DO TUBERCULOSIS TREATMENT SUPPORTERS INFLUENCE PATIENTS TREATMENT OUTCOME?

A study in the Southern service delivery region, Ekurhuleni Metropolitan municipality, Gauteng province, South Africa.

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfilment of the requirement for the degree of Master of Public Health in the School of Public Health.

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Declaration

I, Peter Aggrey Oduor, declare that this research report is my own work. It is being submitted for the degree of Master of Public Health to the University of Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

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P. A. Oduor

10th Day of January 2008

Dedication

This research report is dedicated to my parents Richard and Phoebe Nyang'inja, to my wife Grace and to my two daughters Hope and Clair.

Abstract

This study aimed to investigate the role played by treatment supporters in promoting patients' treatment outcomes in six TB clinics of Ekurhuleni Metropolitan Municipality, Gauteng. A descriptive research design was used to study TB patients who were registered in the clinics in April and May 2006. Interviews were conducted on 216 new adult patients six months after their registration at clinics, all 30 treatment supporters of those who had supporters and the staff responsible for TB at the six clinics at which the patients were registered.

The patients were grouped into those who had supporters 53% (n=115) and those who did not 47% (n=101). Patients' response rate was 97%. Treatment outcomes were compared between these two groups.

Results showed that significantly more supported patients achieved successful outcomes than patients who did not have supporters. The results did not change when transfers and deaths were excluded from the measurement. Successful treatment outcomes were significantly associated with treatment supporters having fewer than 10 patients, patients living with someone, patients of age 40 or more years, male patients, those whose highest education levels were tertiary and secondary.

Patients and clinic staff said that supporters were useful in checking on patients' treatment, giving medicine, counselling and advising patients on medication and in practical help.

Conclusion: Treatment supporters had a significant role in promoting patients' treatment outcomes. It is recommended that TB treatment programme staff should consider using treatment supporters in their programmes.

Acknowledgements

The assistance and guidance of my supervisor Professor Mary Edginton is greatly appreciated. I wish to acknowledge the staff members of the school of Public Health of the University of the Witwatersrand and the Ekurhuleni Metropolitan Municipality for assisting in organising the TB clinics for data collection.

I equally thank my wife Grace as well as my daughters Hope and Clair who accepted the many days that I was away from home while working on the project.

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Abbreviation and definition of terms

- Adherence The process of taking treatment regularly or patients taking medication as prescribed.
- AIDS Acquired Immune Deficiency Syndrome

CBO Community Based Organisations

Clinic supporter/nurse

The nurse responsible for TB treatment and management in the clinic Community supporters

People who work either for pay or as volunteers at community level in association with clinics to make sure that TB treatment is taken.

- DOTS Directly observed treatment strategy which is a WHO recommended system for providing TB treatment that emphasises political commitments, standardised diagnosis of pulmonary cases, standardised treatment, recording and reporting and adequate drug supplies. New additions include addressing challenges of TB/HIV integration and strengthening of health systems, engaging all care providers, empowering people with TB and communities, and promoting operational research. Once infection cases have been detected using microscopy services, clinic nurses and community treatment supporters observe and record patients swallowing the correct dosage of anti TB medicines and document that the patient has been cured.
- EMM Ekurhuleni Metropolitan Municipality
- HIV Human Immunodeficiency Virus

MDR-TB: Multi-drug-resistant Tuberculosis which is a laboratory diagnosis of organisms that are shown to be resistant to at least isoniazid and rifampicin.

- New TB A patient who has never had treatment for TB or who has taken anti-TB for less than one month
- NGO Non-governmental organisation
- SDC Service Delivery Centre
- SDR Service Delivery Region
- SSDR Southern Service Delivery Region
- TB TB is an infection by the *Mycobacterium tuberculosis* organism

Treatment supporter

WHO

A person engaged in supporting a patient with TB treatment to ensure it is taken World Health Organisation

XDR-TB Extreme drug-resistant tuberculosis (TB) is caused by poor TB control, through taking the wrong types of drugs for the incorrect duration. It is resistance to at least isoniazid and rifampin among first-line anti-TB drugs, resistance to any fluoroquinolone, and resistance to at least one second-line injectable drug (amikacin, capreomycin, or kanamycin).

Treatment outcomes definitions as outlined in the TB register

Treatment success

Sum of those patients who were cured plus those who completed treatment but without bacteriologic proof of cure

Cured A patient (initially smear positive) who is smear negative at, or one month prior to completion of treatment and on at least one previous occasion.

Treatment Completed

Treatment completed without bacteriologic proof of cure

Interrupted Treatment

Treatment interrupted for two or more months.

Treatment Failure

A patient remains or becomes again smear positive at 5 months or later during treatment

Transfer Patient transferred to another district; treatment outcome unknown.

Death Death of a patient arising from any cause

1. Introduction

This study focused on investigating whether the community treatment supporters were influencing TB patients' treatment outcomes. The criteria for assigning a treatment supporter to a patient were determined by clinic nurses, treatment supporters and the patients. The clinic nurses asked the new patients if they preferred a treatment supporter to assist them in TB treatment. The patients who preferred to have treatment supporters were asked to choose any treatment supporter in or near their village. The clinic nurse would then inform the treatment supporter and ask her/him to assist the patient. If a supporter had more than ten patients then the patient was asked to choose another. The treatment supporters were attached to the clinics and worked as volunteers in the community. The patients who preferred clinic treatment were supported by clinic nurses who administered the intake of TB medicine.

1.1 Ekurhuleni Metropolitan Municipality

The Ekurhuleni Metropolitan Municipality was established after the municipal elections held on 5 December 2000 and is responsible for the area formerly known as the East Rand. It includes the following councils; Alberton, Benoni, Boksburg, Brakpan, Edenvale, Germiston, Kempton Park, Nigel, Springs and Khayalami. The population is about 2.4 million, in an area covering 190,000 hectares. The municipality is situated in South Africa's economic heartland with vibrant mining industries and business activities. The area has experienced an influx of immigrants both locally and in international arena. There are a number of informal settlements where people live in congested and poor conditions.

The Municipality has been sub-divided into three Service Delivery Regions (SDRs) namely the Southern, Eastern and Northern (figure 1, 2). The project concentrates in the Southern Service Delivery Region (SSDR), which includes Germiston (S1), Alberton (S2) and areas of Boksburg (S3) (1). The Southern Service Delivery Region has a population of 921 366 people based on the 2001-population census (2).

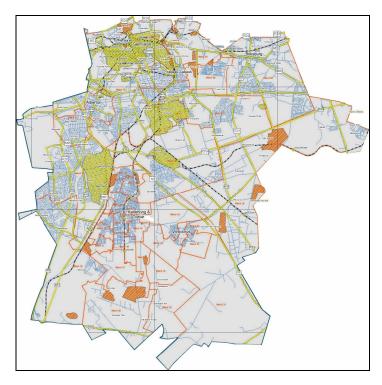


Figure 1: Map of Southern Service Delivery Region (EMM annual report 2004)

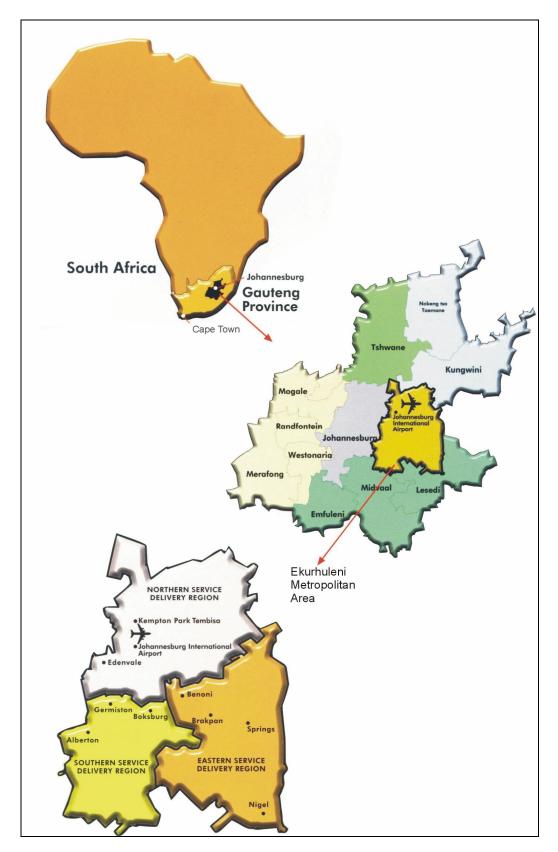


Figure 2: Map of Ekurhuleni Metropolitan Municipality (EMM annual report 2004)

1.2 Tuberculosis numbers and rates and TB services in the Southern service delivery region (SSDR)

Tuberculosis is a major public heath problem in South Africa. In 2006, the World Health Organization ranked South Africa fifth among the world's 22 high-burden TB countries. According to the *World Health Organization (WHO) Global TB Report 2006*, South Africa had nearly 340 000 new TB cases in 2004, with an incidence rate of 718 cases per 100 000 people – a major increase from 338 per 100 000 in 1998 (3). Since South Africa adopted Directly Observed Treatment, Short-Course (DOTS) in 1996, all districts have implemented the core DOTS components, although coverage varies widely within and among districts. Despite South Africa's investments in TB control, progress toward reaching program objectives has been slow. Treatment success remains low compared with other African countries with high HIV/AIDS prevalence and considerably fewer resources. Tuberculosis has remained a major health problem in Ekurhuleni Metropolitan Municipality with DOT treatment success rates for new smear positive patients falling below 60% (1). National treatment success rates in 2003 were 67% with incidence rates of 718/100 000 in 2004 (3) Figure 3 and figure 4 shows TB treatment success rates and incidence rates respectively for the years 2000 to 2004 in the Southern service delivery region (1, 4).

