Journal: Texila International Journal of Academic Research
Publisher: Texila International Journal
ISSN: 2520-3088
Volume 13 Issue 2, 2026
DOI: 10.21522/TIJAR.2014.13.02.Art027

Prevalence of Non -Adherence to Tuberculosis Therapy and Associated Factors among Patients with Pulmonary Tuberculosis at Mwananyamala Regional Referral Hospital, Dar- es- salaam

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Abstract

This study aimed to assess the prevalence of non- adherence to Tuberculosis therapy and associated factors among patients with pulmonary Tuberculosis at Mwananyamala Regional Referral Hospital, Dar es Salaam. It was a cross-sectional study involving Tuberculosis (TB) patients who attended the outpatient clinic at Mwananyamala Regional Referral Hospital. The sample size of this study consisted of 422 participants who were selected through systematic random sampling. Data collection was done by using structured questionnaires incorporated in Open Data Kit (ODK); in addition, the TB treatment card and the Morisky Medical Adherence scale (MMS) were also used. Data analysis was done by Statistical Package for the Social Sciences (SPSS) version 16.0 to find the proportion of respondents choosing different responses. The study findings indicated that most patients adhere to TB treatment by 98%, and only 2% did not adhere to TB treatment. Factors associated with adherence, such as TB drugs' side effects and non-compliance, did not influence non-adherence. The study recommends the same modality of treatment to continue to maintain the adherence level of TB patients. This study has implications for all stakeholders involved in TB patients' management. The practical and theoretical implications provide the benefits of the study to the government, non-governmental organizations, and research organizations.

Keywords: *Non-Adherence, Non-Compliance, Patients, Side Effects*, *Tuberculosis.*

Introduction

Background of the Study

In 1993 the World Health Organization(WHO) declared Tuberculosis(TB) a global emergency disease with 2 billion people affected by the disease [1]. Nevertheless, it is still a disease of public health importance, as in 20 century, TB has become a threat. It is one of the oldest communicable diseases which creates a global problem with significant mortality and morbidity despite of effort of implementing direct observed therapy (DOT) treatment strategies in many countries since 1995 to enhance TB drug adherence[2]. Global estimates show that in every three people, one is infected with Mycobacteria tuberculosis (MTB) and at risk of developing the disease [3]. TB is among the top ten killer infectious diseases worldwide [4]. One of the factors that contributes to the high burden of the disease is non-adherence to prescribed ant- TB drugs by patients, which results in treatment failure and prevent to achieve TB control program goals [5].

Adherence is the degree to which an individual follows a set of agreed actions. In the medical field, it involves: practice of taking prescribed medication, seeking help if symptoms change, attending a consultation, and

Received: 11.02.2026 ***Accepted: 27.03.2026*** ***Published on: 30.04.2026***
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making lifestyle changes. It assumes an equal relationship between two people and its voluntary process [5, 6], It involves three phases, which are: initiation, implementation, and discontinuation phase [7].

There are many factors which results to non-adherence, such as non-compliance and TB drugs' side effects. Non-compliance is an autocratic relationship in which someone follows instructions (compliant) or does not follow instructions (non-compliant) [6]. It can also be defined as a patient behavior aligned with medical advice on how to take drugs [8], and the side effect of TB drugs is defined by WHO as a medical occurrence temporally associated with medicine but not necessarily causally related. It can be any unfavorable or unintended sign, including laboratory findings or symptoms that are temporally associated with the use of a medicinal product [9].

In 2015 more than 9.6 million new cases with TB and mortality of 1.5 million observed globally and in 2018 WHO emphasized on global strategy to end TB by 2030, [2] Significant TB cases about 80% occur in high burden TB countries and sub-Sahara Africa contain 70% of the world TB burden with estimated TB active case of more than 4 million which results to 650,000 death every year, [2].

Tanzania is one of the countries with a high burden of TB, with a prevalence of 275/100000 population and an incidence of 164,000 cases [2]. The highest of TB cases in Tanzania are found in Dar es Salaam by 21.9%, followed by Mwanza with 9.3%, then Shinyanga 6.4%, and Mbeya 6.6% [2].

Given the high burden of TB and MDR-TB in Tanzania, this study seeks to understand the level of non-adherence to TB treatment and factors associated with patients with Tuberculosis. The overall goal of the study is to produce scientific evidence that will guide health providers on how to enhance adherence to TB therapy among individuals on treatment. This will as a consequence reduce cost of treatment to the patients, TB relapse, reduce side effects of injectable anti-TB drugs caused by non –compliance of treatment, in addition, enhanced adherence will reduce duration of treatment and hospital admission if they develop drug resistance TB, reduce physcosocial impact, low cure rate, reduce mortality rate of TB patients and prevent transmission of resistant strain of Tuberculosis disease.

