THE PROFILE OF PATIENTS ADMITTED AT CHARLES HURWITZ TUBERCULOSIS HOSPITAL IN THE GAUTENG PROVINCE

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A RESEARCH REPORT SUBMITTED TO THE FACULTY OF HEALTH SCIENCES, UNIVERSITY OF THE WITWATERSRAND IN PARTIAL FULFILLMENT OF THE REQUIREMENT FOR THE DEGREE OF MASTERS OF PUBLIC HEALTH

JOHANNESBURG 2011

DECLARATION

I, Maranyane Rahab Lesele, declare that this research report is my own work. It is being submitted for the degree of Master of Public Health (Hospital Management) at the University of the Witwatersrand, Johannesburg. It has not been submitted for any degree or for any examination at this or any other university.

October 2011

DEDICATION

I dedicate this research report to: My supervisor Dr. R Jina without whom this would not have been possible, my late parents Ranakedi and Kesilohetse Modiroa for raising me up and showing me the value of education, my friend and confidante, the late Reverend Sisasenkosi, Graduate Mthalane for bringing light during the darkest moments in my life and for showing me that the darkest comes just before dawn ; Agnes Sesing, sister, friend, mentor; her sister Mafenyang Leburu, my sister Gloria Modiroa and her daughter Boitumelo and my younger sister Phumzile Mdluli . Thank you all for loving me unconditionally, and understanding and supporting me.

ACKNOWLEDGEMENTS

I acknowledge the following staff of Heidelberg hospital and Charles Hurwitz TB Hospital: Mr. Mosala, Ms LLP Msiza, Mr. E Mbhungela, Mr, Ms. N Mabena ,Ms E Mahlangu, Mr. D Mahlangu, Mr. J Mwahla, Mr, Mr W Zulu, Mr, Mrs H Khathide, Ms E Dhlamini. Thank you all for supporting me in my studies.

Lastly I appreciated the support of Dr D Basu, Dr M Govender and Ms Pat Goss at Wits School of Public Health.

ABSTRACT

Background

In the WHO report of 2009, South Africa is ranked amongst the 22 countries with the highest burden of tuberculosis (TB). These countries account for 80% of all estimated cases worldwide. South Africa is ranked 3rd amongst five countries with the highest incident cases in 2008, at 0.38 – 0.57 million. TB is a disease of poverty affecting mostly young adults in their most productive years. People living with HIV are also at a much greater risk. TB has been known to be a leading killer among people living with HIV who have weakened immune systems (Corbett, Marston, Churchyard, et al., 2006). In 2007, a total of 1.77 million people died from TB, including 1.75 million people with HIV equal to 4 800 deaths a day

In 2003, a study was conducted in Charles Hurwitz TB Hospital on the epidemiological profile of admitted patients. During the period, programmes like voluntary counseling and testing (VCT) and the antiretroviral (ARV) treatment programme were not yet in place. In the study it was found that the number of TB admissions had increased by 50% from 2001 up to 2003 and the case fatality rate of TB of the population studied was 27%. Patients were no longer presented with TB alone but were co-infected with HIV. The main recommendations of the study were integration of TB and HIV Programmes and monitoring of DOTS. These recommendations were implemented and this study will provide information on whether this has succeeded in improving services at the Hospital. The study will also provide an indication of whether the Hospital is adhering to the National Tuberculosis Control Programme (NTCP) guidelines for admissions and discharges.

Objectives

The aim of the study is to describe the profile of admitted adult patients at Charles Hurwitz TB Hospital. The objectives of the study are to describe the demographic profile, discharge outcomes and average length of stay of TB patients admitted during the study period, and to describe the adherence to the NTCP admission criteria at Charles Hurwitz TB Hospital.

Methodology

A cross sectional study based on retrospective record reviews for patients admitted between 1 January 2007 and 31 December 2008 at Charles Hurwitz TB Hospital was conducted. The study population included all adult patients admitted during the study period. The setting of this study was the adult wards at Charles Hurwitz TB Hospital. Data was collected on various variables that are relevant to the profile of admitted patients.

Findings

A total of 400 patient records were sampled over the two year period. The study indicates that the mean age of most patients were in the economically active age group of 37-38 years, while more males (63%) than females (38%) were admitted. Just over a fifth (22%) of the patients were employed while 5% of patients were receiving grants. Almost all of the admitted patients (93%) were HIV positive and the median CD4 count was 77 cells/mm^3. Of the patients found to be eligible for antiretroviral therapy, only 34% were actually on treatment. The majority of patients were referred back to tertiary institutions for care (60%), while 28% of patients died after the admission. Most of the patients (86%) met the NTCP admission criteria if HIV status with a CD4 counts of less than 200 cells/mm^3 and social circumstances were taken into account.

Conclusion

The study revealed problems with the management of TB patients in the hospital, for example very few patients who were eligible for antiretroviral therapy actually received treatment, and very few patients were on grants. Also of concern is that many patients were referred back to tertiary institutions for further care, although almost all of them were admitted in a stable condition. These problems would need to have been addressed in the future. However, during the study period, the hospital was closed by the Gauteng Department of Health and Social Development. This then raises concerns regarding the management of TB patients in general hospitals.

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LIST OF ABBREVIATIONS

Abbreviation	Full word
ARV/ARVS	Antiretrovirals
COJ	City of Johannesburg
DOTS	Direct Observed treatment short course
FNA	Fine needle aspiration
GDOHSD	Gauteng department of health and social development
HIV	Human immune virus
LP	Lumbar puncture
MDR	Multi drug resistant
NDOH	National Department of Health
NGO	Nongovernmental organization
NTCP	National Tuberculosis Control Programme
PHC	Primary health care
SA	South Africa
SANTA	South African National Tuberculosis Association
TB	Tuberculosis
UK	United Kingdom
UNDP	United Nations Development Programme
USA	United States of America
VCT	Voluntary counseling and testing
WHO	World Health Organization
XDR	Extremely drug resistant tuberculosis

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CHAPTER ONE: INTRODUCTION AND LITERATURE REVIEW

1. INTRODUCTION

In the WHO report of 2009, South Africa is ranked amongst the 22 countries with the highest burden of tuberculosis (TB) (Donald, van Helden, 2009). These countries account for 80% of all estimated cases worldwide. South Africa is ranked 3rd amongst five countries with the highest incident cases in 2008, at 0.38 – 0.57 million. TB is a disease of poverty affecting mostly young adults in their most productive years. People living with HIV are also at a much greater risk. TB has been known to be a leading killer among people living with HIV who have weakened immune systems (Corbett, Marston, Churchyard, et al., 2006). In 2007, a total of 1.77 million people died from TB, including 1.75 million people with HIV equal to 4 800 deaths a day

"Tuberculosis (TB) is still a major global health problem today despite the fact that effective treatment has been available for over 50 years. In the last decade, TB has emerged as a major worldwide public health hazard with increasing incidence among adults and children. It remains a menacing disease especially in developing countries. This is clearly evident by the situation in South Africa (SA) and neighboring countries. In South Africa, the situation has gotten worse, where other forms of TB have emerged, such as Multi Drug Resistant TB (MDR) and the worse form of Extreme Drug Resistant TB (XDR). TB is caused by airborne bacterium called *Mycobacterium Tuberculosis.* People often go for months or years after being infected with the organism before developing the disease, and some never do. This period of infection without disease is called latent TB. Tuberculosis is only spread when a person develops pulmonary disease and is sputum or culture positive; this is called active TB. Tuberculosis is a socio economic disease and inextricably linked with unemployment, poor living conditions, and poor health service provision in both city and country. Despite the disease being curable and the availability of effective preventive measures and chemotherapy, the incidence of tuberculosis is increasing in the developing countries." (Molefakgotla, 2003). In developed countries, TB is most common amongst "neglected" populations, like immigrants in Sweden and the United Kingdom and in the poorer Black population in the United States.

1.1. BACKGROUND INFORMATION

1.1.1. HISTORY OF CHARLES HURWITZ TB HOSPITAL

Charles Hurwitz TB Hospital is the only public health institution in the City of Johannesburg (COJ) rendering services for patients diagnosed with TB that needs long-term admission. The hospital was first run by the nongovernmental organization (NGO) called the South African National Tuberculosis Association (SANTA). SANTA was formed in 1947 as a coalition of fourteen NGOS in Durban. SANTA and the government had an agreement that it will manage admitted TB patients and government would pay per patient per day. SANTA had hospital buildings all over the country that were admitting TB patients. Over time this changed, and the government took over the management and administration of the hospital in July 2006.

1.1.2. THE CATCHMENT AREA SERVED BY CHARLES HURWITZ TB HOSPITAL

Charles Hurwitz TB Hospital is situated in the Southern part of the City of Johannesburg in Soweto which consists mostly of an urban black population. According to the 2001 census, the population of Soweto is 1.1 million. The demographics of the City of Johannesburg are skewed, with the Northern part of the city being affluent and the Southern part being poor (Statistics SA, 2004).