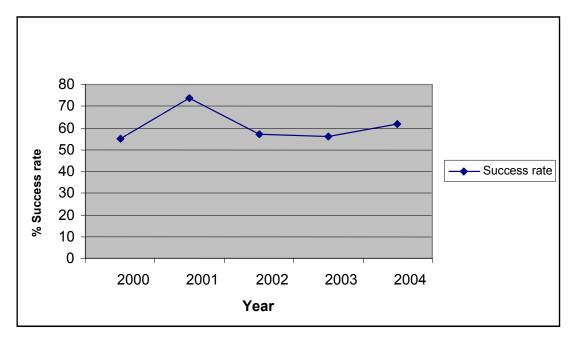


Figure 3: Southern Service Delivery Region TB success rates 2000–2004 (EMM annual reports)

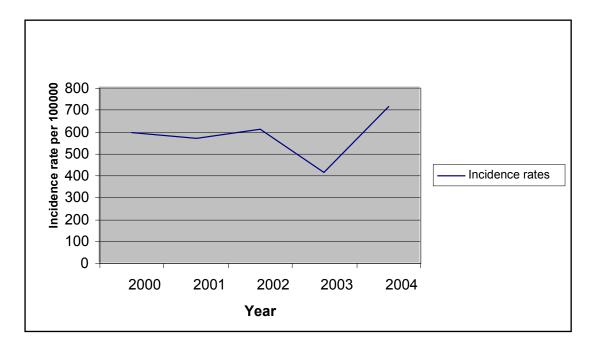


Figure 4: Southern Service Delivery Region TB incidence rates from 2000–2004 (EMM annual reports)

TB services in the area are provided by 31 clinics. The DOTS strategy was introduced in 1998 in keeping with the National Health Policy. Clinic staff responsible for TB treatment provide DOTS support in the clinics while community supporters provide DOT support at patient homes.

1.3 The role of TB treatment supporters in Ekurhuleni Metropolitan Municipality

There is no reliable information that can guide health professionals and clinic nurses in EMM on the role of community treatment supporters. The national policy for community health workers assumes that DOT support is part of their role. There is only one study conducted on DOTS supporters' role in Ekurhuleni Metropolitan Municipality (EMM), specifically in the Southern Service Delivery Region. Ntsele (unpublished study 2000) conducted a study in Germiston on treatment outcomes of patients who had community versus clinic nurses and found no statistical evidence of difference in the cure rates between these two groups.

1.4 Literature review

Introduction

This literature review provides an overview of studies on patient's adherence to treatment, approaches that have been adopted to ensure effective DOTS implementation and constraints faced in TB treatment programs.

Tuberculosis is one of the world's most serious diseases killing approximately 2 million people every year, with an estimated 8 million presenting with disease every year (5, 6). The World Health Organisation shows that TB burden is on the increase due to a breakdown in health services, the spread of HIV/AIDS, poverty and the emergence of multi-drug-resistant TB (7). The DOTS strategy was promoted by the STOP-TB partnership in the 2001 as a strategy that would improve TB diagnosis and treatment.

South Africa is burdened by one of the worst tuberculosis epidemics in the world, with disease rates more than double those observed in other developing countries and up to 60 times higher than those currently seen in the USA or Western Europe. The TB situation is worrying, as cases of XDR-TB have been identified recently. This strain resists both first-and second-line TB drugs; drugs for XDR-TB are not readily available.

South Africa like other countries that implemented the DOTS strategy has faced challenges in TB control. The National TB Control Program (NTP) identified poor patient adherence as a factor that contributed to low cure rates (8). One of the problems currently faced by TB programs is multi-drug resistance that emanates from incomplete treatment /interruptions. The incidence of TB in South Africa has been classified by WHO standards as a 'serious epidemic' (9).

The DOTS strategy aims at increasing patient adherence through encouraging active participation in the program by health care services and ensuring that "every TB patient has the support of another person to ensure that they swallow their medication daily" (8). Both treatment supporters and the patients have a role to play in TB treatment adherence. Treatment supporters are "expected to motivate and empower patients and their families and provide them with a better understanding of TB and the importance of cure" (8). Tuberculosis is a curable disease but statistics show that it is still on the increase (6). The DOTS strategy within the TB program has been set up to involve communities in prevention and treatment of the disease. Many studies have been carried out on improvement of DOTS strategy

implementation. Problems that affected adherence were identified as lack of material support (food and money), transport costs, family income and stigma (10). Incentives are reported to have motivated treatment supporters in their work (11). Kironde et al investigated other factors in Cape Town as altruism - especially those patients who had been patients themselves or knew people affected by the disease, filling in spare time - particularly for younger volunteers, gaining work experience - the attraction of getting good references and contacts, the novelty factor - community participation in TB control in the province was relatively new (12). Lack of proper coordination of treatment supporters was examined as a major determinant in patients' treatment adherence (13). Other studies have identified access to facilities as a factor leading to poor treatment adherence, namely the long distances patients walked to clinics to collect medicine (14). However, Dievler and Pappas in their analysis of the TB situation in Vietnam singled out lack of basic infrastructure within health services, including lack of clinic equipment and cars to follow up patients. They also viewed effective communication between supporters and their patients as a way to improve treatment adherence (15). Given these facts, it could be possible that the DOTS strategy may not achieve its goals because of lack of incentives for treatment supporters, poor coordination with treatment supporters and partial involvement or commitment of patients. Treatment supporters are drawn preferably from communities where patients live and therefore are in a position to visit and attend to patients effectively. Kleinman says, "Close contact with patients can significantly impact on patient's commitment to a correct regimen" (16). Investigating the nature of treatment supporters' services and their linkages with TB clinics would provide evidence of their role in TB treatment.

Robinson warns, "Case finding and treatment programmes are best not begun unless community follow up of patients can ensure that all prescribed treatment is completed" (17). Godfrey-Faussett identifies interventions that would make TB programs successful, as active case finding in communities and this will prevent the transmission of TB (18). The prevalence of tuberculosis in high burden countries can effectively be reduced through enhancing access to treatment (19, 20). According to Mantala DOTS strategy achieved good treatment outcomes in the Philippines because DOT supporters were involved (21). Godfrey-Faussett however indicated that "health services that find it difficult to find cases efficiently will also find it difficult to support patients throughout treatment to achieve a cure. Partnerships with traditional healers, community based organizations (CBOs) and private practitioners could reduce this burden" (18). In Lusaka, Zambia over half of the TB patients received care from

community based organizations (18). Direct treatment observation is essential and should not be a mechanical procedure of dropping medicine into a patient's mouth "supervised swallowing" (21). Frieden and Driver stated, "Direct observation succeeds by building a human bond between a patient and the health care worker or community volunteers" saying that it takes both the TB program and community support for successful treatment of TB (22). The role of treatment supporters is to ensure patients adherence to TB medication (22). A cross sectional study conducted by Maher on "Community TB care in Africa" in the following countries - Botswana, Kenya, Malawi, South Africa, Uganda and Zambia found that health facilities offering patients the option of community supervised or health centre supervised treatment performed effectively (19). Treatment interruption may be caused by some patients' negative perceptions of treatment strategy (23). A study in the sub Saharan Africa found that one community based organisation working closely with TB programs attained a high treatment completion rate through community participation and involvement (24).

There was a decrease in cure rates experienced in the Southern Service Delivery Region from 74% in 2001/2002 to 57% in 2002/2003 (1). This may have been caused by poor monitoring of treatment adherence as Robinson identifies that "some patients do not feel it is necessary to continue with medication, especially after taking treatment for a few weeks" (17). There could be many more reasons why TB treatment programs are failing but it is clear that treatment supporters have a role to play in patients' adherence to treatment and that if this is well implemented; better TB cure rates are likely.

1.5 Aims and objectives of the study

<u>Aim</u>

This study aimed to investigate the role of treatment supporters for patients on TB treatment.

Objectives

For new TB patients with and without treatment supporters, who were registered six months before the study at clinics in the Southern Service Delivery Region (SSDR) of Ekurhuleni Metropolitan Municipality.

- 1. To document their demographic characteristics, experiences and problems related to taking TB treatment
- 2. To compare their TB treatment outcomes
- 3. To examine patient and service factors that were associated with successful treatment outcomes
- 4. To document experiences and problems and suggestions of treatment supporters of those patients who had supporters
- 5. To describe the role of treatment supporters, problems of supporters and suggestions to improve TB treatment stated by TB staff of the clinics

2. Methods

Introduction

This chapter describes how the questionnaires were designed, the manner in which the study subjects were recruited, describes the data collection tools and the ethical considerations.

2.1 Study Area

The area of coverage was the Southern Service Delivery Region (SSDR) of Ekurhuleni Metropolitan Municipality. It is situated in the Eastern part of Gauteng Province, about 20 KM away from Johannesburg city. It is a densely populated industrial region which includes Thokoza, Boksburg, Germiston, Katlehong and Vosloorus towns. The SSDR was subdivided into Service Delivery Centres (SDC) namely Germiston (S1), Alberton (S2) and Boksburg (S3) for administrative purposes. The study focused on the TB clinics providing treatment on daily basis in this region. There were 16 clinics in Germiston, six in Alberton and nine in Boksburg with a total of 31 clinics in the region.

2.2 Study design

A descriptive research design was adopted for this study.

2.3 Study population

• Patients

The patient study population was 115 TB patients with treatment supporters and 101 without. They were all adults (18 years of age and over) in the defined category of 'new' patients diagnosed with any type of TB and who had been registered at clinics in the SSDR of the Ekurhuleni Metropolitan Municipality six months before recruitment into the study. Those excluded were children under 18 years, those on the re-treatment category and MDR patients.

- Treatment supporters of the patients who had supporters.
- Staff members primarily responsible for TB patients at the clinics

2.4 Study sample

Patients

The 31 TB clinics in Ekurhuleni Metropolitan Municipality were written in pieces of paper, picked at random and listed in each of their respective Service Delivery Centres in the Southern Service Delivery Region (SSDR) where the study was based. Germiston (S1) had

sixteen clinics with 376 patients, Alberton (S2) had six clinics with 140 patients and Boksburg (S3) had nine clinics with 274 patients. The population of all "new" adult TB patients registered in the clinics was therefore 790. These patients were numbered in their respective Service Delivery Centres as shown in table 1 below.

