FACTORS PREVENTING COMPLETION OF TREATMENT AMONG REGISTERED TUBERCULOSIS PATIENTS UNDER DIRECTLY OBSERVED THERAPY IN TEMEKE MUNICIPALITY, DAR ES SALAAM

By

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A dissertation Submitted in fulfillment of the Requirements for the Degree of Master of Science (Applied Epidemiology) of Muhimbili University of Health and Allied Sciences

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CERTIFICATION F0R EXAMINATION

The undersigned certify that they have read and hereby recommend for examination of thesis/dissertation entitled '***Factors preventing completion of treatment among registered Tuberculosis patients under directly observed therapy in Temeke Municipality, Dar es Salaam'***, in fulfillment of the requirements for the degree of Master of Science in Applied Epidemiology of Muhimbili University of Health and Allied Sciences.

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I, **Elibariki Reuben Mwakapeje**, declare that this **dissertation** is my own original work and that it has not been presented and will not be presented to any other university for a similar or any other degree award.

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Dedication

This work is dedicated to my parents Mr. and Mrs. Gadi Reuben Mwakapeje, my lovely wife Subira and my sons Reuben and Robin.

Abstract

Background: Tuberculosis (TB) is an ancient infectious diseases caused by *M. tuberculosis, M. bovis* and *M. africanum*. In recent years, there has been an increase in the number of TB cases due to the HIV epidemic. In Tanzania, Tuberculosis has been shown to be the third major cause of death after AIDS and Malaria. In 1999, Malaria led with 22%, followed by AIDS (17%), Tuberculosis (9%), Pneumonia (6.5%), and Anemia (5 %). Failure to complete the treatment regimen or defaulting from treatment has been one of the most challenging problems in tuberculosis treatment. Non completion of treatment is one of the contributing factors for MDR –TB and XDR_TB development.

Objectives: The study aimed to assess factors preventing completion of treatment among registered tuberculosis patients under directly observed therapy in Temeke Municipality. The specific objectives of the study were: To determine the socio demographic and economic characteristics preventing completion of anti TB treatment, to determine the underlying disease and treatment factors preventing completion of anti TB treatment among the registered TB patients, to determine the role of societal (stigma and social support) factors in relation to non completion of anti TB treatment and to assess knowledge on anti TB treatment and behavioral factors among registered TB patients

Materials and Methods: An unmatched case control study design was conducted. A total of 292 (73 cases and 219 controls, ratio 1:3) were studied. Record review of the patients was done using the TB register at the randomly selected TB clinics. Factors associated with non completion of anti TB treatment were assessed using a semi structured questionnaire. Data analysis was done using Epi info version 3.5.1

Results: Of the total population 292 (cases = 73 and controls = 219) were recruited. Among the cases, a total of 50 (68.5%) subjects had opted for community based DOT and 23 (31.5%) subjects opted for health facility based DOT, while for the controls, 163 (74.4%) subjects

opted for community based DOT and 56 (25.6%) subjects had opted for health facility based DOT.

Multivariate analysis showed factors associated with non completion of anti TB treatment to be distance of more than 5km from home to the health facility (Adjusted OR= 3.98, 95%CI= 1.82, 8.73), feeling stigmatized (Adjusted OR= 2.80, 95%CI= 1.45, 5.69), not knowing the duration for taking anti TB treatment (Adjusted OR= 2.99, 95%CI= 1.23, 7.32) and HIV infection (Adjusted OR= 2.22, 95%CI= 1.19, 4.14)

Conclusion and recommendation: This study found that long distance, HIV infection, feeling stigmatized and unknown duration of treatment to be associated with non completion of anti TB treatment. Efforts must be directed towards enforcing the already existing policy and legislation towards stigma as well as including modules on stigma and discrimination to providers of all cadres within service provision.

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List of Abbreviations

AIDS..... Acquired Immunodeficiency Syndrome

CI.....Confidence Interval

DOT.....Directly Observed Therapy

EPTB .....Extra pulmonary tuberculosis.

FDC.....Fixed dose combination

HIV.....Human Immunodeficiency virus

HAART.....Highly active antiretroviral therapy.

IPT.....Isoniazid Preventive therapy

MoHSW.....Ministry of Health and Social Welfare

MDR – TB.....Multi drug resistant tuberculosis

NTLP..... ....National Tuberculosis and Leprosy Programme.

OR .....Odds ratio

TB/HIV.....Tuberculosis and HIV co-infected patients.

TB.....Tuberculosis.

UN.....United Nations

WHO.....World Health Organization.

XDR – TB.....Extremely drug resistance tuberculosis

X^2.....Chi – squared

Definition of operational terms:

Cases: - were registered TB patients who either defaulted from anti TB treatment and traced or missed treatment appointments under directly observed therapy (health facility or community based)

Controls: - were registered TB patients (registered at the same time as cases) who completed their treatment within the stipulated treatment period under directly observed therapy (health facility or community based).

Completed treatment: New patients who have completed their schedule of treatment for six consecutive months

Defaulter: – New patient who fails to complete TB regimen by missing treatment appointment for two consecutive months.

Missed treatment appointments: New registered TB patients who presented at the health facility under directly observed therapy (health facility or community based) and a treatment day (1 or more) is missed such that treatment is prolonged > 30 days than planned due to missed dose(s)

Transfer out: A new patient who has been transferred to another treatment centre/unit and whose final treatment results are not known.

Treatment failure: A patient who returns to treatment, bacteriologically positive, after having interrupted treatment for two consecutive months and who had been on treatment for more than four weeks.

CHAPTER ONE

1 Introduction

1.1 Background

Tuberculosis is an ancient infectious diseases caused by *M. tuberculosis, M. bovis and M. africanum*. Since Pulmonary Tuberculosis is a disease of airborne transmission; patients with the active disease (Tubercle bacilli) expel them into the air by coughing, sneezing, shouting or any other way that will expel bacilli into the air. Overcrowding, poor personal and public hygiene are also risk factors for the transmission of Tuberculosis.

Tuberculosis remains a leading cause of death worldwide from a single infectious disease agent. Indeed up to half of the world's population is infected with Tuberculosis. The registered number of new cases of Tuberculosis worldwide roughly correlates with economic conditions; the highest incidences are seen in those countries of Africa, Asia, and Latin America with the lowest gross national product.

