EXPERIENCES AND FACTORS ASSOCIATED WITH UTILIZATION OF DIRECTLY OBSERVED TREATMENT STRATEGY (DOTs) AMONG TUBERCULOSIS PATIENTS IN MOMBASA COUNTY, KENYA

BY

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DECLARATION

Declaration by candidate

This thesis is my creative work and has not been presented in any institution for any research leading to the award of a degree or any other award.

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DEDICATION

To my parents Mr. and Mrs. Kurera, husband Mohammed Matano, children, Harith and Haytham who provided unwavering support and patience that strengthened me towards achieving my endeavors.

ABSTRACT

Background: Tuberculosis burden in Kenya is 558/100,000 population as per the TB Prevalence survey of 2016. Directly observed treatment for TB, (DOTs) is a TB control strategy recommended by WHO, whereby anti-tuberculosis medications are swallowed by patients under supervision of a health worker, a community volunteer or a family member. Mombasa County has a high Tuberculosis burden (HTB) of 861/100000 population, an increase in TB cases and deaths since 2016 and a decline in cure rate from 73.4% in 2017 to 71% in 2018 despite patients being on DOTs. The study therefore is aimed at documenting experiences of TB patients during DOTs treatment and factors associated with DOTs utilization.

Objectives: To determine factors associated with utilization of DOTs and to evaluate patient's experiences with DOTs in Mombasa County.

Method: A mixed method design was used in the study that was conducted in 8 TB treatment sites in Mombasa County. Participants were TB patients on treatment .In the qualitative approach, Key informant interviews and focus group discussions were conducted among 50 participants. Qualitative data was transcribed and the transcript analyzed thematically. In quantitative approach, consecutive sampling was used to select study participants and structured questionnaires were used to collect demographic and clinical data, from 369 patients' aged ≥18 years on DOTs. Continuous variables were summarized using measures of central tendency and dispersion; categorical variables were summarized by frequencies and proportions. Bivariate and multivariate logistic regression was used to determine factors associated with utilization of DOTs. Odds ratio (OR) was used as measures of association and Statistical significance was considered for p value < 0.05.

Results: The response rate was 100%, mean age of participants was 46.17 ±14.44 years. Among the participants, 224 (60.7%) were males; 35(9.5%) had Drug resistant TB and 334(90.5%) had Drug sensitive TB. Factors significantly associated with DOTs utilization included; Facility TB treatment was sought (AOR=1.21;95%Cl 1.718- 17.47); DOTs provider enquiring on TB patient's progress and providing health education (AOR=7.3; 95%Cl: 2.027- 26.29) and DOTs provider counseling patients on TB drug side effects (AOR=11.72;95%Cl:1.49-92.13) .In in-depth interviews, patients reported, TB drugs side effects, lack of social support and stigma as critical factors associated with utilizing DOTs. Health education for patients contributed to DOTs utilization.

Conclusion: The study demonstrated the following factors being significantly associated with DOTs utilization; Facility first TB treatment was sought, health education on TB and TB drugs side effects, monitoring health progress of TB patients on DOTs, Stigma, lack of social support, loss of employment and distance to health facilities. These factors hinder the successful uptake of DOTs.

Recommendations: Comprehensive and continuous health education on TB and TB drug side effects to patients at the health facilities and monitoring of TB patient's progress by HCWs. Strengthen community support structures through CHVs to educate and encourage patients, family members and community to visit nearest health facility for proper TB diagnosis and treatment and also the benefits of early TB diagnosis.

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List of abbreviations

AFB Acid Fast Bacilli

BCG Bacilli Calmette Guerin

CNR Case Notification Rate

CHV Community Health Volunteer

CHP Community Health Promoter

DOTs Directly Observed Treatment Short Courses

DR-TB Drug Resistant Tuberculosis

DS-TB Drug sensitive Tuberculosis

EPTB Extra Pulmonary Tuberculosis

E Ethambutol

HIV Human Immunodeficiency Virus

H Isoniazid

LTBI Latent Tuberculosis Infection

MDRTB Multi Drug Resistant Tuberculosis

MTB Mycobacterium Tuberculosis

NTLD-P National Tuberculosis and Leprosy and Lung Disease Program

LFTU Lost to Follow up

PLHIV	People Living HIV and AIDs
TB	Tuberculosis
TST	Tuberculin Skin Test
HCW	Health Care Worker
TIBU	TB patient information system
UID	Unique Identification Code
WHO	World Health Organization

Operational Definitions

Completed Treatment	Refers to a tuberculosis patient who has effectively completed both the intensive and continuation phases of treatment, demonstrating no indications of treatment failure. Nonetheless, this designation encompasses situations where there are no documented instances of negative sputum smear, potentially due to the absence of tests or unattainable results.
Compliance	This refers to the degree to which tuberculosis patients have adhered to the prescribed tuberculosis drug regimen in accordance with the TB treatment guidelines.
Continuation Phase	The treatment regimen consists of four months of rifampicin and isoniazid for tuberculosis.
Cured	A tuberculosis patient who fully recover from the disease
Died	A Tuberculosis patient who dies for any reason before or after starting treatment.
Intensive Phase	The first two months of tuberculosis treatment with isoniazid, rifampicin, ethambutol and pyrazinamide that aims to kill the actively growing bacilli (population A)
Knowledge	Refers to information or the facts on tuberculosis and Dots which the tuberculosis patients has.
Loss to follow up	Denotes a tuberculosis (TB) patient who either failed to initiate treatment or experienced an interruption in

	treatment lasting for a consecutive period of two months or more.
Multi- Drug Resistance TB (MDR- TB)	Characterized by resistance to at least the two most potent first-line TB medications, specifically rifampin and isoniazid.
Not evaluated	TB patient in which treatment outcome has not been established.
Regimen	Denotes standardized combinations of medications utilized by the National TB Program. For example, 2RHZE+4RH signifies treatment involving four drugs during the initial two months (rifampicin, isoniazid, pyrazinamide, and ethambutol), followed by two drugs over the subsequent four months (rifampicin and isoniazid).
TB Case	Defined as an individual diagnosed with TB by a healthcare provider who has opted to initiate a complete course of TB treatment.
Therapy	Refers to the treatment intended to treat tuberculosis.
Treatment Failed	Describes a TB patient whose sputum smear or culture yields positive results at month 5 or beyond during the course of treatment.
Treatment success	Represents the cumulative total of patients classified as cured and those who have completed their treatment as prescribed.
Tuberculosis Patients	Refers to the clients who are infected with Mycobacterium tuberculosis and are under treatment.
Utilization	Refers to the extent to which the tuberculosis patients are making effective use of Dots therapy.

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CHAPTER ONE

1.0 Background

Tuberculosis stems from infection by Mycobacterium tuberculosis (MTB) and is a contagious illness primarily impacting the lungs (pulmonary TB) and occasionally other bodily regions (extrapulmonary TB). The spread of the disease happens when individuals harboring pulmonary TB expel bacteria into the air, typically through activities like coughing, sneezing, talking, or singing (Yonge et al., 2016).These bacteria-containing droplets can remain airborne for up to 4 hours, allowing nearby individuals to inhale them and become infected. The tiny droplets can penetrate the alveolar spaces within the lungs, where the bacteria multiply (NTLD-P, 2017).

Tuberculosis (TB) poses a significant challenge to global health and mortality, standing among the top 10 causes of death worldwide attributed to a single infectious agent. The global impact of tuberculosis is estimated to impact approximately 10.4 million individuals (with a range of 8.9 to 11.1 million), resulting in nearly 1.5 million deaths annually. The global incidence rate of tuberculosis stands at roughly 140 cases per 100,000 people. Although TB can affect individuals of all genders and age groups, the highest burden is observed among adult males, comprising 56% of all TB cases in 2019, while adult females accounted for 32% and children for 12% (WHO, 2020). In Kenya, tuberculosis ranks as the fifth leading cause of mortality. In 2019, the country reported and treated 86,504 tuberculosis patients, of whom 8,391 (9.7%) were children. The treatment success rate stood at 81%, accompanied by a mortality rate of 6% (NTLD-P, 2019). Moreover, the TB prevalence survey conducted in 2015/16 revealed that 40% of tuberculosis cases remain

undetected and untreated (Mungai, 2017). This translates to treatment coverage of 59%, down from 63% in 2018.

The year 2020 proved to be particularly challenging in recent public health history, primarily due to the emergence of COVID-19 in Kenya in March 2020. The country witnessed an unprecedented response aimed at containing and mitigating the impacts of the pandemic. Consequently, there was an estimated 15% reduction in TB case identification in 2020, largely attributed to the pandemic and the subsequent response efforts. Additionally, laboratory-based TB diagnosis also declined, adversely affecting case identification and enrollment in TB care and treatment, thereby increasing the risk of active TB transmission within communities (NTLD-P, 2020).

Kenya continues to grapple with a high burden of drug-resistant tuberculosis, prompting the Ministry of Health to implement interventions aimed at bolstering universal access to Drug Susceptible Tuberculosis (DST) testing. In 2020, 72,943 individuals were diagnosed with drug-susceptible tuberculosis (DSTB), while an additional 961 were identified with drug-resistant tuberculosis (DRTB) and commenced treatment under the national tuberculosis program. This translated to treatment coverage of 52%, down from 60% in 2019. Kenya observed a 12.7% decline in Case Notification Rate (CNR), decreasing from 189 per 100,000 population in 2018 to 165 per 100,000 population in 2019, and further dropping to 154 per 100,000 population in 2020 (NTLD-P, 2020).

Mombasa County bears a significant tuberculosis burden (HTB) with a rate of 861 cases per 100,000 individuals and registers high tuberculosis case notification rates within Kenya

(Mungai, 2017). In 2020, Mombasa's case notification rate stood at 271 per 100,000 populations, surpassing the national CNR of 165 per 100,000 populations.

The WHO advocates for the implementation of Directly Observed Treatment, Short Course (DOTs, also known as TB-DOTs) as the primary strategy for controlling tuberculosis. WHO stresses that curing tuberculosis is the most cost-effective method for stopping its spread in communities with high incidence rates. The adoption of the DOTs strategy in Kenya was recommended by WHO in 1993, with complete geographic coverage achieved by 1997. Initially, the total treatment duration for new tuberculosis patients was 8 months; however, a shorter 6-month regimen was introduced in Nairobi province in 2007 and subsequently expanded nationwide by 2009. Kenya has successfully implemented extensive coverage of DOTs (NTLD-P, 2013). The DOTS strategy entails tuberculosis patients ingesting their anti-tuberculosis medications while being supervised by a healthcare worker, community volunteer, or family member, ensuring the proper administration of medications at correct intervals and doses (Muriuki et al., 2016).

Kenya has achieved notable progress in tuberculosis control by adopting the DOTS strategy. Standard treatment duration is usually six months for drug-susceptible tuberculosis and nine months for drug-resistant tuberculosis, employing either a short-term regimen or a combination of second-line drugs (Mungai, 2017).

In 2017, tuberculosis cases under DOTs supervision by healthcare workers, household members, and community volunteers were 3,873 (4.6%), 80,162 (94.3%), and 984 (1.1%), respectively. In Mombasa County, tuberculosis cases under DOTs supervision by

healthcare workers, household members, and community volunteers were 75 (1.95%), 3,611 (93.82%), and 163 (4.23%), respectively (NTLD-P, 2017).

DOTs courses aim to achieve complete and successful treatment, thereby reducing tuberculosis transmission in the community, minimizing tuberculosis-related morbidity and mortality, preventing tuberculosis relapse, and curbing the development of drug-resistant tuberculosis. Effective treatment of tuberculosis necessitates the regular consumption of anti-tuberculosis medications for at least six months. Kenya follows the globally endorsed tuberculosis control strategy outlined by the WHO (NTLD-P, 2013).

DOTs implementation requires the involvement of a treatment supporter approved by both the patient and the healthcare system. Under the DOTs program, tuberculosis patients are supervised while taking their prescribed drugs by various individuals, including healthcare providers, family members, and trusted acquaintances.

Roughly one-third of tuberculosis patients fail to adhere consistently to their medication regimen as prescribed, often resulting in self-administration errors. In the continuation phase of treatment without supervision, some patients may default on their treatment, leading to treatment failure, exacerbating tuberculosis transmission, and fostering the emergence of multidrug-resistant strains (Muriuki et al., 2016).

Efficient case management requires the implementation of DOT during the intensive phase for all newly diagnosed sputum-positive cases. Insufficient utilization of DOTs can elevate tuberculosis transmission, foster the emergence of drug-resistant tuberculosis, elevate mortality rates, and enhance the risk of relapse (Obermeyer, 2008).

1.1 Statement of the Problem

Mombasa County bears a significant tuberculosis burden (HTB) with a rate of 861 cases per 100,000 individuals, compared to Kenya's overall TB burden of 558 cases per 100,000 individuals (NTLD-P, 2019). In 2020, the TB Case Notification Rate (CNR) in Mombasa County stood at 271 cases per 100,000 populations, substantially higher than the national CNR of 154 cases per 100,000 populations for that year. Despite the implementation of DOTs for TB patients, Mombasa County continues to report a considerable number of TB cases and associated deaths. In 2016, there were 3,612 notified tuberculosis cases, resulting in 151 deaths (NTLD, 2016). In 2017, the number of notified cases rose to 3,854. In 2018, there were 3,961 notified cases with a death rate of 5.4%, and in 2019, there were 3,721 notified cases with a death rate of 7% (NTLD-P, 2019).

The implementation of the DOTs strategy has contributed to certain enhancements in TB treatment outcomes. In Kenya, there was a marginal increase of 1% in the treatment success rate for all forms of TB (including new and relapse cases) in 2020, climbing from 84% to 85% compared to 2019. Tuberculosis patients are assigned outcomes which are evaluated as Cured, completed treatment, Died or Treatment failure. These treatment outcomes would show whether DOTs are successful or sub-optimal. Nonetheless, patients face various challenges during the delivery of DOTs services, such as non-compliance, defaulting, loss to follow-up, and mortality during the intensive treatment phase (NTLD-P, 2020). Approximately one-third of tuberculosis patients fail to adhere to their prescribed medications consistently and make errors in self-administration (Muriuki et al., 2016).

Patients undergoing DOTs for tuberculosis (TB) face daily obstacles in adhering to their treatment regimen. These difficulties stem from drug side effects, which can disrupt their

work and social lives by causing tardiness on TB drug refill clinic days, job loss, and increased transportation expenses to TB treatment facilities. Moreover, stigma and discrimination further compound the challenges. For severely ill patients, the demanding nature of daily treatment exacerbates the situation. Despite these challenges, the reasons why some patients discontinue treatment during the continuation phase of DOTs remain poorly understood. Consequently, this research aims to explore patients' experiences with DOTs and the factors influencing their utilization of this treatment method.

1.2 Justification

In 2020, Mombasa County was one of the leading counties in Kenya in terms of reporting the majority of TB cases. The results of the study will provide valuable insights to the Mombasa County Health Management Team (CHMT) regarding the experiences of TB patients undergoing DOTs, which could enhance the quality of care provided to them. This information will aid in developing effective measures to ensure the success of the DOTs strategy in treating tuberculosis. Additionally, the findings will inform decisions about DOTs utilization aimed at combating TB in Kenya and educate healthcare workers to provide comprehensive TB health education to patients, their families, and the community, thus reducing TB transmission.

The year 2020 posed significant challenges for tuberculosis and public health due to the emergence of COVID-19 in Kenya. The response to the pandemic, including movement restrictions, reduced healthcare facility visits, repurposing of health facilities and staff, and the stigma associated with COVID-19 and TB, may have impacted the utilization of DOTs. Some health facilities were transformed into COVID-19 isolation centers, affecting the

diagnosis and follow-up of TB patients. The study will investigate whether COVID-19 hindered the utilization of DOTs among TB patients.

Effective utilization of DOTs is crucial for achieving high cure rates among TB patients, reducing TB transmission in the community, and preventing the emergence of multidrug-resistant TB, ultimately alleviating the burden of the disease. DOTs represent a comprehensive strategy that ensures most individuals with tuberculosis receive appropriate treatment through primary healthcare services.

1.3 Research Questions

1. What are the characteristics of Tuberculosis patients on DOTs in Mombasa County?
2. What are the factors associated with the utilization of DOTs in Mombasa County?
3. What are the experiences of Tuberculosis patients with DOTs in Mombasa County?

1.4 Broad Objectives

To determine factors associated with the utilization of DOTs and explore TB patients' experiences with the DOTs programme in Mombasa County.

