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Faculty of Health Sciences

School of Health Systems and Public Health

Risk factors associated with treatment default in pulmonary tuberculosis patients in Tshwane, Gauteng: case control study

By

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Declaration

I Ntshengedzeni Michael Muvhango declare that the work that I hereby submit for the degree of Medicine (Public Health Medicine) is my own work and has not been presented wholly or in part for any other degree.

Signed

DR NM Muvhango Date:

Dedication

This work is dedicated to my family for all the love, support and inspiration.

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I would like to thank God for making it all happen

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TABLE OF CONTENTS

List of tables

List of figures

Acronyms

AIDS	Acquired immunodeficiency syndrome
TB	Tuberculosis
PTB	Pulmonary Tuberculosis
HIV	Human immunodeficiency virus
MDR-TB	Multidrug resistant Tuberculosis
MDG	Millennium development goals
DOTS	Directly Observed Treatment Short Course
WHO	World Health Organisation
CHC	Community Health Centre
NGO	Non-Governmental Organisation
ETR	Electronic TB Register
HCW	Health Care Worker
ART	Anti-retroviral therapy
AFB	Acid fast bacilli
VCT	Voluntary counselling and testing
CD4	T-helper cells which indicate the stage of HIV or AIDS in a patient
DST	Diagnostic sensitivity testing

Definitions of terms (Source: Department of Health, South Africa[1])

New: A client who has never had treatment for TB or who has taken anti-tuberculosis drugs for less than 4 weeks.

Re-treatment: A client, who has taken treatment for TB before for 4 weeks or more and either relapsed, defaulted or had treatment failure.

Relapse: A sputum smear or culture-positive pulmonary TB client who received treatment and was declared cured or treatment completed at the end of the treatment period and has now developed sputum smear or culture positive pulmonary TB again.

Cure: Client who is smear-negative in the last month of treatment and on at least one previous occasion at least 30 days prior.

Treatment completed: Client who has completed treatment but who does not meet the criteria to be classified as cure or treatment failure.

Treatment failure: Smear positive client who remains or is again smear-positive at 5 months (for new) or 7 months (for retreatment) after treatment start date or whose DST shows MDR-TB at 2 or 3 months.

Died: A patient who dies for any reason during the course of TB treatment.

Treatment default: Client whose treatment was interrupted for more than two consecutive months before the end of the treatment period.

Transfer out: Client who has been transferred to another reporting unit (e.g. district) and for whom the treatment outcome is not known.

Abstract

Background: Tuberculosis is a curable disease. The challenge faced by many TB control programmes around the world is treatment non-compliance. Patients who default their treatment are at risk of clinical deterioration and development of multi-drug resistant tuberculosis. This study therefore aimed at determining the factors associated with tuberculosis treatment default in Tshwane district, Gauteng Province.

Methods: The study was conducted on patients who were diagnosed with TB and registered for treatment in Tshwane health facilities in Gauteng Province. This was a case-control study, carried out in two phases. During phase 1 of the study, TB registers in the health facilities were reviewed retrospectively. All the defaulters/cases and randomly selected non-defaulters/controls were identified from the TB registers and reviewed. During the review, the following data was extracted from TB registers including: demographic information, patient's address, treatment information including dates of TB registration, treatment initiation and completion and treatment outcome. During phase 2 of the study, patients were traced and after giving consent were interviewed using a questionnaire. Data was captured using Microsoft Excell and Epi Info and analyzed using Statistical software (STATA 9.0; StataCorp; College Station, TX). Univariate and multivariate unconditional logistic regression analysis to determine association and Kaplan-Meier method to determine probability of staying in treatment over time were applied.

Results: Of the 1509 cases in phase 1 of the study, 50.8% (767) and 27.6% (417) defaulted TB treatment within the first and second months of treatment respectively. On multivariate analysis, factors found to be significantly associated with treatment default in phase 1 of the study were age (OR 1.46, CI: 1.23-1.73), male gender (OR 1.56, CI: 1.32-1.85) and co-infection with HIV (OR 1.38, CI: 1.12-1.70). In phase 2 of the study, factors associated with treatment default (bivariate analysis) were inadequate TB knowledge (OR 4.08, CI: 1.68-9.60), changing of residence (OR 5.83, CI: 298-11.5), poor attitudes of health care workers (OR 4.18, CI: 1.75-9.97) and

taking treatment without supervision (OR 2.72, CI: 1.42-5.22). None of the risk factors in phase 2 of the study were significant during multivariate analysis.

Conclusions: Many patients defaulted their treatment during the first two months of treatment (intensive phase). Health care workers will need therefore to educate their patients and emphasize the importance of staying on treatment during counselling.

CHAPTER 1: INTRODUCTION

1.1 Background

Tuberculosis (TB) is a major health problem worldwide. The burden of TB has been exacerbated by the emergence of drug resistant strains of TB and Human Immunodeficiency Virus (HIV).

TB remains one of the leading causes of death in low and middle-income countries despite the fact that it is curable using drugs developed decades ago. In countries identified as the most burdened by TB, it (TB) accounts for 80% of the world TB cases.[2] Amongst these countries are China, India, and South Africa. [2]

In responding to the burden caused by TB, WHO member countries are expected to have achieved the targets set out in the Millennium Development Goals by 2015 which include amongst others, stopping and begin to reverse the rising incidence of TB. [2]

South Africa has a National TB control programme and all provinces have adopted Directly Observed Treatment Support. Despite all these improvements TB treatment indicators (cure and defaulter rates) have not reached the WHO acceptable targets.

1.2. Literature review

Tuberculosis (TB) is a global emergency and a cause of high morbidity and mortality in low and middle income economies.[3] In 2010, there was an estimated 8.8 million new cases of TB (range, 8.5 million–9.2 million). [3] In the same year (2010), 1.1 million (range, 0.9 million–1.2 million) HIV negative people who had TB disease died and a further 0.35 million (range, 0.32 million–0.39 million) HIV positive people who had TB disease died. [3] In Africa, TB incidence and mortality have increased tremendously since 1990 as a result of co-infection with HIV. [3]

South Africa occupies third position amongst the countries with the highest TB burden (0.4–0.59 million), after India (2.0–2.5 million) and China (0.9–1.2 million).[4] TB incidence in South Africa has seen a fourfold increase within a decade. [4] In 2009, the incidence (TB) was 971/100,000 which is a huge increase from 187/100,000 in 1989 and it is estimated that 1% of the population of South Africans suffer from TB disease every year. [4, 5]

South Africa has low TB treatment outcomes, with a cure rate at 73% for new cases and 60% for re-treatment cases and these are below WHO targets.[4] TB defaulter (TB patient whose treatment was interrupted for more than two consecutive months before the end of the treatment period)[5] rate stands at 8.5% which is higher than the WHO recommended rate of 3% .[5, 6] Other African countries also report high TB default rates.[7] Worldwide, TB treatment default rate has been estimated at between 1% and 20%.[7] TB treatment defaulters are at risk for clinical deterioration and complications but most importantly they can continue to infect others.[6] Defaulters may develop drug resistant TB and are also likely to die prematurely from TB.[8]

Compliance to long-term therapies such as for TB is determined by several factors as shown in figure 1 below, namely; social and economic factors, health care team and system-related factors, condition-related factors, therapy-related and patient-related factors.[9] These risk factors for default are diverse depending on culture, setting, populations and health systems.[7]

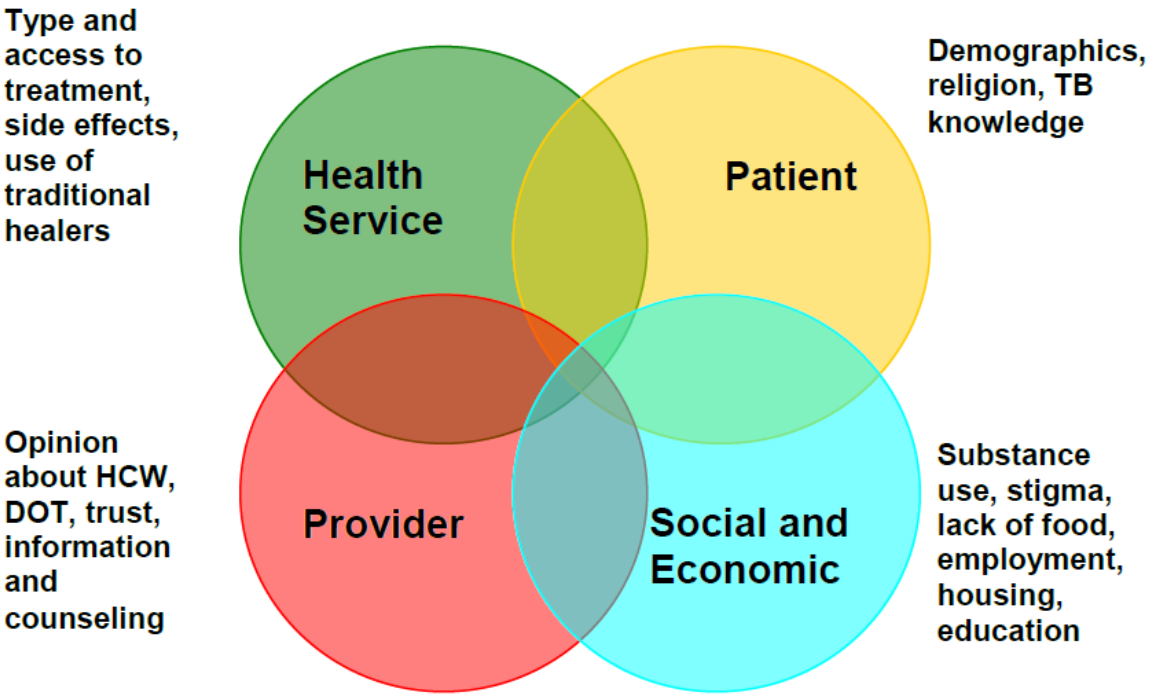

Figure 1: Conceptual framework for treatment adherence and questions domains (Source: Finlay et al[6])

TB treatment defaulters are more likely to be male, younger, unemployed, poor and hard to reach such as the homeless .[8, 10] Being unmarried, unemployed, having education lower than secondary level and stigma were associated with TB default.[6, 10] Having no food, changing place of residence frequently and lack of social support systems also contribute to poor adherence to treatment.[10]

TB treatment default has also been reported in those who are employed.[6] The reasons for defaulting on TB treatment by employed TB patients include being busy at work and not having time to go to the clinic to collect medications, and the clinic being too far from the workplace.[6]

Distance travelled to a health facility affects treatment and adherence.[11] In a study to establish the impact of distance travelled to access TB treatment, it was found that

patients who travelled more than 60 km to a treatment facility had increased risk for defaulting treatment.[11]

Seeing a traditional healer before government health services delays TB diagnosis and initiation of treatment and has been found to be associated with treatment default.[8] A study by Barker et al[12] found that most patients consulted traditional healers before attending government health services and it took longer for these patients to access anti-tuberculosis chemotherapy than did those who went to a general practitioner or primary health clinic. Delay in accessing treatment by those who visited traditional healers was also found to lead to worse performance status, and these individuals were more likely to have high mortality and morbidity.[12]

Lack of knowledge about TB plays a role in whether a patient chooses to adhere to treatment or not.[13] A study by Liefooghe and Muynck[13] found that TB defaulters were patients who believed TB to be a disgrace to their families and believed that TB is not to be spoken about to others. The majority of the defaulters believed that TB brings bad luck and that it becomes difficult for a person to earn a living after they are cured.[13]

Treatment compliance has also been found to be associated with patient satisfaction with the provider of health care.[14] A study in Senegal by Hane et al[15] found that TB control was hampered by poor communication between health care providers and patients at all levels of care. Poor communication occurred at the time of diagnosis, registration as well as during TB treatment.[15] The study also found wide variations in the types of messages that are given to patients when treatment is initiated.[15]

Attitudes of health care workers towards patients play a vital role in influencing patients' adherence to treatment.[6] In a multidrug-resistant TB[16] study conducted in South Africa it was found that a significantly higher proportion of TB treatment defaulters(cases) than controls(non-defaulters) expressed unhappiness with the attitude of the health care workers who assisted them. TB defaulters reported that they were treated with disrespect by the health care provider and this could significantly have contributed to them defaulting on their treatment.[16] Display of unsatisfactory attitudes by health care workers could be as a result of being

inadequately trained, overworked, inadequately supervised or unsupported in their work.[16] This trend is common in countries with a high TB burden.[17]

Smoking and alcohol influence TB treatment default.[18, 19] Among patients with pulmonary TB, smoking was significantly associated with TB treatment default, and failure.[20] Social demands to satisfy patient's needs may be a reason that causes patients to smoke again.[19]

Patients default TB treatment throughout the duration of TB treatment.[21] Several studies agree that treatment default occurs commonly during the intensive phase of treatment and thereafter declines. [22, 23, 24, 25] However other studies have reported higher percentages of TB defaulters in the continuation phase of treatment.[26, 27, 28] There is a lack of agreement between researchers on the exact timing of TB default.[29] Kruk et al[29] in a systematic review study, concluded that current studies are too few to allow for conclusions/generalisations to be made about temporal default trends.