In terms of the entire city, the census report of 2001 compiled by Statistics South Africa (Statistics SA, 2004), reported that the population was 3.2 million with 1 006 930 households. The division of the population according to different race groups is as follows: Black Africans - 73%, Whites - 16%, Colored's - 6% and Asians - 4%. The report also mentions further that 86% of the households have a flush or chemical toilet, 91% of the households have their refuse removed by the municipality at least once a week, 80% of households use electricity as the main source of energy and 22% of the city live in informal dwellings. In terms of age distribution, 42% of the population is under the age of 24, while 6% of the population is over the age of 60 years. More than a third of the population (37%) is unemployed and of the unemployed, 91% are Black and 43% are women. Thirty four percent (34%) of the

city residents speak Nguni at home, 26% speak Sesotho, 19% speak English and 8% speak Afrikaans. This shows that patients who get referred to Charles Hurwitz TB Hospital are often from different backgrounds.

1.1.3. TB SERVICES IN SOUTH AFRICA

Tuberculosis (TB) management in South Africa is supposed to occur at primary health care centers but this is not always the case. There are cases that cannot be managed at primary health care centers and these are referred to TB hospitals. TB control was declared a national priority in 1996, which led to a uniformed effort to managing and controlling the disease. This was reaffirmed in 2000 when TB infection was declared serious in South Africa (SA) and the National TB Control Programme (NTCP) was initiated (National Department of Health, 2000). The NTCP provides guidelines on admission and discharge criteria for TB Hospitals. The guide says that patients should be referred to hospital if the patient presents with the following conditions at a primary health care centre (PHC):

- A patient has a medical reason for admission, i.e. a patient diagnosed with TB but being too ill or weak to go home, including severely ill or emaciated patients without other complications.
- Re-treatment TB cases that need streptomycin injections that cannot be managed at a PHC clinic.
- Social or socio economic medical reasons for admission, when clinic or community supported care cannot be achieved, particularly in the case of high risk groups like alcohol or drug dependence, mentally disturbed patients or previously non-compliant patients.

In all cases a completed TB referral form should accompany referrals. This form must include relevant basic, personal, clinical and diagnostic information e.g. confirmed sputum smear results for Alcohol Acid Fast Bacilli or other reasons for making the diagnosis of TB. This could include clinical findings, an x-ray report or other supporting documents. Admission to TB hospitals should only take place when the diagnosis has been confirmed and the clients are other medical conditions have been stabilized (National Department of Health, 2007).

In general hospitals in Gauteng Province the spread of TB is controlled by the following measures (National Department of Health, 2007).

- All hospitals have designated areas with designated personnel called TB focal points for assessment of suspected TB cases.
- All coughing patients are quickly removed from the patient queues to the focal point.
- Personnel get frequent assessments for TB.
- As a form of protection, specific masks called N95 is given to personnel working in designated TB wards.

1.1.4. SERVICES AT CHARLES HURWITZ TB HOSPITAL

Charles Hurwitz TB Hospital admits referred patients from the clinics and hospitals within COJ. Private practitioners refer to the institution on rare occasions. No walk-in patients are admitted. The statistics of the institution for 2007 is presented in Table 1. From 2006, when the institution was no longer under the administration of a Non Governmental Organization, patients' information has been collected on a monthly basis.

Table 1: Charles Hurwitz TB Hospital: statistics from January - June 2007

Indicators	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**Jun***
Admissions	109	52	165	129	190	0
Discharges	40	63	66	40	105	19
Deaths	25	29	33	26	21	21
Bed Occupancy Rate (BOR)	73%	81%	87%	95%	92%	40%
Average length of stay	70	78	95	92	69	41

* Provincial strike occurred during the month

Source: Charles Hurwitz TB Hospital Information Unit

1.1.5. THE REFERRAL UNITS

The patients that are admitted to Charles Hurwitz TB Hospital are referred from primary health care centers, district, regional and tertiary hospitals in COJ. This referral system follows the Gauteng Department of Health and Social Development (GDOHSD) referral policy. The referring institution adheres to the referral policy of GDOHSD but not always to the NTCP guidelines.

1.2. STATEMENT OF THE PROBLEM

Charles Hurwitz TB Hospital has been struggling to adhere to the admission and discharge criteria of the NTCP. Patients are being admitted without confirmed sputa results, and severely ill and unstable patients with chronic lung disease, diabetes mellitus, severe hypertension and extra-pulmonary TB are often found in the wards. This occurs because general hospitals cannot stabilize patients before referring them to Charles Hurwitz TB Hospital as they are also having large numbers of ill patients.

In a study conducted in 2004 at the hospital, it was found that the number of TB admissions had increased by 50% from 2001 up to 2003 (Douglas, 2007). The case fatality rate of TB of the population studied was 27%. Charles Hurwitz TB Hospital has not been able to adhere to the NTCP Guidelines as patients cannot be turned away as the situation in the referring institutions is understood and because the bed occupancy is relatively low in Charles Hurwitz TB Hospital. The focus of the study was to assess the profile of the admitted patients at the hospital with regards to the NTCP guidelines. This was done to consider whether the NTCP guidelines should be renewed or revised. This study evaluated the profile of patients admitted to Charles Hurwitz TB Hospital based on NTCP guidelines and gave recommendations based on its findings.

1.3. JUSTIFICATION OF THE STUDY

At Charles Hurwitz TB Hospital the profile of patients has been defined in a study done by Douglas in 2004 when the hospital was still under management of the South African National Association for Tuberculosis (SANTA) (Douglas, 2007). This study

seeks to extend on the work done and to check if there have been any changes in the findings. During the period, programmes like voluntary counseling and testing (VCT) and the antiretroviral (ARV) treatment programme were not yet in place. In the study it was found that the number of TB admissions had increased by 50% from 2001 up to 2003 and the case fatality rate of TB of the population studied was 27%. Patients were no longer presented with TB alone but were co-infected with HIV. The main recommendations of the study were integration of TB and HIV Programmes and monitoring of DOTS. These recommendations were implemented; however, problems are still being experienced with adherence to the NTCP admission criteria at Charles Hurwitz TB Hospital.

It is therefore important to do the study on the profile of admitted patients as the outcome of the study will be valuable in assessing past performance and informing operational planning at the hospital. It was also hoped that the recommendations of this study would contribute to the consideration of whether the NTCP admission criteria for TB hospitals need to be reviewed given the current situation in the country. A decision was made to only include adult admissions into the study as the number of pediatric admissions was small (occasionally up to six patients at a time). In terms of the admission policy, any patient older than 15 years are considered to be adult and admitted to the adult ward. For the purpose of this study, these patients were considered to be adults although the age of 18 years is more conventionally used to classify patients to be adults.

The study will allow informed decisions to be made by policy makers as they plan for the future. The information could also be used for allocating budget distributions provincially and also at the institution. The study is feasible and its focus is on the profile of admitted patients over a two year period since government took over the management of the hospital from the Non-Governmental Organization (NGO) administration.

2. LITERATURE REVIEW

The literature review will address the following areas: The spread of TB worldwide, TB in Africa and Sub Saharan Africa, and TB in South Africa. The long-term

hospitalization of TB patients will also be discussed briefly. Although it is well established that tuberculosis has socioeconomic determinants and consequences, this was not the focus of this research report and thus was not addressed in the literature review as well.

2.1. THE SPREAD OF TB WORLDWIDE

In 1993 the World Health Organization declared TB a global emergency because it was killing by then more adults each year than any other infectious disease including malaria and all tropical diseases. In 1999 new cases of TB increased by 8.0 million over a two year period from 1997. This was due to an increase in the incidence in Africa as many African countries are affected by the HIV/AIDS epidemic (World Health Organization, 2001).

TB is a worldwide pandemic. More than two billion people, one third of the world's total population, are infected with the TB bacilli (World Health Organization, 2009a). Out of those who are infected with the *tuberculosis* bacilli, one in every ten will become infected with active TB in his or her lifetime. The World Health Organization (WHO) aims to reach all patients through the health care system using a Primary Health Care approach and is working with other agencies to achieve the target of halving the incidence and spread of TB by 2015 as part of goal 6 of the Millennium Development Goals (UNDP, 2009).

TB is contagious and spreads through the air. If not treated, each person with active TB can infect on average 10-15 people every year. Per capita, the global TB incidence rate is falling, but the rate of decline is less than 1% (World Health Organization, 2009a). In 2007, there were 9.27 million new TB cases, of which 80% were in just 22 countries. Among the 15 countries with the highest estimated TB incidence rates, 13 are in Africa, while half of all new cases are in six Asian countries. The vast majority of TB deaths are also in the developing world, with more than half occurring in Asia (World Health Organization, 2009b).

TB is a disease of poverty affecting mostly young adults in their most productive years. People living with HIV are also at a much greater risk. TB has been known to

be a leading killer among people living with HIV who have weakened immune systems (Donald, van Helden, 2009). In 2007, a total of 1.77 million people died from TB, including 1.75 million people with HIV equal to 4 800 deaths a day (Donald, van Helden, 2009).

Other issues of concern are Multi Drug Resistant TB (MDR) and Extreme Drug Resistant TB (XDR). These are forms of TB that do not respond to the first-line drugs and require advanced and more expensive treatment measures. MDR TB is present in virtually all countries surveyed by the WHO (Donald, van Helden, 2009).