1.4.1 Specific Objectives

1. To determine sociodemographic characteristics of Tuberculosis patients on Directly Observed Treatment (DOTs) in Mombasa County.
1. To determine factors associated with utilization of the DOTs programme in Mombasa County.
2. To explore the lived-in experiences of Tuberculosis patients while on Directly Observed Treatment (DOTs) in Mombasa County

CHAPTER TWO

2.0 Literature Review

2.1 Tuberculosis Etiology

The bacteria Mycobacterium tuberculosis, which causes tuberculosis (TB), continues to pose a serious danger to world health, especially in areas with low resources. This aerosolized transmission route facilitates the spread of the disease to susceptible individuals, underscoring the contagious nature of TB (Yonge et al., 2016). Upon exposure to M. tuberculosis, individuals may either develop active TB disease or harbor latent TB infection, wherein the bacteria remain dormant within the body. Those with active TB often experience symptoms such as persistent cough, fever, night sweats, and unintentional weight loss. However, these symptoms can be mild and nonspecific, leading to delays in seeking medical care and contributing to the continued transmission of the disease within communities (Gebreweld *et al.*, 2018). It is imperative to recognize and promptly treat active TB cases to prevent further transmission and mitigate the burden of the disease.

The infectiousness of individuals with active TB underscores the urgency of early detection and intervention to interrupt transmission chains. Studies have shown that untreated individuals with active TB can infect between 10 to 15 others within a year, highlighting the potential for rapid dissemination of the disease within close-knit communities (WHO, 2018). Efforts to enhance case finding, diagnosis, and treatment initiation are essential components of TB control programs aimed at reducing transmission and achieving disease elimination targets.

2.2 Tuberculosis Epidemiology

Tuberculosis (TB) is one of the leading serious global public health problems. There were 10.4 million reported cases across the globe in 2019, with the incidence being 140 per 100,000 persons. A breakdown of the demography in that year indicates that 56% were persons above 15 years, 32% were of a female gender, and 12% were children under 15 years (WHO, 2020). The bulk of TB burden is particularly heavy in certain regions of the globe: South-East Asia, Africa, and the Western Pacific. Meanwhile, located in this area are countries like India and South Africa, which jointly contribute to the total cases of TB in the world, amounting to two-thirds. Kenya features among the high burden countries for TB, including cases with multidrug-resistant TB (MDR-TB) and TB/HIV co-infections.

The literature on Tuberculosis (TB) epidemiology highlights a comprehensive understanding of the disease's global burden, trends, risk factors, and challenges posed by drug-resistant strains. According to the WHO Worldwide Tuberculosis Report of the year 2023, an in-depth assessment of the TB epidemic is provided, emphasizing progress in prevention, diagnosis, and treatment at various levels. This report underscores the importance of ongoing data collection from national health ministries, covering the vast majority of the global population and TB cases, to inform strategies and targets for combating TB (World Health Organization (WHO, 2023).

detailed study published in BMC Public Health explored the global and regional trends in TB incidence from 2000 to 2021, along with the main risk factors. This research utilized advanced statistical and spatial analysis techniques like ArcGIS Pro. It identified significant spatial autocorrelation in TB incidence rates, meaning that geographical areas tend to have similar TB rates to their neighbors. The study also used ARIMA models for

predicting future trends in TB incidence, highlighting the importance of addressing risk factors in high-incidence regions like Africa, Southeast Asia, and South Asia (WHO, 2018).

Another critical area of TB research focuses on drug-resistant TB strains, which present a significant challenge to eradication efforts. A systematic review published in the Infectious Diseases of Poverty journal, compiled data from hundreds of studies to provide a comprehensive overview of the issue. This meta-analysis found high heterogeneity among studies but established a considerable global prevalence of multi-drug resistant TB at 11.6%. The study underscored the necessity of continued vigilance and innovative strategies to combat drug resistance in TB (WHO, 2018). The situation is further complicated by the emergence of drug-resistant TB, of which, in 2019, 500,000 rifampicin-resistant TB cases occurred, with the 78% being multidrug-resistant. It is further estimated that 1.7 billion persons—about 23% of the world's population—were living with latent TB infection, of which it can progress to active TB at any time in their life (WHO, 2020).

Mungai (2017) further supports that the incidence rate of TB in Kenya is the fifth cause of death, with 558 cases in every 100,000 populations. However, notwithstanding the efforts in combating the disease, an estimated number of 147,000 new TB cases in the year 2019 were noticed, of which only 86,504 cases were subjected to diagnosis, treatment, and reported to the National Tuberculosis Program. This translates to a treatment coverage of 60%, which went on a downward plunge in the year 2020 to 52%. There was a decrease in the case notification rate from 189 per 100,000 populations in the year 2018 to 154 per 100,000 populations in the year 2020 (NTLDP, 2021). Of great concern, too, is the case notification rate in Mombasa County, which is reportedly high at 271 per 100,000

populations compared with the national average. This was anchored on a recent TB prevalence survey, which showed that nearly half of all TB cases in the country went undetected (NTLD-P, 2020).

The latest TB prevalence survey of 2015/16 reveals that about half of the people in the country can be identified with TB. In 2020, within the National Tuberculosis Program, 72,943 cases of tuberculosis susceptible to drugs (DSTB) were diagnosed, and in the same year, an additional 961 cases of tuberculosis resistant to drugs (DRTB) were also identified and started on treatment. 0). This subsequently led to a decrease in the treatment coverage from 60% in the year 2019 to 52% in the year 2020 (NTLD-P, 2020).

2.3 Tuberculosis Diagnosis

Detecting active tuberculosis (TB) cases is crucial for diagnosing TB in adults and adolescents. This procedure entails screening all individuals visiting healthcare facilities by inquiring about specific TB symptoms such as cough, fever, unintended weight loss, and night sweats. Individuals displaying any of these symptoms during screening undergo a thorough clinical assessment, including a physical examination and detailed medical history review, to determine if they qualify as presumptive TB cases. Subsequently, eligible patients provide a sputum sample for laboratory testing. In instances where a patient cannot provide a sputum sample, a chest X-ray is considered for TB diagnosis (NTLDP, 2021).

2.3.1 Laboratory Diagnosis of TB

The vital role of laboratories in diagnosing tuberculosis (TB) cannot be overstated, given their function in detecting active TB cases and conducting drug susceptibility testing (DST). The landscape of TB diagnosis has significantly evolved, incorporating a wide array of diagnostic techniques beyond traditional methods.

Laboratory diagnostics form the cornerstone of TB control strategies, employing both conventional and molecular methods. Techniques such as chest X-rays and sputum smear microscopy have long been standard. However, recent years have seen the introduction of rapid molecular tests, like the Gene-Xpert® MTB/RIF assay and line probe assays, which offer the advantage of quicker results and the ability to detect drug resistance markers directly from sputum samples. These advancements are critical in managing TB effectively, allowing for timely initiation of appropriate treatment regimens.

Diagnosing TB in children poses unique challenges, necessitating innovative solutions to overcome the paucibacillary nature of the disease in this demographic. Advances such as the Xpert MTB/RIF assay have made strides in improving detection rates, yet the reliance on decades-old technologies in many regions underscores the ongoing need for more accessible, sensitive, and specific diagnostic tools (Dunn, Starke, & Revell, 2016).

The identification of TB drug resistance through DST is crucial for guiding effective treatment. This underscores the need for laboratories to employ both phenotypic and genotypic DST methods (García-Elorriaga & Rey-Pineda, 2015). Phenotypic DST, although accurate, is time-consuming, whereas genotypic assays, such as whole-genome sequencing, offer faster results and the potential to predict resistance to a broader range of TB drugs.

In Kenya, the Gene-Xpert® MTB/RIF assay is the preferred initial test for TB diagnosis and detecting rifampicin resistance, while microscopy is used for subsequent smears. Stool samples may be utilized for pediatric patients, and TB LAM is regarded as a supplementary test for TB diagnosis in People Living With HIV (PLHIV). Microbiological testing is

advised for all individuals showing signs of TB, with sputum samples sent for Gene-Xpert® MTB/RIF assay if not available at the health facility. Eligible PLHIV should consider the TB LAM test. Kenya has established an efficient sputum referral system to ensure accurate TB diagnosis and facilitate appropriate treatment (NTLD-P, 2022).

All laboratory diagnostic tests for TB are available in Kenya, primarily conducted at the National Tuberculosis Reference Laboratory located at Kenyatta National Hospital. The National Reference Laboratory oversees various tasks, including developing TB laboratory guidelines, ensuring quality smear microscopy and Gene-Xpert services, conducting staff training, drug resistance surveillance, and participating in research and coordination activities.

In Kenya, efforts to enhance TB surveillance have led to the expansion of services to five additional regional facilities. This expansion aims to alleviate the workload of the National TB Reference Laboratory, allowing it to focus more effectively on its essential functions.

GeneXpert machines are distributed across all 47 counties in Kenya, with 193 machines available in 2020 against a target of 250, aiming to enhance TB diagnostic capacity and provide timely results for early TB treatment initiation (NTLD-P, 2020).

Tuberculosis diagnostic laboratories are instrumental in confirming diagnoses, guiding patient care, and monitoring treatment responses. Establishing a tiered network of laboratories, implementing sample referral mechanisms, and ensuring quality assurance are crucial for effective laboratory management (NTLDP, 2021).

Drug susceptibility testing (DST) is crucial for patients exhibiting inadequate treatment responses, with smear microscopy playing a vital role in subsequent monitoring for

confirmed drug-susceptible TB cases. Patients diagnosed with drug-resistant TB necessitate monthly smear microscopy and culture examinations during the follow-up period (NTLDP, 2021).

2.4 Tuberculosis Management and Treatment

The most infectious TB patient is one whose sputum sample confirms the presence of the bacterium. In most individuals infected with the tubercle bacilli, the immune system can contain the infection, leading to a dormant state known as latent TB. TB is a curable and treatable disease (NTLDP, 2021).

Treating TB not only benefits the individual patient but also the community at large. Health providers treating TB patients play a crucial public health role by prescribing appropriate treatment regimens and ensuring patient adherence until completion of treatment (NTLDP, 2021).

TB treatment involves administering multiple drugs in combination to prevent the emergence of drug resistance. Using single drugs (monotherapy) can lead to rapid development of drug resistance, thus combination therapy is essential. Presently, the majority of anti-TB medications are accessible in tablet form, containing multiple drugs combined in Fixed Dose Combinations (FDC) (NTLD-P, 2013).The typical course of treatment for tuberculosis (TB) spans a period of six months, utilizing a blend of four drugs known for their antibacterial properties: Isoniazid (H), Rifampicin (R), Pyrazinamide (Z), and Ethambutol (E). This therapeutic strategy is divided into an initial phase of two months, succeeded by a four-month continuation phase, specifically designed for treating active, drug-susceptible forms of the disease. However, for instances of TB that show resistance to drugs, the NTLD (NTLD, 2019) advises the use of a different mix of medications that

are both more potent and have fewer adverse effects.In Kenya, the treatment of Multi-Drug Resistant Tuberculosis (MDR-TB) relies on the Standardized Short-Term Regimen-6 months treatment regimen comprised of Bedaquiline, pretomanid, Linezolid (600mg) and Moxifloxacin (BPaLM). The treatment for XDR entails the administration of injection Capreomycin, Moxifloxacin, Linezolid, PAS,Clofazimine High dose INH for 6 to 12 months for the short term regimen. Bedaquiline, Linezolid, Cycloserine, Clofazimine and Pyrazinamide (NTLD-P, 2022).Patients diagnosed with extensively drug-resistant TB (XDR-TB) or exhibiting resistance to second-line anti-TB drugs necessitate more prolonged MDR-TB regimens, which may entail the incorporation of additional drugs such as bedaquiline and delamanid (WHO, 2018).The provision of tuberculosis drugs includes offering patients' information, supervision, and support from healthcare workers or trained volunteers. Treatment adherence is essential, as lack of support can make adherence challenging and contribute to disease spread (WHO, 2018).

Without treatment, TB carries a high mortality rate.

Studies carried out prior to the development of anti-tuberculosis (anti-TB) drugs showed that approximately 70% of patients identified with pulmonary TB, who tested positive through sputum smear tests, and around 20% of individuals with pulmonary TB confirmed by culture tests (despite negative sputum smears), succumbed to the disease within ten years of being diagnosed, according to the WHO (WHO, 2020).

The primary objective of TB treatment is to achieve patient recovery, thereby preventing suffering, transmission of the infection, mortality, long-term complications or sequelae, disease recurrence, and the emergence of drug-resistant TB (NTLDP, 2021).

In Kenya, a patient pathway analysis conducted in 2017 revealed that 42% of the population preferred seeking initial care at private facilities (15% informal; 27% formal). Consequently, there is a strong emphasis on engaging with the private sector in TB prevention, care, and control to ensure alignment with the policies and guidelines adhered to by government facilities in TB treatment. Case reporting and record-keeping in tuberculosis are critical processes for monitoring and evaluating disease control activities at both the county and national levels (NTLDP, 2021).

2.5 Directly observed treatment short-course (DOTs) strategy

The principal approach to tuberculosis (TB) control suggested by WHO is DOTs. For both drug-susceptible and drug-resistant TB, this strategy is regarded as the global standard of care, and it is recognized as essential to improving treatment adherence in TB control initiatives (WHO, 2012).

Kenya has adopted the TB control plan in compliance with WHO guidelines, which include giving all patients free TB drugs and making sure that TB diagnoses and treatment results are accurately recorded and tracked. In Kenya, NTLD-P launched the DOTs strategy in 1993. By 1997, the program had expanded to include the entire country. Children and adolescents with tuberculosis should also receive DOTs since they are highly infected. Various approaches have been introduced to expand access to DOTs, such as community-based TB care DOTs (CB-TBC) and Public-Private Mix for DOTs (PPM DOTs). The duration of TB treatment for new patients was initially 8 months, but a shorter 6-month regimen for drug-susceptible TB was initiated in 2007 in Nairobi and later extended nationwide by 2009 (NTLD-P, 2013).

DOTs represent an effort to enhance adherence to TB treatment and achieve treatment completion, thereby ensuring cure and preventing the development of drug resistance. It involves active monitoring and documentation of drug consumption by an observer, which can occur at health facilities, workplaces, communities, or homes (Karumbi *et al.*, 2015). The treatment supporter, whether a healthcare worker, family member, or community health promoter (CHP), supervises patients to ensure proper medication intake (Asuquo, 2013).

The role of CHPs is vital in DOTs implementation, as they conduct daily home visits to oversee medication administration, provide adherence counseling, and make referrals for adverse events during treatment (Das M. *et al.*, 2014).

DOTs aim to achieve successful treatment outcomes, reduce TB transmission, prevent relapse and TB-related deaths. TB treatment typically involves combination of drugs, often in Fixed Dose Combination (FDC) tablets, which offer advantages such as reduced resistance risk, decreased pill burden, and easier monitoring through DOTs. However, identifying adverse drug effects may pose a challenge for healthcare providers when using FDC drugs (NTLDP, 2021). Successful TB treatment involves a six-month regimen for drug-sensitive TB.

The Intensive Phase, spanning the first two months, aims to rapidly eliminate actively dividing bacteria, leading to sputum negativity and symptom resolution. The four drugs that are used in this intensive phase are; Rifampicin, Isoniazid, Pyrazinamide and Ethambutol (NTLDP, 2021).

Continuation phase: This phase represents the concluding 4 to 6 months of TB treatment, during which two medications, Rifampicin and Isoniazid, are given for 4 to 6 months. The aim is to eradicate any remaining or dormant bacilli and prevent subsequent relapse (NTLD, 2021). The effectiveness of DOTs is heavily reliant on the caliber of services provided and the satisfaction levels among TB patients. The prevention of tuberculosis (TB) is advised by a number of methods, each of which offers a different regimen catered to a particular situation. Despite its effectiveness in pediatric populations, there remains a gap in vaccination strategies for adults. Presently, there is no vaccine available that can reliably prevent TB disease in adults, either preemptively or post-exposure to TB infection (WHO, 2020).

2.6 Factors associated with the use of DOTs among tuberculosis patients

2.6.1 Sociodemographic factors

2.7 Patient Factors

These are individual factors that can influence behavior or decision-making regarding an anticipated issue. They encompass gender, age, place of residence, and occupation.

In Kenya in 2020, there were 72,943 patients identified as having TB, with 66% being male, and the age group of 20-44 years carrying the bulk of the TB burden at 8% (NTLDP, 2021).