This study aims to determine the level of non-adherence to TB therapy, which can reveal what proportional of patients who do not adhere to treatment, and the association between treatment non-compliance, TB drug side effects, and TB treatment non-adherence. Many studies have shown a clear link between non-adherence with treatment failure, social, economic, and treatment factors contribute to non-adherence to TB therapy. In Tanzania, the level of non-adherence is 20%, still high [10], which is above the WHO recommendation [11]. This is a reason why this study is chosen to quantify non-adherence to patients and understand reasons for non-adherence, which will contribute to the implementation of targeted interventions as well as ensure optimal adherence in order to control Tuberculosis [12].

Tuberculosis is one of the main communicable diseases with higher mortality and morbidity worldwide, contributing 10.4 million cases in 2017 globally, with mortality of 1.7 million patients [13]. TB treatment, which has a duration of 6 months, is a foundation of Tuberculosis control and prevention, but non- treatment adherence is the main factor that results in treatment failure or Mult- drug resistance tuberculosis (MDR-TB), and in 2017, there were 558,000 MDR-TB patients worldwide [10]. The current TB treatment faces a lot of challenges due to TB drug side effects and long-term treatment resultong in MDR-TB, and the main cause is treatment non-adherence and loss to follow-up [3]. A mix of different ant- TB drugs and a longer duration of 6 months result in risk of treatment interruption, which may result in

persistence of TB infection, TB relapse, drug resistance, and death. Challenges faced by patients to follow long-term treatment and the number of pills taken daily make adherence a complex behavioral phenomenon [14].

Globally, there is implementation of Direct Observed therapy (DOT) with the intention to reduce treatment failure, drug resistance, and TB relapse, but its influence to reduce TB new cases has been affected by non-compliance to DOT supervisors as well as patients. There is a significant magnitude of non-adherence to chronic disease, including TB disease, globally [15].

In developing countries, there are many factors which affect non adherence to TB treatment which include; drug side effects, age, distance to the health facility, traditional belief leading to self-treatment, pill burden, lack of family support, lack of food, lack of adequate communication from health care professionals and low income, long duration of treatment [11, 15].

Tanzania is one of the countries with a high burden of Tuberculosis, there were 75,845 patients in 2018, with the increase of 6,205 (9%) new cases, compared to 2017. New and relapsed cases were 74,692, of which 48% were bacteriologically confirmed, pulmonary TB patients were 79%, and 14% were children. Dar es Salaam remains a major city with tuberculosis patients in Tanzania. It contributes 20% of all TB cases in Tanzania. There is a variation of TB patients across the country, from which, in previous years, 50% of patients were contributed by seven regions, which are, Mwanza, Arusha, Dar-es-Salaam, Geita, Mbeya, Manyara, and Dodoma [16].

Most of the TB complications are due to non-adherence to TB medications. Non- adherence has been considered as a major obstacle which hinder eradication of TB globally, and the WHO defines non-adherence as patients who do not complete treatment and recommends that non- adherence should not exceed 5% [11, 17]. In Tanzania, adherence is defined as taking all TB drugs for a period of six months, and missing more than 6 doses in four weeks is regarded as non-adherence [18]. It is difficult to assess non-adherence to TB therapy, but up to one fourth of patients do not complete six-moth treatment [19]. Treatment adherence behavior (TAB) can be explained as the extent to which a person practices taking medication, following a diet, and change life style as recommended by Health care provider, conversely, it is non-adherence [5].

Failure to adhere to TB therapy may result in treatment failure as well as Multidrug-resistance pulmonary Tuberculosis, morbidity, mortality, low treatment success rate, long treatment regimen, transmission of TB resistance strain to the community, economic burden as a result of increased admission rate and hospital stay, and acquisition of chronic TB manifestation [20]. Understanding adherence behavior is important for effective and efficient treatment planning, improving understanding of fluctuation in treatment outcome in disease monitoring programs, knowledge of adherence patterns is important in TB program decisions, and consideration of patient experience influences patient-centric management, which will promote treatment adherence [5].

Several efforts have been put in place to manage adherence challenges. The World Health Organization has set targets in its 2017 End TB strategy for reducing deaths by 95% and new cases by 90% in 2035, along with the implementation of the DOT strategy (10). DOT strategy needs every patient to have a treatment partner that observe patient daily while taking medication [11].

WHO also introduced digital adherence technology, funding, and technical support to combat the challenges of non- adherence to achieve its mortality and morbidity reduction [4, 10]. A defaulter tracing system was also created to ensure that patients adhere to treatment to reduce the TB burden across the globe [20]. Fee exemption has been introduced in developing countries, and Fixed-dose

combination of anti-TB drugs has been put in place since 1980 to enhance adherence to TB therapy [20]. TB awareness programs and increased access to health facilities have been put in place to enhance adherence to TB therapy [11].

In 2006, Tanzania, through the National Tuberculosis and Leprosy Control Program (NTLP), introduced Patient-centered TB Treatment (PCT). This approach gave opportunity patient to choose either home-based direct observed treatment (HB-DOT) supervised by supporters of their own choice or Health facility-based direct observed treatment (HF-DOT) supervised by medical staff. The purpose of introducing this was to enhance TB therapy adherence, and currently more than ¾ of all TB patients prefer home-based direct observed therapy [4]. Because of its impact on global health, TB has been considered in the United Nations (UN) goals for reducing incidence cases of MDR-TB and mortality rate, as well as disease risk [21].