TB treatment in patients on antiretroviral therapy present challenges as far as compliance is concerned for the patients and healthcare providers.[30] The proportion of TB treatment default in TB subjects co-infected with HIV is higher compared to subjects not co-infected.[10] Risk factors for TB treatment default in HIV/TB co-infected patients include male sex, smoking, and a CD4 count of less than 200 cells/mm^3.[30]

1.3. Study rationale

Tuberculosis treatment success has long been overshadowed by the number of patients who do not adhere to their treatment as required. Patients who do not complete their treatment, eventually develop drug resistant tuberculosis which is substantially more difficult to treat and requires expensive treatment and additional resources.

For the year 2010/2011,Tshwane district recorded an overall TB treatment default rate of 9%.[31] Amongst the new-smear pulmonary TB patients the default rate was 3%.[31] The district has seen a steady increase in the number of MDR-TB patients in its specialised TB hospitals. For 2010/2011 the number of MDR-TB patients was 92 which is a 15% increase from 82 the previous year. Treatment default may lead to further transmission of TB infection and drug resistant TB. Incorrect addresses and moving to other provinces without proper referrals are some of the reasons that are cited as contributing to the default in the district.[31] Studies on risk factors associated with TB treatment default have mentioned a variety of these factors which are classically grouped into five domains, namely social and demographic factors, economic factors, health system factors, condition and therapy related factors. It is also known that these factors differ in different settings, cultures, populations and locations. This study seeks to establish factors associated with TB treatment default in Tshwane. The findings can then be drawn on to design interventions that will be appropriate for the area.

CHAPTER 2: AIM AND OBJECTIVES

2.1. Aim

The aim of the study was to establish the factors that are associated with tuberculosis treatment default in tuberculosis patients in Tshwane health facilities.

2.2. Objectives

- To assess the proportion of tuberculosis treatment defaulters among individuals initiated on tuberculosis therapy in Tshwane.
- To determine social, economic, patient, condition, therapy, health system and provider related factors associated with tuberculosis treatment default in Tshwane health facilities.

CHAPTER 3: METHODS

In the previous chapter, literature from developed and developing countries was reviewed and presented. In this chapter, the study design, settings, inclusion and exclusion criteria, sampling and sample size, data collection and analysis are outlined.

3.1. Setting

The study was conducted in City of Tshwane Metropolitan Municipality (as shown in figure 2 below) which is classified as a category A municipality and covers an area of + 3 200 km^2.[31] It is one of the three metros within Gauteng Province.[32] It is situated in the northern part of Gauteng Province.[32] It lies adjacent to the Bojanala District Municipality (North-West) on the northern border, to the North West Province on the western border and the Johannesburg Metro on the southern border.[32] The Tshwane Metro Health District serves a total population of approximately 2,390,480 with approximately 1,682,898 being un-insured.[32] The youth represent 22.6% of the population as opposed to the elderly who represent only 6.9%.[33] Majority of citizens fall within the working age group. About 46.2 % of the residents are employed and 21, 5% are unemployed while 32.3 % are not economically active.[33] The District is demarcated into seven regions/sub-districts (1-7) and this follows the incorporation of Metsweding region which was previously a district on its own.[34]

The Tshwane population is dynamic.[33] Tshwane experiences a lot of immigration as well as movements by residents between the different regions of the district.[33] Migrants into Tshwane mainly come from Limpopo, Mpumalanga and the North West province as well as from countries outside South Africa. Region 3 of the district has seen increased immigration tendencies because of the concentration of economic activities in the city centre.[33]

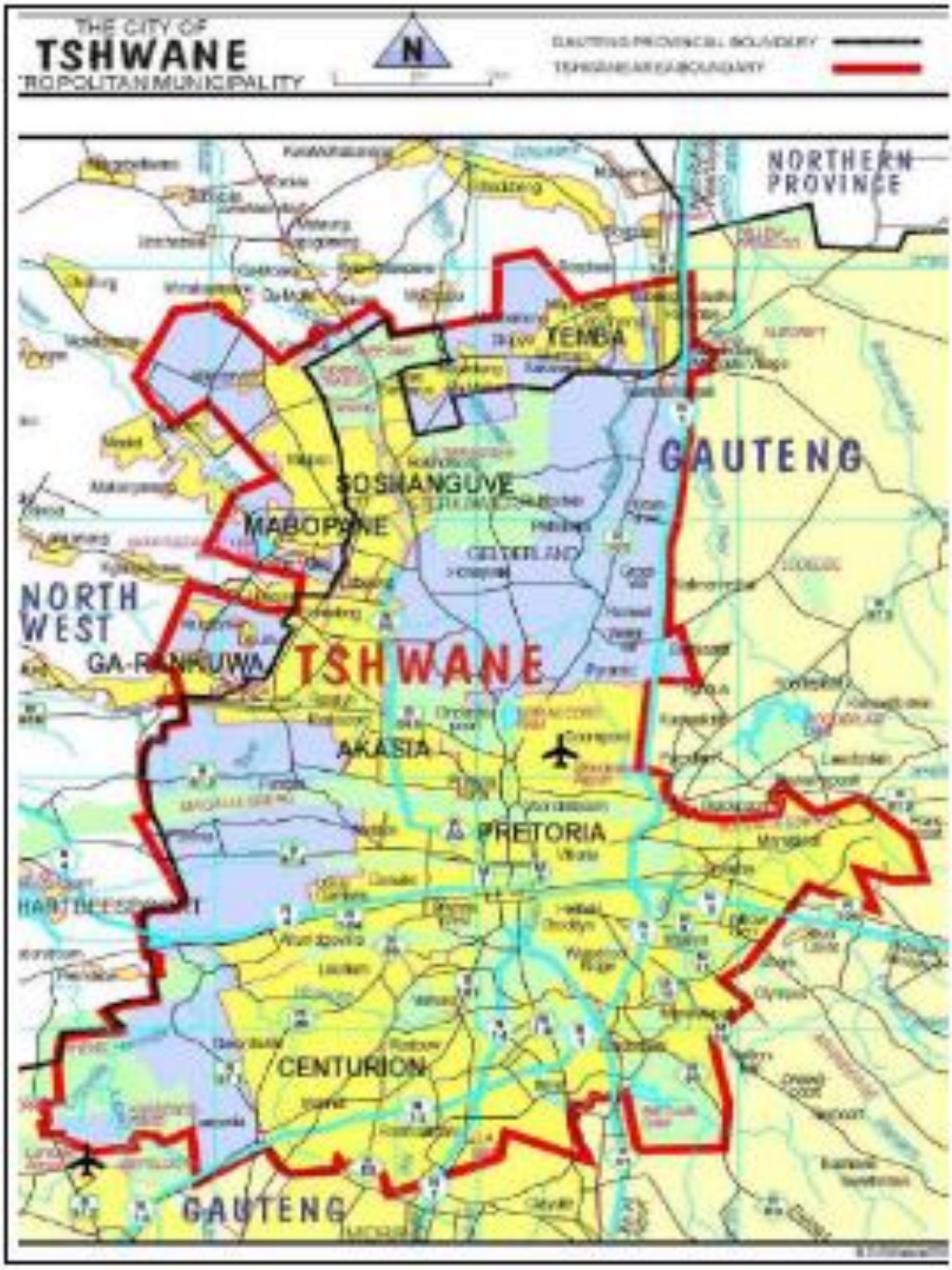

Figure 2: Map of Tshwane District, Gauteng Province[34]

Primary healthcare facilities in the district are divided between local authority and district administration through service level agreements. The district has six district hospitals (Bronkhorstspruit hospital being a district private public partnership hospital), 11 community health centres, 57 clinics, 10 satellites clinics and 16 mobile clinics.

Public health facilities in each region provide a full package of Primary Health Care Services according to District Health System norms and standards including twenty four hour service in some facilities particularly those administered by the district office. Table 1 lists the number of health facilities in each region.

Table 1: Primary healthcare facilities in Tshwane district regions (Source: City of Tshwane[35])

Region	CHC	Clinic	Satellite	Mobile	Hospital
1	5	15	1	6	1
2	3	10	2	2	1
3	1	13	2	2	2
4	0	4	2	1	0
5	0	3	2	1	0
6	2	6	1	0	1
7	1	6	0	4	1
Total	12	57	10	16	6

The district also has a large number of non-governmental organisations (NGOs). These NGOs play a critical role in home-based care, contact tracing, TB defaulters/interrupters tracing etc.

For the study, only CHC and clinics (fixed) were used. Satellites and mobiles and some fixed clinics were excluded from study because most do not offer all TB services. Of the 12 CHC and 57 clinics (fixed), 11 CHC and 37 clinics were included in the study (Table 2). The CHC and clinics in region 5 and 7(previously known as Metsweding) were not included in the study because of difficulties in reaching those facilities. Other facilities not included in the study were facilities where TB registers were not available.

Table 2: Tshwane PHC facilities included in the Study

Region	CHC	Clinic	Satellite	Mobile	Hospital
1	5	14	0	0	0
2	3	5	0	0	0
3	1	9	0	0	0
4	0	4			
5	0	1			
6	2	4			
7					
Total	11	37	0	0	0

3.2. Study design

This study was conducted into two-phases: The first phase was a retrospective review of medical records of TB patients seen at Tshwane healthcare facilities for a period of 4-years from September 2009 to December 2012. The second phase was a case-control study where TB patients were traced and interviewed.

3.3. Study population

The study population comprised of diagnosed and registered TB patients at Tshwane public health facilities under Directly Observed Treatment support. In both phases the patients were classified into two groups: the first group was defaulters (cases) who were TB patients whose treatment was interrupted for (2) two consecutive months or more. Non-defaulters (controls) were TB patients who started and completed a six month TB regimen (without interruption) irrespective of whether treatment was successful (cure, completion, failure) or not.

3.4. Criteria

3.4. 1 Inclusion criteria

This study (for both phase 1 and phase 2) included all tuberculosis patients:

- Able to consent
- Registered/enrolled in Tshwane district clinics as having TB

- Had contact details available

3.4.2. Exclusion criteria

This study excluded all tuberculosis patients:

- Who had died or transferred
- Younger than 18 years
- Had multi-drug resistant TB
- Who were prisoners

3.5. Sample Size

Phase one of the study included all TB defaulters from facility TB registers and a randomly selected control group. For phase two of the study, a sample size of 178 (89 cases and 89 controls) was calculated. This calculation used an odds ratio (OR) of 2.9 (derived from Finlay et al [6]), a power of 90%, an α value of 5%, and at least a 20% difference between cases and control In anticipation of difficulties associated with finding defaulters, the overall sample size was inflated by 75% at the beginning of the study meaning therefore all defaulters will be included in the data extraction from the facility TB registers.

