyzed at the multivariate level it was found that the female sex was independently associated with treatment interruption (P-value-0.03), and the long waiting time of more than one hour at

the TB clinic for review and drug collection remained significantly associated with TB treatment interruption with similar level of significance as in the bivariate level.

4.2.2 Socio-demographic variables

The age group category, 55-64 (OR, 1.75, CI; 0.35-8.75) and 35-44 (OR, 1.73, CI 0.43-7.03) years had the highest likelihood of treatment interruption as compared to the reference group, while the elderly age group of more than 65 years old had less likelihood of treatment interruption (AOR, 0.27, CI=0.04-2.10). However, when analyzed at the multivariate level they were not statistically significant (table 9). Females were less likely to interrupt treatment (AOR 0.4, CI= 0.18-0.93) and this was statistically significant at the multivariate level (P-value 0.03) (table 9). The study participants whose marital status were reported as separated were 9.79 (CI=0.54-175.80) times more likely to interrupt treatment than the widowed group, while the married group were less likely to interrupt treatment (AOR, 2.52; CI=0.3-20.85), though these were not statistically significant. The patients who reported as having completed primary level of education were more likely to interrupt treatment compared to the reference group (AOR, 1.19, CI=0.42-3.37), while those who had reached tertiary level of education were less likelihood of interrupting treatment (AOR,0. 13; CI=0.01-1.55). Patients who did consume alcohol six months before initiation of TB treatment were 0.63 (CI=011-3.49) times less likely to interrupt treatment compared those who did not consume alcohol. In respect to the source of livelihood, the patients whose livelihood was crop farming (AOR, 2.38, CI=0.38-14.96) were more likely to interrupt treatment as compared to those in employment.

4.2.3 Health system related characteristics of the study participants

The patients who preferred 8 am-5 pm opening clinic time (AOR, 0.53, CI=0.18-1.59) were less likely to interrupt treatment as opposed to those who preferred earlier time period. However, this was not statistically significant at both bivariate and multivariate levels. Patients who reported longer waiting time (AOR 6.95, CI=2.46-19.61) at the TB clinic were more likely to interrupt treatment than those who reported less than one hour waiting time with statistical significance at both bivariate and multivariate levels (P-value=0.00). The patients who travelled more than five kms to access treatment were 1.66 times) CI=0.45-6.09) more likely to interrupt treatment compared to those who reported travelling less than 5 kms. In respect to the cost of travel to the clinic, those who reported to have paid more than kes. 200 to access treatment were more likely to interrupt treatment (AOR, 2.64; CI=0.51-13.84) compared to those who walked to the clinic and did not pay any transport.

4.2.4 Disease and Medicine related factors

The study participants who reported that they did not feel better on treatment were almost 11 times more likely (AOR, 10.97, CI= 0.40- 298.99) to interrupt treatment than those who felt better on treatment in less than two months. The type of TB and type of patient was not associated with treatment interruption as there was no significant difference in those who interrupted treatment (AOR 1.23, *CI* =0.35-4.38) and (0.420, CI=11-1.59). The study participants who were HIV negative (AOR, 0.81, CI=0.11-5.74) as well as those who did not know their HIV (OR, 0.26, CI=0.01-5.70) status were less likely to interrupt treatment than the HIV positive participants. However, these were not statistically significant at both bivariate and multivariate levels.

Table4.9: Bivariate and multi-variate analysis of socio demographic characteristics of the study participants, Marsabit County, 2021