Despite the effort taken, including the DOT strategy, adherence to TB therapy remains a major challenge. Digital adherence technology, its impact on adherence is still limited [10]. Introduction of Patient- Centered treatment (PCT), which also failed to enhance adherence. This study considered patient and drug factors that were suspected to be major factors of non –adherence.

TB remains an infectious disease worldwide and results in many deaths in poor countries. Increase in TB drug resistance has worsened the situation, and this is due to non-adherence to TB treatment [15, 22]. WHO estimates that TB death is 54million between 2000 and 2017, and new cases are 10 million yearly, and patients have not recovered after several treatments due to non-adherence to TB therapy. Tanzania is among the top 20 countries with a high TB burden worldwide, ranked as number 15 [23]. It is the WHO designed a high- burden tuberculosis country [24].

One of the agenda items in Sustainable Development Goals (SDGs) is to end the global TB pandemic by the year 2030, in line with this WHO goal of reducing TB deaths by 90% and incidence rate by 80% in 2030 by ensuring adherence to TB treatment is implemented [25]. Treatment of tuberculosis in Tanzania is six months. It is expected that patients take their drugs daily. However, some patients in Tanzania do not take their TB drugs daily, hence they don't complete the six-month treatment [23].

There are limited data on non-adherence in Tanzania[22]. Studies done have limitations on small sample size and data collected from these studies are not informative on provision of prevalence and other factors related to non-adherence and drug resistance at a national level, as samples were not representative, and most of the studies were not done according to the current international recommended methodology [26]. The study determined the proportional of patients who do not adhere to treatment. This enables health workers in TB clinics to provide an effective way on how drugs should be taken to prevent TB relapse, death, and transmission of resistance strain. This study was conducted to determine the prevalence of non-adherence to TB therapy and associated factors among patients with pulmonary Tuberculosis.

Health Believe Model (HBM) was adopted in this study. This model was developed by a social scientist in the United states of America (USA) in 1950 to understand why people fail to adopt prevention strategies of different diseases or screening of various tests to detect diseases. Later, this theory was used for patients' response to compliance and symptoms with medical treatment. The theory suggests that personal belief in the threat of disease, as well as belief in recommended health behaviour will predict whether a person can adopt the behaviour or not.

The concept of HBM comes from behaviour and psychological theory with two components

of health behaviour which include: belief that specific health action will prevent, or cure disease or desire to avoid disease or get well once the disease is already acquired, an individual's course of action is determined by the perception of barriers or benefits aligned with the behaviour. The HBM has six constructs out of which the first four were from when the theory was developed, but the last two were added later.

The constructs are as follows: Perceived susceptibility: This can be explained as the subjectivity of a person's perception of the risk of acquiring a certain disease. Different people have different feelings about the vulnerability of the disease. Perceived severity: This can be explained as individual feelings on the seriousness of acquiring a disease or sometimes leaving a disease untreated. There is a variation in feelings on the severity of the diseases among different groups of people. Normally, they are consider as social consequences (social relationships or family life) or medical impacts such as death or disability) Perceived benefit: This can be explained as individual's perception of effectiveness of actions available to reduce the impact of the disease (or cure the disease). The course of action is taken after considering perceived susceptibility and perceived benefit, in which an individual will accept a recommended health action if it is thought to be beneficial [27].

Perceived barrier: This can be explained as individual feelings about obstacles, implementing a recommended health action. Different people have different feelings about barriers, which can weigh the effectiveness of proposed action against cost implications such as expensive, dangerous (including side effects), time consuming or unpleasant, such as painful. **Cue to action:** This refer to a stimulus needed to initiate decision making process to agree with recommended health action, it can be external such as a newspaper or an article, or receive advice from others, or an illness of a family member, but it can also be internal, such as a wheeze or chest pain. **Self- efficacy:** This can be explained as the level of individual confidence in the ability to perform recommended health behaviour. It considers wether the person performs the desired behavior [27].

Two variables are obtained from this theory: Perceived benefit (reflects compliance part of patients to take anti-TB drugs), which means patients will comply with treatment if they thought that the treatment is beneficial and will not comply (non-compliance) if they thought that the treatment is not beneficial. Perceived barrier (reflected as TB drugs side effects) which may hinder patients from taking anti-TB drugs) All these can lead to non- adherence to the drug, which is the dependent variable.

Many studies show that adherence to Tuberculosis therapy does not reach the required level in Sub-Saharan Africa. In Tanzania, one study done in Kilimanjaro shows 79% of TB patients were adherent, and a study done in Mwanza shows only 83% of TB patients adherent (10). Tanzania is one of the countries with the highest burden of TB, with an incidence rate of 269 (127-464) per 100,000 population in 2017. The mortality rate of TB is 47 (21-83) per 100,000 population in 2017, with MDR-TB patients of 0.9%. The success of treatment of TB is not 90% adherence as required in 2017 [10].