2.2. TB IN AFRICA AND SUB -SAHARAN AFRICA

It has been reported that annually nine million new cases of TB occur worldwide which includes people who are infected with the HIV (Kandel, Mfenyana, Chandia, et al., 2008). This leads to the increase in the global case load more so in developing countries especially Sub Saharan Africa. This is due to failure to address the principal risk factors. Between 1984 and 1990, an increase of 86%, 140%, 154%, and 180% in incidence of TB were reported in Tanzania, Burundi, Zambia, and Malawi respectively (Narain, Raviglione, Kochi, 1992).

In 2003 an estimated 8.8 million new cases of TB resulted in 1.7 million deaths. Twenty-one percent of these cases and 31% of these deaths arose in Africa, home to only 11% of the world's population. (Corbett, Marston, Churchyard, De Cock,2006). There is a strong association between HIV infection and these TB cases. For example, when comparing HIV prevalence in TB patients between the African and the Western Pacific regions, it is found that for the African region it is 38% versus 1% for the Western Pacific region. In the countries with the highest HIV prevalence more than 75% of cases of TB are HIV-associated (Corbett, Marston, Churchyard, De Cock., 2006).

In the general African population when a comparison is made of HIV prevalence and TB patients, TB incidence was 8-3 times higher in HIV positive than HIV negative African people in 2003. While in the rest of the world TB incidence has either declined or become stable since 1999 that of the African region has risen by 11% in

2003(Corbett, Marston, Churchyard, De Cock,2006 . TB is often the first manifestation of HIV in Africa and it is the leading cause of death among HIV infected patients.

In primary health care settings in Zimbabwe, Kenya and Malawi, 43-70% of adults with cough of three weeks or longer were confirmed as being infected with TB. In Kenya, 9% of adults with a diagnosis of acute pneumonia had TB; while in Tanzania 23% of febrile HIV infections were also suffering from TB. In Cote d'Ivoire, the Democratic Republic of Congo and Kenya 38-47% of autopsies in HIV infected adults indicated that TB was the cause of death. True yearly rates in Africa are likely to be even higher because of under diagnosis and under reporting. (Corbett, Marston, Churchyard, De Cock., 2006)

2.3. TB IN SOUTH AFRICA

The control of TB remains a major challenge in South Africa despite the fact that effective TB drugs are available. The seriousness of the epidemic in this country was confirmed in June 1996 when WHO experts stated that SA has one of the worst recorded TB epidemics in the world (Matjila, Hoosen, Stoltz, et al., 2008). The problem of TB in SA is a result of a system of segregation practiced by the SA government before democracy in 1994. Services were fragmented according to Bantustans were there was poor reporting and in the Republic of South Africa there were poor management systems of the disease and also it was most common amongst the disenfranchised (Janse van Rensburg, Engelbrecht, Heunis, et al., 2000).

Subsequent to the WHO report in 1996, the then Minister of Health, Dr. N. Dhlamini-Zuma declared TB to be a national priority. This resulted in strengthening of programmes like Directly Observed Treatment, Short-course (DOTS) and training of managers on TB management. TB indicators were also formulated that Programme managers had to report on a monthly basis.

There were also appointments of Communicable Disease Coordinators at district level and TB coordinators at clinic level. The Communicable Disease Coordinators

monitor performance of the districts in terms of TB management and develop monthly reports. This has made it possible to trace good and worse performing districts in the country. Thus, in 2006 at the launch of the TB Crisis Plan in Soweto, the City of Johannesburg and Amatole district in the Eastern Cape were singled out as worst performing districts in the country. In terms of provinces, the most affected is Kwa-Zulu Natal (National Department of Health, 2008).

Electronic TB registers were also introduced for data capturing at primary health care level and data capturers were appointed specifically to capture TB data. The TB coordinators were trained on computing skills and resources were made available to them. The declaration made resources available for the TB Programme yet patients still present late to hospitals, being diagnosed as having 3+ positive sputum and being very ill.

The fight against the spread of TB is far from over. In the 2009, the WHO Global Report on TB ranked SA as one of 22 high burden countries (Donald, van Helden, 2009). These high burden countries on their own account for 80% of the TB cases in the world. This is happening in spite of SA having a case detection rate above target since 2003 as set by the WHO and National Department of Health. In 1990 the WHO set a target of 70% of case finding of smear positive TB, and having 80% of identified cases completing treatment. In South Africa, the case detection rate is reported by WHO as 78% (World Health Organization, 2009b) but the completion rate for smear positive cases was only 73.8% (Matjila, Hoosen, Stoltz, et al., 2008). Thus in SA, there is fairly good identification of cases, yet treatment success rates have remained low with high default and death rates. In addition to the high default and death rates. SA also has the highest confirmed number of Multi Drug Resistant and Extreme Drug Resistant TB (Donald, van Helden, 2009).

In 2007, a study done in a community health centre in Gauteng province reported that the province had an increase in the incidence rate for TB from 225 to 374 per 100 000 population, although Gauteng has maintained an incidence rate of the third lowest province in the country (Makhetha, 2007). As Gauteng province has high numbers of people migrating into the province from all over the country and in Africa for employment, it is the most densely populated province in the country. Some of

the patients admitted in Charles Hurwitz TB Hospital stay in informal settlements without a fixed address as they originate from all over the country. These patients then increase the TB incidence rate for Gauteng province.

The study that was conducted at the Hillbrow Community Health Centre (Makhetha, 2007), reported that the main problem contributing to the high incidence of TB in SA was the HIV/AIDS pandemic, inadequacies of the health services, and health workers' lack of knowledge on the disease and how to manage it. Lack of testing of TB suspects by health care workers also contributed to the high burden of disease as this delayed the diagnosis of TB. Health care workers also monitored treatment poorly and case holding of TB patients was inadequate (Makhetha, 2007). This showed the importance of proper management of TB by health care workers to decrease the burden of disease in a cost effective manner.

In a previous study done at the Charles Hurwitz TB Hospital in 2007, it was found that TB admissions and mortality increased significantly from 2001-2003 (Douglas, 2007). Patients no longer presented with TB alone but were co-infected with HIV and the number of deaths had increased. The study also found that males were the most affected, and for both sexes, those who were most affected were at the peak of their reproductive and economically active years. Finally the study found that other forms of TB associated with HIV infection, such as sputum negative pulmonary TB and extra pulmonary TB, resulted in increasing proportions of admissions and higher mortality rates. Just over 75% of patients with dual infections had CD4 counts of less than 200 cell/mm^3. The main recommendations of the study were integration of TB and HIV Programmes and monitoring of DOTS.

2.4. LONG-TERM HOSPITALISATION OF TB PATIENTS

The long-term hospitalization of TB patients has been used as a strategy in TB control programmes to manage specific patients suffering from TB. However, the need for this was debated in the 1980s in the USA as hospitalization costs increased with no increased benefit. The American College of Chest Physicians recommended that criteria be set to limit the admission of TB patients to cases which were severely ill, where co-morbid conditions were present, or where there were special social

needs (Yeager, Medinger, 1986). This was met with some concerns and reluctance. Emerging problems also resulted in a further need to consider hospitalization of TB patients. So, for example, in the 1990s, the state of Massachusetts opened an inpatient facility to address new challenges facing TB control, including MDR TB, HIV and TB in drug users. This was found to be successful in improving TB cure rates (Singleton, Turner, Haskal, et al., 1997).

The issue regarding long-term hospitalization of TB patients has never been clearly resolved and there is a dearth of literature, and in essence, evidence on the topic. However, in 2006, the National Institute for Health and Clinical Excellence in the United Kingdom published guidelines on the prevention and control of TB based on current evidence. Here it was recommended that only homeless people and those patients with a clear socio-economic need should be hospitalized for TB management (Story, van Hest, Hayward, 2006). In South Africa, the National TB Control Programme Guidelines makes provision for the admission of TB patients in specific circumstances that have been presented in section 1.1.3 (National Department of Health, 2000).

If one considers that there is some need for the long-term hospitalization of TB patients, the next question to consider is whether this should occur in separate specialised hospitals or in general hospitals. There are advantages and disadvantages in both scenarios, but essentially it depends on the proper functioning of the hospital, be it specialized or general, and the availability of resources and budget to the hospital.

In the Massachusetts study, special units called Tuberculosis Treatment Units (TTU) were set up in general hospitals for patients who were considered difficult to treat. These were namely patients who are admitted either voluntarily or involuntary by means of a court order. As described earlier, these patients were either homeless, had a history of injection drug abuse, MDR patients, patients with HIV, or those with antisocial behavior associated with illicit drug use (Singleton, Turner, Haskal, et al., 1997).

Treatment in the TTU is provided by a multidisciplinary team consisting of physicians, nurses, social workers, and mental health professionals. Included in the team is local and public health nurses, outreach workers and other professionals familiar with each patient's case. The criteria for admission includes no adherence despite all attempts at ambulatory care, medical complexity, and short term isolation for persons whose living arrangements pose a serious threat to public health (Singleton, Turner, Haskal, et al., 1997). This level of care can similarly be provided in a specialized hospital, although access to other disciplines might be limited, and this can sometimes be problematic.