A study conducted in India found that factors like female gender and education were significantly linked to favorable treatment outcomes, while socio demographic factors such as marital status, family type, and socioeconomic status did not impact treatment outcomes significantly. The study revealed that 87.2% of males and 82.3% of females fell within the 15-59 age groups. Among males, 80.3% had favorable treatment

outcomes, whereas among females, 90.6% experienced favorable outcomes (Pooja S. *et al.,* 2015).

A unique study carried out in Bellary, India, revealed a significant difference in the way that men and women use healthcare services, with men demonstrating lower participation than women. With respective ratios of 1.6:1 and 2.5:1 in favor of men, a higher percentage of male patients seeking medical attention had lung symptoms and were newly classified as sputum smear-positive cases. This disparity was associated with the greater prevalence of lung symptoms and sputum positive rates in the community among men. In addition, the study found that older people had reduced sputum positive rates. In addition, it was noted that male treatment outcomes were not as good as those of female patients (Ahmed et al., 2009). These results highlight the need for customized interventions to alleviate healthcare inequities based on gender.

According to the WHO global tuberculosis report of 2014, the male-to-female ratio for tuberculosis was 1.6 globally, varying from 0.7 to 2.9 among high-burden countries. Key findings from Kenya's tuberculosis prevalence survey indicated that males had a higher disease burden, with 809 TB cases per 100,000, and were more likely to have cases missed (Mungai, 2016).

2.7.1 Knowledge of tuberculosis and DOTs

Understanding tuberculosis, its causes, transmission modes, treatment procedures, treatment duration, potential side effects, and appropriate actions to take when side effects occur is crucial.

A study conducted in Indonesia showed that while most patients recognized tuberculosis as an infectious disease, only a few understood that it is transmitted from an infected

person. Some mistakenly attributed tuberculosis to factors such as stress, consumption of spicy foods, and drinking chilled water with ice cubes. Additionally, only a minority of tuberculosis patients were aware of the need to take medication daily and complete the full course for complete recovery (Widjanarko *et al.*, 2009).

The provision of health education was discovered to markedly improve the overall health condition of tuberculosis patients by encouraging the adoption of DOTs. This educational initiative involved imparting knowledge about the adverse effects of medication and offering guidance on recognizing and reporting them to healthcare providers. Throughout the treatment process, healthcare providers are responsible for assessing clinical progress, ensuring medication adherence, verifying the accuracy of medication administration, confirming drug availability, and assessing patients' ability to attend appointments (Pradipta, 2020).

It is crucial to offer thorough guidance at the onset of treatment, including instructions on managing missed clinic appointments, to promote patient adherence to DOTs. Patients are urged to inform clinic personnel if they cannot attend appointments, enabling alternative arrangements to be made (NTLDP, 2021).

The objective of tuberculosis treatment using DOTs is to achieve patient recovery, prevent tuberculosis-related fatalities and complications, mitigate the emergence and dissemination of multidrug-resistant tuberculosis (MDR-TB), lower relapse rates, and protect the community from continued disease transmission (Shallo D.H, 2017).

A study in Ethiopia demonstrated the effectiveness of DOTs by showing a significant increase in tuberculosis treatment success rates (TSR) from 61.3% to 91.2% over 15 years

(Shallo D.H, 2017). This increase correlated with the expansion of population coverage for DOTs from 18% to 70%, resulting in a decrease in defaulters from 29.9% to 2.1% and a decline in mortality rates from 12.5% to 5.4% between 1995 and 2008 (Shallo D.H, 2017).

In Nigeria, research indicated that the use of high-quality drugs within the DOTs strategy led to the rapid disappearance of tuberculosis symptoms within a few weeks of treatment (Ibrahim *et al.*, 2014). However, patients lacking sufficient understanding of the treatment duration may cease treatment prematurely, under the impression that they have been cured. Regular reminders to patients regarding appointment schedules and actions taken when patients miss appointments are essential for promoting proper DOTs utilization and treatment completion (Ibrahim *et al.*, 2014).

2.7.2. Patient Education and Counseling on Initiation and Follow up of TB Treatment

The utilization of DOTs for tuberculosis treatment is vital for preventing the emergence of drug resistance and increasing the likelihood of cure. Counselling serves to delve into and evaluate the psychological and emotional state of the patient, which may be pre-existing, induced by medication, or arising from social challenges. The approach to counseling should be patient-centered, with the goal of achieving DOTs through adherence. Counseling and education aim to achieve several objectives:

- Inform and educate patients and caregivers about tuberculosis.
- Enhance patients' understanding and knowledge of TB DOTs.
- Empower patients to take responsibility for their treatment
- Improve the relationship between patients and healthcare workers.

- Foster a positive relationship between patients and DOTs providers.

Patients must receive education and counseling before initiating DOTs and continue to receive it during follow-up visits at the health facility. Healthcare workers at the TB treatment center should provide counseling. Implementing direct supervision of TB treatment for all identified cases by healthcare professionals, community volunteers, or relatives in treatment facilities can enhance the outcomes for patients. Supervisors of treatment ensure that each dose of TB medication is consumed by the patient according to the prescribed dosage and schedule (NTLD-P, 2021).

The counseling and education process should be conducted systematically to ensure positive reception by the patient. This includes:

- Being friendly and assuring confidentiality to the patient.
- Using simple and appropriate language for the patient's understanding.
- Listening to feedback from the patient and addressing any questions and concerns.
- Clarifying information.
- Exploring factors associated with or barriers to DOTs use.

Providing information to the patient on TB treatment, including treatment duration, possible side effects, the importance of DOTs, TB prevention and transmission, and follow-up visits.

Clarifying the duties and obligations of the patient, family members, healthcare professionals, and Community Health Promoters (CHPs). Counseling and educational sessions are designed to craft a TB treatment strategy that adheres to a patient-centered approach. This strategy encompasses a timetable of clinic appointments for treatment

monitoring, as well as counseling and educational sessions. In the intensive phase, visits are scheduled weekly, whereas in the continuation phase, they occur biweekly (NTLDP, 2021).

2.7.3 DOTs drugs and side effects

DOTs programs have played a pivotal role in the achievements of various large-scale tuberculosis (TB) control endeavors in developing nations. Active TB is typically treatable with antibiotics, though the specific drugs and treatment regimens can vary from one country to another. Typically, curing TB necessitates six to eight months of consistent daily treatment, with effective therapies rendering individuals non-contagious and preventing further spread of TB. The introduction of DOTs has demonstrated enhancements in TB treatment success rates and reductions in the transmission of drug-resistant TB.

Regular monitoring of patients undergoing DOTs is crucial to evaluate their response to treatment. Investigations conducted among tuberculosis patients in Asmara indicated that some experienced adverse effects from TB therapy, including nausea, vomiting, joint pain, drowsiness, loss of appetite, and gastritis. Furthermore, certain patients perceived that the treatment exacerbated their condition (Gebreweld et al., 2018).

Poor adherence to treatment regimen can lead to drug resistance. Health providers can monitor adverse drug effects by educating patients and DOTs providers on recognizing common drug side effects, urging them to report symptoms, and asking patients about their experiences during clinic visits (Arpukumar *et al*., 2019).

Research conducted in Bangladesh and Nigeria has underscored the prevalence of adverse drug reactions among tuberculosis (TB) patients, which leads to morbidity, loss to follow-

up, mortality, and escalated healthcare expenses (WHO, 2019). Consistent monitoring of patients aids in completing treatment and handling adverse drug reactions.

Some patients may find it challenging to adhere to treatment due to the number and size of pills. Therefore, efforts should be made to educate patients, DOTs supporters, and healthcare providers to report any persistence or reappearance of TB symptoms, adverse drug reactions, or treatment interruptions (Demissie *et al*., 2002).

If a scheduled appointment is missed, TB clinics should promptly reach out to the patient, ideally within 24 hours during the intensive phase. It's important to investigate the reason for the patient's absence and motivate them to continue treatment. If a patient declines treatment, every endeavor should be made to convince them to resume (NTLDP, 2021).

2.7.4 Social stigma, discrimination, and confidentiality

Stigma presents a major barrier to the successful execution of the DOTs for tuberculosis (TB). Patients undergoing DOTs often experience repeated encounters with stigma due to the treatment's requirements. Discrimination based on the disease, particularly at healthcare facilities, can further hinder compliance with DOTs.

In India, fear of TB infection prompts people to isolate infected individuals from social settings and even restrict interactions with family members. Patients on DOTs are required to visit public health facilities for observed treatment, leading to frequent exposure to healthcare providers and the surrounding community, thereby exacerbating stigma (Arpukumar *et al*., 2019).

Similarly, in Zambia, TB is often equated with AIDS, instilling fear and leading to social withdrawal and exclusion from community interactions. Patients report experiences such as being pointed at, gossiping by neighbors and exclusion from social events, prompting some to conceal their diagnosis (Kaona *et al.*, 2004).

Research in Brazil suggests that the burden of frequent visits to TB facilities or encounters with healthcare providers may intensify stigma and compromise patients' ability to maintain privacy about their health status, deterring them from completing or seeking TB testing (Amande J *et.al.*, 2016).

In Uganda, high levels of stigma towards TB persist, with many patients desiring confidentiality about their TB status due to misconceptions linking TB and HIV. Social pressures and anxiety over community perceptions of TB patients contribute to poor utilization of DOTs, highlighting the need for counseling to boost patient confidence and adherence to treatment (Sempeera *et al*., 2017).

In rural regions, the impact of TB-related stigma on the utilization of DOTs appeared to be diminished, as patients commonly referred to the illness as "lung disease." However, in urban environments, certain patients conceal their TB status, particularly those from more affluent backgrounds, though they may choose to disclose it to their employer.

Families may also enforce measures such as using separate utensils and bedrooms due to fears of disease transmission (Widjanarko *et al.*, 2009).

2.7.5 Substance abuse and cultural beliefs

These practices include self-medication with homemade remedies, herbs, smoking, alcohol consumption, purchasing drugs from pharmacies or shops, and seeking assistance from

traditional healers. In Timor, there was a cultural belief that tuberculosis could only be cured through a traditional ceremony conducted by a traditional priest (Martins N. *et al.*, 2008).

In Ethiopia, tuberculosis patients often turn to traditional healing methods during or after anti-TB medication to alleviate the side effects of the drugs (Demissie *et al*., 2002).

Treatment for tuberculosis (TB) must be adhered to for a number of reasons, including prevention of disease transmission, recovery, and a decreased chance of medication resistance, relapse, and death. On the other hand, non-adherence to tuberculosis treatment represents a major barrier and a major issue for tuberculosis management globally. Effective attempts to control the disease are hampered by this noncompliance, which greatly adds to therapy inefficacy (Gebreweld F H. et al., 2018). Maintaining patient adherence to treatment plans is essential to attaining favorable results and mitigating the impact of tuberculosis on both individuals and communities. To solve this pressing problem and strengthen overall TB management initiatives, strategies targeted at improving treatment adherence ought to be given top priority.

Similarly, in Zambia, TB treatment guidelines have been distributed to all healthcare facilities to ensure the implementation of the DOTs strategy. This strategy is acknowledged as the most effective approach to fostering adherence among TB patients by having a healthcare provider supervise the patient's medication intake (Kaona et al., 2004).

2.7.6 Community, family, and household support

Research conducted in Indonesia revealed that 60% of tuberculosis (TB) patients disclosed having someone to oversee their treatment, with partners, family members, or community health volunteers commonly assuming this role. Patients regarded these observers as indispensable; without them, they tended to forget their medication schedules and faced challenges in obtaining monthly supplies of pills. Notably, around half of elderly and less educated individuals discontinued treatment due to a lack of social support or a designated observer to monitor their medication intake, accompany them to medical appointments, and procure new medication (Arpukumar *et al*., 2019).

Health education provided by DOTs providers covers treatment duration and potential side effects. Additionally, a supportive and encouraging approach from DOTs providers has been shown to enhance patients' adherence to treatment (Widjanarko *et al*., 2009).

The involvement of family and community members serves as a crucial facilitator for DOTs implementation. Conversely, the absence of such support networks significantly contributes to non-adherence among TB patients. In Ethiopia, research indicated that patients discontinued treatment because they lacked familial and communal backing. They emphasized the importance of care, as well as social and financial assistance, particularly during the intensive phase of treatment. Many patients expressed the need to seek support due to income loss and physical exhaustion (Gugssa B. et al., 2017).

2.7.7 Communication of TB Patient with DOTS provider

Effective communication between patients and healthcare providers is essential for fostering trust and nurturing positive relationships in healthcare settings. In Indonesia,

elderly and less educated patients often struggled to comprehend medical instructions from doctors. DOTs providers are equipped with knowledge about treatment duration and potential side effects, and a supportive approach from these providers can enhance patient adherence to DOTs protocols (Widjanarko *et al.*, 2009).

The manner in which language is employed, both within healthcare facilities and during home visits by DOTs providers, whether they be healthcare professionals, family members, or community volunteers, significantly influences patients' reactions and their adherence to TB treatment (Kaona *et al.*, 2004).

This finding resonates with research conducted in Timor, where TB nurses demonstrated comprehensive knowledge about TB and DOTS and showed strong dedication to their duties. Patients expressed satisfaction with the TB services provided at their local clinics, particularly appreciating the regular health education sessions on tuberculosis facilitated by the TB nurses (Martins N., 2008).

Insufficient knowledge among healthcare workers can detrimentally impact TB treatment outcomes, while poor interpersonal communication has been linked to unfavorable TB outcomes. Healthcare workers should closely monitor TB patients' attendance and address any barriers they encounter to ensure continuous care and support. Special attention should be given to TB patients, focusing on assessing their adherence to medication, as well as their physical, social, and psychological needs (Datiko *et al.*, 2020).

2.7.8 Financial burden and loss of employment

In Kenya, tuberculosis (TB) diagnosis and treatment are provided at no charge in public health facilities. However, patients still face additional healthcare expenses, such as

ancillary drugs and extra tests, along with significant non-medical costs like transportation and lodging. This results in both financial strain and loss of productivity for TB patients and their caregivers. A substantial portion of TB-affected households, including those with drug-resistant TB, experience catastrophic costs. The total cost per TB episode, including both medical and non-medical expenses, is Ksh. 26,041.49, with non-medical costs related to nutrition and food supplements constituting the majority (NTLD-P, 2017).

To cope with these expenses, a considerable portion of TB patients resort to harmful measures like taking out loans, depleting savings, or selling assets. Although TB diagnosis and treatment are provided free of charge in Kenya, the absence of support for food/nutritional assistance, transportation, and time spent seeking treatment undermines the affordability of healthcare for TB patients (NTLDP, 2017).

In Brazil, despite TB drugs being freely provided, the financial and psychosocial burden of DOTs can be substantial due to the numerous clinic visits required, resulting in significant monetary and time costs for patients if not reimbursed (Amande J *et.al*, 2016). Similarly, in Indonesia, rural patients often incur significant transportation expenses, and some must pay for private healthcare services, influencing their utilization of DOTs (Widjanarko *et al.*, 2009).

A study conducted in Asmara found that certain patients experienced job loss due to tuberculosis, either because they were too ill to continue working or due to the demanding treatment schedule. Consequently, this situation reflects the financial strain faced by these patients. As a result, they struggle to afford basic necessities such as food and transportation to access healthcare services, leading to their inability to utilize DOTs

(Gebreweld *et al.*, 2018). Studies highlight the detrimental effects of TB on patients' financial stability, including job loss and inability to afford basic needs like food and transportation to healthcare facilities, thereby hindering DOTs utilization.

Addressing these challenges in Kenya requires multifaceted policy and program interventions, including linking TB-affected households to social protection programs, expanding food support to include malnourished TB patients and children, and integrating all aspects of TB care into the national health insurance package. Additionally, policies are needed to eliminate discrimination and ensure job security for TB patients (NTLD-P, 2017). DOTs implementation may also disrupt patients' work or household responsibilities, further exacerbating financial strain and impacting employment status (Amande J *et.al.*, 2016).

2.8 Health Facility Factors

2.8.1 Distance to TB Clinics

The proximity of TB clinics significantly aids in ensuring patients complete their treatment under DOT for tuberculosis (TB). In Kenya, where the Free TB treatment policy is implemented, patients can choose the nearest clinic for medication after diagnosis. The MOH and the NTLD-P tackle challenges related to distance by educating TB champions and community health promoters (CHPs) within communities to deliver medication to individuals who cannot access the clinic. The involvement of CHVs is viewed as advantageous because they are more familiar with the patients' circumstances, understand the intricacies of TB within their community, can provide support to patients, and help ensure adherence to DOTs (NTLD-P, 2013).