3.6. Sampling Technique

For the retrospective review of TB records during the first phase of the study, all TB cases/defaulters in the facility TB registers were included and controls were randomly selected. For the second phase of the study, all TB (both cases and controls) patients whose records were reviewed were traced and asked to participate in the study.

3.7. Variables studied

Table 3: Variables studied

Demographic	Gender
	Age
	Religion

	Race
	Marital status
	Number of children
	Level of education
Socio-economic	Radio/television ownership
	Home ownership
	Employment status
	Type of occupation
	Missed treatment due to employment
Alcohol use	Ever used alcohol
	Missed treatment due to alcohol
	Spent time in prison
	Missed treatment due to imprisonment
Personal experience	Told someone you had TB
	Felt ashamed of having TB
	Felt ignored due to having TB
	Family support
	Non-health care ware worker support
	Influence by other to stop treatment
Experience with nutrition	Dependent on others for food and shelter
	Taking tablets before and after eating
	Experience of side effects
	Appetite
	Enough food to satisfy hunger
	Support with food
Use of traditional healers	Consulted a traditional healer
	Use of treatment given by traditional healer
	Missed TB treatment due to traditional healer
Health service characteristics	Number of days ill
	Number of clinics attended
	Mode of transport to get to health facility
	Time to get to clinic

	Healthcare worker attitude
Knowledge of TB	Knowledge of TB treatment duration
	Received TB information
Treatment characteristics	Type of TB, HIV status, ART regimen
	Stopped treatment for > 2 months
Mobility of cases	Change of residence
	Missed treatment due to changing of residence

3.8. Measurement tools

Secondary data was collected from health facility TB registers and records using a data extraction form (see appendix 1). Primary data was collected using a questionnaire (see appendix 2) which consisted of a combination of multiple choices and yes/no questions. The questionnaire was adapted from a questionnaire previously used in MDR-TB study in South Africa.[16] The questionnaire was in English and Setswana.

3.9. Data collection

Field workers were hired and trained to extract secondary data from TB registers and patient's records in the facilities. Secondary data extracted included demographic information, patient's address, treatment information including dates of TB registration, treatment initiation and completion and treatment outcome.

Non-governmental organisations through their carers assisted in administering the interviewer directed questionnaire for the collection of primary data. Before the interviews, carers traced the study participants (controls and defaulters) and obtained their consent. Carers were trained so as to understand the aim and purpose of the study and how the interviews should be carried out. The NGOs' carers were ideal for the task since they had vast experience in tracing patients including TB defaulters and collecting data for the Department of Health. The carers also had detailed knowledge of the study setting. They worked with most of the TB patients and are, therefore, aware of their whereabouts. The NGOs carers were not compensated as per agreement with NGOs controlling body. The interviews did not

disturb the carers' work because coordinators ensured that each carer be given a few patients to trace in the area where they were conducting their usual NGO work.

3.10. Data Analysis

The data collected was captured on Microsoft Excel 2007 and Epi Info and subsequently analysed using Statistical software (STATA 9.0; StataCorp; College Station, TX). Comparisons of demographics, HIV status and risk factors between treatment defaulters (cases) and non-defaulters (controls) were performed using Pearson's Chi-square test for categorical variables. Statistical significance was set at $p<0.05$. To estimate predictors of treatment default, unconditional logistic regression was performed to calculate odds ratios (ORs) and corresponding 95% confidence intervals (CIs) for dichotomous variables.

Variables significantly associated with default outcome in univariate analysis (inclusion criterion $p<0.2$) were entered into a multivariate unconditional logistic regression model. For variables with missing information, statistical analysis was performed only for cases with complete information.

3.11. Ethical considerations

Approval

Ethical approval to conduct the study was granted by the Research and Ethics committee of the University of Pretoria. Permission to review TB registers and conduct the study in Tshwane health facilities was obtained from Tshwane district management and from the Director of PHC services in Tshwane Local Authority.

Informed consent

Participants were requested to participate in the study at the point where the NGO's carers approached them with the information leaflet and the questionnaires. The consent was signed by the participant after educating them on the study purpose and benefits of the study. Participants were given the assurance that they can refuse

to participate, stop at any time during the interview without giving any reason and that their withdrawal will not affect their treatment in any way.

Confidentiality

Participants were advised not to write names on the questionnaires. The informed consent was separated from the questionnaires so that participants could not be linked to any questionnaire.

CHAPTER 4: RESULTS

In the previous chapter, the study design, population, setting, sample size, sampling technique, data collection and data analysis were outlined. In this chapter, the results and interpretation of the results are presented. This chapter is divided into two subsections: The first section presents prevalence of TB defaulters, demographic information of cases and controls and socio-demographic factors associated with treatment default. The second section outlines the economic factors, patient knowledge, therapy related factors, health system and provider related factors associated with TB treatment default.

4.1. Phase one: Findings from Patients' Record Review

For the retrospective record review, TB registers were analysed for 48 facilities (eleven (11) CHCs and thirty seven (37) fixed clinics). From 2010 to first quarter of 2012 the total number of TB patients registered for treatment in these facilities was 26577. Amongst the 26577 TB patients registered at these facilities, a total of 1509 defaulted treatment. The proportion of TB treatment defaulters in these health facilities was, therefore, 5.7% (1509/26577). All 1509 defaulters were included in the review. Of the 25068 TB patients not classified as defaulters, 1576 were included in the review.

4.1.1. Characteristics of TB patients included in record review

The case: control ratio was 1.00 : 1.04 as 1509 defaulters and 1576 non-defaulters were included in the review. For the cases, 40% (601/1509) were female, while in controls 49% (766/1576) were females. The mean age of defaulters (36.1±12.2 years) was significantly lower than of non-defaulter (38.3±11.9 years). Table 4 presents the characteristics of treatment defaulters (cases) and non-defaulters (controls).

Table 4: Characteristics of the study population

	Defaulters		Non-defaulters		p-value
	No	%	No	%	
Age (mean ±sd)	36.1±12.2 years		38.3±11.9 years		<0.001
Gender					
Male	908	60	810	51	<0.001
Female	601	40	766	49	
HIV Status					
Positive	1180	82	1169	78	0.007
Negative	252	18	322	22	
DOT support					
Home	653	51	896	72	
Clinic	162	13	153	12	<0.001
no-support	467	36	202	16	
Patient Type					
New patient	1389	92	1440	91	
Re-treatment after defaulter	62	4	77	5	
Relapse	23	2	23	1.5	
Moved in from other facility	17	1	16	1	0.748
Re-treatment after failure	0	0	2	0.1	
Transfer in from facility outside district	8	1	9	0.6	
Unspecified	8	1	11	0.8	
Disease classification					
Pulmonary TB	1268	85	1399	89	0.001
Extra Pulmonary TB	222	15	172	11	
AFB sputum smear					
Positive	357	26	330	22	0.006
Negative	1007	74	1186	78	

4.1.1.1. Patient Type

The majority of patients in both groups (cases and controls) were new and re-treatment after default patients. Ninety two percent (1389/1509) of the defaulters and 91.4% (1440/1576) of the controls were new. Four percent (62/1509) of the defaulters and 5.0% (77/1576) of controls were patients with a history of defaulting TB treatment.

4.1.1.2. Disease classification

Among the defaulters, 85% (1268/1490) had pulmonary tuberculosis, while 89% (1399/1571) of non-defaulters had pulmonary tuberculosis.

4.1.1.3. Smears

Of the defaulters tested, 26.1% (357/1367) were AFB smear positive and 73.7% (1007/1367) were AFB smear negative. Amongst the controls 21.8% (330/1516) were AFB smear positive and 78.2% (1186/1516) were AFB smear negative.

4.1.1.4. Directly observed Treatment Support (DOTS)

The proportions of patients who were on directly observed treatment support (DOTS) are shown in Table 1. Fifty one percent of treatment defaulters (653/1282) were on community/home DOT support compared to 13.0% (162/1282) who were on clinic DOT support. Thirty six percent (467/1282) of defaulters did not have a DOT supporter. For the controls, 72.0% (892/1251) were on home DOT support and 12.0% (153/1251) were on clinic DOT. Sixteen percent (202/1251) of the controls did not have a DOT supporter.

4.1.1.5. HIV status

HIV testing for TB patients through Voluntary Counselling and Testing was conducted for 2923 patients of which 80.4% (2349/2923) were positive (co-infected). Approximately one-fifth (19.6%) (574/2923) of the patients were not co-infected. Co-infection was significantly higher ($p = 0.007$) among cases (82.0%) compared to controls (78.0%).The majority, 63.5% (1491/2349) of the HIV positive patients had a CD4 count of less than 250 and 20.7% (486/2349) had CD4 count of 250 or more The proportion of patients with a CD4 count of less than 250 was 61.8%(729/1180) for defaulters and 65.2% (762/1169) for non-defaulters (figure 4).

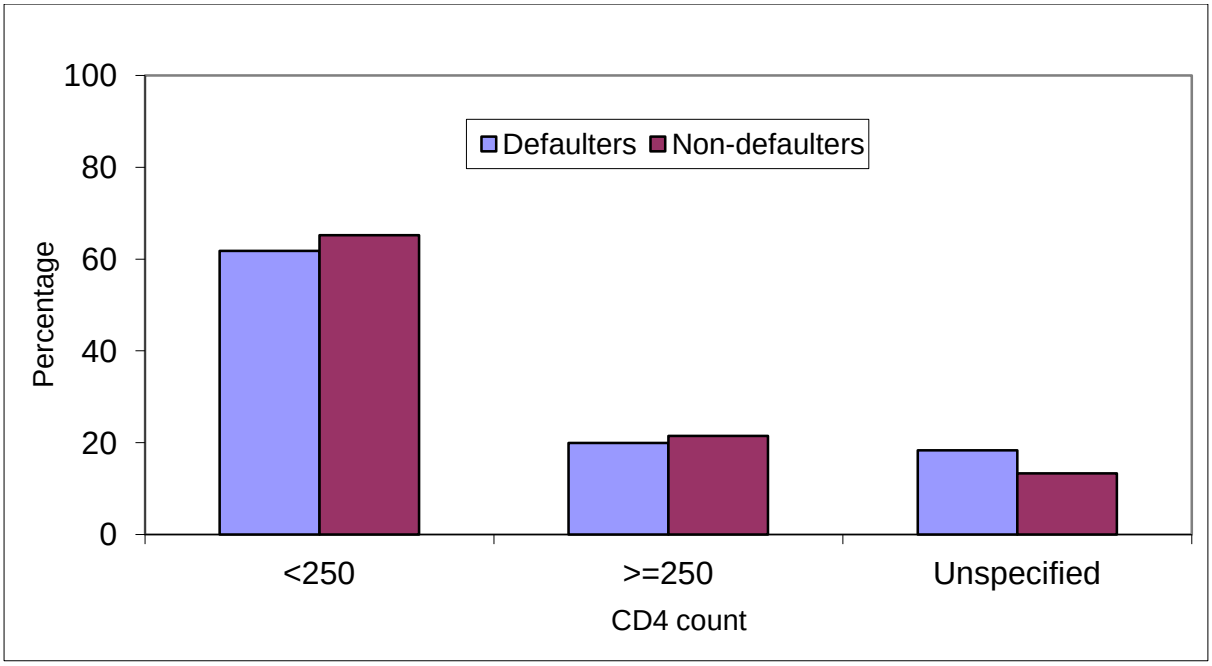

Figure 3: CD4 count for HIV positive patients (n=2349, defaulters, n=1180; non-defaulters, n=1169)

4.1.1.6. CD4 count and Anti-retroviral therapy

Twenty four per cent (563/2349) of the HIV positive patients were on anti-retroviral treatment (ART) and 11.4% (267/2349) had unspecified HIV treatment status. Table 5 below shows 1818 HIV positive patients for whom information was available for CD4 count and HIV treatment (ART). Of the patients with CD4 count of less than 250, 30.0% (404/1367) were on ART, while in those patients with CD4 of 250 or more only 20.6% (93/451) were on ART ($p<0.05$).