In summary, the literature indicates that TB is a global health problem, and sub-Saharan Africa, and especially South Africa are hard hit. This is partially due to the massive HIV crises but also due to the long-standing poor management of tuberculosis individually and at the population level. A possible solution is thought to be long-term hospitalization and thus adherence monitoring of patients. However, whether this is successive still needs to be seen.

3. STUDY AIM AND OBJECTIVES

3.1. STUDY AIM

The aim of the study is to describe the profile of admitted adult patients at Charles Hurwitz TB Hospital from 2007 – 2008.

3.2. SPECIFIC OBJECTIVES

3.1.1. To describe the demographic profile of adult TB patients admitted during the study period.

3.1.2. To describe the discharge outcomes and the average length of stay of adult TB patients at Charles Hurwitz TB Hospital during the study period.

3.1.3. To describe the adherence to the NTCP admission criteria at Charles Hurwitz TB Hospital.

CHAPTER TWO: METHODOLOGY AND PROCEDURES

1. INTRODUCTION

This chapter will discuss the methodology for this study. The methodology was selected on the basis of its aims and objectives. In this chapter, the following will be discussed: study design, study setting, study period, study sampling and data collection tools.

2. METHODOLOGY

2.1. STUDY DESIGN

The study design was a cross sectional study based on retrospective record reviews.

2.2. STUDY SETTING

The setting for the study was Charles Hurwitz TB Hospital.

2.3. STUDY PERIOD

The study period was from 1 January 2007 to 31 December 2008. A reason was made to include two years so that changes over the years could be assessed. In addition, the years 2007 – 2008 were selected as this covered a substantial period of time from the previous study that was conducted allowing for changes in the health services to take effect.

2.4. STUDY POPULATION

All patients admitted to the adult wards of Charles Hurwitz TB Hospital for the period 1 January 2007 to 31 December 2008 formed part of the study population. Patients were included in the study if they are 15 years of age or older.

2.5. STUDY SAMPLING

Records of admitted patients were systematically sampled. Approximately 2000 patients are admitted annually at Charles Hurwitz TB Hospital. The admission register of admissions to the adult ward provided the sampling framework for each year. Two hundred patients' records were systematically sampled from each year, by selecting every 10^{th} patient from the admission register according to the date when the patient was admitted. This was based on a sample size calculation using StatCalc on EpiInfo making an assumption that 20% of the admissions to the hospital would not have adhered to the NTCP guidelines, with a worst acceptable result of 30%. Using a confidence level of 99.9% a sample of 173 records would have to be selected while 61 records would have to be selected for a sample size of 95%. A decision was made to oversample to account for potential missing data. Patient records were retrieved and reviewed by the researcher for the study. No patients were skipped and therefore readmissions would be counted as two separate admissions.

2.6. DATA COLLECTION

Data for the study was obtained from the patients' records, admission registers and nursing records used routinely when the patients are admitted in this hospital. In addition, some data was extracted from various sources of the hospital information management unit. No primary data was collected specifically for this study. All of the data collection was conducted by the primary researcher and no field workers were used.

2.6.1. DATA COLLECTION TOOL

Data was captured on the data collection tool (Appendix A) that was developed by the researcher. The following provides an overview of the data that was obtained:

Objective 1: The demographic profile of all admitted adult patients in the hospital during the study period will be described. This information was collected from the

patients' records and captured on the data collection tool. This included the following information:

- Sex
- Age in years
- Employed (Yes/No/Pensioner)
- Grant Receiver (Yes/No) – (grant receiver means a person who was receiving a temporary disability grant from the Department of Social Development as relief during the acute stages of the disease for four months whilst still taking treatment and while being unable to work)
- Location (name of the extension that patient resides in, e.g. Freedom Park) – (the distance from the area of residence to the hospital is only presented and not the actual name of the area).
- HIV status

Objective 2: Data on the admission date, outcome date and outcome was extracted from the Hospital Information System onto the data collection tool. Outcomes included discharge, death, being transferred out or being referred out of the hospital.

Objective 3: Information on the following NTCP criteria was collected: were there sputum results, was the patient stable, was the patient a re-treatment case who lived far from the clinic, and was the patient having a problem of alcohol and drug abuse that may lead to the patient failing to adhere to treatment**.** Patients with potential social needs were also considered. The following information was obtained from the patient records:

- Patient category (New case, retreatment after failure, retreatment after default, retreatment after cure)
- Method of diagnosis (X-ray, sputum, lumbar puncture (LP), biopsy, clinical, other)
- State on admission (stable, unstable)
- HIV (status and ARV utilization)
- Other Co-Morbid Conditions (diabetes, hypertension, CNS, other)
- Alcohol and/or drug abuse
- Employment status (unemployed or pensioner)

- Distance from facility (lived more than 30km from the hospital)

Data was only collected from the doctors' notes on the patient records and additional information on admission and discharge date and condition was obtained from the Health Information System. This therefore did not allow for duplication of data collection and reduced the possibility of errors.

2.7. DATA ANALYSIS

Information from the collection tool was captured onto an MS Excel spreadsheet. Errors were corrected and the data was cleaned. A new variable "length of stay" was calculated from the date of admission and outcome. A second variable "eligibility for antiretroviral therapy" was also generated and considered whether the patient had a CD4 count of less than 200 cell/mm^3 or more than 200 cell/mm^3. At the time of the study it was the National Department of Health's Policy (National Department of Health, 2004) to offer antiretroviral therapy to patients with a CD4 count of less than 200 cell/mm^3.

The distance from the area of residence to the hospital was calculated using Google Maps for South Africa. This was calculated for each individual patient using the residence as stipulated in the patient records.

The spreadsheet was then imported into EPI-Info software version 8.0 for analysis. Descriptive statistics were conducted and are reported. This included the mean, median, range and standard deviation for continuous variables, such as age and length of stay. Frequencies and proportions were calculated for categorical variables, such as patient category and state on admission. To test for differences across the years, t tests were conducted for continuous variables, while Chi-square tests were conducted for categorical variables. The latter was replaced with Fisher Exact tests when expected cell sizes were calculated to be less than five. A p value of less than 0.05 was considered to be significant in all of the tests of associations.

3. PILOT STUDY

A pilot study on 30 files of patients from 2006 was done to test the feasibility of the study and the validity of the data collection tools. The sampling strategy and tool were found to be adequate and no changes were made.

4. ETHICAL CONSIDERATIONS

Permission for conducting research and accessing documents was sought from the Head of Nursing at Charles Hurwitz TB Hospital. A submission was made to the WITS Human Research Ethics Committee to obtain approval before the study commenced (Ethics Approval Number M10640) (Appendix B). This study was based on reviewing the existing information on patients' records, and some data was retrieved and extracted from the hospital information management unit, but no primary data was collected specifically for this study. No intervention was done as a part of this study. All of the data collection was conducted by the primary researcher and no field workers were used. No patients were interviewed and no HIV testing was done specifically for the study.

Confidentiality was maintained all of the time in the collection, capturing and reporting of the information. Patient file numbers were recorded to retrieve patients' files for data collection, capturing, and reporting of information. Addresses of patient were used to collect data to ascertain where patients came from. This information was however not captured in the Excel spreadsheet and not used in the data analysis. Only the area where patients came from was recorded and analyzed. All information concerning hospital data was kept confidential. Therefore, the data does not contain any information that identifies any of the patients who were included in this study

CHAPTER THREE: RESULTS

1. INTRODUCTION

In this chapter the results of the data analysis is presented according to the said objectives. Using the sampling strategy described, 200 patient files from 2007 and 2008 were randomly selected to obtain a total sample size of 400. The total number of admissions for Charles Hurwitz TB Hospital in 2007 was approximately 3000 and in 2008 was 2500.

2. DEMOGRAPHIC PROFILE

Table 2 shows the mean, median, standard deviation and range of age of the study patients. The mean age for the patients was 38.3 years and the median was 37 years. The p value was 0.9403 which shows that the mean age was not significantly different across the years. The youngest patient included in the study was 17 years and the oldest was 77 years. Of the 400 study patients, 37.5% were females and 62.5% were males (Table 3). In Table 4 the sex distribution is reported for 2007 and 2008. This was not found to be significantly different over the two years as the percentage for females was 37.9% in 2007 and 37.0% in 2008, while the percentage for males was 62.1% in 2007 and 63.0% in 2008.