The DOT component imposes financial and opportunity costs on patients, as well as the possibility of heightened stigma. Easy access to TB treatment is vital for effective TB control, but distance can hinder access, especially for daily observation during the intensive phase (Ibrahim *et al.*, 2014). In Asmara, research found that patients from remote villages faced high transportation costs to reach clinics lacking DOTS services and transportation options. Despite available transport, patients struggled financially during the six-month treatment due to unemployment and limited family support (Gebreweld *et al.*, 2018). Another study highlighted transportation difficulties for TB patients, especially those too weak to walk to healthcare facilities, emphasizing the need to expand decentralized DOTS clinics to address these access challenges (Kaona *et al.*, 2004).

2.8.2 Quality of Care

A study carried out in Kenya (Liefooghe et al., 1997) found that community members viewed peripheral healthcare facilities such as health centers and dispensaries as lacking the necessary equipment and staff for effective TB diagnosis. Given the decentralization of TB services and the National Tuberculosis Program's extensive efforts to enhance smear microscopy services across various facilities (MOH, 2006), it is to establish whether this perception has changed and how it may impact healthcare-seeking habits and patient delays.

2.8.3 Health care Worker's attitudes towards TB patients

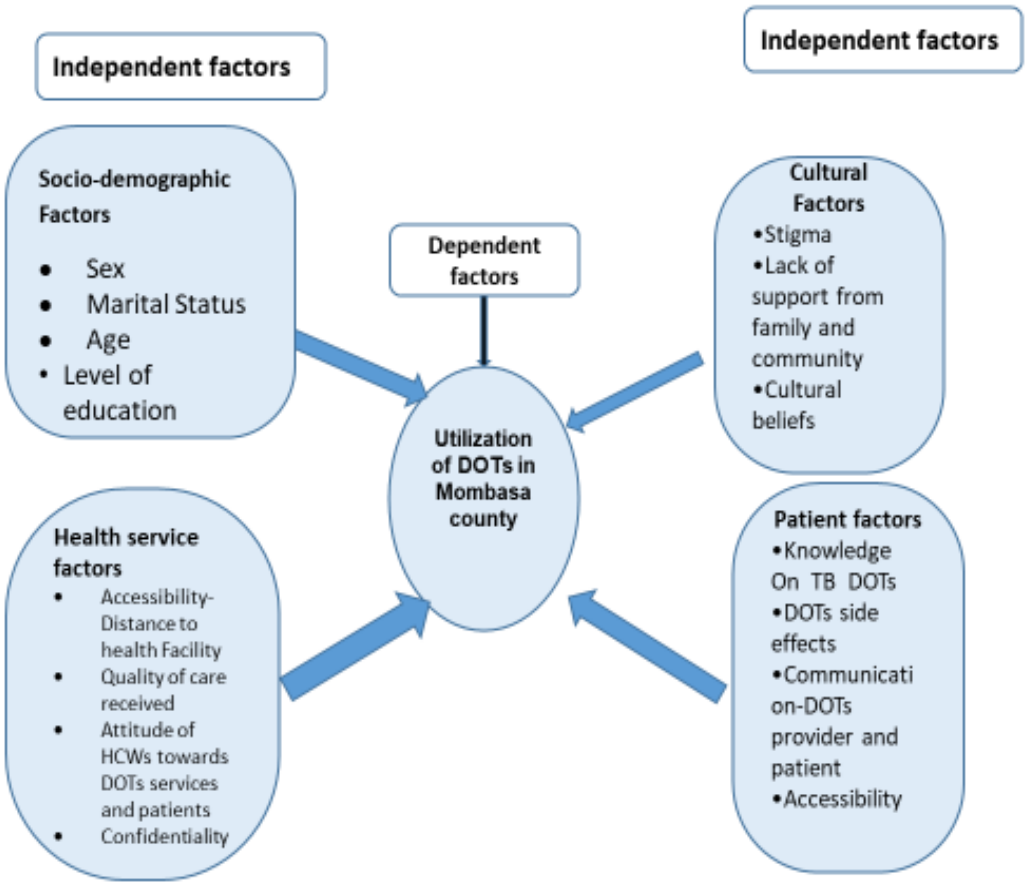
Improving training and management processes for healthcare providers involved in tuberculosis care is crucial. Continuous training for healthcare professionals is a necessary step towards ensuring quality care for tuberculosis patients.

A study conducted in Asmara highlighted that the positive interaction and attitudes of health professionals towards TB patients served as a motivating factor for patients to adhere to treatment. In situations where patients had unavoidable commitments such as attending a relative's funeral, healthcare providers supplied medication for up to 2 to 3 days to prevent medication shortages and missed appointments, thereby reducing interruptions in DOTs attendance during social events (Gebreweld *et al.,* 2018).

Healthcare providers emphasized the importance of family members' support as a beneficial aspect of DOTs because it prevents patient isolation. They identified DOTs as a strength, as it fosters a sense of commitment to treatment among patients, aligning with the strategy's guidelines that advocate for shared responsibility between healthcare workers and patients to achieve treatment success (Queiroz et al., 2012).

In Timor, research findings showed that patients expressed confidence in their interactions with clinic staff. Despite their cultural beliefs regarding tuberculosis, they were willing to adhere to treatment because they trusted and followed the instructions provided by healthcare providers. Some tuberculosis patients who successfully completed treatment attributed their adherence to following instructions from tuberculosis nurses, emphasizing the importance of positive patient-clinic staff relationships as a motivating factor. However, some members of the community criticized nurses in certain tuberculosis centers for their perceived lack of politeness and inadequate performance in their duties (Martins *et al.,* 2008).

Conceptual Framework



Adapted from Zambia *et al*., 2018

Figure 1: Conceptual Framework

CHAPTER THREE

3.0 Study Methodology

3.1 Study Area

The study took place in Mombasa County, which ranks among the counties in Kenya with a high tuberculosis burden, standing at 861 cases per 100,000 individuals. This county spans an area of 229.7 square kilometers and is home to a population of 1,271,920 people, with approximately 60% residing in densely populated informal settlements. The rapid growth in population in Mombasa County puts significant strain on healthcare facilities, making it challenging to adequately address various aspects such as public health, economic growth, and the overall well-being of residents. Tuberculosis remains a prevalent public health concern in this area.

Mombasa County comprises six sub-counties: Changamwe, Nyali, Kisauni, Jomvu, Mvita, and Likoni. The county is served by 323 health facilities, including 92 designated tuberculosis treatment sites. The study focused on eight specific health facilities: Bomu Hospital Changamwe, Magongo Dispensary, Likoni Sub-County Hospital, Mvita Health Center, Tudor Sub-County Hospital, Mikindani Dispensary, Shimo la Tewa, and Kongowea Health Centre. These facilities were chosen because they host chest clinics where tuberculosis patients receive healthcare services, adhere to the guidelines of the NTLD-Program regarding tuberculosis care, and maintain proper registration and documentation of treatment through standard TB treatment cards and registers.

3.2 Study Design

Mixed study design with both qualitative and quantitative approach.

Quantitative approach employed an analytic design. The quantitative approach employed was analytical where numeric data was collected and statistically analyzed to aggregate the data to describe, compare and show relationships among the variables of interest The qualitative employed a descriptive design through phenomenological method where people who have experienced a phenomenon are involved. In the study it was Tuberculosis patients on Anti-TB drugs (DOTs) using several techniques such as interviews, observation and Focused Group discussions.

For the qualitative study Focused group discussions, key informant interviews were conducted in selected health facilities concurrent with the quantitative study. This was possible through the cooperation of the well-trained research assistants.

3.3 Study Population

Individuals aged 18 years and older who have been diagnosed with tuberculosis visit specific healthcare facilities in Mombasa County and are registered for the administration of anti-TB medication, including both the intensive and continuation phases of treatment, regardless of whether they have Drug-Sensitive TB or Drug-Resistant TB. During their treatment, participants have their intake of anti-TB drugs regularly supervised by a healthcare worker, community health volunteer, or a family member.

3.4 Inclusion and Exclusion criteria

3.4.1 Inclusion criteria

- Adult bacteriologically confirmed tuberculosis patient aged 18 years and above, resident of Mombasa County for at least one year

- Tuberculosis patients on TB care for two or more months during data collection
- Tuberculosis patients recorded in tuberculosis registers from January 2019
- Health care workers working in the TB clinic who monitor, follow up with TB patients and drug refill

3.4.2 Exclusion criteria

1. Tuberculosis patients who are very sick could not be able to respond to questions or are mentally incapacitated.

3.5 Study Period

The current study was conducted over a three-month period, from February 1st, 2020, to April 30th, 2020, and involved a cross-sectional approach incorporating both qualitative and quantitative elements.

3.6 Sample Size Determination

The sample size was determined using Cochran's formula (Cochran, 1997), utilizing data from the Tuberculosis prevalence survey of 2016, which indicated a TB burden of 6% in Kenya. This calculation yielded a sample size of 369 respondents, which was then utilized to investigate factors related to the utilization of Directly Observed Therapy.

Cochran's formula (1997)

$$n = \frac{z^2 P (1-P)}{d^2}$$

Where

n=desired sample size

Z=95% Confidence interval or 1.96

P= prevalence of TB in Kenya (0.6)

d=degree of precision 0.05

$$n=\frac{1.96^2\times 0.6(1-0.6)}{0.05^2}$$

n=369

For the qualitative part of the study, 50 participants were enrolled into the study

3.7 Sampling Procedure

The sampling frame consisted of eight high-volume TB treatment public health facilities within the study area. Selected health facilities have chest clinics where 80% of all tuberculosis patients seek care. The primary sampling unit was tuberculosis patients currently on care attending the selected tuberculosis treatment sites. After selecting the study sites, probability proportionate to size was used to allocate sample size to each facility. The workload for the 1st quarter of 2018 divided the sample proportionately within the individual health facility about the total sample size.

Table 1: Showing selected Health facilities and sub-counties

Health Facility	Sub-county
Bomu Hospital (Changamwe)	Changamwe
Mvita Health center	Mvita
Magongo Dispensary	Changamwe
Kongowea Health Centre	Nyali
Likoni sub-county Hospital	Likoni
Mikindani Dispensary	Changamwe
Tudor sub-county hospital	Mvita
Shimo la Tewa Health Centre	Kisauni

Table 2: Qualitative study Participants

Method	Health facilities	No. of participants
In-depth Interview	Magongo Disp., Mikindani Disp., Likoni sub-county hosp., Bomu, Mvita health center., Shimo la Tewa	18
Focussed Group Discussions	Shimo la tewa Dispensary, Kongowea Health center, Tudor sub-county hospital	24
Key informant Interview	Magongo Disp., Mikindani Disp., Likoni sub-county hosp., Bomu, Mvita sub-county hosp., Shimo la Tewa, Kongowea health center, Tudor sub-county hospital	8

Table 3: Sample proportionate to the size

Health Facilities	Health Facility Workload 1st Quarter 2018	Sample Proportionate to size (Proportion of workload)
Bomu Medical Hospital	88	88/405*369=80
Tudor Sub- County Hospital	45	45/405*369=41
Mvita Health Center	23	23/405*369=21
Magongo Dispensary	46	46/405*369=42
Kongowea health center	95	95/405*369=86
Likoni Sub-county Hospital	58	58/405*369=53
Mikindani Dispensary	22	22/405*369=20
Shimo la Tewa H/Centre	28	28/405*369=26
Total	**405**	**N=369**

3.7.1 Selection of study participants

Patients participating in the study were consecutively chosen from those in the continuation phase of tuberculosis treatment who visited the chest clinic of selected health facilities for anti-TB drug refill and follow-up appointments. Selection continued until the predetermined sample size of 369 participants was reached, a feasible task facilitated by TB clinics maintaining daily patient diaries. Healthcare workers at these clinics aided in participant selection as patients arrived. Verification of patients receiving tuberculosis care was performed using the daily TB registration register (TB 4 register), TIBU, and tuberculosis patient records at the selected health facilities in Mombasa County.

The initial participant was randomly selected from tuberculosis patients attending the chest clinic on a specific day and meeting the inclusion criteria. Subsequent participants were chosen consecutively. If a potential participant declined participation, they were replaced by the next eligible patient in the register. This process continued until the desired sample size was achieved.

Participants were Purposively selected from TB patients walking into the selected TB clinic on the particular TB clinic day. Allows researcher to focus on the specific area of interest. Three Focus Group Discussions (FGDs) were conducted in three health facilities: Kongowea Health Center, Bomu Hospital, and Shimo la Tewa Dispensary. Each FGD comprised 8 participants, selected purposively due to challenges posed by Covid-19. Additionally, for in-depth interviews, 3 participants were randomly selected from each of the six health facilities, provided they had been receiving TB care for at least one month during the data collection period.

In Key Informant Interviews, one healthcare worker from each of the 8 health facilities involved in monitoring, following up with TB patients, and managing drug refill processes in TB clinics was selected for participation.

3.8 Data Collection Methods and Procedure

3. 8.1 Quantitative data

The quantitative data was collected through self-administered questionnaire. A structured electronic questionnaire was loaded into a tablet to gather study participants' responses. A data collection assistant was trained to administer a structured questionnaire to the tuberculosis patients on DOTs attending the selected tuberculosis treatment clinics during the TB clinic days.

Each electronic questionnaire was given a number starting from one to the last while collecting data. All study participants were given a unique identification number (UID).

A translated Kiswahili version of a structured electronic questionnaire was developed. A face-to-face interview was conducted using the electronic questionnaire with each study participant number, and information on sociodemographic factors including age, gender, marital status, level of education, occupation, the residence was collected. Information on dependent variables included the use of DOTs, DOTs provider, stigma and discrimination, drug side effects, distance to TB clinics, and communication with DOTs providers.

The data were collected from 369 consented patients with TB who were on DOTs.

3.8.2 Qualitative data collection and management

Focus group discussions (FGDs) and interview guides were initially developed in English and then translated into Kiswahili. Three FGDs were carried out in three health facilities, each involving 8 tuberculosis patients, a measure necessitated by challenges posed by

Covid-19. Only TB patients receiving DOTs were selected to share their firsthand experiences with the treatment regimen.

Furthermore, eighteen in-depth interviews were conducted across six health facilities, purposefully selected for diversity. Within each facility, 3 TB patients were randomly chosen for in-depth interviews, aiming to explore factors influencing DOTs utilization and delve into the experiences of TB patients undergoing DOTs. These interviews took place in separate rooms within the TB clinics.

Key informant interviews were also conducted in the 8 health facilities. One healthcare worker from each facility participating in the study was selected to provide insights into factors associated with DOTs utilization. FGDs were recorded, observations were made, and notes were taken throughout the sessions. Prior consent was obtained from TB patients receiving DOTs before conducting the interviews.

3.9 Data Management

3.9.1 Data entry

Participants' responses were collected using electronic questionnaires administered on tablets. These questionnaires underwent thorough checks for completeness before being uploaded into the principal investigator's (PI) computer using Epi Info version 7.2 software. Subsequently, the data was exported to Microsoft Excel for further cleaning. To ensure confidentiality, all data entered into the study databases were de-identified and linked solely to the questionnaire and unique identification numbers. These files were securely stored in password-protected folders. Additionally, a double-entry system was implemented for added data security.

All paper-based research records, including consent forms, were securely stored in a locked filing cabinet, while soft copies were saved on password-protected computers.

For qualitative data collection, field notes were taken, and audio digital recordings (ADR) were utilized. Furthermore, non-verbal cues and gestures were observed during the data collection process.

3.9.2 Data Analysis

3.9.2.1 Quantitative data analysis.

Data collected via questionnaires were input and analyzed utilizing Ms. Excel 2013 (Microsoft Office, Seattle, USA) and Epi Info 7.2.2 TM (CDC-Atlanta). The variables gathered encompassed sociodemographic factors such as gender, age, residence, occupation, as well as factors influencing the utilization of DOTs including stigma, drug side effects, and health education level. Summary statistics for continuous variables involved measures of central tendency and dispersion, while frequencies and proportions summarized categorical variables. The utilization of DOTs among tuberculosis patients was explored using both bivariate and multivariate logistic regression analyses. The study included a sample of 369 TB patients, selected through consecutive sampling. Association measures were represented by odds ratios (OR), with statistical significance defined at a p-value of < 0.05.

3.9.2.2 Qualitative data analysis

Tuberculosis patients who possessed the necessary information regarding DOTs were selected for participation in the study. A total of fifty respondents took part, comprising twenty-nine males and twenty-one females. Focus group discussions were organized at three study sites, each involving eight TB patients. Furthermore, interviews were

conducted with eight healthcare personnel, one from each study site assigned to the chest clinic, serving as key informants.