Table 5: Association between CD4 count and ART

	CD4 <250		CD4 ≥250		p-value
	No	%	No	%	
HIV +ve patient on-ART	404	30	93	21	<0.001
HIV +ve patient not on-ART	963	70	358	79	
Total	1367		451		

4.1.2. Duration of treatment before default

For both the six and eight month regimens, a high proportion of patients defaulted their treatment during the initial months of treatment. Of the 1509 defaulters, 50.8% (767) and 27.6% (417) abandoned treatment during the first month and second month of treatment respectively (Figure 5). Twenty two percent (22.0%, n=325) defaulted during the continuous phase of treatment. Figure 6 shows the Kaplan Meier Survival Analysis for the probability of defaulters (male and female) staying in treatment over time There is no significant difference between males and females (p=0.250).

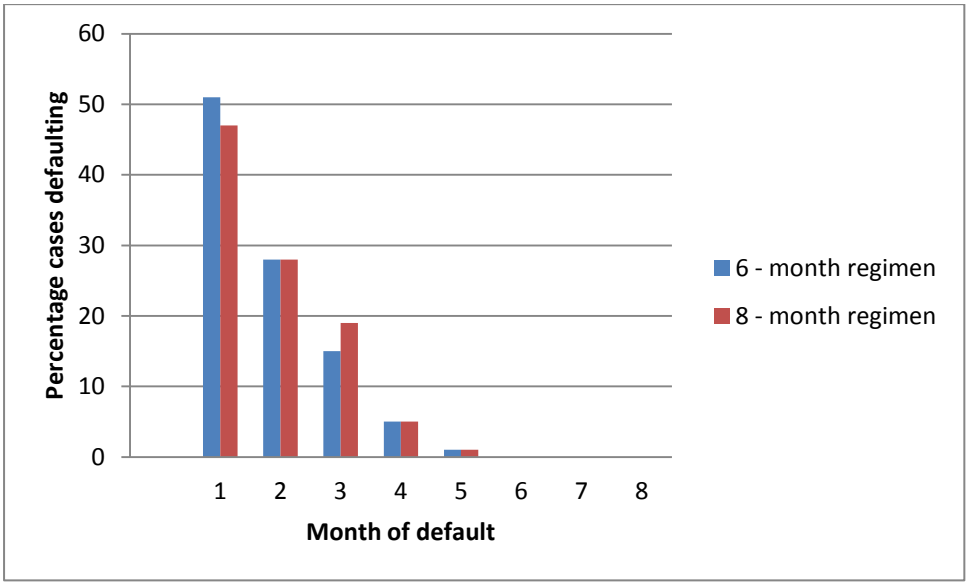

Figure 4: Proportion of defaulters (cases) by time of default (months) for both six (N = 1274) and eight-month (N = 235) regimens in Tshwane District, Gauteng.

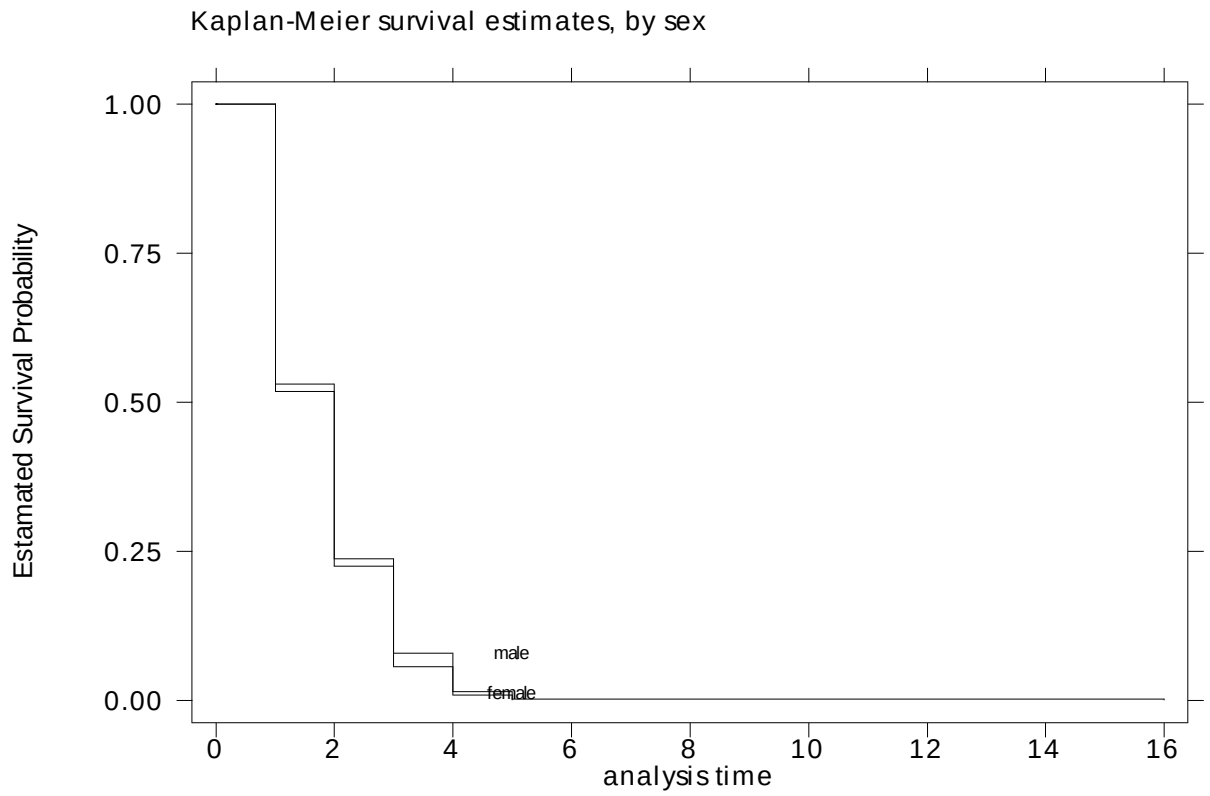

Figure 5: Kaplan-Meier curve comparing male (n=908) and female (n=601) defaulters remaining in treatment over time in Tshwane District, Gauteng

4.1.3. Socio-demographic factors associated with treatment default

The patient socio-demographic characteristics and results of univariate analysis are shown in Table 2. The cases had a mean age of (36.1±12.3 years) and were significantly younger than controls (38.4±11.9 years, $p<0.05$). In univariate analysis, age (odd ratio (OR) 1.30, 95% CI 1.12-1.49) was a risk factor for treatment default. Comparing HIV status of the defaulters and non-defaulters, showed a higher proportion of HIV positive patients in the treatment defaulter group compared to non-defaulters (82% v/s 78%; OR 1.28; 95% CI 1.07-1.54; $p<0.05$).

Table 6: Factors associated with TB treatment default (bivariate analysis)

		OR	95%CI	p-value
Age				
	<37 years	1.30	1.12-1.49	<0.001
	≥37 years	1.0		
Gender				
	Male	1.43	1.23-1.64	<0.001
	Female	1.0		
HIV Status				
	Positive	1.28	1.07-1.54	0.007
	Negative	1.0		
DOT support				
	Home	0.31	0.26-0.38	<0.001
	Clinic	0.45	0.35-0.60	<0.001
	no-support	1.0		
Year of enrolment				
	2009	1.0		
	2010	1.68	0.93-3.01	0.081
	2011	1.41	0.78-2.53	0.247
	2012	1.28	0.68-2.41	0.439

Of the patients who defaulted, 36.0% were not on direct observed treatment compared to 16.0% of non-defaulters. In a univariate analysis, DOT support (Clinic OR 0.45, 95%CI 0.35-0.60; Home OR 0.31, 95%CI 0.26-0.38) was protective from treatment default. The percentage of defaulters decreased with each subsequent year of enrolment, with higher number of defaulter in 2010. Age, gender, HIV Status

were significant risk factors associated with treatment default in multivariate analysis (Table 7).

Table 7: Factors associated with treatment default (multivariate analysis)

		OR	95%CI	p-value
Age	<37 years	1.46	1.23-1.73	<0.001
	≥37 years	1.0		
Gender	Male	1.56	1.32-1.85	<0.001
	Female	1.0		
HIV status	Positive	1.38	1.12-1.70	0.002
	Negative	1.0		
Direct Observed Treatment				
	Home-support	0.29	0.24-0.37	<0.001
	Clinic-support	0.43	0.32-0.58	<0.001
	No-support	1.0		

4.2. Phase two: Findings from Patient's Interviews

Data collection for the study began in August 2012 and ended in February 2013. Three thousand and eighty five (3085) registered patients were included in the retrospective record review. Based on the sample size calculation, a sample of 178 patients (89 cases, 89 controls) was required for the follow-up case-control study. Among the 3085 registered patients, a total of hundred and sixty six (166) patients were successfully traced and consented to be interviewed as shown in Figure 7. A large proportion of patients (84.4%) could not be traced either because they had relocated to other provinces or provided wrong addresses during initiation of TB treatment at the facility. Nineteen patients (0.6%) refused to participate in the study and 9.7% (300) of patients were found to have died.

4.2.1. Demographic factors

Of the 166 patients traced and interviewed, 48.8% (81/166) were cases (TB treatment defaulters) and 51.2% (85/166) were controls. The case: control ratio was, therefore, 1:1.05. The majority of the study participants were between the ages of 30-50 for both cases and controls and the differences in age was not statistically significant (p=0.621). Amongst the cases 41.9% (34/81) were female and 58.0% (47/81) were males. Amongst the controls, 61.2% (52/85) were males and 38.8% (33/85) were females. Most patients were single (64.0% for cases and 60.0% for controls); black African (93.4% for both cases and controls); reported practising religion (58.9% for cases and 60.0% for controls) and roughly half of the participants for both groups had a secondary education (Appendix 8). The demographic characteristics of treatment defaulters and non-defaulters are shown in Table 8.