The World Health Organization (WHO) estimates that eight million people get Tuberculosis every year of which 95% live in developing countries, and an estimated 2 million people die from Tuberculosis every year. It is estimated that between 2000 and 2020, nearly one billion people will be newly infected, 200 million people will get sick and 35 million people will die from Tuberculosis [1]

After a century of decline, Tuberculosis is increasing and there are strains emerging which are resistant to antibiotics. This excess of cases is attributable to the changes in the social structure in cities, the human immunodeficiency virus epidemic and failure of most cities to improve public health programs as well as the economic cost of treating Tuberculosis patients despite free medications in certain countries of the world.

If prescribed Tuberculosis (TB) medications are misused or mismanaged (that is, when drugs are taken in the wrong combination, are fewer than those prescribed, or are taken in insufficient doses or not at the proper time), Multi drug Resistance – Tuberculosis (MDR-TB) and or Extremely drug resistance - Tuberculosis (XDR- TB) can develop.

MDR-TB is a form of TB disease resistant to the most important anti-TB drugs, i.e. isoniazid and rifampicin. MDR-TB takes longer to treat with second-line drugs, which are more expensive and have more side-effects. If these drugs are also misused or mismanaged, XDR-TB can develop.

There is probably no difference between the speed of transmission of MDR-TB or XDR-TB and those of any other forms of TB. The spread of TB bacteria depends on factors such as the number and concentration of infectious people in any one place and the time of exposure, along with the presence of people with a higher risk of being infected, such as those with HIV [1]

HIV infection is the leading risk factor for TB; HIV promotes progression of latent or recent infections of Mycobacterium tuberculosis to active disease, and also increases the rate of recurrence of TB. People living with HIV may also be more susceptible to TB infections. However, a report on the prevalence of TB in HIV-infected patients in Nigeria was reported to be 40% [2], there have been no such reports from Tanzania.

Large and rapidly growing numbers of patients with TB and HIV/AIDS co-infection require coordinated diagnosis, care, and treatment. They must be tackled simultaneously to decrease morbidity, mortality and transmission of TB while avoiding the emergence of drug resistance.

However, for some patients, adherence to treatment schedule is difficult and most of them stop treatment before completing the regimen. Non compliance is often attributable to programme limitations or failures, such as the lack of steady medicine supply within a

country, inadequate properly trained health care providers, poor motivation of health care workers, etc.

The most common reason for treatment default is irregularity of drug taking, premature termination of treatment (mainly by self discharge), development of side effects, and lack of food (hunger). Also some patients firmly believe that, when the symptoms have subsided and they are feeling well again, that they do not need any further treatment [3].

Patients (except those who are still sputum smear positive) will complete treatment after taking the drugs as directed for the full 6 months under DOT.
New smear positive patients have further follow up sputum examinations at the end of the 5^{th} month to determine if they have been cured.

Tuberculosis regimens are divided into the initial phase (intensive) and continuation phase. In the intensive phase the majority of TB bacilli are rapidly killed and infectious patients become non infectious within one to two weeks. The drugs in the continuation phase kill the persistence, thus preventing a relapse after completion of treatment.

TB management uses fixed dose combinations (FDC) which are the combination of 2, 3 or 4 drugs in the appropriate dose in one tablet. These combinations improve compliance with treatment as most patients need to take only 3 or 4 tablets per day during intensive phase of treatment instead of 10 – 12 tablets if single tablets are used.

1.2 Problem statement

Failure to complete the treatment regimen or defaulting has been one of the most challenging problems in tuberculosis treatment. Non completion of anti TB treatment is one of the contributing factors for MDR –TB development.

There are many factors which contribute to patients not completing tuberculosis treatment and these include health service factors, disease and treatment as well as issues socioeconomic and cultural factors like stigma

Health services factors influencing accessibility to drugs would likely contribute to non completion of TB treatment as well as disease factors like TB/HIV co morbidities. This has been supported by a study done in Tanzania among HIV patients receiving isoniazid preventive therapy (IPT) who did not complete their treatment, more than half was due to self cessation or loss to follow up [4].

The presence of the DOTS strategy, whereby a health worker or community member supervises patients swallowing every tablet, is meant to minimize the non completion of TB treatment. The widespread use of DOT may be an important factor in the recent decrease in tuberculosis cases in Tanzania.

Despite the impressive gains in compliance associated with the use of DOT in Tanzania, non completion of treatment with DOT also occurs when TB patients fail to make themselves available for the administration of drug therapy.

Figure 1: Problem analysis diagram on factors preventing completion of anti TB treatment