The main objective of this study was to determine the prevalence of non-adherence to Tuberculosis therapy and associated factors among patients with pulmonary tuberculosis at Mwananyamala Regional Referral Hospital. The specific objectives were: To determine the proportion of non-adherence to TB therapy among patients with pulmonary TB at Mwananyamala Regional Referral Hospital, to ascertain the association between TB treatment non-compliance and non-adherence among patients with pulmonary TB at Mwananyamala Regional Referral Hospital, and to establish the association between TB drugs' side effects and non-adherence among patients with pulmonary

TB at Mwananyamala Regional Referral Hospital.

The novelty of this study includes demonstrating an exceptionally high TB treatment adherence rate (98%) in a regional hospital setting in Tanzania. It also challenges known assumptions by showing that commonly factors, such as drug side effects, did not significantly influence non-adherence in this population.

Materials and Methods

This was a quantitative study with a cross-sectional design. A total of 422 TB patients were involved; The sample was drawn from a sample frame of 900 TB patients from Mwananyamala TB clinic. Assessment of the participants was done on adherence to TB drugs.

The sample size was calculated using a formula used in cross-sectional studies with 95% confidence interval.

$$S = \mathrm{Z2p}\frac{1-\mathrm{p}}{\mathrm{d}^2} + 10\%\ \mathrm{non-respondents}$$

Where S=sample size.

Z=standard normal variate.

P=prevalence of outcome.

d =absolute error.

Z= 1.96.

P=0.2.

d = 0.04 .

Therefore.

S=1.96x1.96x0.2 (1-0.2)/ (0.04) ^2 + 10% non-respondents.

S= 384 + 38 = 422.

The sample size of this study was 422 patients.

The sample size was completed within one month, because the number of follow- up patients per day was over 50 and only 14 patients were needed per day, and systematic sampling was used. The study was conducted in 2021, Dar es Salaam Tanzania, at Mwananyamala Regional Referral Hospital.

Positivism was used in this study because this is a quantitative study, and assumptions are prevalence of non-adherence would be quantified; there is a possibility of determining what factors can influence non-adherence to anti-TB drugs. The factors that can results in non-adherence to ant-TB are: non-compliance with anti-TB drugs, side effects of ant-TB drugs, and other factors that might cause adherence to ant-TB drugs are: proper education of the patients, a good health system structure, and a good patient- to- health care relationship.

Different tools were used to collect data, which include: a structured questionnaire, a TB treatment card, and the MMS-8 scale. The structured Questionnaire was used as it contained specific questions that guided participants to respond to questions related to non-adherence. It was used as an instrument for data collection and was distributed randomly. The researcher used five attributes when developing standardized research questionnaires, and these were: strongly disagree, disagree, neutral, agree, and strongly agree. This enabled easy and timely responses to questionnaires by respondents. Responses from a structured questionnaire were received from the patients, and the questions were structured based on the common causes of non-adherence to TB therapy, non-compliance, and TB drug side effects. TB treatment cards were also used to collect data on adherence. These cards indicated how many doses had been taken by patients for a certain period. Each TB patients had a treatment card, and these cards were obtained from them.MMS-8 scale was also used to collect data related to adherence; questions related to non-adherence were asked, and responses were obtained from patients. ODK software was used as an instrument tool for collecting data, and then the data was sent to the SPSS program for further processing.

In Tanzania, according to the National Tuberculosis and Leprosy program (NTLP) guidelines of 2017, non- adherence is regarded if a patient misses more than 6 doses in four weeks. This study used NTLP 2017 guidelines to assess non-adherence. The TB treatment card

was used to assist the process, and patients who missed more than 6 doses within any of the four weeks of the treatment period were regarded as non-adherent.

Morisky medical adherence scale (MMS-8) was also used to assess non-adherence, in which there were 8 questions asked. For the first seven questions, each question has one mark for yes and 0 for no. Question no 8 Likert scale was used with a score ranging from 0 to 4. Overall score for this scale ranges from 0 to 11, and <2 was considered as adherence, and > 2 was considered as non-adherence. The higher the score, the lower the adherence. The questions were applicable over the entire treatment period, from 1 month to six months.

Compliance was assessed by using a summated rating scale (Likert scale). This scale has been used to assess compliance in most medical conditions and has recently been used by [28] to assess compliance with COVID-19 precaution measures. 5 points Likert scale was used in this study, in which four compliance questions were asked with responses of strongly agree, agree, neutral, disagree, and strongly disagree. Patients who responded to disagree and strongly disagree were regarded as non-compliant to specific questions as well as to the overall score.