Germiston Service Delivery Centre (S1)			
Clinic	No of patients registered in April and May 2006	Cumulative range	
Dukathole	31	1-31	
Zonkizizwe I	27	32-58	
Zonkizizwe II	17	59-75	
Moleleki	49	76-124	
Elsburg Clinic	22	125-146	
Goba Clinic	52	147-198	
Katlehong North	20	199-218	
Motsamai	33	219-251	
Khumalo	17	252-268	
Leondale	19	269-287	
Germiston City	25	288-312	
Palmridge	15	313-327	
Ramokonopi	11	328-338	
Magalula	9	339-347	
Tamaho	21	348-368	
Sunriseview	8	369-376	
Alberton Service De	livery Centre (S2)		
Clinic	No of patients registered in April and May 2006	Cumulative range	
Brackenhurst	21	1-21	
Phola Park	32	22-53	
Dresser	27	54-80	
Edenpark	10	81-90	
Penduka	28	91-118	
Alberton North	22	119-140	
Boksburg Service D	elivery Centre (S3)		
Clinic	No of patients registered in April and May 2006	Cumulative range	
Dawn Park	12	1-12	
Boksburg Civic Cent	27	13-39	
Reiger Park	42	40-81	
J. Dumane CHC	53	82-134	
Tswelopele	18	135-152	
Vosloorus Ext 14	16	153-168	
Vosloorus Ext 28	31	169-199	
Vosloorus Poly	46	200-245	
Vosloorus Ext 9	29	246-274	

Table 1: Sampling frame

The sampling procedure

A multi stage sampling method using probability proportional to size was used in order to give patients registered at clinics with large numbers the same probability of being selected

as patients registered at clinics with smaller numbers (the number of units M_i in the ith cluster forming a measure of size). Two clinics (M=2) were sampled from each SDC using the following **systematic sampling**: the population of patients listed in each SDC was divided by two to obtain a sampling interval involving the selection of every k^{th} patient from the sampling frame, where k, was the sampling interval. From the sampling frame, a starting point was chosen at random between one and the sampling interval (SI), and choices thereafter were at regular intervals. The other random number was obtained by adding the sampling interval to the first random number selected. These numbers represented patients and were used to trace the clinics where the patients with those numbers attended. Two clinics were selected from each of the three Service Delivery Centres using this sampling method resulting in six clinics being selected.

The sampling interval for Germiston SDC was 376/2= 188 and the random start number was 111 and the second number was 111+188= 299. Patient numbers 111 and 299 were registered in Moleleki and Germiston city clinics respectively.

Alberton SDC's sampling interval was 140/2 = 70, random start number chosen was 37 and the second random number was 37+70=107. Two patients with numbers 37 and 107 in the list were registered in Phola Park and Penduka clinics respectively.

For Boksburg SDC the sampling interval was 274/2 = 137, random start number was 79. The second random number was 79+137= 216. Patient numbers 79 and 216 were from Vosloorus Poly clinic and Reiger Park clinic. The two clinics selected in Germiston SDC had 74 registered, those in Alberton SDC had 60 and in Boksburg 88 patients, making a total of 222 TB patients in the sample.

Treatment supporters

The study sample comprised all the treatment supporters of sampled patients in the six selected clinics

TB clinic staff

Each of the six selected clinics had one staff member who was responsible for TB. All six were studied.

2.5 Measurements

The researcher requested the nurse responsible for TB in each of the six selected clinics to introduce the study to patients and supporters during their routine meetings in the clinics. They were then invited by the researchers to participate and to be interviewed. The interviews took about ten minutes and were conducted between the 20th and 30th October

2006. The interviewers were four qualified auxiliary social workers who were researcher's colleagues and were not treatment supporters in the clinics. They were trained on data collection tools to ensure validity and accuracy of the tools. They all lived in Germiston and travelled to the clinics using public transport. The patients attending clinics were identified when they attended. Those who did not attend clinics themselves were visited in their homes for interviews. The interview forms are attached in appendix 2.

Patient Data

Patient data was obtained from interviews. The following variable were collected on each patient: patient numbers at each clinic, age, gender, whether living with a partner or living alone, educational level reached*, number of patients per supporter, patient knowledge about the duration of their treatment*, their experiences in taking TB treatment, the type of TB, how they accessed treatment, any stated problems. Patients with a supporter were asked about the type of supporter and frequency of visits (patients to clinics or between patients and supporters), the role of the treatment supporter as they experienced it and the perceived usefulness of the supporter. The number of patients per supporter was ascertained from clinic staff.

Note:

*Educational level reached was categorised into four groups where non-formal education included all patients with 0 or only 2 grades, primary education included all patients who reached grade 3–7, secondary education for those who reached grade 8–12 and tertiary grade after grade 12.

* Patients' knowledge of the duration of their treatment was assessed according to the type of TB. For pulmonary and all types except TB meningitis, miliary and bone TB, correct duration was noted if patients said six months, incorrect if they said less or more. For TB meningitis and miliary TB, correct duration was nine months and for bone TB, correct was accepted for nine to twelve months.

Treatment outcomes

The treatment outcome of each patient was documented from clinic registers and compared for patients with and without a treatment supporter. The treatment outcomes were defined according to the national TB control programme (8): cured, completed, failure, death, transferred and interrupted. In addition, treatment outcomes were compared for patients of different age groups and genders, patients living with someone or living alone, with correct knowledge about treatment duration, patients for whom supporters collected their treatment

from clinics rather than collecting it themselves, their educational status and whether they had clinic or community supporters.

Treatment supporter Interviews

Each treatment supporter was interviewed. Variables measured were demographic characteristics (gender, age, level of education), outcomes of supported patients, number of treatment supporters per interviewer, their knowledge and experiences of TB treatment, duration of home visits, meetings between supporters and clinic staff, patient problems, ways in which they supported the patients, the frequency of contact with patients, their role, suggestions for improvement and any difficulties faced by supporters in assisting TB patients.

Interviews with TB clinic staff

The clinic staff responsible for TB were interviewed. The variables measured were the position of the staff in the clinic, training of supporters, clinic policies, role of treatment supporters as observed by clinic staff, problems of patients, staff opinions about the usefulness of supporters, ways in which treatment supporters work could be improved, the role of TB staff in assisting patients and treatment supporters, meetings with treatment supporters and other ways apart from supporters in which TB treatment could be improved.

2.6 Ethical Considerations

The researcher ensured that patients' rights were observed. There was no any harm, pain or embarrassment caused to the subjects. The purpose of the research was explained to all the subjects and they were requested to sign an informed consent form attached in appendix 3. The confidentiality was ensured to the uttermost and was agreed upon before the study commenced. Privacy of individuals was not infringed and the respondents had the right to refuse to participate or answer particular questions without any prejudices to their treatment. The investigator and the nurse responsible for TB in the clinics carried out all records review. Care was taken not to reveal/include any names in the report. Ethical clearance and permission to carry out the study was obtained from:

- University of Witwatersrand Ethical Committee: Protocol number MO60633
- Ekurhuleni Metropolitan Municipality

Human research ethics committee clearance certificates are attached in appendix 4.

2.7 Pilot study

A pilot study was conducted in Goba clinic, a clinic other than those sampled for the study before any data collection was carried out in the study sample. The pilot study helped to identify the strengths and weaknesses of the interview questions and corrections were made accordingly. It provided a trial to test the interviewers' ability to accurately use the tools and where they needed re-training before the actual exercise. The pilot study highlighted the need to assign each interviewer in a specific clinic for five days as opposed to original plan of placing the four of them in one clinic per day.

2.8 Data Processing and Data Analysis

The data was pre-coded and entered directly into Epi Info version 3.3.2. The variables were classified in a number of ways and defined as numeric, multiline, text, and date depending on the variable type. The data entry incorporated checks and automatic coding in order to enforce quality control by setting rules and conditions, for example the number of unsuccessful outcomes was equal to number of deaths and treatment interruptions, also the number of patients cured was less than the number of patients registered at the clinic. Before data analysis was conducted, the write and merge commands were used to clean up data table that contained undesired information for instance it was used to recode the values of clinics that were misspelled during the data entry. Missing values for each variable was checked through conducting frequency tables of variables and summarizing the variables, this specifically helped to correct missing values in sex and educational status. The data was analysed for frequencies and compared using tests for significance (Chi-square). Analysis of single table was conducted for odds ratio at 95% confidence limits Cornfield, Chi-square Yates correction was used as it was more appropriate for the study and its associated pvalue gave a statistically significant difference between the two variables measured if p-value < 0.05. Treatment outcomes for the two patients groups were, compared against treatment outcomes at the end of six months to determine any statistical significance.

3. Results

Introduction

The results are described in this chapter using tables, figures and in narrative form. This chapter has been sub divided into three sections highlighting responses from TB patients, treatment supporters and clinic staff. It presents the results on treatment outcomes, experiences and knowledge about TB treatment, method of accessing treatment and problems experienced in treatment, role and usefulness of treatment supporters and ways of improving treatment support.

3.1 TB patients

3.1.1 Response rate

There were 222 patients sampled, 216 patients were interviewed and six refused to participate. The response rate was thus 97%. Four patients who refused to participate had no supporters and four of these had interrupted their treatment. Three were registered at Reiger Park clinic as shown in Table 2.

Age in years	Gender	Clinic	Treatment Supporter	Treatment Outcome
19	Female	Vosloorus Poly	Yes	Completed
24	Male	Penduka	No	Interrupted
26	Male	Reiger Park	No	Interrupted
31	Male	Phola Park	No	Cured
33	Female	Reiger Park	Yes	interrupted
34	Male	Reiger Park	No	Interrupted

 Table 2: Characteristics and treatment outcomes of pts who refused to be interviewed

 Age in users
 Characteristics and treatment outcomes of pts who refused to be interviewed

3.1.2 Number of patients per interviewer

The number of patients interviewed by each of the four interviewers were 72 (33%), 58 (27%), 49 (23%) and 37 (17%) respectively.

3.1.3 Patient characteristics

Gender

Table 3 illustrates the number and proportion of patients with and without treatment supporters by gender. There were more males than females (56% and 44% respectively). The proportion of male and female was similar for patients with and without supporters.

Table 3:	able 3: Gender distribution of patients			
Gender	Patients with supporter Patients without supporter Total N (%)			
	N (%)	N (%)		
Male	65 (54%)	56 (46%)	121 (56%)	
Female	50 (53%)	45 (47%)	95 (44%)	
Total	115 (53%)	101 (47%)	216 (100)	

Age

Most patients (65%) were between 30 and 64 years of age as shown in Table 4. The mean age of the patient respondents was 34.4 years (S.D=10.6) with a range of 18-66 years, a median of 32 years and a mode of 31 years.