Variable	Treatment interrupted (%)	Treatment not interrupted (%)	uOR (95% CI)	P-value	AOR (95%CI)
Sex					
Male	48(25)	147(75)	Ref		
Female	19(17)	93(83)	0.63(0.35-1.13)	0.12	0.40(0.18-0.93)
Age group					
15-24	17(18)	77(82)	Ref		
25-34	20(24)	63(76)	1.44(0.69-2.98)	0.33	1.48(0.48-4.5)
35-44	12(24)	38(76)	1.43(0.62-3.30)	0.40	1.73(0.43-7.03)
45-54	6(24)	19(76)	1.43(0.50-4.12)	0.51	0.63(0.13-3.02)
55-64	9(28)	23(72)	1.77 (0.70-4.50)	0.23	1.75(0.35-8.78)
More than 65	3(13)	20(87)	0.68(0.18-2.55)	0.57	0.27(0.04-2.1)
Marital status					
Widowed	2(1)	18(99)	Ref		
Married	45(24)	140(76)	2.89(0.65-12.95)	0.17	2.52(0.3-20.85)
Single	17(18)	75(82)	2.04(0.43-9.64)	0.37	3.13(0.31-31.95)
Separated	3(30)	7(70)	3.86(0.53-28.24)	0.18	9.79(0.54-175.8)
Education level					
None	34(25)	104(75)	Ref		
Primary complete	18(29)	44(71)	1.25(0.64-2.45)	0.51	1.19(0.42-3.37)
Primary incomplete	6(16)	32(84)	0.57(0.22-1.49)	0.25	0.42(0.11-1.58)
Secondary complete	6(16)	31(84)	0.59(0.23-1.54)	0.28	0.41(0.12-1.45)
Secondary incomplete	2(13)	14(87)	0.44(0.09-2.02)	0.0.29	0.42(0.05-3.75)
Tertiary	1(6)	15(94)	0.2(0.03-1.60)	0.13	0.13(0.01-1.55)
Food availability					
Always available to take with medicines	50(23)	168(77)	Ref		
Not always available	13(24)	42(76)	1.04(0.52-2.09)	0.91	0.93(0.32-2.72)

Available most of the time	4(12)	30(88)	0.45(0.15-1.33)	0.15	0.4(0.08-1.92)
Alcohol *(last 6 months)*					
Yes	5(19)	15(81)	Ref		
No	62(22)	224(78)	0.83(0.29-2.73)	0.73	0.63(0.11-3.49)
Cigarette smoking (*last 6 months)*					
Yes	5(19)	21(81)	Ref		
No	62(22)	219 (78)	1.19(0.43-3.28)	0.74	1.97(0.4-9.63)

Table 4.10: Bivariate and multi-variate analysis of health system related factors of the study participants, Kenya,2021

	Treatment interrupted (%)	Treatment not interrupted (%)	OR (95% CI)	P-Value	AOR (95%CI)
Convenient clinic time					
[8am]	12(30)	28(70)	Ref		
[8am- 5pm]	55(22)	212(78)	0.61(0.29-1.27)	0.18	0.53(0.18-1.59)
Waiting time at TB clinic					
[<1 hr.]	45(17)	215(83)	Ref		
[1-2 hrs.]	22(47)	25(57)	4.20(2.18-8.11)	**0.00**	**6.95(2.46-19.61)**
Distance (KM)					
Less than 5	49(36)	86(64)	Ref		
5-10	20(31)	45(69)	2.18(1.10-4.30)	0.03	1.66(0.45-6.09)
11-15	2(7)	26(93)	1.01(0.35-2.94)	0.98	0.84(0.16-4.38)
16-20	2(9)	20(91)	1.46(0.49-4.37)	0.50	0.89(0.14-5.7)
More than 20km	10(18)	45(82)	1.27(0.59-2.76)	0.54	0.39(0.07-2.18)
Cost of travel					
Nothing (walking distance)	22(22)	22(78)	Ref		
Less than 50	2(10)	2(90)	2.83(0.98-8.18)	0.05	2.06(0.41-10.35)
50-100	11(18)	11(82)	1.39(0.60-3.2)	0.44	0.98(0.25-3.88)
100-200	13(22)	13(78)	1.93(0.87-4.31)	0.11	1.88(0.41-8.60)
More than 200	17(27)	17(73)	2.12(098-4.59)	0.06	2.64(0.51-13.82)
HCW attitude					
Very friendly	50(21)	183(79)	Ref		
Friendly	16(23)	55(77)	1.06(0.56-2.02)	0.85	1.06(0.36-3.07)
Indifferent	1(33)	2(67)	1.83(0.16-20.60)	0.63	1.96(0.08-48.02)

Table 4.11: Bivariate and multi-variate analysis of patient and disease related factors of the study participants, Kenya, 2021