Data analysis for this study was done with the help of SPSS statistical software. Categorical variables were summarized by calculating proportions from frequencies, and means and standard deviations were used to summarize continuous variables. Study population characteristics were compared between TB patients on therapy who are adherent and non-adherent using the chi-square test for categorical variables and the student t-test for continuous variables. Variables with $p<0.2$ in this analysis were included in the multivariable logistic regression model to assess the independent association between non-adherence and the risk factors. All analyses were two-tailed at a significance level of 0.05.

Ethical Considerations

Permission to conduct this research was obtained from the Director of Research Post Graduate Studies, School of Public Health, University of Dar es Salaam and consent was requested from all participants. Name of participants was not recorded to maintain confidentiality.

Results

Characteristics of Study Participants

Among the patients who did not adhere to treatment, 75% were male and 25% female. In a group of non-adherent patients, 87.5% were between the aged of 25 and 45 years, while 12.5% between 68 and 85 years, and none of the patients were between 46 and 65 years. 75% of non-adherent patients were not married, while 25% were married. This study shows that there was an association between marital status and non-adherence, as the p- value was 0.038.

Among patients who fail to adhere to treatment, 75% were not employed, and only 25% were employed. 50% of the patients who did not adhere to treatment had primary education,37.5% had secondary education,12.5% had never gone to school, and none of the patient had university education.

Other factors associated with non-adherence, such as following healthcare instructions, knowledge of TB disease, alcohol use, family support, and distance to the health facility, have been assessed in this study. 25% of the patients who did not adhere to treatment had no knowledge of TB disease, while 75% had knowledge on Tuberculosis disease. 80% who failed to adhere to treatment did not take alcohol, while 20% took alcohol. In a group of non-adherent patients, 62.5% receive family support while taking anti-TB drugs however; 37.5% did not receive family support while taking ant-TB drugs. 62.5% of patients who did not adhere to treatment, distance to the health facility was not a challenge, while 37.5% had a challenge with distance to the health facility

affecting their ability to adhere to treatment. All these factors except Alcohol intake have an association with non-adherence, as their p-value is less than 0.01. These results are illustrated in Table 1.

Table 1. Characteristics of Study Participants by MMS-8 Score

	Total	**Adherence (414, 98%)**	**Non-Adherence (8, 2%)**	**P-Value**
Gander				
Male	288(68.25%)	282(68.12%)	6(75%)	0.625
Female	134(31.75%)	132(31.88%)	2(25%)	
Age				
25-45	270(63.98%)	263(63.53%)	7(87.5%)	0.326
46-65	128(30.33%)	128(30.92%)	0(0%)	
66-85	24(5.69%)	23(5.55%)	1(12.5%)	
Married				
Yes	275(65.16%)	150(36.23%)	2(25%)	0.038
No	147(34.84%)	141(34.06%)	6(75%)	
Employed				
Yes	152(36.02%)	150(36.23%)	2(25%)	0.562
No	270(63.98%)	264(63.77%)	6(75%)	
Education				
Never	24(5.69%)	23(5.56%)	1(12.5%)	0.173
Primary school	208(49.29%)	204(49.28%)	4(50%)	
Secondary school	153(36.26%)	150(36.23%)	3(37.5%)	
University	37(8.76%)	37(8.93%)	0(0%)	
Follow instructions				
Yes	421(99.76%)	414(100%)	7(87.5%)	0.00
No	1(0.24%)	0(0%)	1(12.5%)	
TB knowledge				
Yes	413(97.86%)	407(98.31%)	6(75%)	0.562
No	9(2.14%)	7(1.69%)	2(25%)	
Alcohol intake				
Yes	81(19.19%)	79(19.08%)	2(20%)	0.535
No	335(80.81%)	335(80.38%)	8(80%)	
Family support				
Yes	389(92.18%)	384(92.75%)	5(62.5%)	0.00
No	33(7.82%)	30(7.25%)	3(37.5%)	
Distance effect				
Yes	8(1.89%)	5(1.21%)	3(37.5%)	0.00
No	414(98.11%)	409(98.79%)	5(62.5%)	

Non-Adherence by MMS-8 Scale

Eight questions of MMS-8 were used to assess the level of adherence. For the first seven questions: each question has 1 mark for a Yes response and 0 mark for a No response, and question number 8 a Likert scale was used with a score ranging from 0 to 4. The overall score

for this scale ranges from 0 to 11; the questions were asked considering the overall treatment period, i.e., from the first month to six months.

Out of 422 patients, 98% of the patients adhered to treatment while 2% did not adhere to treatment as indicated in Figure 1.