The research team conducted face-to-face, tape-recorded, in-depth interviews lasting approximately 30-45 minutes on average. Additionally, focus group discussions, each lasting around 90 minutes, were held. Key informant interviews were also part of the process. Each focus group discussion session was facilitated by one moderator, supported by a note-taker and a recorder. All interviews took place at locations chosen by the respondents, with notes taken during the interviews to assist researchers in recalling specific details from each respondent's interview.

Qualitative data analysis involved independent translation and verbatim transcription of all recorded data by the researcher and a research assistant. Subsequently, after verbatim transcription and translation, the data were compiled, and transcripts were thoroughly reviewed to identify emerging ideas.

3.10 Ethical approval and consideration

This study received approval from the Moi University/Moi Teaching and Referral Hospital Institutional Review and Ethics Committee (MU/MTRH IREC) with approval number FAN: 0003506, and it also obtained a license from the National Commission for Science, Technology, and Innovation (NACOSTI) with license number NACOSTI/P/20/4809.

Permission to collect data in Mombasa County was granted by the Mombasa County Health Management Team. Prior to the interviews, each potential study participant was required to provide written consent. Participant confidentiality was ensured through de-identification, and consent forms were securely stored in a lockable cabinet. Data entry was

done on a computer with password protection. Additionally, permission was obtained from the facility in charge before commencing the study.

3.11 Results Dissemination

A report was forwarded to both the Mombasa County Department of Health and the Ministry of Health, as well as to the NTLD-P. The NTLD-P utilized the data to enhance DOTs and expand implementation plans. Furthermore, the findings were utilized to produce papers for dissemination in medical journals at regional and international scientific conferences related to health fields. Additionally, a scientific manuscript summarizing the study's outcomes was prepared for publication in international peer-reviewed journals.

CHAPTER FOUR

4.0 RESULTS

In the study, data was gathered from participants through both quantitative and qualitative methods, achieving a response rate of 100%.

Quantitative Results

4.1 Socio-demographic characteristics of Tuberculosis patients on DOTs

Three hundred and sixty-nine tuberculosis patients participated in the study, achieving a response rate of 100%. The average age of the respondents was 46.17 ±14.44 years, with males comprising 224 (60.7%) of the participants, and 160 (43.4%) respondents having completed secondary school education. Regarding the type of tuberculosis, 334 (90.5%) of the respondents had drug-sensitive tuberculosis. Additionally, three hundred and three (82.1%) of the patients interviewed were newly diagnosed with TB (Table 1).

Table 4: Sociodemographic characteristics of tuberculosis patients on DOTs

Gender N=369	**Frequency**	**%**
Female	145	39.3
Male	224	60.7
Age(Years)		
15 – 24	55	15.0
25 – 34	141	38.2
35 – 44	95	25.7
45 – 54	62	16.8
55 – 64	10	2.7
≥65	6	1.6
Education level attained		
No education	12	3.3

Primary	135	36.5
Secondary	160	43.4
Tertiary	62	16.8
Type of TB		
Drug-Resistant TB (DR-TB)	35	9.5
Drug Sensitive TB (DS-TB)	334	90.5
Categories of TB Patient		
LT	10	2.7
New	303	82.1
Relapse	45	12.2
Treatment after failure	11	3.0

4.2 Factors associated with Utilization of DOTs among tuberculosis patients in Mombasa County

Bivariate and multivariate logistic regression analyses were employed to identify factors linked with the utilization of DOTs among tuberculosis patients. Factors significantly associated with the utilization of DOTs by tuberculosis patients include: receiving treatment at a government hospital (COR=5.478; 95% CI: 0.178-17.47), seeking treatment from a traditional healer (COR=4.21; 95% CI: 1.74-10.22), receiving counseling from the DOTs provider regarding TB treatment and side effects (COR=3.55; 95% CI: 1.18-11.56), the DOTs provider inquiring about the patient's progress (COR=4.145; 95% CI: 1.077-15.944), and the perception of most people avoiding TB patients (COR=4.43; 95% CI: 1.193-16.47). The Chi-Square test was employed to examine the association between these factors.

Table 5: Bivariate Analysis Factors associated with Utilization of DOTs among tuberculosis patients in Mombasa County

Gender		**COR**	**p-value**	**[95% CL interval]**	
Female	145(39.3)	1			
Male	224(60.2)	1.367	0.348	0.712	2.626
Age					
15-24	55(15.0)	1.446	0.555	0.424	4.931
25 – 34	141(38.2)	0.58	0.195	0.254	1.322
35 – 44	95(25.7)	1			
45 – 54	62(16.8)	1.527	0.498	0.449	5.197
55 – 64	10(2.7)	1			.
≥65	6(1.6)	0.161	0.062	0.024	1.093
Education level attained		**COR**	**p-value**	**interval**	
Primary	135(36.5)	1			
No education	12(3.3)	0.56	0.482	0.111	2.817
Secondary	160(43.4)	0.75	0.438	0.363	1.55
Tertiary	62(16.8)	1.322	0.609	0.455	3.841
Where was the first form of TB treatment sought?					
Government hospital	185(50.1)	5.478	0.004	0.178	17.47
Private Clinic/Hospital	164(44.5)	1			
Traditional Healers	20(5.4)	4.213	0.001	1.736	10.221

Does the DOTs provider counsel you on the treatment and side effects?					
No	47(12.7)	1			
Yes	322(87.3)	3.553	0.035	1.092	11.556
The DOTs provider enquires about the patient's progress and provides health education.					
No	34(9.2)	1			
Yes	335(90.8)	4.145	0.039	1.077	15.944
How are TB patients treated in the community?					
The community mainly supports and helps them	201(54.5)	5.857	0.126	2.518	13.627
Most people reject them	55(14.9)	1			
Most people are friendly	48 (13.0)	1.591	0.288	0.0676	3.743
Most people avoid them	65(17.6)	4.432	0.026	1.193	16.465

Table 6: Multivariate Analysis for factors associated with the use of DOTs among tuberculosis patients in Mombasa County

Facility first form of TB treatment sought	COR	P-value	95% CL	AOR	P-value	95%CL
Government Hospital	5.478	0.004	1.718-17.47	1.21	0.845	0.178-8.224
Private Clinic/Hospital	1					
Traditional Healers	4.213	0.001	1.736-10.221	2.78	0.329	0.356-21.63
DOTs provider enquires about the patient's progress and provides health education.						
No	1					
Yes	4.145	0.039	1.077-15.994	7.3	0.002	2.027-26.29
Does the DOTs provider counsel you on the treatment and side effects?						
No	1					
Yes	3.553	0.035	1.092-11.556	11.716	0.019	0.029-0.629
How are TB patients treated in the community?						
The community mainly supports and helps them	5.857	0.126	2.518-13.627	0.367	0.47	0.024-5.579
Most people reject them	1					
Most people are friendly	1.591	0.288	0.0676-3.743	0.161	0.204	0.01-2.695
Most people avoid them	4.432	0.026	1.193-16.465	1.132	0.944	0.037-34.943

4.3 Multivariate Analysis for factors associated with the use of DOTs among tuberculosis patients in Mombasa County

The following factors demonstrated statistical significance: Experiencing side effects from TB medication (AoR=7.3; 95% CI: 2.027-26.29) and receiving counseling and health education from the DOTs provider (AoR=11.71; 95% CI: 0.029-0.629).

Qualitative Results

4.4 Socio-demographic characteristics of the respondents

The study successfully enrolled a total of 50 participants. Three focused group discussions were organized, each comprising eight TB patients selected purposively from three health facilities. Additionally, six health facilities were chosen to provide three TB patients each for in-depth interviews regarding their experience with DOTs. Furthermore, eight healthcare workers employed in TB clinics were selected for key informant interviews, with one representative from each of the eight selected health facilities.

Table 7: Demographic characteristics of the respondents

Gender	**In-depth interview n=18**	**SDGs n=24**	**KII n=8**
Female	8	15	5
Male	10	9	3
Age			
15-24	4	9	0
25-34	8	7	5
35-44	3	4	2

45-54	2	3	1
55-64	1	0	0
≥65	0	1	0
Level of Education			
No Education	3	5	0
Primary Education	7	9	0
Secondary Education	5	7	0
Tertiary Education	3	4	8

4.5 Themes and codes on TB DOTs experiences identified from TB patients in Focused Group Discussions in Mombasa County, 2021

Six sub-themes were identified based on factors influencing the utilization of DOTs. These sub-themes included transportation challenges, loss of income (job loss), social factors, stigma, substance abuse, drug side effects, and the extended duration of treatment, as well as communication with healthcare providers.

Codes, categories, and sub-categories were established to organize these ideas. Connections between categories were established to relate them, and themes were derived from these categories. Three significant themes emerged: patient-related, health service-related, and therapeutic-related, each with specific sub-themes. Responses were categorized under each theme and sub-theme. Interpretation of the qualitative data was guided by patients' descriptions of their experiences and perceptions.

To organize these concepts, codes, categories, and sub-categories were established, facilitating the organization of ideas and the establishment of connections between them.

From these connections, three overarching themes emerged: patient-related factors, health service-related factors, and therapeutic-related factors. Each of these themes contained specific sub-themes that further elucidated the challenges and influences experienced by patients. Responses were systematically categorized under these themes and sub-themes, guided by patients' own descriptions of their experiences and perspectives, allowing for a nuanced interpretation of the qualitative data.

Table 8: Themes and codes on TB DOTs experiences identified from TB patients in Focused Group Discussions in Mombasa County, 2021

Themes	**Codes**
Health Service Related	• Accessibility • Waiting time • Patient-DOTs provider interaction • Patience preference • Confidentiality • Health education
Therapeutic related	• Duration of treatment • Side effects of medication
Patient-related	• Knowledge of TB cause, treatment, and transmission • Substance abuse • Cultural belief • Social support • Stigma

4.6 Patient -related Factors

The analysis of the reports revealed that tuberculosis (TB) often leads to stigma, as reported by most patients and healthcare workers (HCWs). The disease brings about both physical and mental suffering, significantly impacting patients' lives and often necessitating them to leave their jobs, which serve as sources of income and independence. Many TB patients shared their experiences during focused group discussions, including instances of being pointed at in their neighborhoods, neighbors gossiping about their illness, and being excluded from social events. These real experiences, coupled with the perceived stigma, led many patients to conceal their medication or even skip taking it when in the presence of others. Some patients only disclosed their condition to selected individuals, primarily close friends and family members. Stigma presents a major barrier to the successful execution of the DOTs for tuberculosis (TB). Patients undergoing DOTs often experience repeated encounters with stigma due to the treatment's requirements. Discrimination based on the disease, particularly at healthcare facilities, can further hinder compliance with DOTs.

Certain patients expressed reluctance to visit the chest clinic due to the fear of being seen or recognized by neighbors, a concern also echoed by healthcare workers. In in-depth interviews, patients shared their feelings of unease and shame associated with being seen collecting medication.

“I feel uneasy while going to the chest clinic. In case someone sees me, I wake up early before my neighbors to go to the nearby clinic.” - (26-year-old female patient, in-depth interview)

“Even if people are doing their normal activities, I feel that they are looking at me. When I come every day carrying a water bottle and a pack of drugs, I feel ashamed so I hide it in my bag.” - (48-year-old female patient, in-depth interview)

A 26-year-old health worker, who had served as a TB focal person for three years, shared an anecdote highlighting the level of stigma associated with TB within the community:

“Three months ago, I had a TB patient who said that the community fears TB more than AIDS. She told me that if the neighbors happen to know that she had TB and was taking DOTs, the house owner would force her to leave the house.” - (26-year-old male HCW, KI)

These findings agree with study findings in India, where fear of TB infection prompts people to isolate infected individuals from social settings and even restrict interactions with family members. Patients on DOTs are required to visit public health facilities for observed treatment, leading to frequent exposure to healthcare providers and the surrounding community, thereby exacerbating stigma (Arpukumar et al., 2019).

Similarly, in Zambia, TB is often equated with AIDS, instilling fear and leading to social withdrawal and exclusion from community interactions. Patients report experiences such as being pointed at, gossiping by neighbors and exclusion from social events, prompting some to conceal their diagnosis (Kaona et al., 2004).

Stigma presents a major barrier to the successful execution of the DOTs for tuberculosis (TB). Patients undergoing DOTs often experience repeated encounters with stigma due to the treatment's requirements. Discrimination based on the disease, particularly at healthcare facilities, can further hinder compliance with DOTs.

Research in Brazil suggests that the burden of frequent visits to TB facilities or encounters with healthcare providers may intensify stigma and compromise patients' ability to maintain privacy about their health status, deterring them from completing or seeking TB testing (Amande J et.al., 2016).

Some patients noted that stigma often begins within the family, with contagious TB prompting households to implement measures such as using separate utensils and bedrooms. These actions, although seemingly minor, caused significant frustration and stress for patients:

“In the first three months, I lived in an isolated room. I had poor contact with my wife and children. I stayed on my own day and night and it was very stressful. Sometimes I wondered about the meaning of life.” - (50-year-old male patient, FGD)

This study emphasized the significance of family and community support in facilitating the utilization of DOTs, as they often compensated for the loss of income experienced by patients. Given that TB primarily affects individuals during their productive years, financial support from families becomes crucial. Many patients received physical assistance, such as help in walking to the clinic, and financial support from relatives and community members:

“I have no strength to carry water and perform other physical activities after taking DOTs. My neighbors help me. My former employer has also helped me this far.” - (35-year-old female patient, FGD)

“I don’t have any job. I get financial support from my brothers who live abroad, may God help them.” - (26-year-old female, in-depth interview)

Research conducted in Indonesia revealed that 60% of tuberculosis (TB) patients disclosed having someone to oversee their treatment, with partners, family members, or community health volunteers commonly assuming this role. Patients regarded these observers as indispensable; without them, they tended to forget their medication schedules and faced challenges in obtaining monthly supplies of pills. Notably, around half of elderly and less educated individuals discontinued treatment due to a lack of social support or a designated observer to monitor their medication intake, accompany them to medical appointments, and procure new medication (Arpukumar *et al*., 2019).

Nevertheless, approximately fifty percent of the patients included in the study did not receive any type of social or financial assistance from their families or communities. Moreover, numerous patients encountered varying levels of support as the DOTs program advanced.

4.7 Health service-related factors

4.7.1 Health Education

Understanding tuberculosis, its causes, transmission modes, treatment procedures, treatment duration, potential side effects, and appropriate actions to take when side effects occur is crucial.

A study conducted in Indonesia showed that while most patients recognized tuberculosis as an infectious disease, only a few understood that it is transmitted from an infected person. Some mistakenly attributed tuberculosis to factors such as stress, consumption of spicy foods, and drinking chilled water with ice cubes. Additionally, only a minority of

tuberculosis patients were aware of the need to take medication daily and complete the full course for complete recovery (Widjanarko *et al.*, 2009).

A study conducted in Indonesia showed that while most patients recognized tuberculosis as an infectious disease, only a few understood that it is transmitted from an infected person. Some mistakenly attributed tuberculosis to factors such as stress, consumption of spicy foods, and drinking chilled water with ice cubes. A prevalent reason for patients discontinuing TB treatment is their insufficient understanding of TB in general, including the treatment regimen and its duration. Many patients mistakenly believe that once they regain normal weight and feel healthy, they are cured. Additionally, most patients are unaware of the standard 6-month treatment duration and the potential repercussions of discontinuing DOTs.

Effective communication between patients and healthcare providers is essential for fostering trust and nurturing positive relationships in healthcare settings. In Indonesia, elderly and less educated patients often struggled to comprehend medical instructions from doctors. DOTs providers are equipped with knowledge about treatment duration and potential side effects, and a supportive approach from these providers can enhance patient adherence to DOTs protocols (Widjanarko *et al.*, 2009).

The provision of health education was discovered to markedly improve the overall health condition of tuberculosis patients by encouraging the adoption of DOTs. This educational initiative involved imparting knowledge about the adverse effects of medication and offering guidance on recognizing and reporting them to healthcare providers. Throughout the treatment process, healthcare providers are responsible for assessing clinical progress,

ensuring medication adherence, verifying the accuracy of medication administration, confirming drug availability, and assessing patients' ability to attend appointments (Pradipta, 2020).

4.7.2 Distance to Health Facility

The proximity of TB clinics significantly aids in ensuring patients complete their treatment under DOT for tuberculosis (TB). In Kenya, where the Free TB treatment policy is implemented, patients can choose the nearest clinic for medication after diagnosis. The MOH and the NTLD-P tackle challenges related to distance by educating TB champions and community health promoters (CHPs) within communities to deliver medication to individuals who cannot access the clinic. The involvement of CHVs is viewed as advantageous because they are more familiar with the patients' circumstances, understand the intricacies of TB within their community, can provide support to patients, and help ensure adherence to DOTs (NTLD-P, 2013).