Age category in years	Patients N (%)
18-29	8 (4%)
30-49	141 (65%)
50-64	57 (22%)
65+	10 (7%)
Total	216 (100%)

Table 4: Age distribution

Patients living with someone or living alone

Patients were categorised as living alone (single, divorced, widowed or separated) or living with someone (married, staying with partner, relative or friend). There was no significant association between supported and unsupported patients and whether they lived alone or not (OR=0.64, X^2 =0.89, p=0.34). The results are shown in table 5.

Living status	With supporter n (%) Without		Total (n)
		supporter n (%)	
Living with someone	95 (52%)	89 (48%)	184 (85%)
Living alone	20 (63%)	12 (37%)	32 (15%)
Total	115 (53%)	101 (47%)	216 (100%)

Table 5:Patient living with someone or living alone

3.1.4 Patient numbers per clinic

The least number 14 (12%) of supported patients were in Phola Park and the greatest 25 (22%) in Vosloorus clinic. There was a greater proportion of unsupported patients in three clinics namely Reiger Park 34 (34%), Penduka 29 (29%) and Phola Park 19 (19%), while in Germiston, Moleleki and Vosloorus the proportion who had supporters was greater as illustrated in Table 6 below.

Name of clinic	With supporter n (%)	No Treatment supporter n (%)	Total n (%)
Phola Park	14 (42%)	19 (58%)	33 (15%)
Reiger Park	16 (32%)	34 (68%)	50 (23%)
Penduka	19 (40%)	29 (60%)	48 (22%)
Germiston	20 (83%)	4 (17%)	24 (11%)
Moleleki	21 (68%)	10 (32%)	31 (15%)
Vosloorus	25 (83%)	5 (17%)	30 (14%)
Total	115 (53%)	101 (47%)	216 (100%)

 Table 6:
 Number of patients per clinic

3.1.5 Types of TB

Table 7 shows the distribution of patients by each type of TB. The majority of patients (187 or 87%) had pulmonary TB. A higher proportion (59%) with miliary and meningitis TB were without supporters.

Type of TB	Supporter n (%)	No supporter n (%)	Total (n)
Pulmonary TB	102 (54%)	85 (46%)	187 (87%)
Miliary and Meningitis TB	11 (41%)	16 (59%)	27 (12%)
TB bone	2 (100%)	0 (0%)	2 (1%)
Total	115 (53%)	101 (47%)	216 (100%)

3.1.6 Patient Knowledge and experiences

Duration of TB treatment

Most patients (129 or 69%) with pulmonary TB had correct knowledge of their treatment duration, but 58 (31%) did not; 12 patients stated duration less than six months and 46 patients said more than six months. A chi square test showed a significant association between patients who stated six months duration of treatment and being supported (OR=2.17, X^2 =5.13, p=0.02). Details are displayed in table 8.

Table 8:TB treatment duration takes six months

	Knowledge about	Knowledge about duration of treatment		
	Correct	Incorrect		
Supporter	78 (60%)	24 (41%)	102 (54%)	
No supporter	51 (40%)	34 (59%)	85 (46%)	
Total	129 (69%)	58 (31%)	187 (100%)	

A total of 19 patients (70% of 27) with miliary and meningeal TB correctly stated 9-12 months. Correct knowledge of those with non-pulmonary TB was significantly associated with having a supporter (OR=0.32, X²=8.58, p=0.0034).

Knowledge about treatment duration at different clinics

Fifty-eight patients (31% of all) stated incorrect duration periods for their treatment. The two clinics in the Boksburg Service Delivery Centre had the highest number of patients with correct knowledge of six months treatment duration 52 (40% of 129) according to table 9 while Phola Park clinic had the highest proportion of patients who stated the incorrect duration – more of less than six month (16 patients or 28% of 58). Table 8 illustrates the results.

 Table 9: Knowledge of treatment duration of patients with pulmonary according to clinic in service delivery centres

Clinic	< 6 months n (%)	6 months n (%)	6+ months n (%)	Total N (%)
Germiston*	1 (7% of 12)	11 (73% of 129)	3 (20% of 46)	15 (8% of 187)
Moleleki*	0 (0%)	26 (84% of 129)	5 (16% of 46)	31 (16% of 187)
Penduka**	2 (5% of 12)	31 (76% of 129)	8 (19% of 46)	41 (22% of 187)
Phola Park**	4 (16% of 12)	9 (36% of 129)	12 (48% of 46)	25 (13% of 187)
Vosloorus***	3 (10% of 12)	21 (72% of 129)	5 (17% of 46)	29 (16% of 187)
Reigerpark ** *	2 (4% of 12)	31 (67% of 129)	13 (28% of 46)	46 (25% of 187)
Total	12 (6% of 187)	129 (69% of	46 (25% of 187)	187 (100%)
		187)		

* Germiston Service delivery centre

* *Alberton Service delivery centre

* * * Boksburg Service delivery centre

Highest level of education achieved

Out of the two hundred and sixteen patients interviewed, 9 (4%) had no formal schooling, 54 (25%) had reached primary level, 141 (65%) patients had attained secondary level of education and 12 (6%) had studied up to tertiary level. Education and the knowledge of duration are shown in Table 10. A chi square test showed that patients knowledge of treatment duration did not associate with non-formal education (p=0.067). The proportion of patients with correct knowledge clearly increases with increasing education categories. There was a significant association between patients with tertiary and secondary education with their knowledge of TB treatment duration (p=0.02).

Level of education	Correct duration	Incorrect duration	Total n (%)
	n (%)	n (%)	
Non-formal education	3 (33 of 9%)	6 (67% of 9)	9 (2%)
Primary education	41 (76% of 54)	13 (24% of 54)	54 (25%)
Secondary education	99 (70% of 141)	42 (30% of 141)	141 (67%)
Tertiary education	11 (92% of 12)	1 (8% of 12)	12 (6%)
Total	154 (72% of 216)	62 (28% of 216)	216 (100%)

 Table 10:
 Educational level and knowledge of treatment duration

Problems faced by patients in TB treatment

Problems experienced in TB treatment as stated by patients can be seen in table 11. The results showed that 47% of 556 responses to this question stated that they were experiencing symptoms. A higher proportion of patients without supporters were unemployed, otherwise there was no difference in stated problems as categorised between supported and unsupported patients.

Stated problems	Patients with supporters			Patients without supporters		Total responses	
	Ν	%	N	%	Ν	%	
Experienced symptoms	151	48	111	46	262	47	
Lack of food	37	12	36	15	73	13	
Unemployment	28	9	40	17	68	12	
Lack of transport to clinic	27	9	17	7	44	8	
Poor family attitudes	29	9	11	5	40	7	
Poor community attitudes	20	6	10	4	30	6	
Need to take time off work to attend clinics	14	4	12	5	26	5	
Bad clinic staff attitudes	8	3	5	1	13	2	
Total responses	314	100	242	100	556*	100	

Table 11: Problems stated by patients in taking TB treatment

* Some patients gave more than one answer

3.1.7 Type of treatment supporter and frequency of supporter contact

Table 12 shows the type of supporter and frequency of visits. Of those patients who were supported, a total of 78 of 115 (68%) of patients had community supporters while 37 (32%) patients had clinic nurses. The frequency of patients' daily contacts with the clinic staff was higher than with the community treatment supporters (86% versus 76%). The proportion of patients who were observed on daily basis was 79%.

Type of	Frequenc	Frequency of visits*				
supporter	Daily	2-3 times a week	Weekly	2 times a month	Monthly	patients N (%)
Clinic nurse N (%)	32 (87%)	0 (0%)	3 (8%)	1 (3%)	1 (3%)	37 (32%)
Community Supporter	59 (76%)	4 (5%)	9 (12%)	4 (5%)	2 (2%)	78 (68%)
Total	91 (79%)	4 (4%)	12 (10%)	5 (4%)	3 (3%)	115 (100%)

Table 12:Type of supporter and frequency of visits

* visits mean the number of contacts patients had with their supporters

• Number of patients per supporter

The mean number of patients supported by one treatment supporter was 9.7 (SD=3.5) with a range of 5-20, a median and mode of 10. Three supporters had 10 or more patients and 27 had fewer than 10 patients.

Treatment access for patients with supporters

Most supported patients 73 (63% of 115) collected their own TB treatment from clinics, supporter visited 59 (51% of 115) of them at home and 14 (12% of 115) patients were going themselves to the supporter. Forty-two (37% of 115) patients had their medication collected by supporters, who visited 16 (14% of 115) at home and 27 (23% of 115) went themselves to the supporter.

3.1.8 Role of Treatment Supporters

Patients' responses on the role of treatment supporters were grouped in three categories as shown in Table 13 below. Medication and counselling included roles such as checking on patients' treatment, giving medicine, reminding patients about clinic days, counselling and advising patients on medication. Coordination, monitoring and reporting comprised the following roles; asking about patients' progress, attending meetings and giving reports to clinics. Practical help covered relocating patients, accompanying patients to clinic, food preparation and washing of weak patients.

Category of roles	Respondents per answer N (%)
Medication and counselling	93 (57%)
Coordination, monitoring and Reporting	65 (40%)
Practical help	4 (3%)
Total responses	162 (100%)

Table 13: Role of treatment supporters

* Some patients gave more than one answer

3.1.9 Usefulness of treatment supporters

Supported patients were asked whether they found their treatment supporters useful in helping them in TB treatment. One hundred and three of the 110 patients that answered this question (94%) patients agreed that treatment supporters were useful while seven (6%) disagreed for the following reasons: the supporters failed to talk to family members of three patients to change their poor attitude towards them, two said they did not need the services of a supporter, one indicated that the treatment supporter forced him with medicine and

another one said that the supporter was bothersome. Five patients refused to answer this question.

3.1.10 Visits between patients and supporter

Patients stated that patients and supporters interacted specifically for treatment support. However, 45 (39%) patients indicated that they visited their supporters at other times. In these visits, they had discussions on ways of accessing government social grants, education of their children, how TB had affected business activities, the role of church in helping the patients and relocation to a rural area.

Table 14: Summary of variables compared for supported and non supported patients

Variable category	P value of association
Tertiary and secondary education vs knowledge of	0.02*
treatment duration	
Knowledge about treatment duration	0.02*
Knowledge about treatment duration vs non-formal	0.067
education	
Patients living with someone vs living alone	0.34

*Statistically significant in X² test comparing variables with supported and unsupported patients

3.1.11 Treatment outcomes

• Treatment outcome by supporter and no supporter

Treatment outcomes of all patients are shown in Table 15.