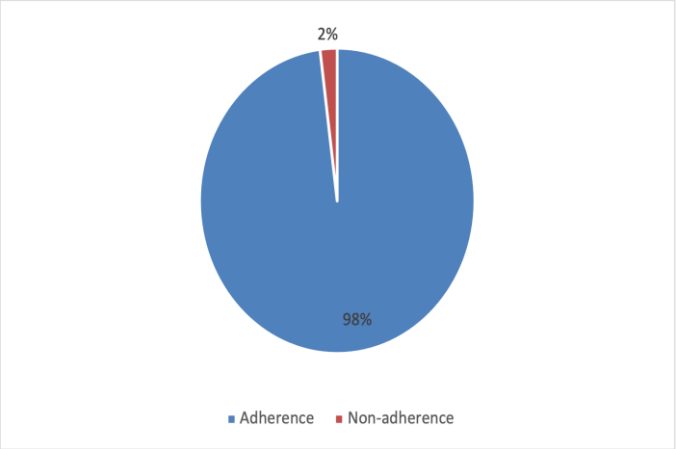

Figure 1. Non-Adherence by MMS-8

Non- Adherence by Treatment card

TB treatment cards were also used to assess non-adherence; all treatment cards (100%) of patients have been completed as per the NTLP guideline recommendation, which means adherence is 100%.

Associations between Tb Drugs Side Effects and Non-Adherence

Out of 8 patients who did not adhere to treatment, 50% had TB drug side effects, while the other 50% did not experience any side effects. Among patients who adhered to TB treatment, (30.68.0%) had TB drug side effects, while 69.32% did not have side effects. This study shows that there is no association between TB drug side effects and non-adherence, as the p-value was 0.261, as shown in Table 2.

Table 2. Association between Overall TB Drugs Side Effects and Non-Adherence

Side effects	Non-Adherence (n, %)	Adherence (n, %)	P-Value
	(8, 2%)	**(414, 98%)**	
Yes	4(50%)	127(30.68%)	0.261
No	4(50%)	287(69.32%)	
Total	8(100)	414(100)	

Association between Specific TB Drugs Side Effects and Non-Adherence

Common TB drugs' side effects have been evaluated in this study, such as discomfort, feeling more sicker, interference with work activities, Numbness, headache, dizziness, and skin rash. Among patients who did not adhere to treatment, 62.5% did not experience discomfort, 37.5% had discomfort; none of the patients felt more sicker or had work interference while taking ant-TB drugs. 25% of the patients experienced numbness, headache, dizziness, and skin rash, while 75% did not have these side effects. In this study, all TB drug side effects evaluated have no association

with non-adherence, as they have a p-value of greater than 0.05, except discomfort, which has a p-value of less than 0.01, as illustrated in Table 3.

Table 3. Association between Specific TB Drugs Side Effects and Non-Adherence

Side effects	Total	Adherence (414, 98%)	Non-adherence (8, 2%)	P-Value
Discomfort				
Yes	9(2.13%)	6(1.45%)	3(37.5%)	0.00
No	413(97.87%)	408(98.55%)	5(62.5%)	
Feel Sicker				
Yes	3(0.71%)	3(0.72)	0(0%)	0.971
No	413(97.87%)	408(98.55%)	5(62.5%)	
Work interference				
No	422(100%)	414(100%)	8(100%)	-
Numbness				
Yes	100(23.7%)	98(23.67%)	2(25%)	0.628
No	322(76.3%)	316(76.33%)	6(75%)	
Headache, dizziness or skin rash				
Yes	50(11.85%)	48(11.4%)	2(25%)	0.628
No	372(88.15%)	366(86.73%)	6(75%)	

Association between Specific Non-Compliance Factors and Non-Adherence

On assessing compliance-specific factors, among patients who did not adhere to treatment, 75% agreed, and 25% strongly agreed that they take drugs before a meal, and none of the patients were neutral on the same question. 87.5% of the patients agreed, and 12.5% were neutral on taking food within 30minutes to 1 hour after taking ant-TB drugs, and none strongly agreed on the same question.71.43% of non-adherent patients agreed, and 28.57% were neutral on taking 3-5 liters of water per day, and none strongly agreed, strongly disagreed, or disagreed on the same question. 50% of the patients were neutral, and the other 50% agreed that they take a diet rich in vegetables and fruits; none of the patient strong agreed or disagreed on the same question. All compliance factors assessed in this study have no association with non-adherence except taking water 3-5 liters per day, which has a p-value of less than 0.01, as illustrated in Table 4.

Table 4. Association between Specific Non- Compliance Factors and Non-Adherence

Compliance Taking drugs before meal	Total	Adherence (414,98%)	Non-adherence (8,2%)	P-value
Strong agree	214(50.71%)	213(46.14%)	1(25%)	0.233
Agree	198(46.92%)	191(47.83%)	7(75%)	
Neutral	10(2.37%)	414(0.72%)	0(0%)	
Taking food after 30min-1 hour				
Strong agree	191(45.26%)	191(45.26%)	0(0%)	
Agree	207(49.05%)	200(48.31%)	7(87.5%)	
Neutral	24(5.69%)	23(6.43%)	1(12.5%)	
3-5 liters of water per day				