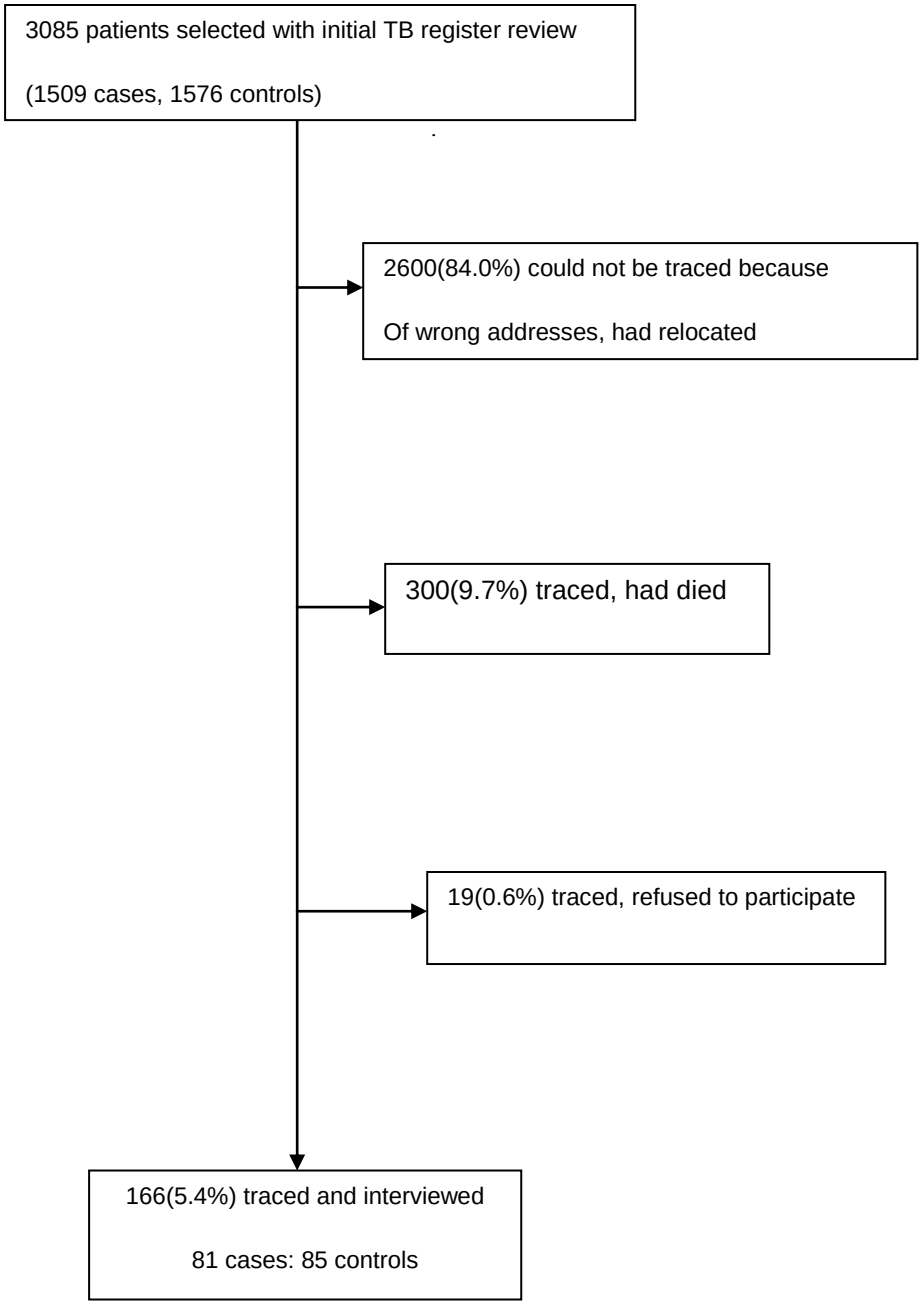

Figure 7: Follow-up for patients on TB treatment

Table 8: Demographic characteristics of the study participants

	Cases		Controls		p-value
	No	%	No	%	
Age					
20-29	9	11	11	14	0.621
30-39	31	38	34	40	
40-49	27	33	22	26	
50-59	13	16	15	18	
60+	1	1	2	2	
Gender					
Male	47	58	44	52	0.532
Female	34	42	40	48	
Marital Status					
Single	51	64	50	60	0.747
Married/separated	29	36	33	40	
Level of education					
None	10	12	8	9	0.910
Primary	19	24	18	21	
Secondary	42	53	48	57	
Tertiary	9	11	10	12	
Ethnicity					
Black	75	94	80	94	1.000
Coloured	5	6	5	6	
Practice of religion					
Yes	47	59	49	60	1.000
No	33	41	33	40	

4.2.2. Socioeconomic characteristics among interviewed patients

Cases and controls were similar in terms of employment and owning material goods but differed in the ownership of houses. Patient radio ownership, television ownership and employment were not significantly associated with TB treatment default. However, a significant proportion of patients (64%) who did not default treatment owned houses compared to defaulters (35%). Table 9 shows the socio-economic factors associated with TB treatment default.

Table 9: Socio-economic factors associated with treatment default

		Patient who defaulted treatment		Patient who did not defaulted treatment		OR	95%CI	p-value
		No	%	No	%			
Radio ownership								
	Yes	65	80	67	79	1.0		
	No	16	20	18	21	0.92	0.43-1.94	0.820
Television ownership								
	Yes	58	72	61	72	1.0		
	No	23	28	24	28	1.01	0.51-1.98	0.982
Home ownership								
	Yes	28	35	46	64	1.0		
	No	53	65	39	46	2.23	1.19-4.17	0.012
Employed								
	Yes	42	52	47	55	1.0		
	No	39	48	38	45	1.14	0.62-2.11	0.657

4.2.3. Knowledge of TB

Several questions were asked to ascertain patient's knowledge of TB and TB treatment (see table 10). Most patients (90% for cases and 95% for controls) reported that they knew that treatment took at least 6 months. When asked whether they were told why treatment is taken for at least six months, cases were 7.2 times more likely to say that they did not know compared to controls (OR 7.22, 95% CI: 3.26-15.9). Cases were also 4.1 times more likely to say that they were not given TB information by the healthcare workers than controls (OR 4.08, CI: 1.68-9.60). Of those who received TB information, cases were 7.3 times more likely to say that the TB information they received was not enough compared to controls (OR 7.34, CI: 3.23-16.6). Fifty eighty percent (58.0%) of cases and 30.0% of controls felt that TB is incurable, 65.0% of cases and 49.0% of controls respectively felt that they may die from TB.

Table 10: Bivariate analysis of knowledge related variables and treatment default

	Cases		Controls		OR	95%CI	p-value
	No	%	No	%			
Knows that treatment taken for ≥6months							
Yes	71	90	80	95	1.0	0.65-7.80	0.200
No	8	10	4	5	2.25		
Told why treatment is given for 6mths							
Yes	40	51	74	88	1.0	3.26-15.9	<0.001
No	39	49	10	12	7.22		
Given TB info by HCW							
Yes	56	70	75	90	1.0	1.68-9.60	0.002
No	24	30	8	10	4.08		
Received adequate information on TB							
Yes	42	53	75	89	1.0		
No	37	47	9	11	7.34	3.23-16.6	<0.001
Feels that TB is incurable							
Yes	46	58	25	30	1.0		
No	34	42	59	70	0.31	0.16-0.59	<0.001
Feels that an individual may die from TB							
Yes	51	65	41	49	1.0		
No	28	35	43	51	0.52	0.27-0.98	0.044

4.2.4. DOT and Support

Forty two percent (42.0%) of cases and 58.0% of controls were given pills one at a time while 58.0% of cases and 33.0% of controls respectively took treatment without direct supervision. Cases that took treatment without direct supervision were 2.7 times more likely to default on TB treatment compared to controls (OR 2.72, CI: 1.42-5.22) as shown in Table 11.

4.2.5. Mobility of respondents

During TB treatment cases were 5.8 times more likely to change residence compared to controls (OR 5.83, CI: 2.98-11.5) (see table 11).

Table 11: Patient and therapy risk factors amongst cases and controls

	Cases		Controls		OR	95%CI	p-value
	No	%	No	%			
DOT supporter give patient pills							
One at a time	31	42	43	58	1.0		
Pill bottles	6	8	2	3	4.16	0.78-22.0	0.093
Plastic bags	37	50	29	39	1.76	0.90-3.46	0.095
Patient takes treatment without direct supervision							
Yes	44	58	25	33	2.72	1.42-5.22	0.003
No	33	42	52	67	1.0		
Patients changed residential address							
Yes	51	65	20	24	5.83	2.98-11.5	<0.001
No	28	35	64	76	1.0		
Saw traditional healer during treatment							
Yes	20	26	13	17	1.78	0.81-3.87	0.148
No	57	74	66	83	1.0		
Dependent on others for food/shelter							

Yes	27	33	26	31	1.12	0.58-2.14	0.743
No	54	67	58	69	1.0		
Takes treatment on empty stomach							
Yes	20	25	15	18	1.51	0.71-3.20	0.285
No	61	75	69	82	1.0		
appetite increases on TB treatment							
Yes	67	83	57	68	2.26	1.08-4.73	0.029
No	14	17	27	32	1.0		
Uses alcohol							
Yes	30	38	23	27	1.59	0.82-3.08	0.167
No	50	62	61	73	1.0		
Spent time in prison							
Yes	5	7	3	4	1.88	0.44-8.19	0.396
No	68	93	77	96	1.0		
Feels supported by family							
Yes	65	80	71	85	1.0		
No	16	20	13	15	1.34	0.60-3.00	0.471

4.2.6. Opinions about health care workers

Cases were 2.5 times more likely to report that they were not satisfied with healthcare worker's attitude compared to controls (OR 2.49, CI: 1.29-4.79). Cases were also more likely to report missing TB treatment because of HCW attitude (OR 4.18, CI: 1.75-9.97) (see table 12).

4.2.7. Health service characteristics

Ninety six percent (96.0%) of defaulters and 95.0% of controls reported attending only one clinic for TB treatment. The dominant methods of transport which were equally used by both cases and controls were bus/taxi (36.0% for cases and 31.0%

for controls) and walking (58.0% for cases and 57.0% for controls) to the health facility. The time to travel to the facilities took less than an hour for the majority of both cases and controls. TB treatment default was however not significantly associated with any health service characteristics (number of clinic patient attended, method of transportation to health facility, time to travel to facility, admission to hospital) (p>0.05) (see table 12).

Table 12: Bivariate analysis of health system/provider risk factors and treatment default

	Patient who defaulted treatment		Patient who did not defaulted treatment		OR	95%CI	p-value
	No	%	No	%			
Number of clinics attended							
≤2	77	96	79	95	1.0		
						0.17-3.55	0.737
>2	3	4	4	5	0.77		
Method of transportation to facility							
Car	5	6	10	12	1.0		
Bus/Taxi	29	36	26	31	2.23	0.67-7.38	0.189
Walk	47	58	47	57	2.00	0.64-6.29	0.236
Time to travel to facility							
<30min	37	46	47	57	1.0		
30-60min	27	34	20	24	1.71	0.83-3.52	0.143
>60min	16	20	15	18	1.35	0.59-3.04	0.471
Ever admitted to hospital							
Yes	32	40	27	33	1.38	0.73-2.62	0.322
No	48	60	56	67	1.0		
Opinion about HCW attitude							
Satisfactory	22	27	40	48	1.0		
Not satisfactory	59	72	43	52	2.49	1.29-4.79	0.006
Missed treatment due to HCW attitude							
Yes	25	31	8	10	4.18	1.75-9.97	<0.001

No	56	69	75	90	1.0		
Patients think he/she will finish treatment							
Yes	66	84	74	91	1.0		
No	13	16	7	9	2.08	0.78-5.5	0.141
Patient thinks treatment made him/her feel better							
Yes	76	91	49	61	1.0		
No	5	9	32	39	6.2	2.64-14.6	<0.001

4.2.8. Opinions about TB treatment

Cases were 6.2 times more likely to report feeling better during treatment compared to controls (OR 6.2, CI: 2.64-14.6).

Multivariate Analysis

Significant factors (13 in total)(Appendix 10) associated with defaulting from TB treatment were included in a stepwise multivariate logistic regression. None of the factors remained in the last step.

CHAPTER 5: DISCUSSION

In the previous chapter, the results of the study were summarized and interpreted. This chapter focuses more on the discussion of the study findings and compares them with studies conducted in both developed and developing countries. The chapter is divided into six subsections: section one elaborates on TB default rate and time of default, section two describes data quality, section three describes the demographic risk factors associated with default, section four focuses on socioeconomic risk factors, section five is on patient/condition and therapy risk factors and the last section is on health system and provider risk factors associated with default.

In the present study, 2600 patients (84.0%) patients could not be traced. Similar retrospective case-control studies highlight difficulties experienced when tracing patients after they have left treatment facilities.[6, 10] Common reasons cited by our tracers (NGO carers) that lead to patients not being found are, wrong addresses provided by patients, relocation of patients to other areas within the district and at times back to provinces where they originally came from. Incomplete address information also leads to poor response rate.[6]

5.1. TB Default rate and time of default

Tuberculosis treatment defaulting is a public health concern in both developed and developing countries.[36] Treatment default results in the development of many drug resistant strains and therefore jeopardises the control of TB.[37] This study observed a default rate of 5.7% among patients registered for TB treatment at 48 facilities included for review. This is lower than the default rate of 9% reported by the Tshwane district ETR for the same time period. It is possible that some facilities in Tshwane with much higher defaulter rates were not included in this study resulting in the significant discrepancy with the ETR.