Patient		Treatment outcomes n (%)					
category	Cured	Treatment completed	Transfer	Interrupt.	Treat. failure	Deaths	N (%)
With supporter	59 (51%)	22 (20%)	12 (10%)	8 (7%)	8 (7%)	6 (5%)	115 (53%)
Without supporter	36 (36%)	15 (15%)	14 (14%)	13 (13%)	12 (12%)	11 (10%)	101 (47%)
Total	95 (44%)	37 (17%)	26 (12%)	21 (10%)	20 (9%)	17 (8%)	216 (100%)

Table 15: TB Treatment outcomes

Treatment outcome success was obtained from combining the cured and completed outcomes categories. Significantly more successful outcomes were measured in patients who were supported (OR=2.34, X² = 8.18, p =0.0042).

It was found that even when the 26 transfers were excluded, patients who were supported were more likely to achieve successful treatment outcomes (OR=2.60, X² = 7.99, p =0.0047),

and when transfers and deaths were excluded the same association remained (OR=2.48, X^2 = 5.46, p =0.019).

Treatment outcomes were compared for patients of different age groups and genders, patients living with someone or living alone, with correct knowledge about treatment duration, patients for whom supporters collected their treatment from clinics rather than collecting it themselves, their educational status and whether they had clinic or community supporters. Patients who had died 17 (8%) by the time of the interviews were included.

A total of 26 (12%), transferred to clinics outside the study region, 12 of whom were supported and 14 were not. The treatment outcomes of these patients were therefore indeterminable and were thus excluded from further analysis.

• Number of patients per supporter

Treatment supporters with fewer than ten patients were more likely to achieve successful treatment outcomes than those who had more than ten patients (OR=6.99, X^2 =13.69, p =0.00022). Table 16 compares outcomes of supporters with 10 or more patients.

Patients per supporter	Successful outcomes n (%)	Unsuccessful outcomes n (%)	Total N
<10	62 (90%)	7 (10%)	69 (67%)
10+	19 (56%)	15 (44%)	34 (33%)
Total	81 (79%)	22 (21%)	*103 (100%)

Table 16: Supporters with 10+ or <10 patients

* 12 of the 115 patients were excluded as explained above

• Patients living with someone or living alone

Table 17 shows treatment outcomes for patients living with someone. It was found that patients living with someone were more likely to achieve treatment success than patients living alone (OR=5.68, X² = 18.8, p =0.000015).

Living status	Successful outcomes	Total (n)	
Living with someone	120 (76%)	37 (24%)	157 (83%)
Living alone	12 (36%)	21 (64%)	33 (17%)
Total	132 (70%)	58 (30%)	190 (100%)

 Table 17:
 Outcomes of patients living with someone or living alone

* Excludes 26 patients as explained above

• Supporter fetching medicine from clinics for patients

The treatment outcomes was more likely to be successful if the treatment supporters fetched medicine for patients from clinics than when patients collected own treatment from the clinics (OR=4.16, $X^2 = 7.2$, p =0.0073). This data is shown in table 18.

Treatment outcomes	Successful outcomes n (%)	Unsuccessful outcomes n (%)	Total N (%)
Supporter fetches	57 (88%)	8 (12%)	65 (63%)
Patient fetches	24 (63%)	14 (37%)	38 (37%)
Total	81 (79%)	22 (21%)	103 (100%)

Table 18: Supporter collecting patients' treatment from clinics

• Type of supporter

Table 19 shows the data for treatment outcomes of patients supported by clinic staff and community supporters. Successful outcomes and the type of supporter (clinic or community) were not associated (OR=0.42, $X^2 = 2.36$, p =0.12).

Type of supporter	Successful	Unsuccessful	Number of
	outcomes	outcomes	patients n (%)
Clinic nurse n (%)	24 (68%)	11 (32%)	35 (34%)
Community supporter n (%)	57 (84%)	11 (16%)	68 (66%)
Total	81 (79%)	22 (21%)	103 (100%)

 Table 19:
 Clinic staff and community supporters' outcomes

• Educational status and outcomes

There was a significant association between successful treatment outcomes and higher educational status. Comparisons were for secondary and tertiary education compared with non-formal and primary education (OR=0.26, $X^2 = 13.74$, p =0.00021). There was no association between successful treatment outcomes and non-formal education compared with all other education levels (OR=0.12, $X^2 = 2.41$, p =0.067). Educational status and outcomes are shown in table 20.

Level of education	Successful outcomes n (%)	Unsuccessful outcomes n (%)	Patients n (%)
Non-formal and primary	22 (47%)	25 (53%)	47 (25%)
Secondary and tertiary	110 (77%)	33 (23%)	143 (75%)
Total	132 (70%)	58 (30%)	190 (100%)

 Table 20:
 Educational status and treatment outcomes

Gender

In Table 21 are the treatment outcomes by gender showing that males were more likely to achieve successful treatment than females (OR=3.22, X² = 11.97, p =0.00054).

	1. Treatment outcomes by gender		
Gender	Successful outcomes	Unsuccessful treatment outcomes	Total N (%)
	N (%)	N (%)	
Male	83 (81%)	20 (19%)	103 (54%)
Female	49 (56%)	38 (44%)	87 (46%)
Total	132 (70%)	58 (30%)	190 (100)

 Table 21:
 Treatment outcomes by gender

• Age

Patients of 40 year of age and more were more likely to have successful treatment outcomes than patients under 40 years of age (OR=5.11, $X^2 = 23.15$, p =0.000015) as shown in table 22. No significant differences were found for patients 30 years of age and more or less than 30 years (OR=0.85, $X^2 = 0.06$, p =0.81), patients age category 50 years and above or less than 50 years (OR=0.99, $X^2 = 0.02$, p =0.89) and for patients age less than 60 years or 60 years and above (OR=2.22, $X^2 = 1.73$, p =0.15).

 Table 22:
 Treatment outcome by age 40+ or <40 years</th>

Age in years	Successful outcomes N (%)	Unsuccessful treatment outcomes N (%)	Patients N (%)
40+	92 (84%)	18 (16%)	110 (58%)
<40	40 (50%)	40 (50%)	80 (42%)
Total	132 (70%)	58 (30%)	190 (100%)

Duration of TB treatment and treatment outcomes

The outcomes of patients who stated the correct duration of their TB treatment were compared with those who were incorrect as shown in table 23.

Those who were correct were more likely to have successful treatment outcomes (OR=4.34, $X^2 = 18.28$, p =0.00002).

Table 23:TB treatment duration correct or incorrect

Treatment	Successful outcomes N	Unsuccessful treatment	Patients N
duration	(%)	outcomes N (%)	(%)
Correct	102 (79%)	27 (21%)	129 (69%)
Incorrect	27 (47%)	31 (53%)	58 (31%)
Total	129 (69%)	58 (31%)	187 (100%)

Variable category	P value of association
Supported vs non supported patients (all patients)	0.0042*
Supported vs non supported excluding transfers	0.0047*
Supported vs non supported excluding transfers and deaths	0.019*
Supporters with <10 vs 10+ patients	0.00022*
Age 40+ vs other age categories	0.000015*
Gender (Males vs females)	0.0005*
Tertiary and secondary education vs other educational	0.00021*
levels	
Patients living with someone vs living alone	0.000015*
Supporter fetches treatment vs patient fetches treatment	0.0073*
Correct knowledge about treatment duration	0.00002*
Age 30+ vs other age categories	0.81
Age 50+ vs other age categories	0.89
Age 60+ vs other age categories	0.15
Non-formal vs other education levels	0.067
Clinic vs community supporter	0.12

 Table 24:
 Summary of relationship of defined variables and treatment outcomes

*Statistically significant in X² test comparing variables with treatment outcomes

3.2. Treatment supporters

3.2.1 The response rate

There were a total of 30 supporters for the 115 patients who were supported. All were interviewed 100% response rate). Three interviewers interviewed eight treatment supporters each and one interviewed six.

3.2.2 Characteristics of treatment supporters

Gender

A higher proportion 26 (87%) treatment supporters were females while only 4 (13%) were males.

Age

The mean age of the treatment supporters interviewed was 40.7 years (S.D=12.9) with a range of 26-77 years, a median of 38.5 years and a mode of 28 years. The age distribution is shown in Table 25.

Age range in years	Treatment supporte	
	Frequency=n	Percentage (%)
18-29	5	17
30-49	19	35
50-64	3	7
65+	2	7
Total	29	100

Table 25: Distribution of Treatment Supporters by age

3.2.3 Knowledge and experiences of treatment supporters

Knowledge about duration of TB treatment

Most treatment supporters 26 of the 30 (87%) said that TB treatment for pulmonary TB should take six months while the four (13%) said more than six months. A total of 18 (67% of 26) patients supported by supporters with incorrect knowledge did not give the correct duration of TB treatment.

• Difficulties faced by supporters in their work

The treatment supporters had faced difficulties in assisting patients in matters relating to medication and food. Details are in Table 26.

Difficulties in treatment support	Number of supporters n (%)
Medication and food	50 (53%)
Patients complain of no food, side effects of drugs,	
TB treatment time consuming	
Relationship and communication	22 (23%)
No cooperation from patients, patient not at home,	
do not attend at supporters home, alcohol and	
substance abuse	
Myths and stigma	15 (16%)
Myths about TB in community and stigma of TB in	
community	
Other problems	7 (8%)
Patient with no permanent homes, no identity books	
Total Supporter Responses	94 (100%)*

Table 26: The difficulties faced by supporters in assisting TB patients

*Some supporters gave more than one answer

3.2.4. Duration of home visits

Treatment supporters were asked how long it took them to attend to patients during the home visits. Fifteen (50%) stated that it took them less than 30 minutes to attend to one patient, seven (23%) 30-60 minutes, two (7%) 1-2 hours and six (20%) said that it depended on the condition of the patient and ranged between two and three hours.

3.2.5 Meetings between supporters and clinic staff

Twenty eight treatment supporters said they had meetings with clinic TB staff, once a month for 22, every two weeks for 1 and weekly for 5. Two did not go to the meetings.

3.2.6 Patient problems

Patients' problems as stated by the treatment supporters were similar to those stated by the patients themselves.

3.2.7 Role of Treatment Supporters

Medication and counselling of patients came out as the major role that treatment supporters perceived for themselves. This is presented in Table 27.