Strong agree	108(25.59%)	108(26.09%)	0(0%)	0.000
Agree	153(36.26%)	148(35.75%)	5(71.43%)	
Neutral	152(36.02%)	150(36.23%)	2(28.57%)	
Disagree	8(1.89%)	7(1.69%)	0(0%)	
Strong disagree	1(0.24%)	1(0.24%)	0(0%)	
Taking diet rich in vegetables				
Strong agree	127(30.09%)	127(30.09)	0(0%)	0.000
Agree	184(43.6%)	180(43.48%)	4(50%)	
Neutral	107(25.360)	103(24.88%)	4(50%)	
Disagree	4(0.96%)	4(0.96%)	0(0%)	
Overall P-Value				0.382

Multivariable logistic Regression

From the data analysis plan, any variable that predict the outcome and has a p-value of less than 0.2 was considered in the multivariable logistic regression to determine the independent association between non-adherence, non-compliance, and risk factors. These variables were: marital status, follow instruction, knowledge on TB, family support, distance to the health facility, discomfort, and taking 3 to 5 liters of water per day, as shown in Table 1.

Married patients were more likely to adhere to treatment (OR 5.809, CI 95%,1.157-29.151) than non- married patients, and the results were statistically significant as the p value was less than 0.05. Patients who follow healthcare instructions were more likely to adhere to treatment (OR 9.193, CI 95%,9.193-9.193) than those who do not follow instructions, and the results were statistically significant as the p-value was less than 0.05. Patients who had TB knowledge were 19.381 times more likely to adhere to treatment (CI 95%,3.314-113.342) than those who did not have TB knowledge, and the results were statistically significant as the p-value was less than 0.05. Patients who receive family support while taking ant- TB drugs were 7.68 times more likely to adhere to treatment (CI95%,1.75-33.697), but the results are not statistically significant as the p-value was greater than 0.05.

Patients who had no challenge with the distance factor to the health facility were less likely to adhere to treatment (OR 0.02, CI 95%,0.04-0.109) than those who had a challenge, and the results are statistically significant as the p- value was less than 0.05. Patients who had no discomfort symptom were less likely to adhere to treatment (OR 0.25, CI 95%,0.05-0.127) than those who had discomfort symptoms and the results were statistically significant as the p-value was less than 0.05. Patients who take 3-5 liters of water per day while taking ant- TB drugs were 2.6 times more likely to comply with treatment (CI 95%,0.05-0.127) than those who do not take the same amount of water, and the results are statistically significant as the p- value was less than 0.05, as illustrated in Table 5.

Table 5. Multivariable Logistic Regression

	Multivariable models	
	Odds ratio (95% CI)	**p-value**
Marital status - Yes	5.809 (1.157-29.151)	0.03
Follow instructions -Yes	9.193(9.193-9.193)	0.00
TB knowledge-Yes	19.381(3.314-113.342)	0.01
Family support -Yes	7.680(1.750-33.697)	0.07

Distance effect-No	0.02(0.04-0.109)	0.00
Discomfort-No	0.25(0.05-0.127)	0.00
Taking 3-5 liters of water-Yes	2.6(2.110-3.241)	0.00

Hypothesis Testing

The first null hypothesis stated that; non-compliance does not influence Tuberculosis therapy non-adherence. The results indicated that a significant level of variable non-compliance is 0.382, which was above 0.05, so we failed to reject the null hypothesis, and the conclusion was that non-compliance did not influence on Tuberculosis therapy non-adherence. In assessing specific non - compliance factors, only one factor (discomfort) had a p-value of less than 0.05, as shown in Table 4.

The second null hypothesis stated that TB drug side effects do not influence Tuberculosis therapy non- adherence. Results indicated that the significance level of the variable TB drug side effect was 0.261 higher 0.05 then we failed to reject the null hypothesis, and Therefore the conclusion was that TB drug side effects did not influence on Tuberculosis therapy non-adherence.

Discussion

From the results, assessing non-adherence by using MMS-8 score majority of patients had adherence of 98.% and non-adherence was 2%, these findings are similar to the study done in Tanzania by Mkopi et al.[29], from which majority of patients 95.7% adhered to treatment and non-adherence was only 4.3%, most of patients follow health care instructions and actions which results to higher level of adherence, these findings support two major components of Health belief Model (HBM) which are belief of specific health actions to prevent or cure disease and desire to avoid disease or to get well once the disease is acquired.

Assessment of non-adherence using treatment card shows that all treatment cards of the patients (100%) have been completed as per NTLP recommendation, which means patients have been taking drugs as required, adherence was 100%. All patients accepted all health recommendations and took drugs as planned; these findings support one construct of HBM, which is perceived benefit (perception of effectiveness of the actions available to cure disease), and is similar to a study done by Oshi et al. [30] , which highlighted that proper documentation and monitoring of the treatment card improve adherence.

Specific side effect factors were also assessed, and only one factor (discomfort) was associated with non-adherence, with a p- value of less than 0.05. These results are similar to those of Neves et al.[31], which suggests that discomfort is related to non-adherence. It shows that there is an obstacle for a patient to implement the recommended health action. This supports one construct of HBM, which is perceived barrier. However, overall side effects had no association with non-adherence, as the p-value was 0.261, which was greater than 0.05. These results contradict those of Noor Haslinda and Muhamad Hanafiah Juni [32], which showed that there was an association between TB drug side effects and non-adherence.