Table 2: Age distribution of patients admitted to Charles Hurwitz TB Hospital for the total sample and by year (2007 – 2008) (n=400)

AGE	TOTAL	YEAR		p VALUE
		2007	2008	
Means	38.3	38.3	38.4	0.9043
Median	37.0	37.0	37.0	
Standard deviation	10.5	11.0	9.9	
Range	19 - 77	19 - 77	20 - 58	

Table 3: Sex distribution of patients admitted to Charles Hurwitz TB Hospital for the total sample (n=400)

SEX	FREQUENCY	PERCENTAGE
Female	150	37.5%
Male	250	62.5%

Table 4: Sex distribution of patients admitted to Charles Hurwitz TB Hospital by year (2007 – 2008) (n=400)

SEX	2007		2008		p VALUE
	n	%	n	%	
Female	89	37.9%	61	37.0%	0.854
Male	146	62.1%	104	63.0%	

Table 5 shows the employment status of the patients. Just over a fifth (22%) of the patients were employed, 74.8% were unemployed and 3.3% received an old age pension. The employment status by year is reported in Table 6. The number of patients receiving old age pension dropped significantly from 5.1% in 2007 to 0.6% in 2008, while the number of unemployed went up from 73.2% in 2007 to 77.0% in 2008 (p value 0.044). The increase in the unemployed shows further the relationship between unemployment, poverty and TB.

Table 5: Employment status of patients admitted to Charles Hurwitz TB Hospital for the total sample (n=400)

EMPLOYED	FREQUENCY	PERCENTAGE
Yes	88	22.0%
No	299	74.8%
Pensioner	13	3.3%

Table 6: Employment status of patients admitted to Charles Hurwitz TB Hospital by year (2007 – 2008) (n=400)

EMPLOYED	2007		2008		p VALUE
	n	%	n	%	
Yes	51	21.7%	37	22.4%	0.044
No	172	73.2%	127	77.0%	
Pensioner	12	5.1%	1	0.6%	

In Table 7, we note that less than 5% of the patients were receiving a grant (4.8%). Table 8 below shows the percentages and frequencies of grant receivers by year. More people received grants in 2007 than in 2008. The p value was 0.0010 which is significant. The percentage of grant receivers for 2007 was 7.7% and in 2008 the percentage for recipients was 0.6%. This shows that less people received grants possibly due to changes in the Department of Social Development's procedures for awarding grants.

Table 7: Distribution of grant receivers amongst patients admitted to Charles Hurwitz TB Hospital for the total sample (n=400)

GRANT RECEIVER	FREQUENCY	PERCENTAGE
Yes	19	4.8%
No	381	95.3%

Table 8: Distribution of grant receivers amongst patients admitted to Charles Hurwitz TB Hospital by year (2007 – 2008) (n=400)

GRANT RECEIVER	2007		2008		p VALUE
	n	%	n	%	
Yes	18	7.7%	1	0.6%	0.0010
No	217	92.3%	164	99.4%	

Table 9 presents the mean, median, standard deviation and range of distances between the patients' areas of residences and the hospital. The mean distance was 14.7 kilometers, the median 13 kilometers with a range of 2 – 66 kilometers. There

was no significant difference in the mean distance from patients' areas of residence to the hospital over the two year period.

Table 9: Distance from patients' areas of residences to hospital for the total sample and by year (2007 – 2008) (n=400)

DISTANCE IN KILOMETERS	TOTAL	YEAR		p VALUE
		2007	2008	
Means	14.7	14.4	15.1	0.4700
Median	13	13	13	
Standard deviation	9.6	9.4	9.7	
Range	2 – 66.3	2 – 66.3	2.2 – 48.8	

3. HIV STATUS

Of all of the admitted patients, 373 (93.3%), tested positive for the Human Immunodeficiency Virus (HIV) and 5, which is 1.3%, tested negative. Twenty two patients (5.5%) had declined testing (Table 10). Fewer patients declined testing in 2008 (3.0%) compared to 2007 (7.2%) (Table 11). The percentage of patients who tested positive was 91.9% in 2007, while it went up to 95.2% in 2008. These differences across the years were, however, not found to be significant (0.1388).

Table 10: HIV status of patients admitted to Charles Hurwitz TB Hospital for the total sample (n=400)

HIV STATUS	FREQUENCY	PERCENTAGE
Positive	373	93.3%
Negative	5	1.3%
N/A	22	5.5%

Table 11: HIV status of patients admitted to Charles Hurwitz TB Hospital by year (2007 – 2008) (n=400)

HIV STATUS	2007		2008		p VALUE
	n	%	n	%	
Positive	216	91.9%	157	95.2%	0.1388
Negative	2	0.9%	3	1.8%	
N/A	17	7.2%	5	3.0%	

The table below shows the CD4 count for the selected patients. In 2007 the mean CD4 count was 179 cell/mm^3 (range 1-1610 cell/mm^3) and the median was 62 cell/mm^3, while in 2008 the mean CD4 count was 314.26 cell/mm^3 (range 0.35-1190 cell/mm^3) and the median 140 cell/mm^3. The p value was 0.0003 which is significant, indicating that in 2008 the patients who were admitted had a significantly higher CD4 count than the ones in 2007. The difference between the mean and median indicates that the data is skewed and therefore the median provides a better reflection of the data.

Table 12: CD4 count of patients admitted to Charles Hurwitz TB Hospital for the total sample and by year (2007 – 2008) (n=400)

CD4 COUNT (IN cell/mm^3)	TOTAL	2007	2008	p VALUE
Mean	238.00	179.73	314.26	0.0003
Median	77	62	140.00	
Standard deviation	313.53	285.96	331.58	
Range	0.35 - 1610	1 - 1610	0.35 - 1190	

It was further checked if patients were on ARV therapy. Of all of the patients in the study, 73 reported ARV usage (18.3%), while 327 were not on ARVs (81.8%) (Table 13). Further analysis showed no significant difference in the ARV usage across the years (Table 14).

Table 13: Antiretroviral usage distribution amongst patients admitted to Charles Hurwitz TB Hospital for the total sample (n=400)

PATIENT ON ARVS	FREQUENCY	PERCENTAGE
Yes	73	18.3%
No	327	81.8%

Table 14: Antiretroviral usage distribution amongst patients admitted to Charles Hurwitz TB Hospital by year (2007 – 2008) (n=400)

PATIENT ON ARV	2007		2008		P VALUE
	n	%	n	%	
Yes	42	17.2%	31	18.8%	0.815
No	193	82.0%	13	81.2%	

The association between ARV therapy usage and eligibility (that is having a CD4 count of less than 200 cell/mm^3) was assessed (Table 15). Of the 191 patients (67% of those who were tested) who met the criteria to receive ARV therapy based on the CD4 count alone, 65 (34.0%) were actually on treatment.

Table 15: The association between antiretroviral therapy usage and eligibility antiretroviral therapy for the total sample (n=284)

PATIENT ON ARV	ELIGIBLE FOR ARV (N=191)		NOT ELIGIBLE FOR ARV (N=93)		P VALUE
	n	%	n	%	
Yes	65	34.0%	2	2.2%	0.0000
No	126	66.0%	91	97.8%	

4. OUTCOMES OF PATIENTS

Of the selected patients, 241, that is 60.3%, were referred to tertiary institutions for further management and 42 that is 10.5% were transferred to other provinces. Patients who were referred or transferred could be considered to be discharges. One hundred and eleven patients died (27.8%) and 6 (1.5%) absconded (Table 16).

More patients were referred in 2008 than in 2007 for further management. Additionally, more patients transferred out to other provinces in 2008 than in 2007 while less patients died in 2008 than in 2007 (Table 17). The p value is 0.0188 which is significant.

Table 16: Outcomes of patients admitted to Charles Hurwitz TB Hospital for the total sample (n=400)

OUTCOME	FREQUENCY	PERCENT
Referred	241	60.3%
Transferred out	42	10.5%
Death	111	27.8%
Absconded	6	1.5%

Table 17: Outcomes of patients admitted to Charles Hurwitz TB Hospital by year (2007 – 2008) (n=400)

OUTCOME	2007		2008		p VALUE
	n	%	n	%	
Referred	131	55.7%	110	66.7%	0.0188
Transferred out	2.3	9.8%	19	11.5%	
Death	75	31.9%	36	21.8%	
Absconded	6	2.6%	0	0.0%	

Of the patients who died, 63.1% (n=180) were male patients and 39 % (n=109) were female patients.

5. LENGTH OF STAY

The average length of stay of patients is shown in Table 18. In 2007 the mean length of stay was 59 days (range 0-174 days) and the median was 63 days, while in 2008 the mean length of stay was 51 days (range 1-115 days) and the median was 55 days. The p value is significant indicating that in 2008 patients stayed for a significantly shorter period than in 2007.

Table 18: Length of stay for patients admitted to Charles Hurwitz TB Hospital for the total sample and by year (2007 – 2008) (n=400)

LENGTH OF STAY	TOTAL	2007	2008	p VALUE
Mean	55.8	59.0	51.0	0.0334
Median	57.0	63.0	55.0	
Standard deviation	36.51	40.45	29.50	
Range	0 - 174	0 - 174	1 - 115	

Table 19 shows the mean, median, standard deviation and range for length of stay by outcome. Patients died on average within 21.7 days of admission (median of 12 days), while the patients who stayed for a longest period where those patients who were referred to tertiary institutions for further management (mean of 74.3 days, median of 70 days). The p value is 0.0000 indicating that the difference in the length of stay by outcome was significant. The data appears to be skewed and therefore the median provides a better measure of the length of stay.