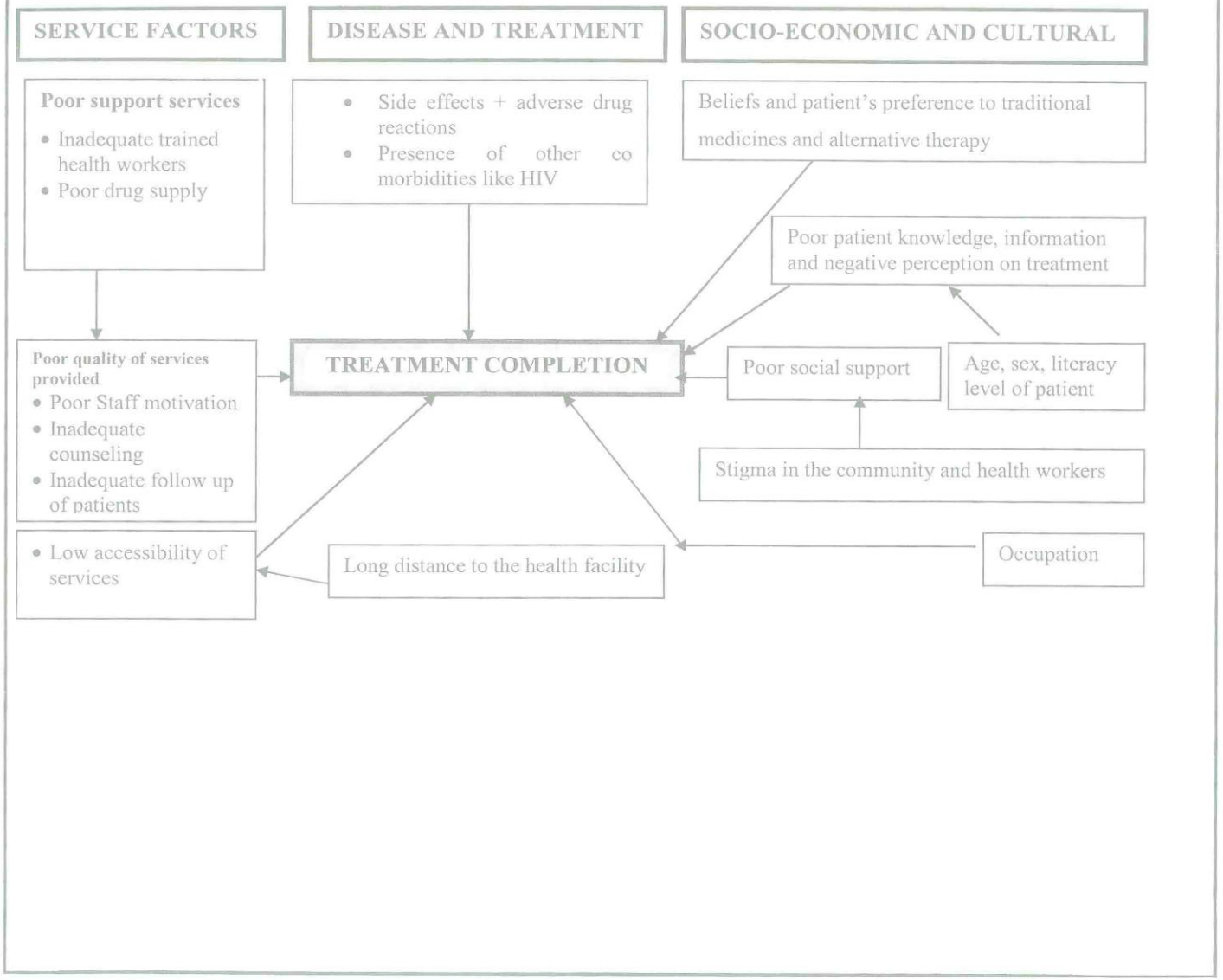


Figure 1 above shows a diagram analysis of factors which affects non completion of anti TB treatment. However, service factors like poor support and poor quality of services provided were not studied.

1.3 Rationale of the study

Cure of TB cases, and especially smear-positive cases, is without doubt the most effective measure for interrupting the chain of transmission of Mycobacterium tuberculosis.[5,6]. Much as we know how to treat it, TB is far from being eradicated anywhere in the world. Treatment completion is a key to controlling and preventing drug-resistant TB.

Directly observed therapy (DOT), recommended by the World Health Organization (WHO) is a proven way to improve treatment completion. Studies show that DOT increases completion of TB treatment and reduces both disease transmission and drug resistance. [7,8] According to a WHO report, the prevalence of drug-resistant TB is three times lower in countries where DOT is used widely [9].

Successful treatment completion may depend on how DOT is administered. If DOT is used to limit patients' freedom for the sake of monitoring compliance without any concern for patient understanding or life circumstances, it will not help patients cooperate with providers [10, 11]. Only when DOT implementation considers broader individual and community factors can it help patients complete their treatment regimens [12 – 14].

Few studies done elsewhere have shown that one of the factors mitigating TB treatment completion is presence of co morbidity of infections like HIV status. For these reasons, determination of rate and factors associated with non completion of TB treatment is the most important public health indicator for evaluating the current situation and the possible future of TB in a community

In Tanzania, no studies have been done to assess the factors leading to treatment non completion of anti TB treatment among TB patients. Understanding the factors leading to failure to complete treatment among TB patients will help the National TB/Leprosy program in developing

innovative intervention strategies that will improve the quality of care and treatment of TB patients in Tanzania.

This study aimed to assess factors influencing non completion of anti TB treatment among the registered tuberculosis patients and identify factors that are implicated and make recommendations that, if implemented, will improve the treatment completion rates to the WHO target of 85%.

1.4 Broad Objective

To assess the factors which prevent completion of treatment among registered TB patients under directly observed therapy in Temeke Municipality, Dar es Salaam.

1.5 Specific Objectives

1. To determine the socio demographic and economic characteristics preventing completion of anti TB treatment among TB registered patients
2. To determine the underlying disease and treatment factors preventing completion of anti TB treatment among the TB registered patients
3. To assess knowledge on anti TB treatment and behavioral factors among registered TB patients
4. To determine the role of societal (stigma and social support) factors in relation to non completion of anti TB treatment

CHAPTER TWO

2 Literature review

Non-compliance is cited as a major obstacle to the control of tuberculosis at the level of public health [15, 16]. It is also a serious problem in the treatment of individual patients and in the development of drug resistant strains.

In Brazil, the treatment default rate among TB patients managed at out-patient health units ranged from 15% to 28% in different settings [18]. In Tanzania (Dar es Salaam), a study reported that, of the 565 TB patients 87% completed treatment and 13% did not. Non completion was physician - initiated in 33% due to side effects, patients – initiated in 58% due to self - cessation or loss to follow up and due to death in 8% [19]

To eliminate TB, attention must be paid to both treatment initiation and completion rates as the failure to complete anti-TB treatment can result into the development of active TB and its subsequent transmission to susceptible contacts [17]. Therefore the introduction of directly observed therapy (DOT) has been welcomed worldwide as an effective method to stop this trend.

Directly Observed Treatment Short Course (DOTS) means that a supervisor watches the patient swallow the tables. This ensures that a TB patient takes the right drugs, in the right doses at the right intervals. To implement DOT, there have to be government/political commitment with increased and sustained financing, a clear case definition by sputum smear microscopy, standardized treatment directly observed by health (health facility based DOT) or community member (community based DOT), regular drug supply and standardized recording and reporting system [51].

Studies have shown that DOT enhances treatment completion. One study done in Thailand found that patients who were randomly assigned DOT (and who chose to be supervised by health centre staff, community member, or family member) had higher cure and treatment completion rates than self – supervised controls [50]

Countless factors have been associated with poor treatment completion, including its complexity and duration, adverse side effects, cost and difficult access to health care services [20], alcohol consumption [21], lack of preventive treatment and unemployment [22].

Various studies in Africa, Asia and Latin America have shown different reasons for default, the main reasons being lack of time to regularly visit a health facility [23, 24], lack of money for transport [25], poverty, lack of material incentives [26] and most of all lack of information or insufficient health education [27].

A study conducted in Mbarara district, Uganda in 1995 showed a low TB treatment completion rate of 56% and this low rate was due to use of short course therapy, previous TB treatment, being smear positive and if patient returned for repeated smear [22].