Several studies report different times at which TB treatment default occurs, with some reporting that the majority of TB patients default on their treatment during the

early phase of treatment and others maintaining that the majority of TB patients abandon their treatment later in the continuation phase.[22, 23, 24, 25, 26, 27, 28] In this study, almost 80% of cases defaulted in the first and second month of treatment. This may be attributed to the fact that most patients feel marked improvement after the first and second months of treatment.[29] The duration of treatment and the complexity of treatment itself also play a role in determining the actual time of default.[29]

5.2. Data quality

The number of defaulters who were new smear positive pulmonary TB patients was 332 in the 48 facilities included in the study while the number of defaulters during the same time period recorded in the ETR system which included all facilities in the district was 302(Appendix 9). This disparity could be as a result of difficulties related to maintaining high quality data recording which faces many TB programs around the world.[6] Electronic recording systems offer many potential benefits but this depends on the accuracy of paper-based registers that are used before data could entered into the ETR.[6]

5.3. Demographic factors

Previous studies have demonstrated that tuberculosis treatment default is common among young adults (20 – 45 years of age)[6,10, 36, 37, 40] while a study by Kliiman and Altraja[42] found TB treatment default to be common in older patients. The current study, found that the likelihood of default was significantly higher among young adults (OR 1.30, CI: 1.12-1.49).

Being male has been found to be significantly associated with treatment default in many studies. [6, 36, 37, 40] Similarly in this study, male gender was found to be significantly associated with treatment default (OR 1.43, CI: 1.23-1.64). High default in men compared to women may be as result of men being providers for their families.[27] Men leave home early for work and may find it difficult to honour clinic appointments.[27] High default rate observed in men may also be related to the fact that women are more motivated than men and demonstrate a greater need and

desire to become better and be cured of the disease.[30] The adverse side effects do not seem to deter their resolve during the difficult period.[30]

High numbers of TB treatment defaulters have been found to be HIV co-infected and this dual infection has been found to be the cause of high mortality in developing countries.[6, 40] In this study, 80.4% of defaulters were co-infected with HIV and being HIV positive was found to be associated with TB treatment default (OR 1.38, CI: 1.12-1.70). This is as a result of progressive clinical deterioration of HIV-infected individuals to a point that they become unable to go facilities to take TB medications.[27, 30] In addition, HIV-infected people also suffer from opportunistic infections which worsen their health status and this makes them more likely to default on TB treatment.[27] On the contrary, TB default rates in HIV-infected patients on ART have been found to be similar to those in HIV-negative TB patients which therefore implies that being on ART is protective of TB treatment default.[27, 30]

TB patients with primary education or no education are more likely to default compared to those with secondary or tertiary education[40, 41, 43] while others studies have not shown a significant association.[33] Our study found that the level of education was not associated with TB treatment default.

Alcohol has been previously reported as a risk factor for default[6, 10, 40, 42] but this study did not show a significant association between alcohol and treatment default. In our study, marital status was not significantly associated with default but other studies report that marital status is a significant risk factor for treatment default.[10]

5.4. Socioeconomic factors

Unemployment has been shown to be significantly associated with default in many studies.[10, 42] However, in Finlay[6], treatment default was associated with patients missing treatment due to employment. Reasons cited by patients included that they were busy and did not have enough time and work was a long distance from the TB clinic. No significant association between treatment default and employment was found in the current study. Significant proportion of defaulters did not own houses and this was found to be associated with increased likelihood of defaulting TB treatment. Living in a house with family members provides a support structure that is

critical for instance, in reminding patient to take treatment.[44] Other socioeconomic factors such as owning a radio/television were not found to be associated with treatment default.

5.5. Patient, condition and therapy factors

In line with other studies conducted in Kenya[10], Ghana[37] and India[43] our findings indicated that inadequate knowledge of TB is related to treatment default. Notably, 30% of default patients in this study were not given TB information by healthcare workers, and the risk of default was significantly higher amongst those not given information. Inadequate TB knowledge results in patients not knowing the symptoms of TB, transmission routes and the duration of treatment.[45] Inadequate knowledge can also result in delayed diagnosis.[45] This ultimately causes patients to believe that TB is incurable and as a result, they do not see the importance of having to adhere to the 6 month duration of TB treatment.[45]

Changing of residential address has been reported to be associated with default in other settings.[6, 17] In our study, change of residential address was also found to be significantly associated with TB treatment default. Changing of residence maybe as a result of unstable socio-economic position.[10] Patients will change residences looking for work in other areas.[10] This is likely to occur without adequate arrangement with the treating facility and the patient is likely to run out of TB drugs and ultimately default on treatment.[10]

5.6. Health system and provider risk factors associated with default

Distance patients travel to access treatment in other settings is associated with treatment default.[11]. However, Amoran[36] and colleagues in their study reported that distance from the health facility was not significantly associated with treatment default and this was similar to our findings.

Healthcare workers attitude was proven to increase the risk of treatment default among tuberculosis patient.[6, 43]. In our study more than seventy percent of patients who defaulted treatment were unsatisfied with the attitudes of service providers. Unsatisfactory attitudes towards TB patients by healthcare workers seem to be as a result of perceived infectiousness of TB patients.[45]

5.7. Limitations of the study

The retrospective nature of the study lends itself to potential recall bias and difficulties in knowing the temporal association between risk factors and treatment default. The study also experienced difficulties with finding defaulters because of the following; wrong addresses supplied, changing of residence etc. Other facilities within the district especially facilities that are found in Metsweding area could not be included because of lack of resources to access those facilities. A default rate for the district as a whole could, therefore, not be calculated.

CHAPTER 6: CONCLUSIONS AND RECOMENDATIONS

6.1 Conclusion

In conclusion, the results of the study are important in addressing the issue of treatment default in Tshwane. The default rate for the facilities included in this study was 5.7%. The key contributing factors to TB treatment default in Tshwane were found to be young age, male gender, HIV Status, employment, inadequate TB knowledge, taking treatment without direct supervision, healthcare worker attitude and change of residential address. Some of these factors are amenable to change such as giving sufficient TB information to patients and improving attitudes of healthcare professionals. Addressing these modifiable factors, should improve the quality and outcomes of the TB programme in Tshwane.

6.2 Recommendations

Factors associated with treatment default identified in the study can be addressed if sufficient resources can be made available to implement some of the interventions suggested below:

- **Assessing for non-adherence**. Health care workers need to assess TB patients on the possibility of defaulting their treatment. This can be achieved by looking at how TB patients are complying with their treatment during the initial phase of treatment. It has been shown that a good predictor of adherence to treatment is early compliance.[13] Therefore patients who forget to take their treatment (this can ascertained by checking TB treatment card) or attend their clinic appointments are at greater risk of defaulting their treatment.[13] Patients who are identified as most likely to default can then be offered support and guidance so they can overcome individual treatment barriers that are likely to contribute to non-adherence.[13]
- **Intensified counselling**. The study revealed that patients have inadequate TB knowledge and contributing to this could be the fact that healthcare workers are overloaded with work. This, as a result, reduces the time health

care workers spend counselling patients on the importance of treatment adherence. Intensive counselling of TB patients has been shown to be effective in improving adherence.[46] To ensure that patients are adequately informed about TB in Tshwane, it will therefore require that facilities utilise already available personnel such as health promoters, HIV counsellors etc in counselling TB patients. Issues to be addressed during this intensified counselling sessions which can be done in group or individual sessions are: identifying areas that patients have concerns or uncertainties about TB and clarifying them; ensuring that patients have the correct understanding of the duration of treatment, how TB drugs are to taken and side effects of the drugs; increasing patient motivation and being proactive by looking for possible problems that may impact on treatment adherence. Patients also need to be encouraged to form treatment support clubs. Counselling sessions should also educate patients on effective transfer of TB care to other treatment centres within the district or outside the district if needed.[6]

- **Telephonic reminders.** At the moment district tracer teams start tracing patients when clinics suspect a patient to be non-adherent and this occurs after a week of not presenting for treatment. Clinics should be able to send telephonic reminders after they realise that a patient has not presented for a clinic appointment.
- **Strengthening tracer teams.** District tracer teams should be supported with cars and other resources so that they are able to perform their tracing duties without hindrances.
- **Strengthen and increase HIV/TB collaboration activities in facilities.** The district should scale up the number of facilities initiating anti-retroviral therapy as well as strengthen HIV/TB collaborative activities since the study revealed that most HIV/TB co-infected patients were not on treatment. Patients on treatment for HIV and TB have been shown to have lower default rates compared to HIV-infected TB patients not on ART.[27]

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Appendices

Appendix 1: Data extraction form

Extraction form number ☐ ate ☐

1. Name of clinic ☐

2. Research identification number ☐

3. Age ☐ 4. Gender: Female ☐ Male ☐

5. Residential address ☐

6.Telephone/cellphone number ☐

7. Date of diagnosis: ☐

8. Type of TB: Pulmonary ☐

9. Type of patient: New patient ☐ Retreatment ☐

10. Date started on treatment: ☐

11. Date completed treatment: ☐

12. Duration of treatment: ☐

13. TB treatment outcome: Cured ☐ Completed ☐ Failure ☐ Defaulted ☐

14. DOT observer: Yes ☐ No ☐

15. HIV status: Reactive ☐ Unreactive ☐

16. Sputum smear microscopy results: + AFB ☐ -AFB ☐

Appendix 2: Patient information leaflet and questionnaire

STUDY TITLE: Risk factors for treatment default in pulmonary tuberculosis patients in Tshwane, Gauteng: a case-control study

INVESTIGATOR: DR Muvhango NM

INSTITUTION: University of Pretoria

Dear Participant

1) INTRODUCTION

We invite you to participate in a research study. This information leaflet will help you to decide if you want to participate. Before you agree to take part you should fully understand what is involved. If you have any questions that this leaflet does not fully explain; please do not hesitate to ask Dr NM Muvhango.

2) THE NATURE AND PURPOSE OF THIS STUDY

The aim of this study is to establish the factors that lead TB patients to default on their TB treatment. Knowing these factors can help the district to plan accordingly in reducing the number of TB patients who are interrupting their treatment. **The researchers also request your permission to access other information such as the type of TB you had from your TB clinic files and registers.**

3) EXPLANATION OF PROCEDURES TO BE FOLLOWED

I am going to ask you a set of questions relating to your TB treatment. Some of the questions will be **about your work, where you stayed during treatment, HIV status, your overall experience of the health service you received at the facility you were treated in etc** This will take about 30 minutes.

4) RISK AND DISCOMFORT INVOLVED

Some of the questions in this questionnaire maybe of a sensitive nature and might be uncomfortable for you to answer. There are no other risks in participating in the study.

5) POSSIBLE BENEFITS OF THIS STUDY

Although you will not benefit directly from the study, the results of the study will enable us to improve TB treatment services in the clinics in Tshwane.

6) WHAT ARE YOUR RIGHTS AS A PARTICIPANT?

Your participation in this study is entirely voluntary. You can refuse to participate or stop at any time during the interview without giving any reason. Your withdrawal will not affect you or your treatment in any way.

7) HAS THE STUDY RECEIVED ETHICAL APPROVAL?

This study has received written approval from the Research Ethics Committee of the Faculty of Health Sciences at the University of Pretoria. A copy of the approval letter / letters is available if you wish to have one.

8) INFORMATION AND CONTACT PERSON

The contact person for the study is Dr NM Muvhango. If you have any questions about the study please contact him at cell 0825371595

9. COMPENSATION

Your participation is voluntary. No compensation will be given for your participation.

10. CONFIDENTIALITY

All information that you give will be kept strictly confidential. Your name will not be used in the database, you will only be identified by a unique study number.

Research reports and articles in scientific journals will not include any information that may identify you.