Variable	Treatment interrupted (%)	Treatment not interrupted (%)	OR (95% CI)	P-Value	AOR (95%CI)
duration to feeling better (months)					
<2	44(19)	182(82)	Ref		
2-4	20(26)	56(74)	1.48(0.80-2.71)	0.21	0.79(0.33-1.9)
5-6	2(47)	1(53)	8.27(0.73-93.31)	0.09	1.13(0.06-19.97)
did not feel better	1(50)	1(50)	4.14(0.25-67.43)	0.32	10.97(0.40-298.99)
Type of TB					
Pulmonary	61(22)	219(78)	Ref		
Extra Pulmonary	6(22)	21(78)	1.03(0.40-2.65)	0.96	1.23(0.35-4.38)
Type of patient					
New	65(23)	212(77)	Ref		
Previously treated	2(15)	28(85)	0.53(0.18-1.56)	0.25	0.42(0.11-1.59)
BMI category					
Severely Malnourished	22(19)	91(81)	Ref		
Moderately Malnourished	23(25)	68(75)	1.40(0.72-2.72)	0.32	1.32(0.57-3.09)
Normal	18(22)	64(78)	1.16(0.58-2.34)	0.67	0.71(0.28-1.78)
Overweight	2(22)	7(78)	1.18(0.23-6.09)	0.84	1.01(0.13-8.08)
Obese	1(100)	0			1
Not Evaluated	1(10)	10(90)	0.41(0.05-3.40)	0.41	0.49(0.04-6.10)
HIV status					
HIV+	4(21)	15(79)	Ref		
HIV-	62(22)	216(78)	1.08(0.34-3.36)	0.90	0.81(0.11-5.74)
Not done	1(10)	9(90)	0.42(0.04-4.33)	0.46	0.26(0.01-5.70)

CHAPTER FIVE

DISCUSSIONS, SUMMARY, CONCLUSION AND RECOMMENDATIONS

5.0 Discussion

5.1 Proportion of study participants whose TB treatments were interrupted

Our study found that high proportion of the TB patients who were initiated on TB treatment between January 2019 and December 2020, had interrupted TB treatment. This study found that more male patients interrupted their TB treatment than the female patients.

Tuberculosis treatment interruptions had been documented in other countries, including Africa. For example, a study by Eveline Kimani et al in Kiambu County on factors influencing TB treatment interruption and treatment outcomes in Kiambu County, found that more male patients interrupted TB treatment as compared to the female gender (Evelyn KimaniI, 2016-2019). This study showed that for every female who interrupted TB treatment, there were two males interrupting. Another study in Kenya by Wanyonyi et al on factors associated with interruption of tuberculosis treatment in Nandi county of Kenya, found that treatment interruption was common challenge in Nandi County in Kenya. Similar to our study this study found that up to a third of TB patients interrupted their TB treatment and more male gender interrupted TB treatment as compared to female gender ((A. Wanyonyi, P. Wanjala, J. Githuku et al, 2015). The high proportion of TB treatment interruption in this study could be due to poor health seeking behaviour coupled with poor staffing levels in the county and also uneven distribution of health facilities in

the county. Pre-treatment counseling could be inadequate due to overwhelmed staff which is mostly very low in most facilities in the county. Other studies that had similar findings included a study in Kenya on determinants of tuberculosis treatment interruption among patients in Vihiga county by Paul Wekunda et al, where treatment interruption was also found to be higher among the male TB patients (Paul Wekunda Waliaula, 2021). This study also found that the TB treatment interruption was more prevalent among the older age group category of 55-64 years old as compared to the lowest prevalence among the elderly cohort of above 65 years old. A similar finding was posted by a study, in Kenya in 2019 by Katana et al on tuberculosis poor treatment outcomes and its determinants, where the older age group above 5 years had higher proportion of patients interrupting their TB treatment as compared to other age groups (Katana, 2019).

When analysis of the data was done by Sub County of residence, Moyale Sub County had the highest proportion of TB patients interrupting their TB treatment. The level of literacy of the TB patients was an important aspect of TB treatment adherence. This study found that those TB patients who reported that they had completed primary level of education, had the highest proportion of treatment interruption when compared with those with tertiary level of education who were less likely to interrupt TB treatment. Similar studies had agreeing findings with the current study. This included, a study on determinants of TB treatment interruption among patients in Vihiga County, Wekunda et al, which found that those patients who had attained primary level of education or below had higher odds of TB treatment interruption (wekunda, 2021).

A study on factors contributing to TB treatment interruption which was conducted in Imenti south in Meru County in Kenya found that in agreement with our study Male gender had higher proportion of treatment interruption. The study also looked at the age categories, level of education, marital status of the participants where it was found it found that the proportion of study respondents interrupting TB treatment were those who were in the age category of 15-34 years, those who had primary level of education and also those who were reported as married had higher proportion of TB treatment interruption (Samuel Waithaka, 2019), This was similar finding to our study which found male gender, primary level of education had higher proportion of TB patients interrupting their treatment. However our findings were not statistically significant. On the other hand those who reported as separated in marriage had higher proportion of treatment interruption as compared to this study where they found the married patients had higher proportion of treatment interruption.