Association between specific non-compliance factors and non-adherence was tested, and only one factor (taking water 3-5 liters per day) had an association with non-adherence, as the p-value was below 0.05. These results support a study done by Popkin et al.[33] which indicates that drinking plenty of water reduces gastrointestinal irritation, supports continued use of drugs by reducing side effects, and supports compliance. It shows that the seriousness of the disease and treatment were highly considered by the patients, this

support one construct of HBM, which is perceived severity.

Multivariable logistic regression was done on the variables that predict the outcome with a p-value of less than 0.2. Married patients adhere to treatment more than non-married patients; these results are similar to those of Kidenya et al.[34], which shows marital status influences adherence. This can be explained as advice received from family members, including a spouse, may influence treatment adherence, it supports one construct of HBM, which is cue to action, and this is the external part of this construct external stimulus can influence a certain behavior such as spouse advice.

Logistic regression was also done between following health care instructions and non-adherence, from which most patients who followed instructions adhere to treatment more, as compared to those who did not follow instructions These results are similar to those of Ndwiga et al. [35] which shows that following healthcare instructions influences adherence. The findings also support the construct of HBM, which is perceived benefit. Patients perceived that taking medication as advised is an effective way to reduce the impact of the disease or cure it which why they were able to follow instructions as recommended.

Similarly, logistic regression was done between TB knowledge and non-adherence; the results showed that patients with TB knowledge adhere to treatment more, as compared to those who do not have TB knowledge. These results are similar to those of Sani et al.[11] which show TB knowledge influences adherence. Knowledge received by patients from health care staff may act as an external stimulus to adhere to treatment. This supports one construct of HBM, which is the cue to action especially, the external part of the construct. This study recognized that there is adequate knowledge given to the patients as well as to the close relatives of the patients on TB disease, adherence to treatment, and side effects of the drugs, which overall influence adherence to medication.

Logistic regression between family support and non-adherence was also done, and results show that patients who received family support while taking ant- TB drugs are more likely to adhere to treatment as compared to those who do not receive family support, but these results were not statistically significant. These findings are similar to those of Urnilla Afrilian et al. [36] from which family support influences adherence. Family support can act as an external stimulus that influences adherence to treatment, this support one of the constructs of HBM, which is the cue to action. This study recognized that family members have been highly involved in recent years as part of the management of the patients. It is now a requirement that each patient should have a treatment supporter, all these influences adherence to treatment.

Again, logistic regression between the distance factor to the health facility and non-adherence was done, and the results show that patients who had no challenge with the distance factor to the health facility were less likely to adhere to treatment. These results contradict those of Aziz et al.[4]. from which patients with no distance factor challenges were more likely to adhere to treatment; also, these results contradict the HBM construct, which is perceivedas a barrier. This can be explained as there might be other factors that affect the ability of the patients to adhere to treatment, which have not been explained in this study.

Logistic regression between discomfort and non-adherence was done, and results show that patients who had no discomfort symptom were less likely to adhere to treatment. These results contradict those of Neves et al. [31], which suggest that patients with no discomfort symptoms were more likely to adhere to treatment.The results also contradict one of the HBM constructs which is the perceived barrier. This can also be explained that there are other

factors that affect treatment adherence, which have not been explained in this study.

Lastly, logistic regression was done between taking 3-5 liters of water and non-compliance, and the results show that patients who take 3-5 liters of water per day are more likely to comply with treatment. These results are similar to those of Popkin et al[33] which indicates drinking plenty of water to facilitate drug compliance by reducing organ damage. These results also support one of the constructs of HBM, which is perceived severity. Patients believed that taking enough water would reduce the side effects of the drug, which in the long run would reduce liver damage thus why they were able to follow instructions as recommended by healthcare professionals.

Conclusion

This study was done to determine the prevalence of non-adherence, and associated factors (non-compliance and TB drug side effects) in patients with Pulmonary Tuberculosis. Data analysis shows that the majority of patients adhere to treatment; common factors that cause non-adherence, such as non-compliance and TB drug side effects, do not influence non- adherence in this study.

In this study, TB therapy non-adherence was thought to depend on non-compliance and TB drugs, side effects. It was observed in this study that non- compliance and TB drug side effects do not influence non-adherence, therefore results are not a true reflection of the proposed conceptual framework. However, the HBM explained very well all of the variables used in this study.

Conflict of Interest

There is no conflict of interest.

Funding

No funding was received for this research project.

Ethical Approval

Ethical approval was obtained from the Director of Research Postgraduate Studies, Schol of Public Health, at the University of Dar es Salaam.

Data Availability

Data from this study is available on request.

Author Contribution

Beno Mbeya: Conceptualization, Methodology, Writing original draft, data curation, formal analysis.

Theresia Ambrose: Writing review, editing and supervision.

Acknowledgment

Thanks to my supervisor and all participants for their support in this research work.

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