Category of supporter roles	Total N (%)
Medication and counselling	68 (54%)
Educate/talk/counsel patients about taking medicine, watch them take pills,	
encourage patients	
Practical help	40 (32%)
Take food to patients, cleaning of patient houses, wash bed ridden	
Coordination, monitoring and Reporting	17 (14%)
Write/tick on card when pills taken, assist in application for government	
social grants	
Total responses	*125 (100%)

*Some supporters gave more than one answer

3.2.8 Suggestions on how the role of treatment could be improved

Treatment supporters suggested ways their role could be improved; incentives, more training

and extra resources are mostly listed. These are listed in Table 28.

Suggestion of supporters	Treatment Supporters N (%)
Incentives	
Increase pay, stipend payment in time	26 (24%)
More training	24 (22%)
Extra resources e.g. kits, badges	21 (20%)
Patient care Provide transport to clinic for bedridden patients Provide food to patients	19 (18%)
Recognition	
Appreciation from clinic staff, recognition from government	14 (13%)
Other*	3 (3%)
Total Responses	**107 (100%)

Table 28: Supporter suggestions for improving their roles

* Open clinics nearer to communities, employ more nurses, patients choice for supporters.

** Some supporters gave more than one answer

3.3. Clinic staff

3.3.1 Response rate

The staff responsible for TB in all the six clinics were interviewed.

3.3.2 Position of staff

There was a professional nurse at each of the three clinics Germiston, Reiger Park and Penduka clinics, a nursing assistant at each of Moleleki and Phola Park clinic and a primary health care nurse at Vosloorus Poly Clinic.

3.3.3 Training of supporters

The clinic staff indicated that all treatment supporters had been educated on the duration of TB treatment in courses run over 69 days by the Department of Health.

3.3.4 Clinic policies

Staff asked about clinic attendance policies said that all patients were advised to attend their clinics/supporters on daily, twice a week or weekly basis depending on the phase of treatment. Patients too sick to attend had their medication collected by treatment supporters.

3.3.5 Problems of patients as stated by clinic staff

Clinic nurses said that TB patients were faced by social, economic, cultural and clinical problems, specifically lack of food, side effects of TB drugs, unemployment, lack of transport, having to take time off work. They felt problems could be overcome with home visits, observed tablet swallowing, and clinic attendance, a full course of treatment, advice and counselling of patients.

3.3.6 Role of Treatment Supporters

Nurses said that treatment supporters were responsible for advising and counselling of patients, they conducted door to door visits, traced newly diagnosed patients, referred patients to clinic, collected pills and gave patients, monitored swallowing of pills, checked on treatment interrupters, gave report of treatment support to the clinic, helped weak patients in household chores, educated community to bring TB suspects and helped in TB campaigns.

3.3.7 Improving the role of treatment supporters

Nurses suggested that supporters needed to be encouraged in meetings, given incentives, re-trained, paid promptly on stipends and recognised in the health structure by government.

3.3.8 Usefulness of treatment supporters

All the clinics nurses interviewed said that treatment supporters were very useful to TB patients in the community. When asked to state the reason for their answer, they stated that the health system relied on treatment supporters' work since they were strategically positioned in the communities where the patients lived. The activities conducted by supporters were outlined by clinic nurses as; helping very sick, weak and old patients, conducting referrals, giving feedback on home visits, educating community on TB and helping in tracing treatment interrupters.

3.3.9 Meetings between treatment supporters and the clinic staff

Three clinics had meetings with supporters on a monthly basis and two were meeting once a week while one had suspended all the supporter meetings after they demanded for their stipends two months ago.

3.3.10. Suggested other ways in which TB treatment could be improved

Clinic nurses suggested that patients should be advised to stop drinking alcohol and smoking, increase the number of nurses in the clinics, hold TB awareness campaigns in hostels and taxi ranks, use technology to remind patients, debrief the staff and treatment supporters and educate patients on TB treatment.

3.4. Study limitations

A descriptive research design was used in this study. This imposed several limitations that could have influenced the data collected and the conclusions reached. These include the following;

- The study assumed that a treatment supporter was present for the entire course of treatment. It did not take into account situations whereby a supporter could have been absent.
- Interview data relied on what people said. The reliability of patient interview data would have been influenced by their ability to recall their experiences; some patients may have had poor memories and may not have given complete and/or accurate information.
- Clinics were chosen from within each Service delivery centre using systematic sampling with a random starting point weighting of the clinics within each SDC according to TB patient case load, this strategy has potentially biased the samples in favour of patient outcomes in the SDCs with smaller caseloads. The ordering of the

clinics from which they were selected can dramatically affect the outcomes since only two were identified from each SDC.

4 Discussion

This section discusses the major findings of the study in three main categories namely, the influence of treatment supporters on patients' treatment outcomes, role of treatment supporters, factors associated and not associated with success treatment outcomes.

4.1 The influence of treatment supporters on patients' treatment outcomes

The results showed that there were more successful treatment outcomes in patients who had supporters. Further there was stated patients' satisfaction on the role of treatment supporters. This was in line with several other studies. One conducted in South Africa found improved outcomes from DOT using lay health workers (25). A randomized controlled trial of community health workers versus family members in Swaziland yielded the similar results that the treatment supporters could improve treatment outcomes of TB patients (26). A Thai study found DOT to be effective while adapting the model of DOT by family members, supported by a once weekly home visit from health worker (27).

It was observed that the treatment success rates (71% for patients with supporters and 51% for those without) were lower than the WHO targets of 85% cure for new smear positive patients. In addition these were success rates (cure and completed), so were considerably below the global target (28). There is a need to emphasize the use of treatment supporters in TB treatment and motivate them so that WHO targets may be reached in future. There were 26 patients transferred elsewhere, supporters could have a role in either preventing these or in ensuring that transferred patients did attend another clinic.

It is acknowledged that there could have been factors other than treatment supporters presence that could have influenced the treatment outcomes such as extent of TB and drug resistance. Although data on these variables were not collected, there is potential influence of these factors on treatment outcome. The results may have been influenced sampling strategy that had potential bias since the probability of a patient being picked was not equal in each of the Service Delivery Centre.

4.2 Role of treatment supporters

Treatment supporters and clinic staff opinions

A total of 78 (68% of all supported) patients were observed by community supporters while 37 (32%) patients were observed by clinic nurses. There was no significant association in treatment outcomes of the two patient supporters meaning that community supporters were as effective as clinic nurses. It does not however address the issue of whether attending clinics was as convenient for patients. Treatment supporters stated their role in three categories; medication and counselling of patients, practical help and coordination. The clinic nurses stated that the health system relied on treatment supporters' work since they were strategically positioned in the communities where the patients lived. The clinic staff are considerably assisted by supporters carrying out tasks of conducting door to door visits, tracing newly diagnosed patients, checking on treatment interrupters and helping weak patients in household chores.

The role of treatment supporters was found in this study to be far more than just observation of treatment but included emotional support and motivation of patients, negotiation with families, education of communities and financial/material support of patients. Clinic staff and treatment supporters described the role as active finding of TB suspects/ case detection, supervision of treatment at the patient household, assisting in collection of medicine, tracing of interrupters and conducting home visits. Treatment supporters in Thailand were found to be effective in increasing adherence to treatment (27).

Patients' opinions

There was a demonstration of patients' satisfaction of treatment supporters' role. Medication and counselling of patients came out as the major role of treatment supporters. They assisted the patients with TB to take their medication as prescribed. The supporters watched patients take their medication and recorded the dose taken on a card and encouraged them on TB treatment. Some patients were supported in medicine collection, washing and food preparation. The supporters provided adequate counselling, easy access to treatment especially to the weak patients while receiving ongoing support of the clinic staff. However, some patients were dissatisfied mainly because treatment supporters failed to talk to family members of patients to change their negative attitudes and these patients also felt that supporters were forcing them with medication.

4.3 Factors associated and not associated with success treatment outcomes.

Treatment supporters who had less than 10 patients registered a higher treatment success rate 77% as compared to treatment supporters who had more than 10 patients. It is possible that these treatment supporters had a manageable number of patients and hence had higher success rate than those who had more than ten patients. A recommendation is made for further studies to determine the optimum number of patients a treatment supporter should have to obtain higher success rate.

Patients of aged 40 years and above were more likely to have successful treatment outcomes than patients of aged less than 40 years. The reason could be that there were more supported patients in age 40 years and above than in other age categories who achieved treatment success. Treatment support could be emphasized in age groups less than 30 years, more than 50 years and in the older category more than 60 years who were less likely to achieve treatment success.

It was found that males were more likely to achieve successful treatment outcomes than females. This was evidenced by the number of supported male patients which was higher than their female counterparts. There was gender disparity in distribution of treatment supporters and this should be corrected in future TB programs.

Patients living with someone were more likely to achieve treatment success, because it is likely the patients were also reminded to take their medication by their partners and to go to the clinic. The treatment supporters may have emphasized their support through the patient's partner.

The proportion of patients with correct knowledge clearly increased with increasing education categories. Tertiary and secondary education levels significantly associated with patients' knowledge of treatment duration. Patients who had tertiary and secondary education had also significantly achieved successful treatment outcomes. Educational exposure may have contributed to comparatively favourable results in this study.

Knowledge about duration of treatment

The currently recommended treatment of new pulmonary TB is a drug combination that must be taken for six months. Adults with pulmonary tuberculosis are treated with a 6-month regimen consisting of daily isoniazid, rifampicin, ethambutol and pyrazinamide for the first 2 months, followed by isoniazid and rifampicin for 4 months (29).

There was a significant association between correct knowledge of patients about treatment duration and being supported. It is likely that the supporters were educating their patients on duration of treatment. In this study more than 72% of patients and 87% of treatment supporters stated six months duration for TB treatment. However, it was surprising 13% of treatment supporters did not know the correct duration of treatment of TB, yet the clinic staff stated that all supporters had been educated on the duration of TB treatment in courses run over 69 days by the Department of Health. A large proportion (67%) of patients supported by these supporters did not give the correct duration of TB. It is important that the clinic staff know this and correct it, provide updates and ongoing training for supporters.

Several studies have been conducted on patients' knowledge about TB treatment duration. According to Peltzer, the patients must possess some minimum level of health knowledge and motivation for them to fully understand the treatment regimen, how to take their drugs, and the reasons for the long duration of TB treatment (30). Studies in India, Swaziland, Thailand and Zambia indicated that poor knowledge about the length of treatment predicts interruption behavior and identified that lack of knowledge was a limitation to patients' completion of full course of treatment (31).