Most of the study participants who interrupted their TB treatment were among those who did not have food always available to take with medicine. Lack of adequate food at home made patients not stick to regular treatment prescription since the effect of medicine was worse when take them on empty stomach. Other studies that reported similar findings include, Factors influencing adherence to tuberculosis treatment in Asmara, Eritrea. a qualitative study by Gebreweld et al which found that patients interrupted their TB treatment because of lack of food and the patients were stressed and felt hopeless due to lack of food leading treatment interruption (Gebreweld et al, 2018). The lack of food was partly due to patients losing their jobs due to sickness, and taking medication without food

led to increased intolerance to the medication and side effects of the medicine led them to interrupting their treatment.

The proportion of TB patients who interrupted their TB treatment was higher among those whose TB clinic opening time was 8am or earlier compared to those whose preferred time was the normal working hours. In addition, TB patients who waited longer at the TB clinic for review and drug refill had higher proportion interrupting treatment than those who had shorter waiting time at the clinic. Studies have found findings in agreement with the current study. A study by Wanyonyi et al reported that TB patients who reported an average waiting time of more than one hour at the TB clinic were more likely to interrupt their treatment than those who waited for less than one hour (Wanyonyi et al, 2017). Most of the TB patients were either businessmen, or livestock keeper. They needed to be served promptly so they could proceed with their daily chores. However, when they experience delay in clinic opening time, they preferred to prioritize their day-to-day work than going to the clinic and waiting longer to collect their medicine, hence treatment interruption becomes inevitable.

5.2 Factors associated with TB treatment interruption among TB patients in Marsabit County, 2020

The factors associated with the treatment interruption were, socio-demographic characteristics such as age and sex of the study participants, level of education, marital status, health system related factors for example clinic opening time, distance and cost of travel to health facility, waiting time at the clinic, disease and medicine related factors e.g feeling better on treatment, type of patient, and HIV status of patients.

Suliman Q et al in their study on risk factors for early treatment interruption among newly diagnosed patients in Malaysia, found that sociodemographic factors such ethnicity, education level, and smoking status were all associated with treatment interruption among the TB patients (Suliman, 2022). Marsabit county being one of the pastoralist counties in Kenya had poor access to education, and low level of education could lead to poor health seeking behaviour. Though TB treatment in Kenya is free, there were other cost indirectly associated with it. Transport cost was sighted as one of the factors leading to interruption of treatment. A study by Bernard N. Muture on factors associated with default from treatment among tuberculosis patients in Nairobi agrees with this finding (Bernard N Muture, 2011). In this study, we also found that TB patients who waited at the clinic for more than one hour interrupted their treatment more frequently as compared with those who waited for less than one hour. A study by Qabale Golicha et al in Igembe south sub county of Meru County on factors associated with tuberculosis treatment interruption, found that waiting time of more than one hour for either drug refill, patient review or nutritional counseling and clinical evaluation, contributed to higher frequency of treatment interruption among TB patients (Golicha, 2020). Longer waiting time at the clinic would discourage patients from returning to the facility in the next appointment since this may make them delay to report to their work places. The longer waiting hours at the clinic may also be considered poor quality of care and this will discourage them from visiting the clinics. Other factors associated with treatment interruption include feeling better on treatment, type of patient and HIV status of the patients. A study in Ghana on determinants of TB treatment interruption reported that a significantly high proportion of the patients who interrupted TB treatment, gave feeling better on treatment as reason for

interrupting their treatment (Der, 2016). This seemed to be a common factor contributing to treatment interruption and could be due to the fact that patients come to health facilities mostly when they are very sick but ones they start feeling better and strong enough with clinical signs and symptoms resolution they feel they are cured and so stop coming to the facility to continue with treatment. Patients usually start feeling better on medication just two weeks into the treatment. In this study we found that the HIV infected people did not interrupt TB treatment more frequently than the HIV uninfected patients. Though HIV infection traditionally posed greater challenges in adhering to treatment due to pill burden, patients' treatment adherence was not affected by their HIV status in this study. This could be explained by good quality health education both at the TB and HIV clinics. In contrast to our study finding, a study by Kigozi et al on factors influencing treatment default indicated that the HIV patients defaulted more frequently than the HIV negative patients (Kigozi, 2017).