The majority of participants noted that the proximity of the hospital facilitated their adherence to DOTs. During the intensive phase, patients were advised to attend a specific chest clinic under a DOTs provider. Subsequently, they were given the option to select a chest clinic closest to them for the continuation phase of treatment.

One participant, a 24-year-old male, expressed that being only 300 meters away from the chest clinic made it easier for him to adhere to his DOTs treatment. He acknowledged that if he had to travel 900 meters, he might have discontinued the treatment.

However, a few patients identified transportation as a hindrance. They mentioned that despite the availability of transportation services, covering the daily expenses for six months proved to be a challenge. If a scheduled appointment is missed, TB clinics should

promptly reach out to the patient, ideally within 24 hours during the intensive phase. It's important to investigate the reason for the patient's absence and motivate them to continue treatment. If a patient declines treatment, every endeavor should be made to convince them to resume (NTLDP, 2021).

For instance, a 51-year-old female residing in Tsunza, a village 15 kilometers from Mombasa town, shared during a Focus Group Discussion (FGD) that she initially had to travel from Likoni Sub-county hospital for the first two months of medication while staying at her niece's place in Likoni. However, due to the expenses, inconvenience of commuting daily, and not wanting to burden her niece, she chose to go to Changamwe Health Center, despite it still being a considerable distance away, as she prioritized her recovery.

4.7.3 Communication with DOTs Provider

The reception provided by healthcare providers, including effective communication, seemed to significantly influence patients' adherence to DOTs. Most patients in the study expressed satisfaction with how they were received and treated by healthcare professionals and DOTs providers at the health centers. In focus group discussions, participants shared their experiences:

A 26-year-old male TB patient described his nurse as angelic, emphasizing her ability to understand his emotions without needing words. He highlighted their close and supportive relationship, stating that she motivates and encourages him to complete his DOTs.

An 18-year-old female student, who had dropped out of school due to TB, recounted her initial struggles with treatment side effects and peer ridicule. Despite wanting to discontinue DOTs to pursue her education, she was persuaded by health personnel to

prioritize her health. She expressed profound gratitude towards them, recognizing the importance of her health over everything else.

Improving training and management processes for healthcare providers involved in tuberculosis care is crucial. Continuous training for healthcare professionals is a necessary step towards ensuring quality care for tuberculosis patients.

A study conducted in Asmara highlighted that the positive interaction and attitudes of health professionals towards TB patients served as a motivating factor for patients to adhere to treatment. In situations where patients had unavoidable commitments such as attending a relative's funeral, healthcare providers supplied medication for up to 2 to 3 days to prevent medication shortages and missed appointments, thereby reducing interruptions in DOTs attendance during social events (Gebreweld *et al.*, 2018).

A male nurse, aged 30, acting as a key informant, discussed his approach to patient care. He emphasized his responsibility to care for his patients and described going above and beyond to support them. For instance, he arranges for medication collection by community health volunteers for patients who are unable to come to the clinic, ensuring they do not miss a single day of treatment. Additionally, he follows up with patients who are late or absent, sending a community health volunteer to their homes to ascertain the reason and deliver the medication if needed.

4.7.4 DOTs side effects and the long period of treatment

Directly Observed Therapy (DOT) is implemented to ensure patients adhere to their complete drug regimen, aiming to enhance their well-being and thwart drug resistance.

Many individuals reported experiencing adverse effects such as nausea, vomiting, joint pain, and fatigue while on DOT. Some patients even believe that DOT worsened their condition. During in-depth interviews, participants expressed their struggles, with one mentioning feeling severely ill, losing balance, and contemplating treatment cessation. Financial strain due to hospitalization and reliance on others for support further hindered adherence for some. Concerns about the treatment's duration were also raised, with suggestions to shorten it to mitigate associated challenges. Additionally, the inability to provide universal supplements to alleviate side effects DOTs programs have played a pivotal role in the achievements of various large-scale tuberculosis (TB) control endeavors in developing nations. Active TB is typically treatable with antibiotics, though the specific drugs and treatment regimens can vary from one country to another. Typically, curing TB necessitates six to eight months of consistent daily treatment, with effective therapies rendering individuals non-contagious and preventing further spread of TB. The introduction of DOTs has demonstrated enhancements in TB treatment success rates and reductions in the transmission of drug-resistant TB.

DOTs represent an effort to enhance adherence to TB treatment and achieve treatment completion, thereby ensuring cure and preventing the development of drug resistance. It involves active monitoring and documentation of drug consumption by an observer, which can occur at health facilities, workplaces, communities, or homes (Karumbi *et al*., 2015). The treatment supporter, whether a healthcare worker, family member, or community health promoter (CHP), supervises patients to ensure proper medication intake (Asuquo, 2013).

Regular monitoring of patients undergoing DOTs is crucial to evaluate their response to treatment. Investigations conducted among tuberculosis patients in Asmara indicated that some experienced adverse effects from TB therapy, including nausea, vomiting, joint pain, drowsiness, loss of appetite, and gastritis. Furthermore, certain patients perceived that the treatment exacerbated their condition (Gebreweld et al., 2018).

The role of CHPs is vital in DOTs implementation, as they conduct daily home visits to oversee medication administration, provide adherence counseling, and make referrals for adverse events during treatment (Das M. *et al.*, 2014).

4.7.5 Loss of source of income/employment) due to DOTs

The primary challenge faced by many patients undergoing DOTs was the loss of employment or the ability to work. This was often due to their illness preventing them from continuing to work or because the time-consuming nature of DOTs made it difficult to find daily employment. One participant, who attributed their job loss to tuberculosis (TB), shared their experience during a focus group discussion. They worked as a gatekeeper at a church but had to quit due to TB and the demands of DOTs, as their health declined. With no one to assist them initially, they struggled until finding support from their economically unstable grandson, whom they chose to stay with until completing treatment.

A study conducted in Asmara found that certain patients experienced job loss due to tuberculosis, either because they were too ill to continue working or due to the demanding treatment schedule. Consequently, this situation reflects the financial strain faced by these patients. As a result, they struggle to afford basic necessities such as food and transportation to access healthcare services, leading to their inability to utilize DOTs (Gebreweld *et al.,* 2018).

The loss of income led to financial hardship, causing anxiety about accessing food regularly. Many patients mentioned struggling with food scarcity, which exacerbated their situation. A woman interviewed individually, living alone and in the fifth month of treatment, recounted how she initially could afford a diverse diet including eggs, milk, and meat but had to stop due to rising costs. This dietary change immediately affected her health, leading to symptoms like shivering and unsteadiness.

CHAPTER FIVE

5.0: Discussion

5.1: Socio-demographic Characteristics

From our findings socio-demographic characteristics of the respondents revealed a predominance of males having Tuberculosis , this is consistent with studies conducted in Western Kenya , which consistently showed males as the most Tuberculosis affected population, representing 65% of all notified TB cases (Nyamogoba *et al.,* 2018).The study findings also concur with findings of Kenya Prevalence survey whereby in 2020, patients notified to have TB were 72,943 of whom were male. The age-group 25 – 35 years carried the majority of Tuberculosis burden. Typically the most productive years of adulthood (Mungai *et al.,* 2017).Most of the respondents had a secondary school education level being newly diagnosed Tuberculosis patients. The type of TB, majority of the respondents had Drug Sensitive Tuberculosis. DOTs, as endorsed by the WHO since 2012, stands as the global standard of care for both drug-susceptible and drug-resistant TB (WHO, 2012). The primary objective of the DOTs strategy is to boost adherence to the entire Tuberculosis regimen of drug therapy, ultimately enhancing patient outcomes and mitigating the emergence of drug resistance.

5.2 Factors associated with Utilization of Directly Observed Treatment Therapy among Tuberculosis patients in Mombasa County

This study sought to identify the factors associated with the utilization of DOTs and to explore TB patients' experiences with this treatment approach in Mombasa County. Where the first form of TB treatment was sought was significantly associated with utilization of DOTs. The study findings show seeking treatment from a traditional healer in the bivariate

analysis was significantly associated with DOTs utilization. Traditional healers use herbs and not the standardized TB treatment regimen thus posing a risk of patient delay to initiation of DOTs and thus pose of risk of active TB transmission in the community.

The DOTs provider enquires about the patient's progress and provides health education on TB treatment and side effects, emerged as significant factor associated with utilization of DOTs in TB treatment in Mombasa County. The counseling sessions provided by DOTs providers, along with health education Health care providers play a crucial role in monitoring adverse drug effects and educating both patients and DOTs providers on how to recognize common drug side effects. While most TB patients complete their treatment regimen without experiencing significant adverse drug effects, poor adherence to the prescribed treatment can lead to TB drug resistance. The study findings resonate with research conducted in study in Asmara, where TB patients reported that experiencing side effects made them believe the treatment was exacerbating their condition and interfering with their daily activities (Gebreweld *et al.*, 2018).

Health care Providers are to encourage TB patients to promptly report any symptoms they experience and inquire about their well-being during clinic visits for drug refills. Some of the adverse drug side effects include acute hepatotoxicity, peripheral neuropathy, and optic neuritis (NTLDP, 2020).

A study conducted in Bangladesh highlighted a notable number of adverse drug reactions reported by patients, which pose a considerable global public health concern due to their contribution to morbidity, loss to follow-up, mortality, and increased healthcare costs. Various studies, including investigations carried out in Ethiopia, have underscored the

difficulties encountered by numerous TB patients in adhering to treatment guidelines (Begashaw et al., 2016). Inadequate utilization of DOTs has been identified as a significant factor contributing to Tuberculosis treatment failure and the development of drug-resistant TB (Shallo D.H, 2017).

Regular monitoring of patients undergoing DOTs is crucial to evaluate their response to treatment. Investigations conducted among tuberculosis patients in Asmara indicated that some experienced adverse effects from TB therapy, including nausea, vomiting, joint pain, drowsiness, loss of appetite, and gastritis. Furthermore, certain patients perceived that the treatment exacerbated their condition (Gebreweld et al., 2018).

Regular patient health education by DOTs providers is important since patients lacking sufficient understanding of the treatment duration may cease treatment prematurely, under the impression that they have been cured. Regular reminders to patients regarding appointment schedules and actions taken when patients miss appointments are essential for promoting proper DOTs utilization and treatment completion (Ibrahim *et al.*, 2014).

A study conducted in Indonesia showed that while most patients recognized tuberculosis as an infectious disease, only a few understood that it is transmitted from an infected person. Some mistakenly attributed tuberculosis to factors such as stress, consumption of spicy foods, and drinking chilled water with ice cubes (Pradipta, 2020).

To ensure the continuous use of TB medications. Patients should receive comprehensive health education and counseling before commencing DOTs and continue to receive it during follow-up visits at the healthcare facility. Counseling sessions should be conducted by healthcare workers at the TB treatment center. The counseling process involves

exploring and evaluating the patient's psychological and emotional state, which may be pre-existing, drug-induced, or emerging due to social challenges during treatment initiation or progression. The approach is centered around the patient, with the aim of achieving proper utilization of DOTs through adherence (NTLD-P, 2021).

In a study in Indonesia, TB patients often did not understand or remember their doctor's instructions. DOTs providers play a crucial role in educating patients about treatment duration and side effects during clinic visits, which motivates patients to adhere to DOTs (Widjanarko et al., 2009). The provision of health education was discovered to markedly improve the overall health condition of tuberculosis patients by encouraging the adoption of DOTs. This educational initiative involved imparting knowledge about the adverse effects of medication and offering guidance on recognizing and reporting them to healthcare providers. Throughout the treatment process, healthcare providers are responsible for assessing clinical progress, ensuring medication adherence, verifying the accuracy of medication administration, confirming drug availability, and assessing patients' ability to attend appointments (Pradipta, 2020).

Patients who receive inadequate counseling and health education may misinterpret symptom improvement as a sign of cure, potentially leading them to stop TB medication prematurely. This finding corresponds with a study conducted in Kolkata, where patients in the intensive phase who lacked proper counseling were found to be non-adherent to DOTs (Partha Sardar *et al*., 2009).

This study findings echo results from a study in Brazil, where the perception of symptom improvement led to non-adherence to DOTs because patients mistakenly believed they

were cured when their physical condition improved. However, patients in this study who had been undergoing treatment for at least three months acknowledged the difficulties of managing TB symptoms and medication side effects but remained committed to completing their treatment regimen, recognizing that only completing the full course ensures TB cure (Queiroz *et al*., 2012).

These findings are align with a study conducted in India, where Community Health Volunteers provide counseling on Directly Observed Treatment to tuberculosis patients during clinic visits, facilitating referrals in case of treatment complications (Das et al., 2014). Following the intensive phase of treatment, patients lack daily contact with healthcare professionals, necessitating vigilant oversight from family members or community health volunteers due to concerns about medication adherence and the perception of being cured during the continuation phase. Educating TB patients has been shown to significantly reduce non-adherence to DOTs (Obermeyer et al., 2018).

Therefore, healthcare providers should receive training to offer tailored health education considering patients' backgrounds and local customs. Understanding tuberculosis, its causes, transmission modes, treatment procedures, treatment duration, potential side effects, and appropriate actions to take when side effects occur is crucial.

5.3 Lived-In Experiences of patients while on DOTs in Mombasa County

5.3.1 Patient related Factors

Stigma

The findings of the study revealed that tuberculosis (TB) often leads to stigma, as reported by most patients during the focused group discussions. The disease brings about both

physical and mental suffering, significantly impacting patients' lives and often necessitating them to leave their jobs, which serve as sources of income and independence.

Many TB patients shared their experiences during focused group discussions, including instances of being pointed at in their neighborhoods, neighbors gossiping about their illness, and being excluded from social events. These real experiences, coupled with the perceived stigma, led many patients to conceal their medication or even skip taking it when in the presence of others. Some patients only disclosed their condition to selected individuals, primarily close friends and family members.

Stigma presents a major barrier to the successful execution of the DOTs for tuberculosis (TB). Patients undergoing DOTs often experience repeated encounters with stigma due to the treatment's requirements. Discrimination based on the disease, particularly at healthcare facilities, can further hinder compliance with DOTs.

Stigma leads to reluctance to seek treatment at health facilities, contributing to feelings of guilt, fear of prejudice, and low self-esteem among patients. Consequently, patients often keep their TB diagnosis secret for fear of eviction or other negative consequences, which further isolates them from their families and communities (Begashaw *et al*.,2016).

Stigma poses a significant obstacle to the effective implementation of the Directly Observed Treatment Short Course (DOTs) for tuberculosis (TB). Patients undergoing DOTs often experience repeated encounters with stigma due to the treatment's requirements. Discrimination based on the disease, particularly at healthcare facilities, can further hinder compliance with DOTs.

In India, fear of TB infection prompts people to isolate infected individuals from social settings and even restrict interactions with family members. Patients on DOTs are required to visit public health facilities for observed treatment, leading to frequent exposure to healthcare providers and the surrounding community, thereby exacerbating stigma. These actual experiences and perceived stigma results in many patients hiding their drugs or even skipping taking them in the presence of people. Some only disclose it to selected people, mostly to close friends and families (Arpukumar *et al*., 2019).

Social support

This study emphasized the significance of family and community support in facilitating the utilization of DOTs, as they often compensated for the loss of income experienced by patients. Given that TB primarily affects individuals during their productive years, financial support from families becomes crucial. Many patients received physical assistance, such as help in walking to the clinic, and financial support from relatives and community members.

Community support, particularly from family members, plays a crucial role in DOTs utilization, as seen in studies from Addis Ababa and China, where such support contributed to treatment success. Some patients, especially those who were seriously ill at the start of DOTs, required assistance to attend treatment sessions. Illness imposes both physical and psychological distress, which can adversely affect patients' lives, compelling them to abandon employment, which serves as a financial resource and symbolizes independence (Xu et al. 2009; Bagchi *et al*., 2010).

The importance of family and community support in enabling DOTs utilization, with the absence of such support being a key reason for not utilizing DOTs. The study findings

resonates with research conducted in Brazil, which also emphasized the impact of TB on individuals during their economically active years, often necessitating financial support from their families due to low employment levels or unemployment (Queiroz *et al.*,2012). A study conducted in Brazil revealed that healthcare workers (HCWs) and tuberculosis (TB) patients acknowledged the importance of family support in promoting effective utilization of Directly Observed Therapy (DOTs). However, patients reported experiencing feelings of estrangement from their family members. Notably, receiving care and support, both technically and emotionally, along with financial assistance when dealing with a stigmatizing illness, reflects the patients' strong desire for recovery (Queiroz *et al.,* 2012).