Table 19: Length of stay for patients admitted to Charles Hurwitz TB Hospital by outcome for the total sample (n=400)

LENGTH OF STAY	DIED	REFERRED	TRANSFERRED OUT	ABSCONDED	p VALUE
Mean	21.7	74.3	41.2	41.8	0.0000
Median	12.0	70.0	34.0	28.5	
Standard deviation	27.9	25.2	39.1	42.2	
Range	0-174	13-70	0-167	2-121	

6. ADHERENCE TO THE NTCP ADMISSION CRITERIA

The tables below (Table 20 and 21) show the diagnosis of patients when being admitted to Charles Hurwitz TB Hospital according to the NTCP criteria for admission. In 2007, 234 (99.6%) of the patients were confirmed as TB before

admission while in 2008, 165 (100%) were confirmed for TB on admission. The p value is 0.4014 which is non-significant.

Table 20: Confirmed TB in patients admitted to Charles Hurwitz TB Hospital for the total sample (n=400)

TB CONFIRMED	FREQUENCY	PERCENT
Yes	399	99.8%
No	1	0.3%

Table 21: Confirmed TB in patents admitted to Charles Hurwitz TB Hospital by year (2007 – 2008) (n=400)

TB CONFIRMED	2007		2008		p VALUE
	n	%	n	%	
Yes	234	99.6%	165	100.0%	0.4014
No	1	0.4%	0	0.0%	

The tables below (22, 23) shows the method of diagnosis of patients before being admitted to Charles Hurwitz TB Hospital. Most of the patients 343 (85.8%) were diagnosed by sputum. In 2007, 216 (91.9%) of the patients were diagnosed by sputum and in 2008, 127 (77%) were diagnosed by sputa. The p value is 0.002 which is significant.

Table 22: Method of TB diagnosis for patients admitted to Charles Hurwitz TB Hospital for the total sample (n=400)

DIAGNOSED BY	FREQUENCY	PERCENT
Sputum	343	85.8%
CXR	51	12.8%
FNA	1	0.3%
Sonar	4	1.0%
N/A	1	0.3%

Table 23: Method of TB diagnosis for patients admitted to Charles Hurwitz TB Hospital by year (n=400) (2007 – 2008)

DIAGNOSED BY	2007		2008		p VALUE
	n	%	n	%	
Sputum	216	91.9%	127	77.0%	0.0002
CXR	16	6.8%	35	21.2%	
FNA	1	0.4%	0	0.0%	
Sonar	1	0.4%	3	1.8%	
N/A	1	0.4%	0	0.0%	

Most of the admitted patients were new cases 314 (78.5%) followed by retreatment patients (n=85, 21.3%) (Table 24). In 2007, 185 (78.8%) of the admissions were new cases, retreatment patients were 48 (20.9%) and there was only one (0.4%) relapse patient, while 129 patients (78.2%) in 2008 were new cases, 36 patients (21.8%) were retreatment patients and there was no case of relapse. The p value was 0.6878 which is non-significant (Table 25).

Table 24: Admission category of patients admitted to Charles Hurwitz TB Hospital for the total sample (n=400)

PATIENT CATEGORY	FREQUENCY	PERCENTAGE
New case	314	78.5%
Retreatment	85	21.3%
Retreatment after cure	32	8.0%
Retreatment after completion	8	2.0%
Retreatment after default	11	2.8%
Retreatment after failure	8	2.0%
Retreatment after interruption	22	5.5%
All other re-treatment cases	4	1.0%
Relapse	1	0.3%

Table 25: Admission category of patients admitted to Charles Hurwitz TB Hospital by year (2007 – 2008) (n=400)

PATIENT CATEGORY	2007		2008		p VALUE
	n	%	n	%	
New Case	185	78.8%	129	78.2%	0.6878
Retreatment	49	20.9%	36	21.8%	
Relapse	1	0.4%	0	0.0%	

The tables below show the status of patients on admission. Most of the patients (n=355, 88.8%) were stable on admission, while a small percentage were unstable (n=45, 11.3%). Table 27 shows in 2007, 203 (86.4%) of the admissions were stable on admission and 32 (13.6%) were unstable. In 2008, 152 (92.1%) were stable and 13 (7.9%) were not stable. The p value is 0.0737 which shows that there was a marginally significant increase in the percentage of patients who were admitted in a stable condition in 2008 compared to 2007.

Table 26: State of admission of patients admitted to Charles Hurwitz TB Hospital for the total sample (n=400)

STATE ON ADMISSION	FREQUENCY	PERCENTAGE
Stable	355	88.8%
Unstable	45	11.3%

Table 27: State of admission of patients admitted to Charles Hurwitz TB Hospital by year (2007 – 2008) (n=400)

STATE ON ADMISSION	2007		2008		p VALUE
	n	%	n	%	
Stable	203	86.4%	152	92.1%	0.0737
Unstable	32	13.6%	13	7.9%	

The table below shows the co-morbid disease in patients admitted during the study period. A large percentage of patients had no co-morbid conditions (n=399, 99.8%)

and only one (0.3%) had leg ulcers. HIV co-morbidity has been presented earlier in the chapter.

Table 28: Co-morbid diseases in patients admitted to Charles Hurwitz TB Hospital for the total sample (2007 – 2008) (n=400)

CO MORBID CONDITIONS	FREQUENCY	PERCENT
Ulcers	1	0.3%
N/A	399	99.8%

Table 29 shows alcohol abuse by patients and Table 30 presents drug usage of patients. One patient (0.3%) admitted to abusing alcohol, while one patient (0.3%) was on epileptic drugs and another (0.3%) indicated that he/she was deaf. It is clear that this aspect of the records was not correctly completed.

Table 29: History of alcohol abuse recorded in patients admitted to Charles Hurwitz TB Hospital for the total sample (2007 – 2008) (n=400)

ALCOHOL ABUSE	FREQUENCY	PERCENT
Yes	1	0.3%
No	191	4.7%
N/A	208	5.2%

Table 30: History of drug use recorded in patients admitted to Charles Hurwitz TB Hospital (2007 – 2008) for the total sample (n=400)

DRUG ABUSE	FREQUENCY	PERCENTAGE
Yes/Deaf	1	0.3%
Epilepsy	1	0.3%
N/A	398	99.5%

Table 31 provides a summary of NTCP criteria adherence in patients admitted to the hospital. An admitted patient was considered to have met the NTCP criteria if at least one of the criteria was met for an individual patient. If HIV co-morbidity was not considered 396 (99.0%) patients did not meet the NTCP criteria, while if HIV patients

with a CD4 count of less than 200 cell/mm^3 were included, then 205 (51.3%) of patients admitted would not have met the NTCP criteria.

To consider social reasons for admissions, patients who were unemployed or pensioners were excluded, as well as patients who lived further than 30 kilometers (assuming that this would be a 15 minute drive) away from the hospital. If such patients are considered to have met the NTCP criteria, then without considering HIV co-morbidity, 83 (20.8%) patients did not meet the NTCP criteria, while if HIV patients with a CD4 count of less than 200 cell/mm^3 were included, then 56 (14.0%) of patients admitted did not meet the NTCP criteria.

Table 31. Summary of NTCP criteria adherence in patients admitted to Charles Hurwitz TB Hospital for the total sample (2007 – 2008) (n=400)

NTCP criteria	**Met criteria**	**Did not meet criteria**
Confirmed TB by sputa	343 (85.8%)	57 (14.2%)
Retreatment case	85 (21.3%)	315 (78.7%)
Stable	355 (88.8%)	45 (11.2%)
Co-morbid conditions (HIV)	- 373 (93.3%)	- 27 (6.7%)
Alcohol/drug dependence	1 (0.3%)	399 (99.7%)
Total that did not meet NTCP criteria (excluding HIV co morbidity)		**396 (99.0%)**
Total that did not meet NTCP criteria (including HIV co morbidity)		**26 (6.5%)**
Total that did not meet NTCP criteria (if CD4 count < 200 cell/mm^3)		**205 (51.3%)**
Patients with potential social problems considered: - Unemployed/Pensioner - Lived more than 30 kilometers from hospital		
Total that did not meet NTCP criteria (excluding HIV co morbidity)		**83 (20.8%)**
Total that did not meet NTCP criteria (including HIV co morbidity)		**10 (2.5%)**
Total that did not meet NTCP criteria (if CD4 count < 200 cell/mm^3)		**56 (14.0%)**

CHAPTER FOUR: DISCUSSION

1. INTRODUCTION

In this chapter the findings of the study are discussed in relation to the objectives, and based on the literature review.

2. DEMOGRAPHIC PROFILE

The study indicates that most of the patients were in the economically active age group of 37-38 years, while more males than females were admitted. In a study done by Douglas in 2003 at the same hospital the mean age was 37 years, same as this study and still more males were admitted than females (Douglas, 2007). This indicates that TB is a disease that affects the age group that is supposed to be in the working age group making it a challenge to be active in the labour market. If the population in this age group is ill then they are not in a position to care for their dependants fuelling the poverty cycle. In a study done in the rural North West Province by Molefakgotla in 2003 on Direct Observed Therapy Short Course, it was found that most of the patients were in the age group of 25-34 years and then 35-54 years and that more males were admitted than females (Molefakgotla, 2003.)