Type of support

Treatment supporters played an important role in ensuring that medicines collected from clinics on behalf of patients were taken as prescribed. This was evidenced by the successful outcomes of the patients who had their pills collected by treatment supporters compared to those who collected on their own from the clinics, even though the frequency of patients' daily contacts with the clinic staff was higher than with the community treatment supporters. Supporters should balance their time for patients who fetch medicine on their own from clinics to achieve better outcomes, the study showed that the frequency of patients' daily contacts with the clinic staff was higher than with the community treatment supporters. The study revealed that treatment support was not daily for all patients; at the same time the clinic staff said that all patients were expected to attend their clinics/treatment supporters daily. There is need to emphasise daily support in the program for better treatment outcomes. The study found that about two thirds of patients who had interrupted treatment did not have treatment supporters. If all patients had treatment supporters treatment interruption would be prevented or minimised. However, treatment outcomes of patients of clinic nurses were no better than those of community supporters. This means that community supporters were as effective as clinic nurses in treatment support.

4.4 Patients stated problems

Cooperation and relationship between patients and supporters

There was dialogue between patients and treatment supporters; this was evidenced by patients' ability to discuss their problems with supporters. Some of these discussions resulted in patients receiving referral services or attended to by the clinic staff. Some patients were dissatisfied with the services rendered by treatment supporters as they highlighted unfriendly attitude of supporters while nurses cited poor relationships with treatment supporters/health care workers. Peltzer observed that lack of relationship and poor communication between patients and treatment supporters could influence patient treatment outcomes (30). These findings were in line with Frieden and Driver who examined issues of building human bond between patients and health care workers and treatment supporter (22). Cooperation of patients was viewed as an important factor in TB treatment, it was also the responsibility of the patient to decide everyday or week whether or not to take their medicine. In this study some treatment supporters expressed frustration when patient was not at home when they went to watch medication, this was because treatment was observed largely at patient's homes. This was in total contrast with the results of Dick et al who found that it was the patients who were getting frustrated when the treatment supporter was not at home (32). A possible solution to this problem could be when the patient and the supporter agreed on a specific place and time to administer the medication as Chadhaetal recommends (33).

Experienced symptoms

In this study about half of the patients said they experienced symptoms and side effects of drugs. This was equally prevalent in those with and without treatment supporters. The coordination role of treatment supporters came into play, when they referred such patients to clinics for treatment, gave treatment advice and counselled them.

4.5 Supporters stated problems

The TB program in some clinics suffered lack of incentives for supporters. Treatment supporters expressed a need for stipend increment, more training and extra resources as factors that would motivate them. The supporters even went on strike demanding for better terms of payment in one clinic. The government policy recognises community based health workers as volunteers who are paid stipends. The treatment supporters need to be re-

trained in various aspects of DOT support to work effectively. Incentives were observed as motivating factors to supporters in their role (11, 12).

5 Conclusion and recommendations

5.1 Conclusion

This study has highlighted the positive role of treatment supporters in influencing successful outcomes of treatment of TB patients. To achieve these outcomes, supporters must have promoted treatment outcomes. The treatment support seemed to focus on supervision of pills intake, tracing patients who had interrupted treatment, collection of medicine and treatment counselling. There was a demonstrated patients' satisfaction about supporters' role as they highlighted frequent visits of supporters, advice on treatment and practical help. The supporters gave patients support they required in a manner that was appropriate to their emotional and material needs. The treatment outcomes provided proof of usefulness of treatment supporters, as supported patients were more likely to have successful treatment outcomes than those without supporters.

5.2 Recommendations

Increase the number of supporters

Supporters who had many patients performed worse than those who had less. It is recommended that more/all patients should have treatment supporters as only 53% of the sample had supporters. Some supporters were supporting more than ten patients.

DOT support

DOT support was not daily as revealed by the study, the results would have been much better if supporters did it daily as required. By definition DOT is daily observed treatment. There is need to encourage treatment supporters to provide daily support.

Support for TB clinic staff and treatment supporters

The clinic staff proposed encouragements and debriefing sessions for treatment supporters and TB staff. It is recommended that the TB program should also ensure that treatment supporters and the TB nurses receive the necessary incentives, recognition and psycho social support since the work entailed handling patients in critical conditions including dying patients. They even sometimes attend funerals. This will help in addressing the burn out effect that usually results in caregivers, treatment supporters and counselors.

Dissemination of report

This report will be disseminated to The University of the Witwatersrand, Ekurhuleni Metropolitan Municipality, and submitted for publication with the help of my supervisor.

Findings will be shared with the School of Public Health, Ekurhuleni Metropolitan Municipality district health management and staff, research participants including clinic staff and coordinators. The findings will also be presented to Gauteng Health Department policy makers and to communities including the treatment supporters and patients.

Fixed Sample in selected clinics

Service	Clinics	No of adult TB patients	No of community		
Delivery		registered in April and May	treatment supporters		
Centre		2006	attached to clinic		
Germiston	Germiston	25	5		
S1	clinic				
	Moleleki	49	8		
Alberton	Phola park	32	4		
S2	clinic				
	Phenduka	28	5		
Boksburg	Vosloorus	46	4		
S3	Poly Clinic				
	Reiger Park	42	4		
	Clinic				
Total		222	30		

Note: These are new TB treatment patients

APPENDIX 2

QUESTIONNAIRE I					
TE	B TREATMENT				
PATIENTS INTI	ERVIEW QUESTIONS				
	SECTION A DEMOGRAPHICS				
1. Study number: P	s		PNS _		
2. Sex:	Male] F	emale	
3. Age (in years):					
4. Marital Status			Single Married Live with p Divorced Separated Other		
5. Educational level:	Highest	Grade		-	
6. Name of clinic attending:					
7. Date of registration in cli	nic (check in patient c	ard):			
8. Do you have a person wh	o holns/sunnorts voi	in TR treat	mont?		
o. Do you have a person wh	io neips/supports you	Yes		No	
9. What mode of transport o	to you use to get to th	ne clinic?			
			W	alk	
			Та	ixi	
			Tra	ain	
				cycle	
				wn car	
			Fa ca	imily r	
				eg a lift	
				her	
10. For how long should yo	u take TB treatment?				

11. How do you get your treatment?		
11.a) I go to clinic to fetch my pills	Daily	
	3 times a week	
	2 times a week	
	Weekly	
	every 2 weeks	
	every month	
	other	
11. b) Treatment supporter collects my pi	lls from clinic & brings to me a	t home
	Daily	
	3 times a week	
	2 times a week	
	Weekly	
	every 2 weeks	
	every month	
	other	
	3 times a week 2 times a week Weekly every 2 weeks every month other	
12. How do you take your pills?		
	No one watches	
	Clinic nurse watches	
	Treatment supporter	
	watches	
	Sometimes someone watches	
	Someone watches (say who)	

Г

	Taking time off work	
	Being unemployed	
	Family attitude bad	
	Community attitude bad	
	l feel sick	
	Side effects of drugs	
	No one to collect medicine for me	
	Transport to clinic	
	lack of food	
	Clinic staff attitude	
	Other (specify)	
Write respons		
write respons		

	SECTION B			
	PATIENTS WITH TREATM	IENT SUP	PORTERS	
4. What is your relatio	nship with the supporter?		Neighbor	
			colleague	
			family member	
			no relationship	
			Church member	
			Other	
5. Do treatment suppo	rters ever accompany you t	to the clini	c to fetch pills?	
	Yes		No	
6. What does the treat	ment supporter do for you?			
	Ask about my pro	gress		
	Give medicine	ala dava		
	Remind me on cli	•		
	check if took med Counsel and advi			
		se me om		
	Others (specify)			
7. Do you ever go to tr	eatment supporter's home			
		Yes	No	
If ves how ofter) do vou ao to treatment su	nnorter's	home for heln?	
If yes, how ofter	n do you go to treatment su	pporter's		
lf yes, how ofter	າ do you go to treatment su	pporter's	Daily	
lf yes, how ofter	n do you go to treatment su	pporter's	Daily every 2nd day	
lf yes, how ofter	n do you go to treatment su	pporter's	Daily every 2nd day every 3rd day	
lf yes, how ofter	n do you go to treatment su	pporter's	Daily every 2nd day every 3rd day every 4th day	
lf yes, how ofter	n do you go to treatment su	pporter's	Daily every 2nd day every 3rd day	
lf yes, how ofter	n do you go to treatment su	pporter's	Daily every 2nd day every 3rd day every 4th day every 5th day	
lf yes, how ofter	n do you go to treatment su	pporter's	Daily every 2nd day every 3rd day every 4th day every 5th day Once a week	
lf yes, how ofter	n do you go to treatment su	pporter's	Daily every 2nd day every 3rd day every 4th day every 5th day Once a week once in 2 weeks	
lf yes, how ofter	n do you go to treatment su	pporter's	Daily every 2nd day every 3rd day every 4th day every 5th day Once a week once in 2 weeks once in 3 weeks	

	lf yes, Explain why		
	If No, state why		
). What do y ou have?	you think your tre	eatment supporter could do to help with any proble	ems
		Bring medicine to me	
		Convenient for me to fetch medicine from him/her	
		Talk/counsel/encourage me	
		Give me food	
		Tell me when to go to the clinic	
		Talk to my family I don't know	
		Other (specify)	
W	/rite responses h	ere	
S=Patient w NS=Patient Ipporter	vith supporter without		

QUESTIONNAIRE II

TB TREAT	MENT				FORM CPS
TREATMENT SUPPO					
DEMOGRAPHICS					
1. Study number:				CPS	
2. Sex:	Male			Female	
3. Age (in years):			-		
4. Marital Status			Single Married Live with p Divorced Separated Other		
5. Educational level:	Highest	Grade	-	-	
6. Name of clinic attached to:					
7. Number of patients under y	our care:		-		
8. a. Where do you see your T	B patients fo	r treatment	supporters Clinic their home my home Work Other		
 b. How do you support you I go to the clinic with them to fet I go to the clinic myself to collect homes I go to the clinic myself to collect 	ch medicine t medicine an	-			

c. For selected category in 8a, How often do you see them?