Disease and treatment factors are among the factors contributing to non completion of TB treatment. Studies have shown that HIV patients infected with TB are likely to be not completing anti TB treatment and moreover their mortality rate is higher than HIV patients without TB [28, 29]. The rate of defaulting from treatment has been shown by others to be also increased in patients with extra pulmonary TB (EPTB), and is likely to be related to HIV positivity [31].

A study conducted in Thailand found that 33% of TB/HIV co-infected patients abandoned treatment due to massive treatment adverse effects [32]. In another study, defaulting was found to be associated with male sex and HIV positivity [33].

Knowledge about TB disease and its treatment at the time of defaulting have been shown to be important in case studies in Africa. In a study done in Ethiopia, however, those with an essential knowledge deficit were not more likely to default from treatment than those with no deficit [34].

Defaulting has also been associated with male sex and HIV positivity [35]. A study done in the US reported that, low treatment completion rates among TB patients have been associated with homelessness, substance abuse, lack of patient understanding of the benefits of therapy and treatment toxicity [36,37].

A study done in Metro Manila, Philippines found that, being female and aged 30 – 44 years, unemployed, being above per capita poverty threshold, having experienced at one of the signs and symptoms of TB, taking the medication at the health facility and patient's understanding of DOT predict TB treatment completion [38]

The study done in Ethiopia revealed that, adequate knowledge about various aspects of TB disease was found to be protective factor for defaulting from anti TB treatment in 2002, in addition to knowledge, medication side - effects was also thought to be associated with non compliance to anti TB treatment [39]

Studies in America, Canada, Hong Kong and Ethiopia have found older age, especially over 60 years, to be associated with high defaulting rate in TB treatment [40]. In contrast, as was documented in South Africa that the 26 – 40 years age group appeared more likely to default [41]. In a study done in US, it was found that, patients who were young, postpartum, had no health insurance, or reported treatment side effects were at increased risk of treatment incompletion [42].

Other studies done in industrialized countries have shown that alcohol usage, low education level, low annual income [43], younger age and longer duration of treatment [44,45] were

associated with non completion of anti TB treatment. In developing countries, completion to TB therapy seems to be related to shorter home – to – clinic distances [46, 47]
A study from Brazil [48] showed that social support is highly valued by poor TB patients. For homeless and alcoholics, a flexible approach to ambulatory treatment has shown promising results in Tomsk, Russia [49]

Tanzanian TB program has been performing favorably for many years with DOTS coverage maintained at 100% since 1986 and treatment success rate has been increased from 73% in 1995 to 84.8% in 2006. [51]

Moreover, tracing of patients who failed to turn up for treatment through reminder letters, telephone calls, and home visits is a major component of many programmes. In Baltimore, MD, USA, patients who missed clinic appointments were rigorously followed up by the nurse outreach team and field investigators [52]

CHAPTER THREE

3.0. Methodology

3.1. Study design

This was an unmatched case control study design in which cases and controls were recruited from four randomly selected TB clinics in Temeke Municipality, Dar es Salaam during July 2009 and February 2010.

3.2. Study area

The study was conducted in Temeke Municipality, Dar es Salaam region, according to the 2002 census; Dar es Salaam has a projected population of 4.9 million (for 2009). Dar es Salaam lies in the eastern cost of Tanzania and is the largest business centre of the country [53].

Temeke is one of the three administrative districts of Dar es Salaam region, with an area of 656 square Kilometers and it is the largest district with a population of 927,310 with a growth rate of 4.3% per year. Residents are of mixed ethnicity and those from the rural part of the district are engaged in low income generating activities like small scale farming, petty trading and fishing. A small proportion of urban inhabitants are employed by government, parastatal or the informal sector.

Due to high burden of tuberculosis, Temeke is regarded as a region in the National Tuberculosis and Leprosy Programme which is sub divided into seven districts namely: - Wailes, Mbagala Kizuiani, Tambukareli, Kigamboni, Yombo Vituka, Keko and Mbagala Rangi Tatu. Tuberculosis services are provided in 37 out of 116 health facilities found in the district [54].

Although Temeke has a good health service coverage with about 90% of the population living within 5 kilometers of a health facility, other important health indicators remain poor [54]. The population per physician ratio is 1:18,637 and mortality rate among children under five years of age is 181/1000, compared to 154/1000 for Tanzania.

Four health facilities were randomly selected out of those providing TB services in the district in order to obtain the required sample size. These were Temeke Hospital, Tambuka Reli dispensary, Mbagala Kizuiani dispensary and Mbagala Rangi Tatu dispensary.

The number of enrolled cases and controls per health facility was obtained by proportionate sampling technique based on the number of registered patients in those facilities between July and August 2009, who were expected to finish their treatment schedule by February, 2010.

3.3. Study population

The study population consisted of newly registered TB patients in which cases and controls were recruited from 4 randomly selected health facilities out of 37 that provide treatment services for TB in Temeke Municipality.

Cases: - were registered TB patients who either defaulted from anti TB treatment and traced or missed treatment appointments under directly observed therapy (health facility or community based)

Controls: - were registered TB patients (registered at the same time as cases) who completed their treatment within the stipulated treatment period under directly observed therapy (health facility or community based).

Completion of anti-TB treatment: Is a situation when a patient completes his/her schedule of treatment for six consecutive months

Non completion of anti-TB treatment: Is a situation when a patient has interrupted his/her treatment schedule by either defaulting or missing even a single treatment appointment during the period of taking anti-TB treatment.

Inclusion criteria for cases

Tuberculosis patients registered between July and August, 2009 for receiving anti TB treatment who were:

i. Resident in Temeke Municipality and attending any of the four randomly selected TB clinics
ii. Either female or male and aged 18 years and above.
iii. Diagnosed to have either TB alone or TB/HIV co – infection.
iv. Did not complete treatment within the stipulated period of six months
v. Willing to participate in the study by giving verbal informed consent.

Inclusion criteria for controls

Tuberculosis patients registered between July and August, 2009 for receiving anti TB treatment who were:

i. Resident in Temeke Municipality and attending any of the four randomly selected TB clinics
ii. Either female or male and aged 18 years and above.
iii. Diagnosed to have either TB alone or TB/HIV co – infection.
iv. Completed treatment within the stipulated period of six months
v. Willing to participate in the study by giving verbal informed consent.