In another systematic review and meta-analysis study by Ai Ling Oh et al, on the prevalence and predictive factors of tuberculosis treatment interruption, it was found that male gender had higher predictive risk of TB treatment interruption compared with the female gender (Oh, 2022). Other socio-demographic factors that had influence on treatment interruption in this study were alcohol use disorders, and smoking as we as employment status all of which had statistically significant influence on TB treatment interruption. This was in contrast to our study where we found that these socio-demographic factors were not statistically significant association with the treatment interruption.

5. 3 Study limitation

The study covered the period from 2019 to 2020.

1. The long period of study was considered to affect result due to recall bias by patients who were treated and discharged long before the start of the study.
2. High replacement rate and non-attainment of sample size, however replacement was done scientifically and the random sampling powered the study.

5.4 Conclusion

The proportion of TB patients interrupting treatment is high and the male sex is contributing higher proportion of treatment interruption. Modifiable factors of male sex and long waiting time were found to be significantly associated with TB treatment interruption.

5.5 Recommendations

The County health department needs to design an intervention targeting the male TB patients to significantly reduce male treatment interruption. Expansion of TB service delivery points and early opening of the clinics could help reduce waiting time hence reduction in treatment interruption.

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APPENDIX I: QUESTIONNAIRE: THE ENGLISH VERSION

Individual Patient's Questionnaire Number: ☐

Patient registration number: ☐

Date of Interview: _____

Health facility name……... Date……

Instructions:

Indicate the response in the box

Section A: Demographic Information

Qn.1. Sub county of residence: _ _____

Qn.2. Age in Years: 1. (15-24) 2. (25-34) 3. (35-44) 4. (45-54) 5. (55-64) 6. (>65	☐
Qn.3. Gender 1. Male 2. Female	☐
Qn.4. Marital Status 1. Married 2. Widowed 3. Separated 4. Single 5. Cohabiting	☐
Qn. 5 How much formal education did you get? 1. None 2. Primary complete 3. Primary incomplete 4. Secondary complete 5. Secondary incomplete 6. Tertiary	☐

Section B: Patient Related Factors

Qn.6. Have you smoked cigarettes in the last 6 months? 1.Yes 2. No 3. Cannot remember	
Qn.7. Did you drink alcohol in the last 6 months? 1. Yes 2. No 3. Cannot remember	
Qn.8. Do you have a Treatment Supporter? 1. Yes 2. No	

Section C: Socioeconomic Variables

Qn. 9. Source of livelihood

1. Employed 2. Businessman 3. Pastoralist 4. Crop farmer 5. Agro pastoral

Qn.10. During the time you were taking TB medicines, what would you say was your situation in terms of food availability?

1. Always available to take with medicines 3. Not always available 2. Available most of the time 4. Never available

Section D: Health-Care System Related

Qn. 11. What would be the most convenient TB clinic opening times for you?

1.[8am] 2. [8am- 5pm] 4. [5pm]

Qn.12. How much time do you usually wait at the TB clinic before being attended?

1.[<1 hr.] 2. [1-2 hrs.] 3. [>2hrs]

Qn.13. How much distance do you travel to collect your TB medicines (Km)?

1. [<20] 2. [5-10] 3. [11-15] 4. [16-20] 5. [>20]

Qn. 14. How much does it cost you to get to the health facility (Kes)?

1.Nothing (walking distance) 2. [<50] 2. [50-100] 3. [100-200] 4. [>200]

Qn.15. Who supervised you when you were taking your TB medicine? (DOT Status)

1.None. 3. Health Worker at the facility. 2. Family member 4. Community volunteer

Qn. 16. How would you rate the attitude of staff who attended you at the health facility?

1.Very friendly 2. Friendly 3. Indifferent 4. Unfriendly 5. Very unfriendly

Qn. 17. When you went to pick your medicines at the TB clinic, what would you say about the availability of medicines there?

1.Always available 2. Sometimes not available ☐

Qn. 18. I just want to take some time to find out what you know about TB. The following is/ are symptoms of TB (Yes, or No) ☐

a) Coughing [1. Yes 2. No] ☐

b) Night sweats [1. Yes 2. No] ☐

c) Loss of Weight [1. Yes 2. No] ☐

d) Chest Pains [1. Yes 2. No] ☐

Qn. 19. TB treatment should be taken until [Yes or No] ☐

a) 6 months [1. Yes 2. No]

b) One feels better then stop on your own [1. Yes 2. No] ☐

c) 6 months completed and health worker tells you to stop [1. Yes 2. No] ☐

Section E: Stigma and Discrimination

Qn.20. Who do you live with?