Daily	
every 2nd day	
every 3 rd day	
every 4 th day	
every 5 th day	
Once a week	
once in 2 weeks	
once in 3 weeks	
once in 4 weeks	
Other (specify)	_

r	
L	

d. If you visit patients at home, how long does it take you to do the support job?

Is the hom	ne visit time the same for all your T <u>B patients</u> ?	
	Yes No	
9. What do you do f	or the patients you are supporting?	
	Watch them take medication	
	Encourage them	
	write/tick on card when medicine taken	
	educate/talk/counsel them about taking TB medicine	
	Take food	
	other	
10. What problems	do patients tell you about, relating to the TB treatmen	t?
	Taking time off work	
	Being unemployed	
	Family attitude bad	
	Community attitude bad	
	I feel sick	
	Side effects of drugs	
	No one to collect medicine for me	
	Transport to clinic	
	lack of food	
	Clinic staff attitude	
	Other (specify)	

11.	What are the pro	blems you are	e facing in	assisting	your patients i	n TB
trea	itment?	-	-	_		_

patient not at home when I visit
patients do not attend at my home
patient complain of side effects
patient complain of no food
It takes time for me to visit patients
Other (specify)

12. What do you do to overcome these difficulties?

Monitoring of medication Collection of medicine Transport Provision of food Tell clinic staff to treat side effects Don't know Other (specify)



13. How long should patients take TB treatment? (in months)

14. Do you have meetings with TB clinic staff? Yes	No	
If yes, How often do you meet with TB clinic staffs staff?	Weekly	
every 2 w	eek	
Monthly		
every 2 m	onth	
Never		
other (spe	ecify)	
15. What do you suggest can improve role of treatment supported	ers?	
	Yes	No
Increase pay		
Appreciation from clinic staff		
More training		
Provide transport to clinic		

Extra resources e.g. kits

Other (specify)

QUESTIONNAIRE III

KEY INFORMANT INTERVIEWS WITH TB CLINIC STAFF

1. Study No.	-	
2. Name of clinic:	-	
3. Position in clinic:	-	
4. Do you have treatment sup	porters attached to this clinic?	
	Yes	No
5. How many treatment suppo	orters are there?	
6. What do the treatment supp	oorters do? List and Explain	
7. How often do you meet with	n treatment supporters in the clinic	.?
· · · · · · · · · · · · · · · · · · ·	Daily	
	Weekly	
	Every 2 we	eeks
	Every 3 we	eeks
	Monthly	
	Never	
	Other _	
8. Did the treatment supporter	rs complete the 69 days course?	
9. How many treatment suppo	Yes Prters are supporting more than se	No ven patients?
10. Patients may have probler patients tell you about relating	ns in taking treatment, what proble g to TB treatment? List them	∍ms do
11. What do you do to help the supporters?	e treatment	
esphericie.	Train more treatment supporters	
	debriefing sessions	
	Meeting with them	
	Give incentives	
	Retrain treatment supporters Others	

12. What	t do you do to help th	e TB patients in treatmer	nt?	
	Advise and counsel patients about TB			
		Encourage supervised sw	•	
		Encourage them to come	to clinic regularly	
		Encourage home visits	raa traatmant	
		Encourage taking full cou Others		
13. Do ye	ou think treatment su	pporters are useful in as	·	ts?
		Yes	No	
	lf useful, explain why?			
-	lf not useful, explain why?			
14. What supporte	t would improve the r ers?	ole of treatment		
-				
-				
-				
15. Are t	here ways apart from	supporters in which TB	treatment adhere	ence

could be improved?

PATIENT INFORMATION LEAFLET

Hi my name is _____; I am one of a team of four interviewers involved in a study being conducted for a course at the University of Witwatersrand. We want to study people who are taking TB treatment and ask them some questions about how they are getting their treatment. We are interested to know if Treatment supporters are helpful.

I would like to ask for your participation in a ten minutes interview on the role of Treatment supporters in TB treatment if you do not mind.

We do have permission from Human Research Ethics Committees of University of Witwatersrand and Ekurhuleni Metropolitan Municipality allowing us to conduct this research.

You were randomly chosen from TB patients on treatment in clinics in Ekurhuleni Metropolitan Municipality.

Participation in this study is voluntary and you are free to refuse to participate or to withdraw your consent and to discontinue participation at any time. Such refusal or discontinuance will not affect your regular treatments or Medical care in any way. Also, you do not have to answer all questions; you may answer some questions but not all. If you refuse to answer questions, it will not affect your TB treatment at all. If you agree to participate in this study, would you please sign the consent form?

We will not disclose your name or connect your name with anything you say.

INFORMED CONSENT OF PATIENTS

I have been fully informed about the study, which will ask me questions about my TB treatment. I have also received, read and understood the above written information (Participant Information Leaflet and Informed Consent) regarding the study.

I am aware that the results of the study will be anonymously processed into a study report, and my name will not appear in any report.

In signing this consent form, I agree to the questions and I understand that I am free to refuse to participate or to withdraw my consent.

PARTICIPANT:

Printed Name	Signature / Mark or Thumbprint	Date and Time	

WITNESS:

Printed Name

Signature

Date and Time

CLINICS TB STAFF INFORMATION LEAFLET

Hi my name is _____; I am one of a team of four interviewers involved in a study being conducted for a course at the University of Witwatersrand. We want to study if the Treatment supporters influence TB patients' treatment outcomes and would like to ask your opinion about how they assist patients in their treatment.

I would like to ask for your participation in a ten minutes interview on the role of Treatment supporters in TB treatment if you do not mind.

We do have permission from Human Research Ethics Committees of University of Witwatersrand and Ekurhuleni Metropolitan Municipality allowing us to conduct this research.

You were randomly chosen from clinics TB staff in Ekurhuleni Metropolitan Municipality.

Participation in this study is voluntary and you are free to refuse to participate or to withdraw your consent and to discontinue participation at any time. Such refusal or discontinuance will not affect your regular treatments or Medical care in any way. Also, you do not have to answer all questions; you may answer some questions but not all. If you refuse to answer questions, it will not affect your TB treatment at all. If you agree to participate in this study, would you please sign the consent form?

We will not disclose your name or connect your name with anything you say.

INFORMED CONSENT OF CLINIC STAFF MEMBERS

I have been fully informed about the study which will ask me questions about the role of treatment supporters in influencing TB treatment outcomes. I have also received, read and understood the above written information (Participant Information Leaflet and Informed Consent) regarding the study.

I am aware that the results of the study will be anonymously processed into a study report, and my name will not appear in any report.

In signing this consent form, I agree to the questions and I understand that I am free to refuse to participate or to withdraw my consent.

PARTICIPANT:

Printed Name	Signature / Mark or Thumbprint	Date and Time

WITNESS:

Printed Name

Signature

Date and Time

TREATMENT SUPPORTERS INFORMATION LEAFLET

Hi my name is _____; I am one of a team of four interviewers involved in a study being conducted for a course at the University of Witwatersrand. We want to study if the treatment supporters influence TB patients' treatment outcomes and ask them some questions about how they are assisting patients in their treatment.

I would like to ask for your participation in a ten minutes interview on the role of Treatment supporters in TB treatment adherence if you do not mind.

We do have permission from Human Research Ethics Committees of University of Witwatersrand and Ekurhuleni Metropolitan Municipality allowing us to conduct this research.

You were randomly chosen from Treatment supporters in clinics in Ekurhuleni Metropolitan Municipality.

Participation in this study is voluntary and you are free to refuse to participate or to withdraw your consent and to discontinue participation at any time. Such refusal or discontinuance will not affect your regular treatments or Medical care in any way. Also, you do not have to answer all questions; you may answer some questions but not all. If you refuse to answer questions, it will not affect your TB treatment at all. If you agree to participate in this study, would you please sign the consent form?

We will not disclose your name or connect your name with anything you say.

INFORMED CONSENT OF TREATMENT SUPPORTERS

I have been fully informed about the study which will ask me questions about my role as a treatment supporter of TB patients. I have also received, read and understood the above written information (Participant Information Leaflet and Informed Consent) regarding the study.

I am aware that the results of the study will be anonymously processed into a study report, and my name will not appear in any report.

In signing this consent form, I agree to the questions and I understand that I am free to refuse to participate or to withdraw my consent.

PARTICIPANT:

Printed Name	Signature / Mark or Thumbprint	Date and Time	

WITNESS:

Printed Name

Signature

Date and Time

APPENDIX 4

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL) R14/49 Odour

CLEARANCE CERTIFICATE

PROTOCOL NUMBER MO60633

 PROJECT
 Do Tuberculosis treatment supporters influence

 patients; treatment outcomes? A study of Southern Service Delivery Region, Ekurhuleni Metro

 Municipality, Gauteng, SA

INVESTIGATORS

DATE CONSIDERED

Mr PA Odour

School of Public Health

DEPARTMENT

06.06.30

DECISION OF THE COMMITTEE*

APPROVEDUNCONDITIONALY

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 06	.08.01
----------------	--------

D CHAIRPERSON

(Professor A Dhai)

*Guidelines for written 'informed consent' attached where applicable

cc: Supervisor : Prof M Edginton

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10005, 10th Floor, Senate House, University.

I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. I agree to a completion of a yearly progress report.

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES



Ekurhuleni

METROPOLITAN MUNICIPALITY

Southern Service Delivery Region Alberton Service Delivery Centre

Renfift & Social Development

Givie Carne Adbartan

Tel: (011) 861-2539

Fax. (011) 861-8835

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From: Research Ethics Committee Ekurhaleni Metropoliton Municipality (In co-operation with Ekurhaleni Region B Gauteng Provincial Health Department)

Empuires: Dr. Joseph Sepuya 811-8612539 sepuyat@ekurimleni.com

Dear Mr. P.A. Oduor

RE: Ethics Committee approval to do research in Ekurhuleni ontitled :"Do tuberculosis treatment supporters influence patient adherence to treatment"? A study in Southern Service Delivery Region, Ekurhuleni Metropolitan Municipality, Gauteng Province, South Africa

Thank you for your application for Ethics approval to conduct the above research in Ekurhuloni Metropolitan Municipatity. I am pleased to inform you that permission for the above study was granted by the Ethics committee. The committee wishes you success in your research and will expect you to present the findings of the study at the Ekurhuleni Annual Research Conference.

Yours sincerely

Sugar

Dr J. Sepuya far Ekurhiltun Research Ethics Committee

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