Exclusion criteria for cases and controls

Tuberculosis patients who:

i. Do not meet the above mentioned inclusion criteria
ii. Mentally handicapped provided by clinical evidence

3.4. Sample size

Since the proportion of cases and controls exposed to risk factors for not completing treatment in the population was unknown, 50% was chosen as the frequency of exposure in controls in order to enable the calculation of a sample size that would be able to detect an odds ratio of 2.28. Using 95% confidence limits and a power of 80% and 3 controls per case, the Statcalc facility in Epi Info was employed to calculate the sample size. The result of the calculation was 73 cases and 219 controls.

Table 2. Showing the result of sample size calculation:

Conf. Limits	Power of study	Ratio of Case: control	Expected frequency of exposure among controls	Odds Ratio	Sample size in controls.	Sample size in cases	Total Sample size
95.0 %	80.0 %	1:3	50.0 %	2.28	219	73	292

Sample Size = 292, (219 Controls and 73 Cases) by Epi Info StatCalc.

For every **case** (patient who either defaulted TB treatment and traced or missed treatment appointments) three **controls** (patients who attended their last visit at the TB clinic after completing anti TB treatment) were selected. Cases and controls were interviewed in order to assess the factors acting as barriers or motivating their treatment incompletion status.

Table 1 below shows that, the highest proportion of cases and controls (56.2%) was recruited from Temeke Hospital followed by Mbagala Kizuiani dispensary. This recruitment was based on the number of TB patients who were registered between July and August, 2009 for anti TB treatment at each of the randomly selected TB clinic.

Table 1. Proportional distribution of cases and controls by TB Clinics in Temeke Municipality, 2010.

Name of TB Clinic	Cases, n (%)	Controls, n (%)
Mbagala Kizuiani Dispensary	15 (20.5)	45 (20.5)
Mbagala Rangi Tatu Dispensary	8 (11.0)	24 (11.0)
Tambuka Reli Dispensary	9 (12.3)	27 (12.3)
Temeke Hospital	41 (56.2)	123 (56.2)
Total	**73 (100)**	**219 (100)**

3.5. Sampling procedures

3.5.1 Selection of TB clinics

Although each of the 37 TB clinics keeps different numbers of registered TB patients, this study randomly selected four clinics using a table of random numbers based on the number of registered TB patients between July and August 2009 for each TB clinic in Temeke Municipality who were expected to finish their treatment schedule by February, 2010 until the sample size was reached

Cases:

Cases were recruited sequentially from the TB register corresponding to those who had either defaulted from treatment or missed treatment appointments. This was done retrospectively for four months in the registers before the commencement of the study and also prospectively for two months until the end of the study in February 2010 when all the required cases and controls had been recruited. This strategy was used in order to obtain an adequate number of cases (those not completing treatment) within the available time-frame of the study.

Controls:

Controls were recruited sequentially from the TB register corresponding to those who had completed their treatment schedules within the stipulated period of six months. The same procedure used for recruiting cases from the TB registers was also used to recruit controls.

3.6. Data collection procedures

A semi-structured questionnaire was developed in English to be administered to both cases and the controls. However, because English is a foreign language in Tanzania and spoken by few, the researcher conducted a conceptional translation of questionnaire into Kiswahili, the national

language, to facilitate communication with the study participants. Back translating was also done to make sure the meaning remains almost the same.

Both the clinical officers (who were managing TB patients at each of the selected health facility) and the community health workers were recruited as the research assistants. The community health workers had the responsibility of tracing patients who missed their treatment appointments or defaulted from treatment i.e. the cases.

Training of the research assistants was conducted for three days before data collection in order to familiarize them with the data collection tool and study methodology as well as to get consistent information. A role play was done to re emphasize the skills and techniques of interviewing.

The trained research assistants at their workplaces (randomly selected TB clinics), enrolled the study participants as per sample size at each health facility, face to face interviews using semi-structured questionnaires was conducted by research assistants at the end of anti TB treatment for patients who completed their treatment and by trained community health workers for patients who either missed treatment appointments or defaulted from anti TB treatment after tracing them basing on the contacts they provided.

The eligible respondent was approached by initially seeking for the verbal informed consent, explained that this interviewing will take place whenever he/she comes for the visit to take his/her medication. When permission was granted, the questionnaire was administered and the subject was thanked after finishing for agreeing to participate in the study, but in the situation when the informed consent was denied the research assistants skipped to the next eligible respondent and followed the same procedures.

Record review of the anti TB treatment outcome status (Cases and Controls) was done using the TB registers at the selected TB clinics in the region in order to ascertain the patient's treatment completion status retrospectively, the reviewed information were recorded in the questionnaire of each study participants.

The following information was collected during interviews:

i. Socio demographics information

ii. Factors associated with treatment completion including individual factors

a. Individual factors – knowledge on taking anti tuberculosis treatment, distance between home and health facility.
b. Use of other medications/traditional medicine
c. Social factor – social support, stigma etc.
d. Economic factors – cost of accessing treatment, etc.
e. Health system factors – availability of medicines, counseling, provider/patient relationship, long waiting time etc.

Tuberculosis patient's registers were used to obtain the following information:

i. Adherence to treatment schedule in the previous four months before commencement of the study.
ii. HIV status of the patient
iii. Registration dates of both TB and TB/HIV patients
iv. Last date seen at TB clinic.
v. Date expected for next visit
vi. Date expected for treatment completion

At each selected health facility, a new/specific register was opened with names and personal details of enrolled subjects to enable easy recruitment of the subjects. These registers were exactly the same as the one kept in each health facility with the TB coordinator as the custodian for confidentiality and ease of accessibility.

Using a separate register was very convenient for the researcher because it was possible to take it away from the clinic for further study and assessment without interfering with the routine clinic processes.

3.7. Pre-Testing

Pre-testing of the data collection instrument with a selected sample of 5 cases and 15 controls was done prior to conducting the main study. The results were used to refine the questionnaire by adjusting response options which were unclear in the initial questionnaire.

3.8. Ethical consideration

Ethical clearance for conducting this research was obtained from the Muhimbili University of Health and Allied Sciences – Ethical review board (**see appendix. 3**) and permission for conducting research was obtained from the Temeke Municipal Council research unit (**see appendix. 4**).

Participant's names and identifiers were not included in the data collection tool in order to maintain confidentiality. Participants were assured that their participation in the study was voluntary and they were free to withdraw from the study without any negative implications in their treatment at the clinic.