CONSENT TO PARTICIPATE IN THIS STUDY

I confirm that the person asking my consent to take part in this study has told me about nature, process, risks, discomforts and benefits of the study. I have also received, read and understood the above written information (Information Leaflet and Informed Consent) regarding the study. I am aware that the results of the study, including personal details will be anonymously processed into research reports. I am participating willingly. I have had time to ask questions and have no objection to participate in the study. I understand that there is no penalty should I wish to discontinue with the study and my withdrawal will not affect any treatment in any way.

I have received a signed copy of this informed consent agreement.

Participant's name _____(Please print)

Participant's signature _____ Date ___/____/_____

Investigator's name _____(Please print)

Investigator's signature _____ Date ___/____/____

Witness's Name _____(Please print)

Witness's signature _____ Date ___/____/____

Questionnaire

Instruction to fieldworkers for completing the questionnare:

1. *Tick all that are appropriate*

Questionnaire number ☐ late ☐

SECTION A. Demographic characteristics

1. Gender: Male ☐ Female ☐

2. How old are you? ☐

3. Country of birth: South Africa ☐ other ☐

4. Practices religion: Yes ☐ No ☐

5. Race: Black ☐ White ☐ Indian ☐ Coloured ☐ Other ☐

6. Marital status: Married/partner ☐ Single ☐

7. How many children do you have? ☐

8. What is the highest level of education you have completed?

Tertiary ☐ Sec ☐ Primary ☐ None ☐

9. At the time of your TB treatment, with whom did you live? Alone ☐ family ☐

Partner ☐ friend ☐ Children ☐ coworker ☐

SECTION B: Socioeconomic characteristics at initiation of treatment

1. At the time of your TB treatment, did you own a radio? Yes ☐ No ☐

2. At the time of your TB treatment, did you own a television? Yes ☐ No ☐

3. At the time of your TB treatment, did you own a house? Yes ☐ No ☐

4. At the time of your TB treatment, were you employed? Yes ☐ ☐

5. If you were employed, what type of occupation? Labour ☐ Other ☐

6. How much were you earning? >1000/month ☐ <1000/month ☐

7. Did you ever miss treatment due to your employment? Yes ☐ No ☐

SECTION C: Alcohol use and drug use

1. At the time of your TB treatment, did you ever use alcohol? Yes ☐ No ☐

2. If alcohol user: were you taking 3 or more drinks in 1 day? Yes ☐ No ☐

3. At the time of your TB treatment, did you ever miss treatment due to alcohol use? Yes ☐ No ☐

4. Have you ever spent time in prison during your TB treatment? Yes ☐ No ☐

5. Did you ever miss treatment due to imprisonment? Yes ☐ No ☐

SECTION D: Personal experience

1. Did you tell someone that you were diagnosed with TB? Yes ☐ No ☐

2. Did you feel ashamed you were diagnosed with TB? Yes ☐ No ☐

3. Did you feel ignored or neglected because you were diagnosed with TB? Yes ☐ No ☐

4. At the time of your TB treatment, did you feel supported by your family? Yes ☐ No ☐

5. Did you ever feel that you did not have enough support during treatment? Yes ☐ No ☐

6. Did you feel that you had enough support during treatment? Yes ☐ No ☐

7. Did you ever feel influenced by others to stop treatment? Yes ☐ No ☐

SECTION E: Personal experience with nutrition/food

1. At the time of your treatment, did you depend on others for food and shelter? Yes ☐ No ☐
2. During your TB treatment, did you ever take tablets: Before eating ☐ After eating ☐
3. Did you ever take TB treatment on an empty stomach? Yes ☐ No ☐
4. If yes, did you experience any side effects? Yes ☐ No ☐
5. Did your appetite increase on TB treatment? Yes ☐ No ☐

☐ ☐

6. If yes, did you have enough food to satisfy your hunger? Yes No

7. Did you ever spend more than a day without food during treatment? Yes ☐ No ☐

8. During your TB treatment, were you ever provided with food to support TB treatment? Yes ☐ No ☐

9. Did you receive food from clinic while on treatment? Yes ☐ No ☐

10. Were you ever denied food or shelter because of having TB? Yes ☐ No ☐

SECTION F: Use of traditional healers

1. At the time of your TB treatment, did you see a traditional healer? Yes ☐ No ☐

2. If yes: how many traditional healers did you see? ☐

3. What type of healer did you see? Faith healer ☐ Herbalist ☐ Sangoma ☐

4. Were you ever given treatment by a traditional healer? Yes ☐ No ☐

5. Did you take the treatment at the same time as TB treatment? Yes ☐ No ☐

6. Did a traditional healer ask you to stop treatment? Yes ☐ No ☐

7. Did you miss treatment due to traditional healer? Yes ☐ No ☐

8. Whose treatment helped most? Traditional healer/herbalist ☐

TB health care worker ☐ Neither ☐ Both ☐

SECTION G: Health service characteristics

1. How many days were you ill until your first consultation with the doctor? ☐

2. How many different clinics did you attend for TB treatment? ☐

3. At the time of your TB treatment, how were you getting to the health facility? Car ☐ Taxi ☐ Bus ☐ Bicycle ☐ Walk ☐ Other ☐

4. How long did it take to get to the health facility? < 30 minutes ☐ 30-60min ☐ > 1 hour ☐

5. Were you ever admitted to the hospital for TB treatment? Yes ☐ No ☐

6. If admitted, did you miss TB treatment? Yes ☐ No ☐

7. How much time did you spend waiting at clinic? Did not wait ☐ < 1 hr ☐ > 1 hr ☐

8. Were the hours convenient? Yes ☐ No ☐

9. During your TB treatment, what was your opinion about the health care worker' attitude? Satisfactory ☐ Not satisfactory ☐

10. Did the health care worker treat you with respect during your treatment? Yes ☐ No ☐

11. Did you miss treatment due to health care worker's attitude? Yes ☐ No ☐

12. Did you trust the HCW? Yes ☐ No ☐

13. Did you trust the hospital/clinic? Yes ☐ No ☐

14. Do you think the treatment made you feel better? Yes ☐ No ☐

15. Did you think you will finish taking treatment? Yes ☐ No ☐

SECTION F: DOT and support characteristics

1. At the time of your TB treatment, how did the DOT supporter give you your pills?

Pill bottles ☐ Plastic bags ☐ One at a time ☐

2. Did you take treatment without direct supervision? Yes ☐ No ☐

3. If you took pills without direct supervision: were you given pills by health worker care to take alone? Yes ☐ No ☐

4. If yes, why were you given pills to take alone? HCW trusted me ☐ given bags of pills ☐ No one to supervise me ☐ Took pills home for the weekend ☐ Clinic too far/not accessible ☐ I was travelling >3 days ☐ Family member DOT partner ☐

Too ill/disabled to go to clinic ☐ work/school ☐ other ☐

SECTION G: Knowledge of TB

1. Did you know you are taking the treatment for = > 6 months? Yes ☐ No ☐

2. Were you told why the treatment is for 6 months or more? Yes ☐ No ☐

3. Were you given any TB information by the HCW? Yes ☐ No ☐

4. If you were given information, was it: Useful ☐ Not useful ☐

5. Did you receive enough TB information? Yes ☐ No ☐

6. Did you feel that it is not possible to cure TB? Yes ☐ No ☐

7. Did you feel that you may die from TB? Yes ☐ No ☐

SECTION H: Treatment characteristics

1. In what type of facility were you initiated on treatment? Clinic ☐ Hospital ☐

2. In what type of facility did you complete your TB treatment? Clinic ☐ Hospital ☐

3. Was it for the first time for you to be on treatment for TB? New patient (Y) ☐
Reactivated (N) ☐

4. Did you stop taking treatment for 2 months or more? Yes ☐ No ☐

5. During which month of the TB treatment did you stop?

Intensive (first 2 months) ☐ early continuation (3-4 months) ☐

Late continuation (5-8 months) ☐ Unknown ☐

6. At the time of your TB treatment. What was your HIV status? Reacti ☐ Unreac ☐

7. If HIV reactive: Were you on anti-retroviral therapy? Yes ☐ No ☐

8. ART regimen: Regimen 1 ☐ Regimen 2 ☐

9. How long were you on anti-retroviral therapy before you stopped your TB treatment?

< 3 month ☐ < 3 month ☐

10. If on ART: Did you get TB and HIV treatment from the same facility? Yes ☐ No ☐

SECTION I: Mobility of cases and controls

1. Did you change residence during TB treatment? Yes ☐ No ☐

3. How many times did you change residence during TB treatment? ☐

4. Did you ever miss treatment due to changing residence? Yes ☐ No ☐

Appendix 3: Ethics approval letter

The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.

* **FWA** 00002567, Approved dd 22 May 2002 and Expires 20 Oct 2016.
* **IRB** 0000 2235 IORG0001762 Approved dd 13/04/2011 and Expires 13/04/2014.

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Faculty of Health Sciences Research Ethics Committee
Fakulteit Gesondheidswetenskappe Navorsingsetiekkomitee

DATE: 30/07/2012

NUMBER	**139/2012**
TITLE OF THE PROTOCOL	Risk factors associated with treatment default in pulmonary tuberculosis patients in Tshwane, Gauteng: case control study
PRINCIPAL INVESTIGATOR	**Student Name & Surname:** Dr Muvhango NM **Dept:** Public Health Medicine;University of Pretoria. **Cell:** 0825371595 **E-Mail:** nmmuvhango@webmail.co.za
SUB INVESTIGATOR	Not Applicable
STUDY COORDINATOR	Not Applicable
SUPERVISOR (ONLY when STUDENTS)	Dr Moodley SV **E-Mail:** Saiendhra.Moodley@up.ac.za
STUDY DEGREE	MMed
SPONSOR COMPANY	Not applicable
MEETING DATE	25/07/2012

The Protocol and Informed Consent Document were approved on 25/07/2012 by a properly constituted meeting of the Ethics Committee subject to the following conditions:

1. The approval is valid for 1 year period [till the end of December 2013], and
2. The approval is conditional on the receipt of 6 monthly written Progress Reports, and
3. The approval is conditional on the research being conducted as stipulated by the details of the documents submitted to and approved by the Committee. In the event that a need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

Members of the Research Ethics Committee:

Prof M J Bester	(female)BSc (Chemistry and Biochemistry); BSc (Hons)(Biochemistry); MSc(Biochemistry); PhD (Medical Biochemistry)
Prof R Delport	(female)BA et Scien, B Curationis (Hons) (Intensive care Nursing), M Sc (Physiology), PhD (Medicine), M Ed Computer Assisted Education
Dr NK Likibi	MBB HM – Representing Gauteng Department of Health) MPH
Dr MP Mathebula	(female)Deputy CEO: Steve Biko Academic Hospital; MBCHB, PDM, HM
Prof A Nienaber	(female) BA(Hons)(Wits); LLB; LLM; LLD(UP); PhD; Dipl.Datametrics(UNISA) – Legal advisor
Mrs MC Nzeku	(female) BSc(NUL); MSc(Biochem)(UCL, UK) – Community representative
Prof L M Ntlhe	MbChB (Natal) FCS (SA)
Snr Sr J Phatoli	(female) BCur(Eet.A); BTec(Oncology Nursing Science) – Nursing representative
Dr R Reynders	MBChB (Prët), FCPaed (CMSA) MRCPCH (Lon) Cert Med. Onc (CMSA)
Dr T Rossouw	(female) MBChB (cum laude); M.Phil (Applied Ethics) (cum laude), MPH (Biostatistics and Epidemiology (cum laude), D.Phil
Dr L Schoeman	(female) B.Pharm, BA(Hons)(Psych), PhD – Chairperson: Subcommittee for students' research
Mr Y Sikweyiya	MPH; SARETI Fellowship in Research Ethics; SARETI ERCTP; BSc(Health Promotion)Postgraduate Dip (Health Promotion) – Community representative