1. Family 2. Friends 3. Alone 4. Other

Qn.21. How many other people live with you?

1.(0) 2. (1-3) 3. (4-6) 4(>7)

Qn.22. How long have you stayed in your current dwelling/ house?

1. (12 months) 2. (3-12 months) 3. (>12 months)

Qn.23. Did you inform your family or friends that you were on TB treatment?

1. Yes 2. No

Qn.24. If no to Qn.23 above, why?

1. Fear of being isolated by friends or relatives 2. No one to trust

3. Other

Section F: Disease and Medicine Related

Qn. 25. Did you experience any side effects when you were taking TB treatment? 1.Yes 2. No	
Qn.26. If yes to above question, which side effects did you experience? (Write all that apply in the box) 1.Diarrhoea & Vomiting 2. Headaches and dizziness 3. Skin rashes 4.Numb feet or hands 5. Yellow eyes 6. Painful limbs 7.Others	
Qn. 27. From the day you started taking your TB medicines, how long did it take you before you felt better? (months) 1.[<2] 2. [2-4] 3. [5-6] 4. [Did not feel better]	
Qn.28a). Did you complete your TB treatment? (if yes go to Qn,29) 1. Yes 2. No	
Qn.28b). If the response to the above question is No, what were the reasons for you to stop treatment? (List all that apply) 1.Side effects 2. Feeling well 3. Too many tablets 4. Stigma 5. Distance 6. Cost of travel 7. Lack of family support 8. No food 9. Inadequate supply of medicines 10. Medicine not working 11. Not feel better on medicines 12. No reason 13) Other	

Qn.29. Disease Classification (Tick appropriately according to treatment card or TB register)

1.PTB-Bacteriologically confirmed. PTB-Clinically diagnosed 3. EPTB 4. PTB and EPTB 5. Not Indicated

Qn. 30. HIV Status (as indicated on TB treatment card or TB register)

1. Positive 2. Negative 3. Not Known/indicated

Qn.31 a). Was the patient taking other medicines besides TB treatment?

1.Yes 2. No

Qn.31 b). If yes to the above question, which medicines was the patient taking?

1.HAART 3. Psychiatric (antipsychotic, antidepressants) 2. Anti-hypertensives 4. Other

Qn.32. In your opinion, what could make patients complete their TB treatments?

APPENDIX II: DATA ABSTRACTION FORM

I. Type of TB 1.Pulmonary TB 2. Extraulpmonary
II. Type of patient 1. New 2. Relapse 3. Treatment failure 4. Treatment after lost to follow up
III. Nutritional status of the patient 1. Normal 2. Mild malnutrition 3. Moderate malnutrition 4. Severe Malnutrition 5. Overweight 6. Obese
III. HIV status of the patient 1. HIV positive 2. HIV negative 3. Not done
IV. Type of DOT support 1. Health care worker 2. Household member 3. Community health volunteer

APPENDIX III: PATIENT CONSENT FORM

Dear Sir/ Madam

I am conducting a study on drivers of tuberculosis treatment interruption among Tuberculosis Patients. The findings of the study will be used to improve TB patient management and thus reduce further spread of TB in the community.

The study and its procedures have been approved by the Kenya Ministry of Health through the Kenya field epidemiology and laboratory training program, institutional research and ethical committee and department of health services of Marsabit county. I will now administer a questionnaire in order to collect data. This should take about 30 minutes to complete. There are no foreseeable risks associated with the interview and you can contact me on the following mobile number, 0725894439, if you have any further questions after the interview.

Your participation in this study is voluntary. I therefore kindly request you to assist with answering the questions included in this questionnaire. Please note that any information which may identify you will be kept strictly confidential and your responses will in no way lead to any adverse effect on you and no medical care will be withheld from you because of the responses you may provide.

If you agree to this interview, you may sign below but if you do not agree, you can let me know at this point and I will not proceed with the interview.

Signature/ Thumb print of respondent……

Date/time……

APPENDIX IV: AUTHORITY PERMIT – NACOSTI

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVA

Ref No: 439328

Date of Issue: 24/Aug

RESEARCH LICENSE

This is to Certify that Dr.. Boru Okotu of Moi University, has been licensed to conduct research in Marsabit on the topic: of treatment interruption among tuberculosis patients in Marsabit county for the period ending : 24/August/2022.

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