Interviews of the participants did not interfere with their processes of getting anti TB treatment because it was either conducted after a patient has completed his/her treatment schedule or conducted at a place of residence of defaulted or missed treatment appointment patients when he/she was traced out. Verbal informed consent was sought from the participants before they were interviewed.

3.9. Data management and analysis plan

The data obtained were coded and entered into the computer by allowing for duplicate data entry by using Epi info software version 3.5.1. After finishing data entry, compare duplicate data entry errors, data cleaning was done in order to ensure all the information entered into the dataset is pertinent to the study. Data were analyzed using Epi Info version 3.5.1.

Descriptive analysis was done for the basic demographic characteristics of the cases compared with controls. Odds ratios with their 95% confidence limits were calculated for all risk factors assessed first in a bivariate model.

Unconditional logistic regression was used to control for the potential confounders i.e age and sex. All factors that were significant (P≤.05) in univariate analysis were entered in the multivariate model. A step wise approach was used to build up the logistic regression model. The factors that found to be statistically significant at the level of P ≤0.05 were included in the model.

The final model was derived by removing non significant (P>.05) variables as determined by the likelihood ratio test. Adjusted odds ratios (AORs) and corresponding 95% confidence intervals (95% CIs) were calculated for variables that remained in the final model.

CHAPTER FOUR

3 RESULTS

3.1 Basic Socio demographic characteristics

Among the cases, a total of 50 (68.5%) cases had opted for community based DOT and 23 (31.5%) subjects opted for health facility based DOT, while for the controls, 163 (74.4%) subjects had opted for community based DOT and 56 (25.6%) subjects opted for health facility based DOT.

The proportion of defaulters in the participating TB clinics were Mbagala Kizuiani Dispensary 0(0%), Mbagala Rangi Tatu Dispensary 3(3.6%), Tambuka Reli Dispensary 5(8.5%) and Temeke hospital 20 (18.7%)

Table 3 below displays the socio demographic information of cases and controls in Temeke Municipality.

Table 3: Socio demographic characteristics of study population

Socio demographic information	Cases n (%)	Control n (%)	OR	95% CI	P value
Marital status					
Married	31(42)	102(46.6)	0.85	0.48,1.49	0.54
Not married	42(57.5)	117(53.4)			
Sex					
Male	48(65.8)	123(56.2)	1.5	0.83, 2.70	0.15
Female	25(34.2)	96(43.8)			

Occupation status					
Unemployed	37(50.7)	107(48.9)	1.08	0.61, 1.89	0.78
Employed	36(49.3)	112(51.1)			
Level of education					
None	32(43.8)	65(29.7)	**1.85**	**1.06, 2.32**	**0.03**
Completed primary education and above	41(56.2)	154(70.3)			

Table 3 above displays the socio demographic characteristics among the cases and controls. Cases were two times more likely not to be educated than controls (OR = 1.85, 95%CI = 1.06, 2.32, p value = 0.03). Other parameters were not statistically significant.

The mean age of the study subjects was 34.5 years (median 31, SD 12.9) while that of the cases was 33.4 years (Median 30.0, SD 11.1) and controls was 34.8 years (median 32.0, SD 13.4)

3.2 Factors preventing completion of anti tuberculosis treatment

In this study, enrolled subjects were assessed for their level of knowledge and behavioral factors which might have influenced their non completion of anti tuberculosis treatment. Table 4 shows these factors for cases and controls that were registered in the randomly selected health facilities.

Table 4: Knowledge and behavior factors preventing completion of anti TB treatment among registered patients

Variable	Cases n (%)	Control n (%)	OR	95%CI	P - value
Reasons for long anti TB treatment duration					
Known	34(46.6)	89(40.8)	1.26	0.74, 2.15	0.38
Unknown	39(53.4)	130(59.2)			
Side effects of anti TB treatment					
Known	43(58.9)	171(78.1)	0.4	0.23, 0.71	0.001
Unknown	30(41.1)	48(21.9)			
Implication of not completing anti TB treatment					
Known	56(77.8)	183(83.6)	0.68	0.36, 1.33	0.26
Unknown	17(22.2)	36(16.4)			
Use of traditional medicine					
Ever used traditional medicine	15(20.5)	11(5.0)	**4.9**	**2.13, 11.22**	**< 0.0001**
Never used traditional medicine	58(79.5)	208(95.0)			
Taking anti TB drugs at the right time					
Having someone to remind	44(60.4)	157(71.7)	0.59	0.34, 1.04	0.07
Not having someone to remind	29(39.7)	62(28.3)			
Skipping taking anti TB drugs					
Ever skipped	62(84.9)	5(2.3)	**241.24**	**80.76, 720.58**	**< 0.00001**
Never skipped	11(15.1)	214(97.7)			

Table 4 above shows knowledge and behavior factors preventing completion of anti TB treatment among registered patients. Cases were more likely to use traditional medicine at the same time when using anti-TB drugs (OR = 4.9, 95%CI = 2.13, 11.22, p value < 0.0001) and also likely to skip taking their anti-TB drugs hence interfered their schedule of anti-TB treatment (OR = 241.24, 95%CI = 80.76, 720.58, p value <0.00001).

Table 5: Socio demographic and economic characteristics preventing completion of anti tuberculosis treatment

Factors	Treatment outcome		Univariate analysis		
	Cases n (%)	Controls n (%)	Crude OR	95%CI	P – value
Distance from home to health facility			**4.80**	**2.24, 10.34**	**< 0.00001**
> 5 km	21(28.8)	17(7.8)			
< 5 km	52(71.2)	202(92.2)			
Level of education					
None	32(43.8)	65(29.7)	**1.85**	**1.03, 3.31**	**0.02**
Completed primary education and above	41(56.2)	154(70.3)			
Stigma					
Yes	25(34.2)	31(14.2)	**3.16**	**1.63, 6.11**	**< 0.001**
No	48(65.8)	188(85.8)			
Cost of transport from home to health facility					
None	16(21.9)	22(10.0)	**2.51**	**1.17, 5.39**	**0.01**
More than Tshs 250 per day	57(78.1)	197(90.0)			
Duration for taking anti TB treatment					
Unknown	15(20.5)	13(5.9)	**4.10**	**1.73, 9.78**	**< 0.001**
Known	58(79.5)	206(94.1)			