In a study done in Brazil on the epidemiological profile of TB cases reported among the health care workers in the National TB Control programme the following results were noted: most of the patients were in the age group 35 to 39. That study also found that patients had common co-morbid condition of AIDS, alcoholism, and smoking. More males were admitted than females (do Prado, Galavote, Brioshi, et al., 2008). Njaramba in 2003 also did a study on MDR patients at Sizwe Specialized TB Hospital and found that more males were admitted than females (Njaramba, 2003).

The sex disparity in the incidence of TB can be attributed to physiological, socio-economic or cultural differences between males and females that determine the risk of being infected (Njaramba, 2003). Men are more likely to frequent congregate settings which are a fertile ground for the transmission of the *mycobacterium*. This

was presented in a study done at a specialized Hospital in Gauteng Province on Multi Drug Resistant patients (Njaramba, 2003). In a study done in the Cape Town suburbs in 1996 characterized by high unemployment and poverty where TB had reached epidemic proportions there was a pattern with a particular lifestyle. The areas had a greater number of drinking places (shebeens), and had characteristics of a dangerous lifestyle with overcrowding, poverty and unemployment (Munch, Van Lill, Booysen, et al., 2003). The high number of TB notifications in the unemployed, with its associated poverty emerged as the strongest association.

A study done in 1996 of a peri urban population in SA showed that TB affects more men than women except in the adolescent age group. Most of the infected men were in the age group 20-39 years (Sacks, Pendle, 1998). Studies done in the following health districts in the Free State province: Kopano, Tshepo and Hlanganani by HST showed that more males were infected than females and the males were in the economically active age group (Janse van Rensburg, Engelbrecht, Heunis, et al., 2000). This concurs with the results of this study.

Globally it has been found that TB is a disease of poverty affecting mostly young people in their most productive years (World Health Organisation 2009a). Similarly, this study showed that most of the patients were unemployed and others depended on the social grants given by government for the unemployed. However, these were very few (5%). This grant is offered to ill patients whilst on treatment when they are unable to continue working or seek employment. If a patient eats well whilst on treatment, treatment outcomes improve (Bruso, 2010). The grant is given against that background that patient should have money to be able to buy nutritious foods. There can be no specific diet that can be said is ideal but patients with TB should eat a healthy and varied diet (Nutrition Information Centre, undated). In addition, the grant can assist patients to access health services.

The selected patients were unemployed even though they were at an employable age, whether it was due to lack of employment opportunities or lack of skills to compete in the open labour market, that was not ascertained by the researcher. TB is both associated with poverty, and increases poverty because it attacks the

economically productive fraction of the population. TB can also indirectly lead to unemployment as patients may be too ill to search for jobs or be active at work.

Even in TB studies in the developed world like Switzerland, the disease affects those who are fragile, which in that situation includes the old and their population of immigrants, and not the economically active younger age group like in our setting. The immigrants come from the under developed countries. In the USA, TB primarily affects the poorer populations in the communities, such as those without health insurance (Hansel, Merriman, Haponik, et al., 2004).

Similarly, in London, in 2004, there was an outbreak of cases of TB. In the whole of the UK, London accounted for 40% of all the TB cases. This prompted an investigation into questioning the TB control systems whether they are still effective. Before this outbreak, TB was not a public health risk in London as patients were fully ambulatory, they adhered to treatment and took treatment on their own. Further research identified categories of patients who were considered to be “problematic” in the TB control programme, resulting in the outbreak. These were homeless people, prisoners, and patients with socioeconomic needs (Story, van Hest, Hayward, 2006). The same problem and category of patients were also identified in the Netherlands. A programme for patients who have social ills should be not only clinical but also include social remedies that will address issues like lack of accommodation, addiction and diagnosing prisoners in time (Story, van Hest, Hayward, 2006).

3. CO-MORBIDITY WITH HIV

The study showed that most of the patients tested positive for HIV. In this study almost all of the patients were HIV positive. If patients who declined to be tested are excluded, 98.7% of the study populations were found to be positive. This has more than doubled from the previous study at the hospital, where 46% of patients were found to be HIV positive (Douglas, 2007). It can be assumed that this percentage would not change significantly as some of the patients who declined to be tested would also be positive. These findings confirm the findings of the study done in Brazil on the epidemiological profile of admitted patients in a large regional hospital. That

study found that patients had AIDS as a common co-morbidity and 18.4% of those patients died (do Prado, Galavote, Brioshi, et al., 2008).

However, it is worrying that only a small percentage of eligible HIV positive patients were on ARV therapy (18.3%) and a large percentage were not on therapy (81.7%), in spite of the fact that ARV therapy is free and offered to patients who test positive for HIV and who agree to be on treatment. Furthermore, eligibility for ARV therapy was assessed using a CD4 count of below 200 cell/mm^3, as this was the policy during the study period (National Department of Health, 2004), and it was found that only 34% of patients who met this criterion were actually on treatment. The percentage of patients who were eligible for ARV (n=191, 67.3%) is however lower than previously found at the hospital (over 75%) (Douglas, 2007)

The CD4 count for the selected patients were significantly higher in the second year of the study. This could potentially be due to the intensified programme on HIV testing making information more available to patients and encouraging users of health care to undergo voluntary counseling and testing, and increasing access for patients by increasing sites for Voluntary Counselling and Testing (VCT). With this, ARV therapy was also made more easily available and readily to patients who have been diagnosed as suffering from both TB and HIV/AIDS. If patients are on ARVs their CD4 count improves and so too does their general condition. However, the study raises concerns regarding the implementation of this and the uptake of ARV use by patients.

Two major changes have occurred with HIV policies in 2010. Firstly, a policy was introduced by the National Department of Health (NDOH) in April to increase the number of patients testing for HIV by changing from Voluntary Counselling and Testing (VCT) to Health Care Worker Testing (HCT) whereby health care workers must at all times offer HIV testing to patients, clients, and relatives who visit health institutions (National Department of Health, 2010). This, however, will need to be monitored and evaluated to measure whether patients who test positive and who are eligible for ARV therapy actually do receive treatment and are correctly managed.

The second change is related to the guidelines on ARV treatment eligibility and commencement. In December 2009 the President made an announcement that changed the criteria for accessing ARVS for those who are HIV infected. All pregnant women and children who are infected with HIV can access treatment. TB patients whose CD4 count is less than 350 cell/mm^3 would also be offered treatment. According to the old policy, 191 patients were eligible for ARV therapy. With the new policy, a further 19 patients would be eligible for ARVS, meaning that about three quarters of patients (73.9%) would require ARV therapy. These would increase expenditure for TB Hospitals to buy medication for admitted patients. Patients would also stay longer in hospital as they will be monitored for reactions towards the medications.

The increase in the new TB cases can be due to the fact that the HIV pandemic presents a massive challenge to TB control in terms of case detection; follow up of suspects, and implementing and monitoring programmes like Direct Observed Therapy Supervised (DOTS), which is a tool that can be used in managing the disease. The TB and HIV epidemics have reached very high levels. When a patient is admitted it is an opportune moment for staff to educate the patient on the interaction of both epidemics. Services like VCT should be offered to patients and ARV medication provided if required. There is documented evidence that the risk of TB infection is reduced by 70-90 % in HIV positive patients if they are on ARV treatment (National Department of Health, 2007).

A lot of resources that is both human and material were concentrated on managing HIV. It is only recently that the NDOH took a decision to collaborate TB/HIV programmes so as to also pay detail to TB management. SA is one of the 22 countries according to the WHO globally which has the highest number of TB cases. In a study done in 1996 by the WHO the conclusion was that the global burden of TB remains high in sub-Saharan Africa due to high rates of *Mycobacterium tuberculosis* and HIV co-infection. In the fourth WHO global report of 2008 for the NDOH it was shown that an estimated 73% of new TB patients are co infected with HIV (Chaisson, Martinson, 2008).

4. TREATMENT OUTCOMES

4.1. MORTALITY

TB treatment when taken correctly without defaulting is highly effective and is also very cheap. In spite of all this, TB remains a serious cause of illness and death worldwide. In the WHO notified cases of the disease 95% are from developing countries and 98% of deaths occur in these countries (Grange, Zumla, 2002). The death rate in this study was high, in keeping with the findings of the WHO TB report (Donald, van Helden, 2009) which reported that TB was a leading killer amongst people living with HIV/AIDS. More deaths occurred in 2007 than in 2008. This finding correlates with the findings which indicated that the CD4 for the selected patients was higher for the patients in 2008 than in 2007. Patients died on average within 2 - 3 weeks of admission to the hospital.

In a study done at the hospital from 2001-2003 by Douglas it was found that admissions and mortality had increased significantly (Douglas, 2007). In this study, deaths decreased by year. In 2007 there were 75 deaths (31.9%) and in 2008, 36 deaths (21.8%). This does not show a huge improvement from the figure reported in 2001-2003 (27%) (Douglas, 2007). When the study was done in 2001-2003 the programme of offering patient ARVS was not as yet implemented. One of the recommendations of the study was to offer patients ARVS and it is being done even though the uptake is not 100%.