5.3.2 Health service-related factors

Health Education

Understanding tuberculosis, its causes, transmission modes, treatment procedures, treatment duration, potential side effects, and appropriate actions to take when side effects occur is crucial. In this study findings DOTs providers counselling and providing TB patients with health education was significantly associated with the utilization of DOTs in Mombasa County. DOTs providers are equipped with knowledge about TB infection, treatment duration and potential side effects, and a supportive approach from these providers can enhance patient adherence to DOTs utilization (Widjanarko *et al.*, 2009).

A study conducted in Indonesia showed that while most patients recognized tuberculosis as an infectious disease, only a few understood that it is transmitted from an infected person. Some mistakenly attributed tuberculosis to factors such as stress, consumption of spicy foods, and drinking chilled water with ice cubes. Additionally, only a minority of

tuberculosis patients were aware of the need to take medication daily and complete the full course for complete recovery (Widjanarko *et al.*, 2009).

Effective communication between patients and healthcare providers is essential for fostering trust and nurturing positive relationships in healthcare settings. In Indonesia, elderly and less educated patients often struggled to comprehend medical instructions from doctors.

The provision of health education was discovered to markedly improve the overall health condition of tuberculosis patients by encouraging the adoption of DOTs. This educational initiative involved imparting knowledge about the adverse effects of medication and offering guidance on recognizing and reporting them to healthcare providers. Throughout the treatment process, healthcare providers are responsible for assessing clinical progress, ensuring medication adherence, verifying the accuracy of medication administration, confirming drug availability, and assessing patients' ability to attend appointments (Pradipta, 2020).

Distance to Health Facility

The majority of respondents during the Focused group discussion expressed a strong motivation to adhere to their treatment regimen, largely due to the convenient proximity of the health facility. They noted that the close distance to the hospital facilitated the utilization of Directly Observed Treatment (DOTs). However, patients residing far from health facilities mentioned that despite the availability of transportation services, covering daily expenses for six months proved to be challenging

To access TB medication, individuals would require bus fare or fuel to reach the hospital. Consequently, the DOT component of treatment imposes financial burdens and opportunity costs on patients, in addition to the potential for heightened stigma. While distance posed only a minor concern for some patients, others encountered significant challenges. Some participants reported walking or spending at least Ksh.100 per day on transportation to reach the chest clinic.

Similar studies have highlighted that long distances to health facilities and financial constraints contribute to delays in TB diagnosis, non-adherence to DOTs, treatment failure, and loss to follow-up, thus discouraging patients from utilizing DOTs. If a scheduled appointment is missed, TB clinics should promptly reach out to the patient, ideally within 24 hours during the intensive phase. It's important to investigate the reason for the patient's absence and motivate them to continue treatment. If a patient declines treatment, every endeavor should be made to convince them to resume (NTLDP, 2021).

To address distance barriers, the Ministry of Health trains TB champions and community health promoters (CHPs) to deliver medication to patients unable to access the clinic. The presence of CHPs is seen as advantageous because they are embedded within the patients' communities, possess a deep understanding of the local TB context, and can provide valuable health education and support to patients, thus enhancing utilization of DOTs.

The proximity of TB clinics significantly aids in ensuring patients complete their treatment under DOT for tuberculosis (TB). In Kenya, where the Free TB treatment policy is implemented, patients can choose the nearest clinic for medication after diagnosis. The MOH and the NTLD-P tackle challenges related to distance by educating TB champions

and community health promoters (CHPs) within communities to deliver medication to individuals who cannot access the clinic. The involvement of CHVs is viewed as advantageous because they are more familiar with the patients' circumstances, understand the intricacies of TB within their community, can provide support to patients, and help ensure adherence to DOTs (NTLD-P, 2013).

In the study findings patients had a say in determining the frequency and location of DOTs. They had an opportunity to seek treatment at their health facility of choice and nearest to their homes. Supervision for TB patients on DOTs during intensive phase of TB treatment is crucial indicating that certain patient needs are to be taken into consideration, which is crucial for DOTs adherence. Most participants felt motivated to adhere to their treatment regimen as the distance to the healthcare facility was manageable, underscoring the importance of effective communication between patients and service providers in fostering trust and nurturing positive healthcare relationships. In Indonesia, elderly and less educated patients often struggled to comprehend medical instructions, highlighting the significance of health education provided by DOTs providers regarding treatment duration and potential side effects. A supportive DOTs provider can inspire patients and enhance the utilization of DOTs.

Patients were given a voice in determining the frequency and location of DOTs supervision, demonstrating a consideration of their needs, which is crucial for adherence. Despite the manageable distance for some, transportation costs remained a concern for others, with some having to walk or spend a significant portion of their daily budget on transportation to reach the chest clinic. Similar studies have noted that distance to healthcare facilities and

financial burdens contribute to delays in TB diagnosis, non-adherence to DOTs, treatment failures, and loss to follow-up, discouraging patients from fully utilizing DOTs.

DOTs, Duration of DOTs and Side effects

DOTs programs have played a pivotal role in the achievements of various large-scale tuberculosis (TB) control endeavors in developing nations. Active TB is typically treatable with antibiotics, though the specific drugs and treatment regimens can vary from one country to another. Typically, curing TB necessitates six to eight months of consistent daily treatment, with effective therapies rendering individuals non-contagious and preventing further spread of TB. The introduction of DOTs has demonstrated enhancements in TB treatment success rates and reductions in the transmission of drug-resistant TB. In Nigeria, research indicated that the use of high-quality drugs within the DOTs strategy led to the rapid disappearance of tuberculosis symptoms within a few weeks of treatment (Ibrahim *et al.*, 2014).

Healthcare workers also highlight the positive role of family support in DOTs, as it helps prevent patient isolation. Furthermore, healthcare workers view DOTs as a strength, as it fosters a sense of commitment to treatment among patients, aligning with the strategy's goal of shared responsibility between healthcare workers and patients to achieve treatment success. The level of support and care provided to TB patients by healthcare providers, including the quality of communication, seemed to have a notable influence on the patient's adherence to Directly Observed Treatment (DOTs) (Queiroz et al., 2012).

Many patients commonly experience side effects from DOTs medications, leading some to believe that DOTs were exacerbating their condition. These side effects typically include

nausea, vomiting, joint pain, and feelings of drowsiness or weakness, which may hinder patients' ability to walk or work. This suggests the importance of providing medications to alleviate side effects alongside DOTs treatment, or at the very least, ensuring patients are informed about the anticipated side effects and how to manage them effectively.

The protracted duration of DOTs treatment significantly impacts patients, disrupting their daily routines and activities. This poses challenges for both patients and their families, as it can lead to financial strain, physical exhaustion, and psychological distress (Bagchi et al., 2010).

Other research has identified that the lengthy duration of tuberculosis treatment poses financial and emotional challenges for both patients and their families, leading to treatment failure in some cases. This suggests a potential need for greater flexibility in the TB treatment protocol, allowing for a more convenient schedule for Directly Observed Treatment (DOTs) that does not disrupt patients' work commitments. Some patients on DOTs felt with the frequent visits aside from direct cost may interfere with a patient's work schedule or home production responsibility such as child care, loss of wages or loss of employment (Amande J *et.al.*, 2016).

However, involving family members and relatives in the patient's treatment plan is vital to ensure their understanding and commitment throughout the entire Directly Observed Treatment Short-course (DOTs) regimen. In Kenya, TB diagnosis and treatment are offered free of charge in public health facilities. However, there are associated healthcare expenses, including payments for supplementary drugs, additional diagnostic tests, as well as significant non-medical costs like transportation and lodging expenses. TB patients and

their caregivers lose valuable productivity hours while incurring substantial out-of-pocket expenses seeking care.

Loss of Employment

The majority of respondents experienced a loss of income or employment, leading to financial dependency. Many reported losing their jobs due to illness or being unable to secure daily work because of the time commitments associated with DOTs. A study in China highlighted how economic strain, including loss of employment, increased food expenses, and transportation costs, poses significant financial challenges for patients and their families. Despite the availability of free TB treatment, financial difficulties, particularly related to transportation expenses, continue to hinder DOTs utilization. Participants noted that these financial constraints make adhering to DOTs challenging, especially for those who are unemployed and lack consistent financial support from their families or relatives. To cope with these expenses, a considerable portion of TB patients resort to harmful measures like taking out loans, depleting savings, or selling assets. Although TB diagnosis and treatment are provided free of charge in Kenya, the absence of support for food/nutritional assistance, transportation, and time spent seeking treatment undermines the affordability of healthcare for TB patients (NTLDP, 2017).

A study conducted in Asmara found that certain patients experienced job loss due to tuberculosis, either because they were too ill to continue working or due to the demanding treatment schedule. Consequently, this situation reflects the financial strain faced by these patients. As a result, they struggle to afford basic necessities such as food and

transportation to access healthcare services, leading to their inability to utilize DOTs (Gebreweld *et al.,* 2018).

Similarly, another study highlighted that TB patients encountered challenges related to insufficient funds for transportation, as they were too weak to work for money or even walk to the healthcare facility (Russuel *et al.,* 2018).

A significant proportion of households affected by TB, including those affected by drug-resistant TB, face catastrophic costs. The total cost incurred per TB episode amounts to KSh. 26,041.49, with direct non-medical costs related to nutrition and food supplements comprising the majority. To cope with these financial burdens, a substantial percentage of TB patients resort to harmful coping mechanisms such as taking out loans, using savings, and selling assets (NTLD-P, 2017).

While TB diagnosis and treatment are provided without direct charges in Kenya, addressing expenses related to food/nutritional aid, transportation, and time spent seeking treatment remains crucial to ensure accessible healthcare (NTLD-P, 2017).

Implementing various policy and programmatic measures to alleviate and offset the costs faced by TB patients and their households is critical in Kenya. This includes connecting TB-affected vulnerable households with existing social protection programs, tailoring food assistance to meet the needs of malnourished TB patients and their families, ensuring equitable distribution to vulnerable groups, and incorporating all aspects of TB care into the National Health Insurance Fund (NHIF) benefit package to expand coverage among TB patients.

Additionally, there's a need to formulate and enforce policies and legislation aimed at eradicating discrimination and ensuring job security for TB patients (NTLD-P, 2017).

Effective Communication between DOTs providers and TB patients

This study emphasized the importance of positive interactions and attitudes displayed by healthcare professionals towards TB patients. Patients reported that effective communication and positive attitudes from health workers served as motivational factors for adhering to DOTs. The study underscores the significance of healthcare workers actively listening to patient concerns and engaging in conversations, as it fosters a sense of care and support among TB patients. Such practices help establish rapport, instill a sense of belonging within society, and assist patients in coping better with their daily challenges.

Effective communication between clients and service providers is a crucial element of healthcare, facilitating the development of trust and fostering positive relationships between healthcare providers and patients. In a study conducted in Indonesia, elderly and low-educated patients often struggled to comprehend the instructions provided by doctors. Health education regarding treatment duration and potential side effects is provided by DOTs providers. A supportive and approachable DOTs provider can inspire patients and further enhance the utilization of DOTs (Widjanarko et al., 2009).

The language used by DOTs providers, whether healthcare workers, family members, or community volunteers, both at healthcare facilities and in patients' homes, significantly influences patients' reactions and their adherence to TB treatment (Kaona et al., 2004).

This finding is consistent with a study in Timor, where TB nurses demonstrated a strong understanding of TB and DOTS and showed great dedication to their roles. TB patients expressed satisfaction with the TB services provided at their local clinics. Those who completed their treatment, following the guidance of TB nurses, received regular health education on tuberculosis at the healthcare facilities (Martins N., 2008).

A lack of knowledge among healthcare workers can adversely impact TB patients' treatment outcomes. Poor interpersonal relationships and communication have also been linked to negative TB outcomes. Healthcare workers should monitor TB patients' weekly attendance and address any barriers they encounter to ensure continuous care and support. TB patients require special attention, particularly regarding assessing medication adherence and addressing their physical, social, and psychological needs (Datiko et al., 2020).

CHAPTER SIX

6.0 Conclusion

This study revealed that factors significantly associated with the utilization of DOTs by TB patients included the initial site visited by patients for tuberculosis treatment, the occurrence of TB drug side effects, the engagement of DOTs providers in monitoring patient progress, and the provision of health education. TB patients in Mombasa County identified stigma, lack of social support, loss of employment, and distance to health facilities, as barriers to DOTs utilization. Furthermore, effective communication and positive attitudes displayed by healthcare providers towards TB patients were identified as facilitators and enablers in the utilization of DOTs.

6.1 Recommendations

1. Comprehensive and continuous health education by HCWs and Community Health Promoters (CHPs) on TB and TB treatment side effects with focus on male TB patients at health facilities.
2. County Health Management team to strengthen social support structures through sensitization of CHPs on Tuberculosis.
3. NTLD-P through County tuberculosis and leprosy coordinators to strengthen social support structures thorough CHPs which can address factors identified by the study
4. CHPs to educate and encourage community to visit the health facility for proper diagnosis and treatment of tuberculosis given that TB services are accessible and free in all government health facilities.

6.2 Study Limitations

This study did not differentiate between respondents in the intensive and continuation phases of DOTs treatment. Recall bias may have been introduced, as part of the study relied on TB patients recalling their experiences with DOTs.

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Appendices

Appendix 1: Questionnaire

Experiences and Factors Associated with Utilization of Directly observed Treatment Short Courses (DOTs) among TB patients in Mombasa County, Kenya.

Questionnaire No: _____ Date of interview (DD/MM/YY): _____

Participant's Information

Name: (initials) Tel no:

Age (Years): Gender □Male □Female

County: Sub County: Ward:

Village:

Socio-demographic characteristics

Marital Status *(Tick one only)*

Single □

□Married (Monogamous)

□Married (Polygamous)

□Divorced/separated /Widowed

Religion

□Christian□Muslim □Hindu□African tradition□Atheist

Education level attained

□No education □ Primary□ Secondary□ Tertiary

Occupation

□Unemployed□Casual (informal Employment□Formal□employment

Tuberculosis

1. **Type of TB**

□Drug Sensitive TB (DS-TB) □ Drug Resistant TB (DR-TB)

Type of TB Patient

□ New

□Relapse

□Treatment after failure

□loss to follow-up

Type of TB

□Pulmonary TB□ Extra pulmonary TB□

Exposure to TB and TB treatment

2. Did you suspect that you had tuberculosis before you sought care and treatment?
   □Yes □ No

3. What were the significant symptoms that presented when you sought care and treatment? **Tick all that apply**
   □Cough/coughing blood

   □ Fever

   □ Night sweats

   □ Chest pains

   □ Weakness

   □ Fatigue

□ Shortness of breath

□ Weight loss

4. Where was the first form of TB treatment sought?

□Purchased drugs from chemist/ pharmacy

□Herbalist

□Health center/dispensary

□Traditional Healers

□Government hospital

□Private Clinic/Hospital

5. Who influenced your decision to seek the appropriate TB diagnosis and treatment?

□ Family member

□Friend

□ Pharmacist/Chemist

□ Private clinic

□ Staff at dispensary/health centers

□ Self-Referral□

□ Community Health Volunteer

6. What do you cause TB?

□Bacteria □Myths □ Dirty water

7. (i). Has TB made you lose your source of income?

□ Yes□No

(ii). If yes, why?

□ Too weak to work

□Time-Consuming treatment arrangements□

□Long treatment periods

□Drugs side effects

8. How long does TB treatment take?

□ 6months

□9 months

□12 months

□24 months

Directly Observed Treatment (DOTs) in TB treatment

9. Are you on DOTs?

□ Yes □No

10. If Yes to Question 9

(i). Who told you about DOTs?

□ Health care worker

□Community health volunteer

□Family member

□Media

(ii). Who is your DOTs provider?

□ Health care worker□ Community health volunteer□ Family member□ Friend

11. Do you believe you can completely cure TB when you use DOTs?

□ Yes□ No

12. Where can proper DOTs be achieved?

□ Dispensary

□ Private Clinic

□ Health Centre

□ Home

13. How long does TB DOTs take?

□ 2 months

□ 6months

□ 9 months

□ 12 months

□ Don't Know/ no response

14. How often do you generally seek the services of a DOTs provider?

□ Daily

□ Weekly

□ Once a month

□ Twice a month

15. How long does it take from home to the health facilities for those taking DOTs?

□0 – 1 hr.

□2– 3 hrs.

□Over 4 hrs.