Factors	Treatment outcome		Univariate analysis		
	Cases n (%)	Controls n (%)	Crude OR	95%CI	P – value
Type of DOT					
Health facility based DOT	23(31.5)	56(25.6)	1.34	0.72, 2.48	0.32
Community based DOT	50(68.5)	163(74.4)			
Age groups (years)					
		109(49.8)			
< 31	40(54.8)				
		110(50.2)	1.22	0.70, 2.15	0.46
≥31	33(45.2)				
Occupation status					
Unemployed	36(49.3)	107(48.9)	1.02	0.58, 1.79	0.95
Employed	37(50.7)	112(51.1)			
Sex					
Male	48(65.8)	123(56.2)	1.50	0.83, 2.70	0.14
Female	25(34.2)	96(43.8)			
HIV infection					
Positive	33(45.2)	63(28.8)	**2.04**	**1.14, 3.66**	**0.01**
Negative	40(54.8)	156(71.2)			

In table 5 above it shows that, the following factors were found to be statistically significant; staying at a distance of more than 5km from home to health facility (OR = 4.8, 955CI = 2.24, 1034, p value < 0.00001), completion of primary education and above (OR = 1.85, 95%CI = 1.03, 3.31, p value = 0.02), Stigma (OR = 3.16, 95%CI = 1.63, 6.11, p value < 0.001), cost of transport from home to the health facility (spending more than Tshs 250 per day) (OR = 2.51,

95%CI = 1.17, 5.39, p value = 0.01), lack of knowledge on the duration for taking anti TB treatment (OR = 4.10 , 95%CI = 1.73, 9.78, p value < 0.01) and HIV infection (OR = 2.04, 95%CI = 1.14, 3.66, p value = 0.01.

Table 6: Final model for the multivariate analysis on other factors preventing completion of anti tuberculosis treatment

Factors	**Treatment outcome**		**Multivariate analysis**		
	Cases	**Controls**	**Adjusted**	**95%CI**	**P – value**
	N = 73	**n = 230**	**OR**		
Distance from home to health facility			**3.98**	**1.82, 8.73**	**< 0.001**
> 5 km	21(28.8)	17(7.8)			
< 5 km	52(71.2)	202(92.2)			
Stigma					
Yes	25(34.2)	31(14.2)	**2.80**	**1.45, 5.69**	**< 0.01**
No	48(65.8)	188(85.8)			
Duration for taking anti TB treatment					
Unknown	15(20.5)	13(5.9)	**2.99**	**1.23, 7.32**	**0.02**
Known	58(79.5)	206(94.1)			
HIV infection					
Positive	33(45.2)	63(28.8)	**2.22**	**1.19, 4.14**	**0.01**
Negative	40(54.8)	156(71.2)			

Table 6 above shows factors that remained to be statistically significant in the multivariate logistic regression after adjusting to age and sex as follow;

Distance from home to the health facility (AOR = 3.98, 95%CI = 1.82, 8.73, p value < 0.001), stigma (AOR = 2, 80, 95%CI = 1.45, 5.69, p value < 0.01), not knowing the duration for taking anti TB treatment (AOR = 2.99, 95%CI = 1.23, 7.32, p value = 0.02) and HIV infection (AOR = 2.22, 95%CI = 1.19, 4.14, p value = 0.01).

CHAPTER FIVE

5.0. Discussion

The findings in this study demonstrate that, most of the studied subjects were in the age groups of 21 – 40 years. These age groups are the most productive and yet they are the most at risk of acquiring TB. The majority of the study subjects were employed with more than half having completed primary education and above. More than three quarters had good knowledge of anti TB duration and side effects. However, less than half knew why Anti TB treatment should take a long duration.

In this case control study, factors found preventing completion of anti TB treatment among the cases and controls included long distance from home to the health facility, feeling stigmatized, distance of more than 5km from home to the health facility, not knowing the duration for taking anti TB treatment and HIV status.

5.1. Knowledge and behavior of studied subjects

The study found that cases were less likely to know about anti TB treatment duration than controls. This means that knowledge of anti TB treatment duration discourages treatment completion. The study which was done in Java, Indonesia [55] reported that half of the non adherent TB cases from the private hospitals didn't know the duration of treatment, where as 87% of the adherent TB patients reported that the duration for anti TB treatment was at least six months.

Knowing about the type of treatment and duration of treatment prepares the patient to accept and follow treatment to completion. However, an observation that cases were less educated than

controls in this study could also explained the given results if assumption is made that being educated is associated with having more knowledge.

Knowledge of anti TB treatment duration has been investigated in a study which was done in Turkey where patients who were provided with information of anti TB treatment duration had a higher treatment completion rate [56]. The Turkey study seems to confirm the importance of providing patients with adequate anti TB treatment information.

Skipping anti TB treatment was found to be more common among the cases than the controls. Those who skipped were 254 more likely not to complete anti TB treatment compared to those who did not, the reasons provided by the cases for skipping anti TB drugs were that they were facing side effects 14 (19.2%) and were finding them to be unnecessary 17 (23.2%).

Skipping anti TB treatment was also found to be a problem in a study done in Addis Ababa [55] where they found illness and attendance at funerals to be two of the most frequently cited reasons for skipping anti TB treatment. Hungry patients who lack the strength or motivation to continue treatment have also been found elsewhere [56].

Those who ever used traditional medicine while taking anti TB drugs were five times (5.15) more likely not to complete anti TB treatment compared to those who never used traditional medicine while taking anti TB drugs. TB patients may delay seeking medical care because of other cultural beliefs; in this regard they may initially seek the help of traditional healer.

A study done in Malawi revealed that TB patients who visited traditional healer spent a median period of four weeks taking traditional medicine; during this time almost three quarters of the patients did not complete their standard anti TB treatment [57].

5.2. Factors preventing completion of Anti tuberculosis treatment.

Half of the cases studied had opted for community based DOT; while for the controls, more than seventy percent had opted for community based DOT. In comparing community and facility DOT, studies done elsewhere have also found that DOT outside the health facility, by either health personnel or laymen, is feasible and can result in treatment outcomes that are similar to those under conventional DOT at the health facility [58, 59].

In Nepal, both DOT at the health facility and community based DOT obtained success rates that met the international target of 85% [60]. However, this case control study did not find opting for either health facility based or DOT based treatment having any influence in treatment completion.