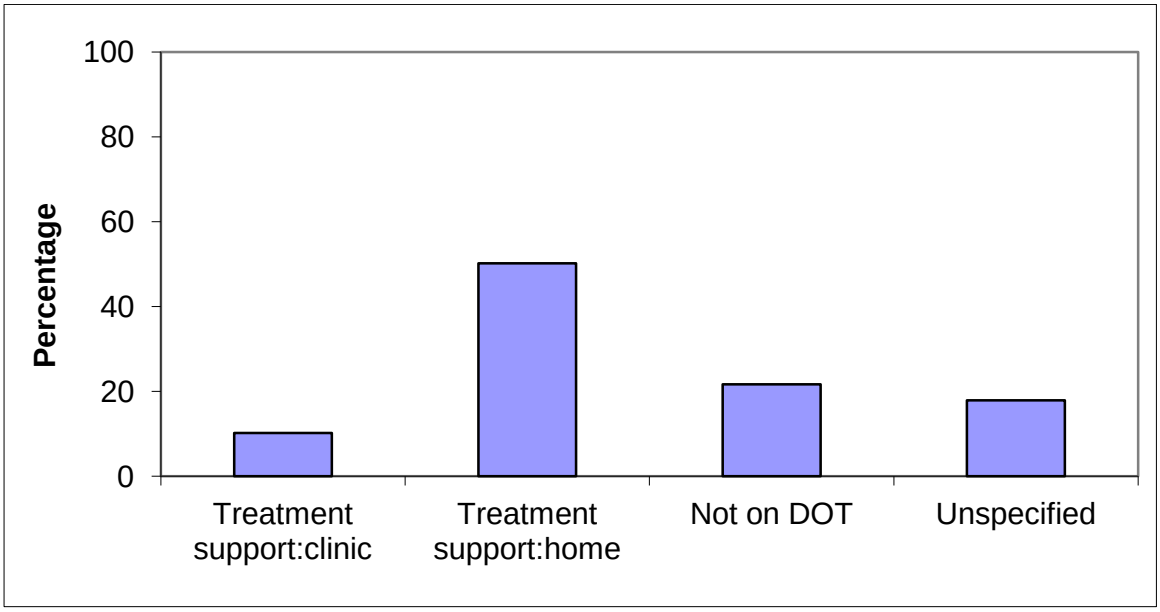
2012/08/06MS: dd 2012/08/06: C:\Documents and Settings\user\My Documents\Protokolle\Grade briewe\Letters 2012\139.2012.doc

2012/08/06MS: dd 2012/08/06: C:\Documents and Settings\user\My Documents\Protokolle\Grade briewe\Letters 2012\139.2012.doc

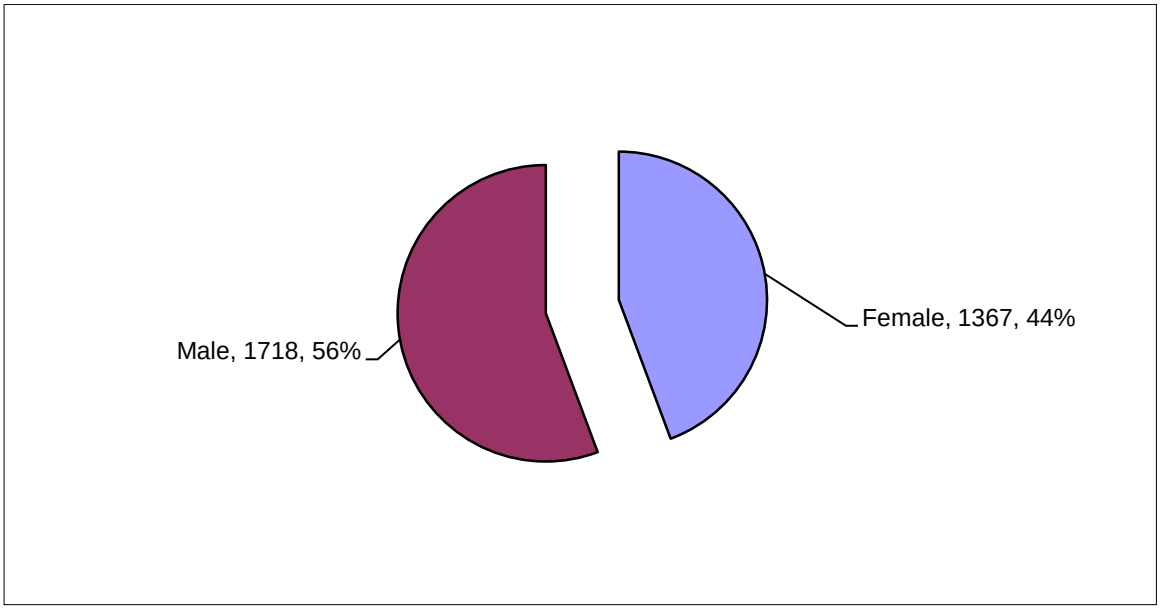
Appendix 4: Patient type characteristics

Patient Type	Cases	Controls	Number	Percentage
Re-treatment after default (RD)	63	77	139	4.5
New patient (N)	1389	1440	2829	91.7
Relapse (RC)	23	23	46	1.5
Moved in from a facility in Tshwane (M)	17	16	33	1.1
Re-treatment after failure (RF)	0	2	2	0.1
Transfer in from facility outside district	8	9	17	0.6
Unspecified	8	12	20	0.7
Total			3086	100

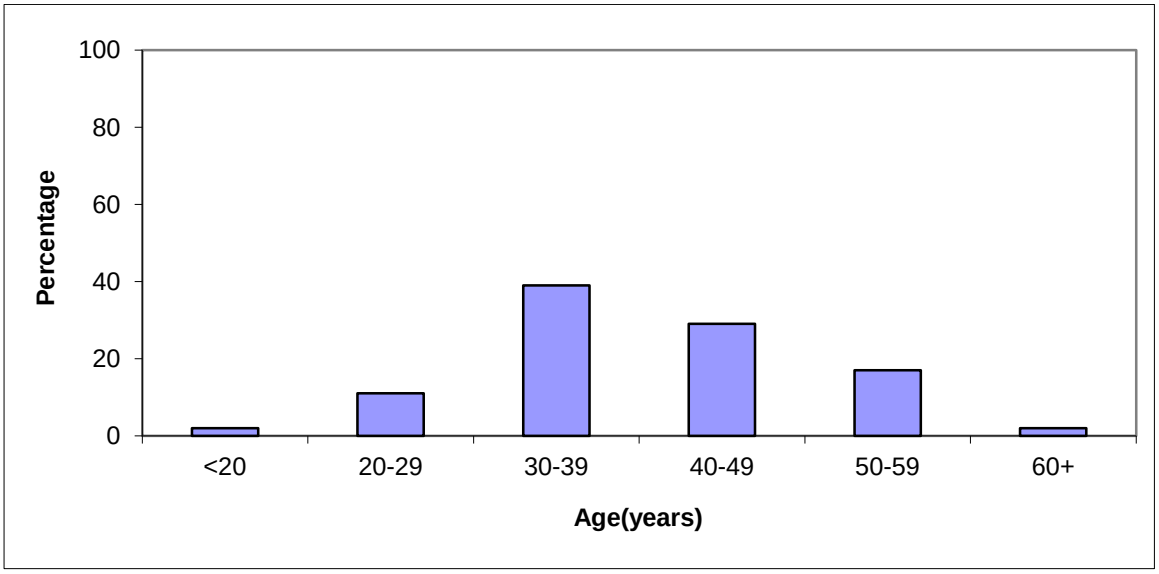
Appendix 5: DOT support characteristics, N=3085



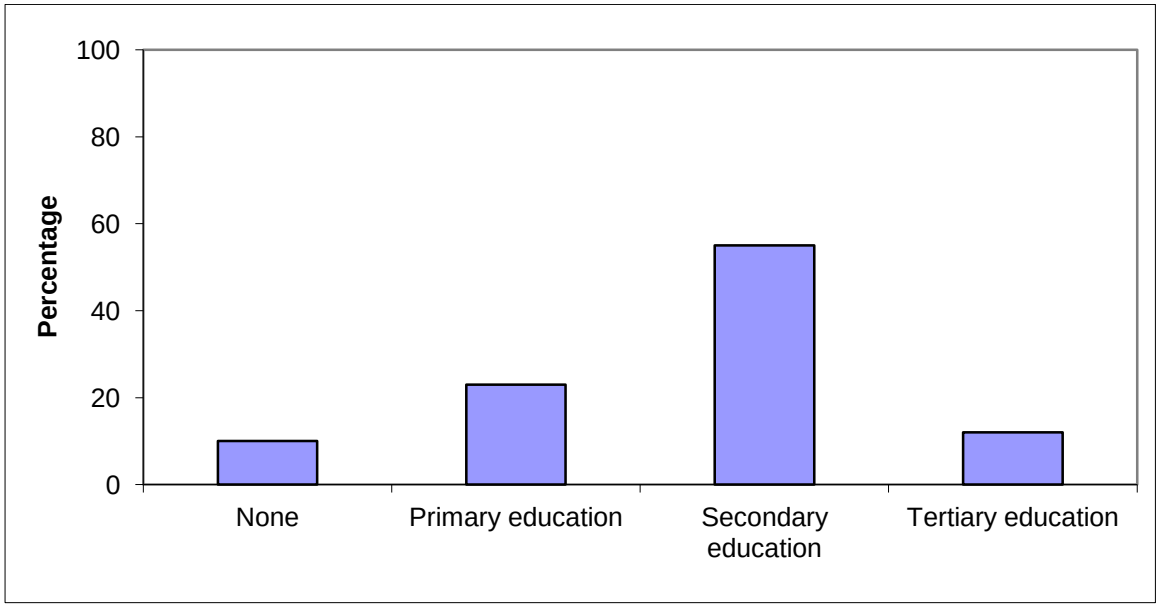
Appendix 6: Gender distribution of the study population, N=3085



Appendix 7: Age distribution of patient interviewed



Appendix 8: Distribution of level of education of patients interviewed



Appendix 9: Comparison of retrospective record review data and ETR data for default TB outcome for 2010

Total TB patients	ETR(Electronic TB Register) data	Review data
All TB patients registered	12567	10729*
Total smear positive PTB patients	3674	---- #
Smear positive PTB defaulters	301	332
Total TB defaulters	-----	1506
Default rate for all TB patients		

*the total for 48 facilities

Record review did not review all TB cases except for defaulters

Appendix 10: Significant variables in the initial model for multivariate analysis.

		OR	95%CI	p-value
Home ownership	Yes	1.0	1.19-4.17	0.012
	No	2.23		
Told why treatment is given for 6 months	Yes	1.0	3.26-15.9	<0.001
	No	7.22		
Given TB info by HCW	Yes	1.0	1.68-9.60	0.002
	No	4.08		
Received adequate info on TB	Yes	1.0	3.23-16.6	<0.001
	No	7.34		
Feels that TB is incurable	Yes	1.0	0.16-0.59	<0.001
	No	0.31		
Feels that an individual may die from TB	Yes	1.0	0.27-0.98	0.044
	No	0.52		
DOT supporter give patient pills	One at a time	1.0		
	Pill bottles	4.16	0.78-22.0	0.093
	Plastic bags	1.76	0.90-3.46	0.095
Patient takes treatment without direct supervision	Yes	2.72	1.42-5.22	0.003
	No	1.0		
Patient changed residential address	Yes	5.83	2.98-11.5	<0.001
	No	1.0		
Appetite increases on TB treatment	Yes	2.26	1.08-4.73	0.029
	No	1.0		
Opinion about HCW attitude	Satisfactory	1.0	1.29-4.79	0.006
	Not satisfactory	2.49		
Missed treatment due to HCW attitude	Yes	4.18	1.75-9.97	<0.001
	No	1.0		