16. Means of transport used to get to health facilities

□Bicycle

□ Motorbike

□Walk

□Vehicle (matatu)

17. Total cost incurred to and from the govt/public health facility

□Less than Ksh 100

□Ksh 101 and above

18. Severity of illness during the first visit to the health facility

□Could still do a full day's work

□Could do only light chores outside the house

□Housebound/bedridden

Perception of TB DOTs

19. After taking DOTs, is TB infectious

□ Yes□No

19. Is the Health care worker at a health facility qualified to diagnose and treat TB?

□ Yes□No

20. Are TB drugs available at the health facility?

□ Yes□No

21. Is The health facility experiencing drug stockouts?

□ Sometimes□Frequently □ Always□Never

22. How long does it take to be served as a patient by the DOTs provider?

□ 10-15 minutes□20-30 minutes □ 1-hour□More than 1 hour

23. Is the waiting time at the health facility between diagnosis and treatment long?

□ Yes□No

24. What do you think about the TB drugs administered as DOTs?

□ Drugs cure TB faster

□Drugs are too big, and many

□One feels intimidated when being observed as they swallow the drugs

25. Do you get any drug side effects from DOTs?

□ Yes□No

26. Are DOTs providers kind to TB patients?

□ Yes□No

27. Who would you prefer to be your DOTs provider?

□ Health care worker

□Community health volunteer

□Family member

□ Friend

28. Does the DOTs provider counsel you on the treatment and side effects?

□ Yes□No

29. The DOTs provider enquires about the patient's progress and provides health education throughout the treatment.

□ Yes□No

30. The DOTs provider gives patients time to ask questions regarding TB treatment whenever they need clarification.

□ Yes□No

31. Has the DOTs provider ever missed supervising you when taking the TB drugs?

□ Yes□No

32. Do you think there is a relationship between TB and HIV?

□ Yes□No

33. Is TB disease curable?

□ Yes □No

34. Can TB be transmitted from one person to another?

□ Yes□No

Stigma

35. Does anyone else know that you have TB?

□ Yes □No

36. How are TB patients treated in the community?

□Most people reject them

□Most people are friendly

□Most people avoid them

□ Community mainly supports and helps them

37. Do you get moral or financial support from family members?

□ Yes□No

38. Do you think that family members and other people would feel free to shake hands, and share rooms, plates, spoons, and basins with you if they found out about your TB?

□ Yes□No

39. Would you remain friends if you found that your friend has been diagnosed with TB?

□ Yes □No

40. Were you sacked from your job because the employers discovered you have TB?

□ Yes□No

41. Do you attend social events?

□ Yes□No

Appendix 2: Focused Group Discussion Guide

Experiences and Factors associated with Utilization Directly Observed Treatment Strategy among TB Patients and in Mombasa County

Reminder to moderator:

To determine socio-demographic characteristics of Tuberculosis patients on Directly Observed Treatment (DOTs) in Mombasa County.

To determine factors associated with utilization of the DOTs program in Mombasa county.

To explore the lived-in experiences of Tuberculosis patients while on Directly Observed Treatment (DOTs) in Mombasa County.

Discussion Questions

Do you know about DOTs?

How did you feel about taking DOTs?

⇒PROBE How did your close friends, family, and coworkers treat you when they found out you were taking DOTs?

⇒PROBE: During the 1st two months of DOTs, who was your DOTs provider? (HCW, CHV, family, friend)

Does your DOTs provider try to help you with other concerns (transportation, financial issues, health education, substance abuse)? If not, would you have liked assistance with these issues?

Is the DOTs service provided at convenient times for you?

Are the DOTs providers available when you need them?

What convinced you of the importance of taking TB DOTs medicines?

What are your thoughts about having someone watch you take your medicine:

In the clinic (health department)?

In your home?

At CHVs Home or In another location?

Do you feel that taking TB DOTs prevents you from doing the things you usually do in your life?

Hanging out with friends? Working?

For any of you taking TB DOTs, did you have any problems?

What were these problems?

What could your doctor, hospital, or health department have done to make it easier for you to take your DOTs?

More support from the health care worker and CHV?

Provided a different health worker? If so, what characteristics are essential to you?

Provide incentives such as food? Transportation? Other?

Can you describe your overall experience with DOTs for TB treatment?

Do you think you have benefitted from the DOTs program?

Has DOTs enabled you to comply with treatment even during the non-intensive phase?

Appendix 3: Informed Consent Form

Study Title

Experiences and Factors associated with Utilization Directly Observed Treatment Strategy among TB Patients and in Mombasa County

Introduction

My name is Emily Chinyavu Kurera. I am a Master's degree student from Moi University. I am here to gather information on the **Experiences and Factors associated with Utilization Directly Observed Treatment Strategy among TB Patients and in Mombasa County**. This information will help improve the quality of care given to TB patients, understand the DOT strategy and make informed decisions and policies for the community to support existing structures towards eliminating TB in Kenya in line with Kenya's world TB day theme, "It's time for a TB free Kenya ."The study will determine whether the ongoing TB effort for DOTs has been effective.

A questionnaire has been prepared to conduct a facility-based cross-sectional study. You are, at this moment, kindly being asked to participate in this study.

Procedure

This document, known as the informed consent form, provides you with details about the study, which we will further discuss. Upon comprehending the study and if you choose to participate, you will be requested to sign this consent form. It's important to note that your involvement in this research is entirely voluntary, and there will be no pressure to participate. The primary objective of this research study is to assess the utilization of

DOTs and the factors associated with it among TB patients in Mombasa County. Following your agreement to participate in the study, you will be asked several questions related to the study. There are no financial benefits or costs associated with participating in the study.

However, the findings and knowledge gained from this study may help improve the quality of care given to TB patients, understanding of the DOTs strategy, and making informed decisions and policies for the community.

Risks

All information and data provided by you for this study, including records, will be treated with the utmost confidentiality to minimize the risks of disclosing the information you provide. No names will be disclosed in any report; instead, you will be identified by a participant identification number. Additionally, an identifying mark will be placed on your TB patient card to prevent duplicate enrollment during subsequent visits. Your personal information will not be released without your explicit written consent. The data will be securely stored in password-protected computers, and hard copies will be stored in lockable cabinets accessible only to authorized investigators. You will not be personally identified in any publications related to this study.

Benefits

Contributions will help improve the quality of care given to TB patients, understand the DOT strategy and make informed decisions and policies for the benefit of the community to support existing structures towards eliminating TB in Kenya in line with Kenya's world TB day theme, "It's time to end TB."

Consent signing

I _____ have read/been read to the information shown above by the investigator and had the opportunity to ask questions and all were answered satisfactorily.

I declare that the information I will give is correct to the best of my knowledge. I hereby give consent for my participation

Participant's name: _____

Signature or thumbprint: _____ Date:

_____

Witness: _____ Date _____ Signature

_____

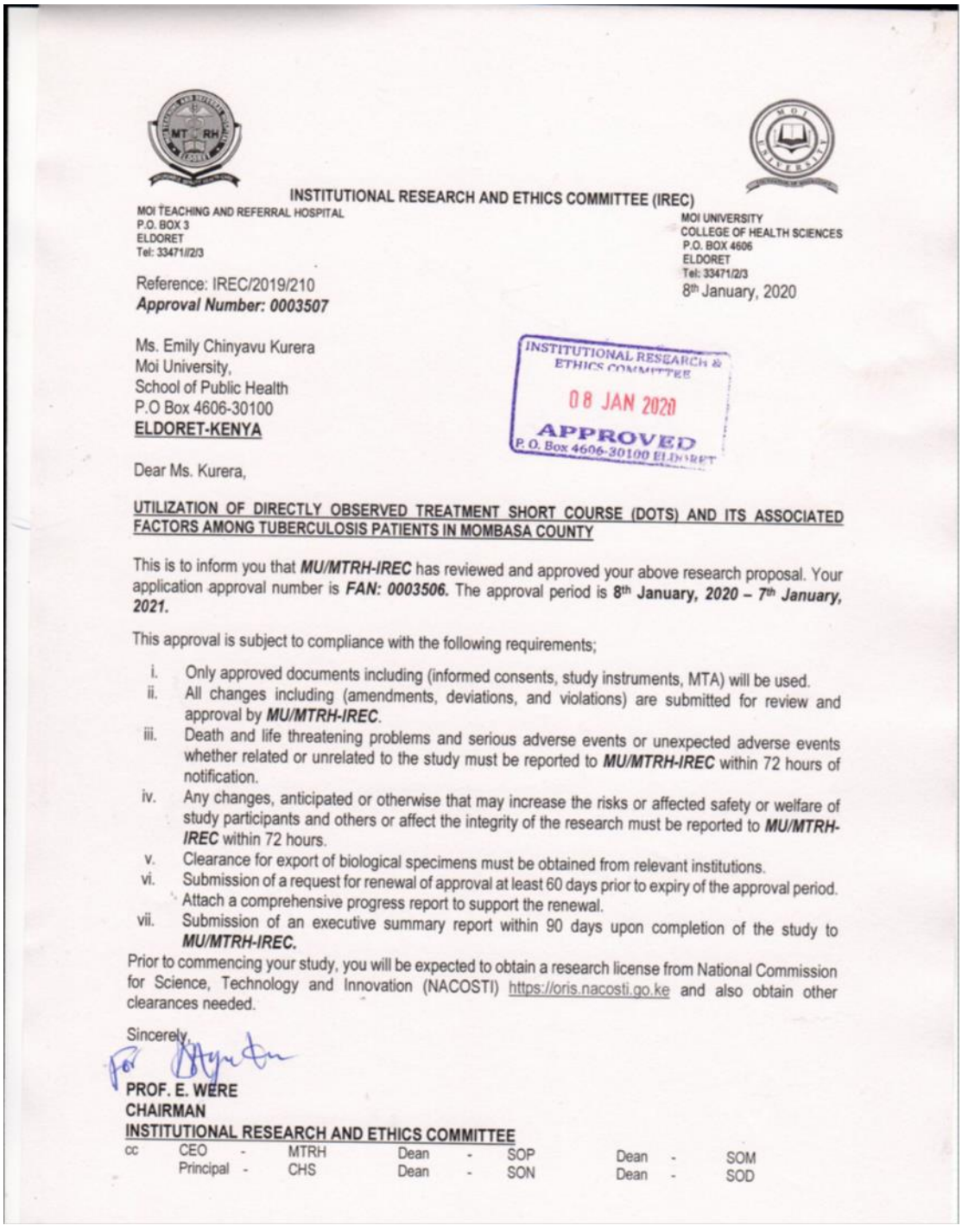
Name of person obtaining consent:

_____

Signature _____ Date

_____

Appendix 4: IREC Approval Letter



INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471//2/3

MOI UNIVERSITY
COLLEGE OF HEALTH SCIENCES
P.O. BOX 4606
ELDORET
Tel: 33471/2/3

Reference: IREC/2019/210
Approval Number: 0003507

8th January, 2020

Ms. Emily Chinyavu Kurera
Moi University,
School of Public Health
P.O Box 4606-30100
ELDORET-KENYA

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
08 JAN 2020
APPROVED
P. O. Box 4606-30100 ELDORET

Dear Ms. Kurera,

UTILIZATION OF DIRECTLY OBSERVED TREATMENT SHORT COURSE (DOTS) AND ITS ASSOCIATED FACTORS AMONG TUBERCULOSIS PATIENTS IN MOMBASA COUNTY

This is to inform you that ***MU/MTRH-IREC*** has reviewed and approved your above research proposal. Your application approval number is ***FAN: 0003506.*** The approval period is **8th January, *2020 – 7th January, 2021.***

This approval is subject to compliance with the following requirements;

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

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

Sincerely,

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc CEO - MTRH Dean - SOP Dean - SOM
Principal - CHS Dean - SON Dean - SOD

Appendix 5: Mombasa County Data Collection Permission Letter

COUNTY GOVERNMENT OF MOMBASA

DEPARTMENT OF HEALTH SERVICES
OFFICE OF THE COUNTY DIRECTOR OF HEALTH

Uhuru Na Kazi Building, 5th Floor
Email: msachd2013@gmail.com

P.O Box 91040 – 80103
MOMBASA

Ref: MSA/CH/ADM.37/VOL.I/50

Date: 28th January 2020

The CEO
Coast general Teaching and Referral hospital
Sub county Medical officers of health
Mombasa County

Dear Sir/Madam

RE: AUTHORIZATION FOR DATA COLLECTION BY EMILY CHINYAVU KURERA

The above named student is pursuing Masters of Science Degree in Field Epidemiology at MOI University Eldoret.

This office has no objection and therefore Permission has been granted for her to collect data for her thesis "**Utilisation of DOTS and its associated factors amongst TB patients in Mombasa County**".

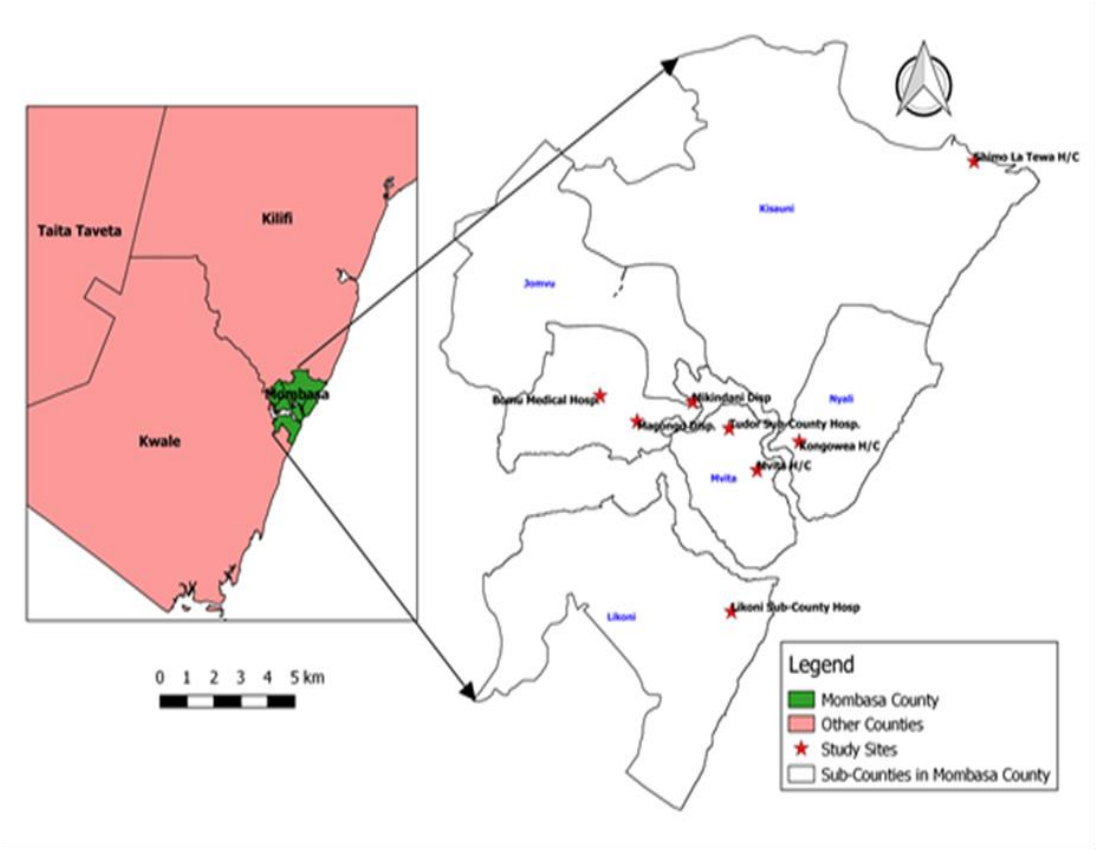
Kindly accord her the necessary support.

Payment Number:

COUNTY DIRECTOR OF HEALTH
P. O. Box 91040 - 80103,
MOMBASA COUNTY.

DR ANISA BAGHAZAL
RESEARCH COORDINATOR
FOR: COUNTY DIRECTOR MEDICAL SERVICES
DEPARTMENT OF HEALTH
COUNTY GOVERNMENT OF MOMBASA

APPENDIX 6 : Figure showing Map of the selected Tuberculosis treatment Health facilities in Mombasa County



APPENDIX 7: NACOSTI Research License

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: **591578**

Date of Issue: **17/April/2020**

RESEARCH LICENSE

This is to Certify that Ms.. Emily Chinyavu Kurera of Moi University, has been licensed to conduct research in Mombasa on the topic: Utilization of Directly observed treatment Short courses (DOTs) and its associated factors among Tuberculosis patients in Mombasa county, Kenya for the period ending : 17/April/2021.

License No: **NACOSTI/P/20/4809**

591578

Applicant Identification Number

Director General
NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Verification QR Code

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