This case control study found stigma to be negatively associated with treatment completion that those who were stigmatized were twice more likely not to complete anti TB treatment. Patients who were segregated by their family members by not eating with them using the same utensils, telling others about their TB status felt that they were stigmatized and then they refrained from continuing with anti TB treatment in order to be accepted with their family members. In addition a study done in Nepal have shown that TB patients were stigmatized because it was believed that TB is hereditary or caused by a killing in a family [61].

Cost of transport from home to the health facility had impact on making TB patient not to complete their treatment schedule. Some patients were staying at a walking distance from their home to the health facility but those who were staying at a distance from the health facility had to incur cost of transport to the health facility. Among patients from Timor – Leste [55] cost of transport, difficulty of accessing treatment and time away from work or school, were the most important factors that influenced anti TB treatment completion.

Distance from home to the health facility was associated with not completing anti TB treatment. Those who were living more than 5 km away from the health facility were five times more likely not to complete their anti TB treatment. This is because they had to incur cost of transport from their homes to the health facility such that at a time when a patient had no money for transport, she/he was likely to fail attending the health facility for anti TB drugs collection. Similar findings have been found in a study done in Nigeria [62].

It can therefore be suggested that more TB health clinics need to be set up in the existing primary health care facilities to enhance greater patient coverage and this finding is important to be included in the ongoing Primary Health Care Development program (MMAM) 2007 – 2017)

Even where free medication is available, many patients are not successfully treated. Death might be one of the reasons for non completion of treatment (while on treatment or before start of treatment) and loss to follow up. Non completion of treatment may result in prolonged excretion of bacteria that may acquire drug resistance, cause transmission of disease and lead to increased morbidity and mortality [63]. This is contrary to the findings of this case control study, where cost of transport was not associated with treatment completion.

Those who were co infected with HIV infection were twice (1.83) more likely not to complete their anti TB treatment compared to those who were not co infected with HIV infection. The reason for HIV co infected patients not completing their anti TB treatment might be due to multiple drugs (anti TB and ARV) and other opportunistic infections. This finding is different from what was found in the study conducted in New York where patients with HIV infection was found to be more likely to complete their anti TB treatment compared to those without HIV infection [64].

5.3. Study limitations

In this study, recall bias might have been introduced in the control group, but the same questionnaires were used for both the cases and controls, study subjects were drawn from clearly defined population and multiple data collection tools were used in order to control for the biases.

This study also did not investigate health facility factors such as availability of anti TB drugs which are important attributes in treatment completion.

Inclusion of cases by taking patients who missed their treatment schedule for even one visit might have interfered with providing the real picture of defaulting in the selected clinics because these patients had another chance of continuing with their treatment although in this study they were grouped in the category of not completing their anti-TB treatment schedule.

In one of the study area i.e. Temeke hospital, there were TB/HAART project which was going on during the study period, this might have interfered with the findings of this study because at some occasions the same patients were recruited into these two different studies and this might obscure the real treatment completion status in that area.

CHAPTER SIX

6. Conclusion and Recommendation

6.1. Conclusion

This study found the following factors to be significant predictors of treatment completion, having a dual infection i.e. TB with HIV co infection, knowledge on why anti TB treatment takes long duration, stigma, distance from home to the health facility, using traditional medicine while taking anti TB drugs, knowing the duration for taking anti TB drugs, and skipping to take anti TB drugs.

It was also found that, most of the cases and controls were in the age groups of 21 – 30 years which are the most productive age groups and yet are the most risk age groups of acquiring TB and HIV infections. The general socio demographic characteristics among the cases and controls indicated that there was no statistical significant different showing that they were drawn from the same population.

6.2. Recommendations

6.2.1. Repackage information about anti TB treatment completion

The Ministry of Health and Social Welfare through TB/Leprosy program should repackage information on anti TB treatment to address issues associated with anti TB treatment completion including imparting knowledge to TB patients on why anti TB treatment takes long duration, impact of dual infection with HIV infection to ant TB patients, implication of skipping taking anti TB drugs, stigma issues to TB patients and Health care workers and knowing the duration for taking anti TB drugs in relation to anti TB treatment completion.

6.2.2. Policy

The Ministry of Health and Social Welfare should use the National Multisectoral HIV Prevention Strategy to address issues of stigma and discrimination to people who are living with HIV (and opportunistic infections) in the provider training modules of all cadres within service provision. Relevant bodies should ensure issues of stigma are addressed at all levels including work settings, in schools and in the community

6.2.3. Research

Further studies should be done in order to establish the best approach to improve knowledge about anti TB treatment completion among TB patients in ways that can change basic beliefs about the likely success of anti TB treatment. There is also little information available in Tanzania about the role of traditional healers in the diagnosis and management of TB patients, therefore further studies should be carried out.

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Appendices

7. Appendix 1: Informed Consent Form

7.1. English Version

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
DIRECTORATE OF RESEARCH AND PUBLICATIONS, MUHAS

ID-NO ☐ ☐ ☐

Consent to participate in a study

Greetings! My name is .....I am a TFELTP resident at Muhimbili School of Public Health and Social Sciences, working on this research project with the objective of assessing factors influencing treatment completion among registered tuberculosis patients on directly observed therapy in Temeke Municipality.

Purpose of the study

This research goal is to collect information to assess factors influencing treatment completion among registered tuberculosis patients on directly observed therapy in Temeke Municipality. You're being asked to participate in this study because you have particular information that may be important to the study.

If you agree to join the study, you will be required to respond to the questionnaire for the purpose of the research.

Confidentiality

I assure you all information we collect on forms will be entered into computers with only the study identification number. Only people working on this research study will have access to the information.

Risks

We do not expect any harm to happen to you because of joining to this study.

Right to Withdraw and Alternatives

Taking part in this study is completely your choice. You can also stop participating in this study at any time, even if you have already given your consent. Refusal to participate or withdraw from the study will not involve penalty or loss of any benefits to which you are otherwise entitled.

Benefits

If you agree to take part in this study, it shall be of great pleasure as this study is meant to assess the factors influencing incompletion of treatment among registered TB patients under directly observed therapy in Temeke Municipality.

Who to Contact

If you ever have questions about this study, you should contact the study coordinator or the

Principal investigator: Elibariki R. Mwakapeje

Muhimbili University of Health and Allied Sciences.

P.O.Box 65001, Dar es salaam. (Tel. 0784 342 389)

If you ever have questions about your rights as a participant, you may call Prof.E.F. Lyamuya, Chairman of the College Research and Publications committee, P.O.Box 65001, Dar es Salaam.Tel:2150302-6