In a study done in the United States in 2000 on hospitalization for TB, it emerged that in spite of curative therapy mortality remains high (Hansel, Merriman, Haponik, et al., 2004). The purpose of the study was to describe the characteristics associated with mortality. It emerged that most of the patients were male, non-white, lived in areas of median income, had no medical insurance or had public funded health insurance, and that mortality was high for patients who were admitted as compared to patients who were not admitted (Hansel, Merriman, Haponik, et al., 2004). The difference in the US study compared to findings from Charles Hurwitz TB Hospital, was the mean age for mortality, where patients who died at the US hospital were older (mean age of 65.1 years) (Hansel, Merriman, Haponik, et al., 2004). This is

unlike the situation of the developing countries were TB affects people who are in the economically active group.

4.2. OTHER TREATMENT OUTCOMES

More referrals were made in 2008 than in 2007 to other provinces. This could indicate that these patients were migrants, possibly due to work. Ultimately most of the selected patients (60.3%) were referred to tertiary institutions for further management. There is a problem of shortage of beds in tertiary institutions due to large number of patients that they see. Patients that test positive for then TB are referred to our institution even if they are relatively ill. In Charles Hurwitz TB Hospital when they complicate they are referred back from the initial institution that referred them.

5. LENGTH OF STAY

The recommended average length of stay according to the National Tuberculosis Control Programme (NTCP) for admitted TB patients is 14 days (National Department of Health, 2000). This is far shorter than the average length of stay for patients in this study (56 days), although patients did stay for a significantly shorter period in 2008 (51 days) than in 2007 (59 days). At certain times patients who come to the hospital for admission are very ill and then they stay longer than expected. The length of stay of patients who were eventually referred out to tertiary institutions was much longer (74 days) than patients were transferred out (41 days)

In certain instances admitting doctors do not trust the Direct Observed Treatment Short Course (DOTS) supervision at clinics; and then want patients to stay until they are tested to be sputum negative after four months before being discharged. This makes compliance with the NTCP guidelines very difficult and in addition, it becomes difficult to assess whether the DOTS programme is effective.

6. ADHERENCE TO THE NATIONAL TUBERCULOSIS CONTROL PROGRAMME

The aim of the National Tuberculosis Programme Control Programme (NTCP) is to reduce the prevalence of TB and furthermore, reduce and prevent drug-resistant forms of TB. This aim can only be achieved if there is an effective diagnosis, treatment and improved communication systems between the hospital, laboratory and its down referral systems (Loveday, Thompson, Ndlela, 2007).

The study looked at the results with a view of adhering to the NTCP criteria in three ways. Firstly it was adherence according to criteria as written, namely, do patients have confirmed sputa results on admission, is the patient a retreatment case of TB, is the patient's condition stable on admission, are there any co-morbid conditions, and is the patient abusing alcohol and or drugs? Most of the patients in this study (n=343, 85.8%) were diagnosed by sputum and confirmed with TB on admission according to the NTCP criteria however there were 57 (14.2%) that did not have confirmed sputa results on admission. There had been a significant decline in the percentage of patients diagnosed by sputum from 2007 (91.9%) to 2008 (77.0%). A large percentage of patients were not retreatment cases and 315 (78.7%) and 45 (11.2%) were not stable on admission. Twenty seven patients (6.7%) had co- morbid conditions and 399 (99.7) of the patients said that they were not abusing drugs or alcohol.

The study also looked into adherence to the criteria using HIV co-morbidity. When HIV co-morbidity was not considered, 396 (99%) patients did not meet the NTCP criteria, when HIV co-morbidity was considered this was reduced to 26 patients (6.5%). More specifically if HIV co-morbidity was only considered when the CD4 count was less than 200 cells/mm^3, then 205 (51.3%) patients would not have met the NTCP criteria.

Part of the criteria is to consider if patients have social problems. This could include the fact that they are unemployed or pensioners or that they are staying very far from the hospital (considered to be more than 30 kilometers away for the purpose of this study). If this was taken into consideration, then only 83 patients (20.8%) did not meet the criteria for admission even before excluding patients with HIV. If HIV co-

morbidity was considered as well, then 10 patients (2.5%) would be considered to have not met the NTCP criteria for admission. If HIV co-morbidity was considered with a CD4 of less than 200 mm cell/mm^3 then 56 (14.0%) of patients would not meet the criteria. This shows that it is a challenge to admit patients strictly adhering to the criteria for admission to TB Hospital.

The question that can be asked based on the study findings is, is the criteria relevant and responsive to the HIV/TB collaboration? Is it responsive to the two epidemics? The study found that if HIV co-morbidity was considered then a half to almost all of the patients would meet the criteria for admission. In addition, if social needs were considered, a less than a fifth of the patients would not meet the criteria for NTCP criteria. It is therefore apparent that it is hard to assess strict conformance with the criteria. This is due to the nature of the criteria such that it allows for flexibility in co-morbid conditions and in social needs. In South Africa, where both of these are rife, almost all patients are able to meet the criteria.

These findings are very different from those reported by a study done in 2008 in KwaZulu-Natal assessing the tuberculosis programme in the context of increasing drug resistance. There it was found that clinicians did not adhere to the diagnostic guidelines of the NTCP. The TB register showed that 85% of PTB cases were diagnosed in the absence of sputum microscopy, while for 45% of the admitted patients, the diagnosis of TB was made by chest x-rays instead of sputum microscopy as is required by the guidelines. There was also poor documentation of clinical history suggestive of TB (Loveday, Thompson, Ndlela, 2007).

If almost all of the patients met the criteria for long-term hospital admission, it is of concern that a high number of patients (60.3%) who were referred back to tertiary institutions. Further sub-analysis shows that 99.6% (n=240) of these patients were actually stable on admission. Further investigation into the reasons for the their referral is warranted as it would be problematic if patients' conditions were actually deteriorating while being admitted to Charles Hurwitz TB Hospital.

8. LIMITATIONS OF THE STUDY

The study has a number of limitations:

As the study was based on a record review, the reliability of the data captured is influenced by correctness and completeness of information in patient records and on the DHIS. Furthermore, only one method of data collection was used (i.e. a record review) and no patient interviews were done for follow up of questions and to get a better understanding of the situation. Similarly, there was no further follow up on why patients who qualified to be on ARV therapy were not on medication as it is free and available in the facility. The findings and recommendations of the study were however discussed with the clinicians.

The study looked at employment status of the patients and not type of employment, educational qualifications, race, and migrancy status. In terms of HIV, patients without HIV test results are offered VCT on admission. However, not all patients had an HIV test result, and the study did not actively seek to test these patients for HIV.

CHAPTER FIVE: CONCLUSION AND RECOMMENDATIONS

1. INTRODUCTION

In this chapter, a conclusion is drawn based on the findings, and recommendations are made within the context of the study.

2. CONCLUSION

More males were admitted than females concurring with previous studies. Most of the admitted patients were unemployed or were receiving social grants. Ninety eight percent of the patients were HIV positive and 67% were eligible for ARV therapy. The age group of the patients that were mostly infected was in the economically active group yet most of them were unemployed. Mortality was high but about two thirds of patients were eventually referred back to tertiary institutions.

Adherence to all of the criteria from the NTCP was a challenge. Patients were admitted for more than 15 days. The mean length of stay was 55.8 days; more than what the criteria says. Patients were admitted then referred back to the institutions were they came from probably because of their health status that Charles Hurwitz TB Hospital could not manage but this was not investigated in this study. The admission criteria was formulated during the HIV/AIDS epidemic yet it does not indicate the fact that there was consideration that some of the admitted patients might be very sick and would have to stay for long in the hospital.

In studies done in the US, Spain, UK, Switzerland, and Brazil, TB is common amongst the poor, HIV infected, immigrants, homeless, drug abusers and elderly in residential homes. The situation in South Africa is somewhat different. Young people who are in the economically active age group especially males suffer from TB as proved in the research.

The TB epidemic is fuelled by the HIV epidemic in Africa and sub Saharan Africa which leads to high mortality of the patients. The relationship between TB and HIV cannot be ignored. Management of both conditions is important for control of TB to

be achieved. Only then can the Millennium Development Goal to halt the spread and incidence of TB by 2015 be achieved.

TB was once associated with old people who were sitting in hospital verandahs having shortness of breath, coughing a lot, with sputum mugs and who were smoking a lot. The picture has now changed completely with young people in their prime years being sufferers and end up with other forms of TB like MDR and XDR.

2.1. THE CLOSURE OF CHARLES HURWITZ TB HOSPITAL

While the study was undergoing in 2010, a decision was taken by the Gauteng Department of Health and Social Development to close down the hospital and incorporate in-patient TB management and care into district hospitals. Patients suffering from TB are now admitted in TB wards in general hospitals. The Charles Hospital TB Hospital was finally closed on the 31st of October 2010. The decision was based on the fact that it was not cost effective to maintain the hospital. Rental to SANTA was too expensive at eighty thousand rands per month, and patient numbers were reduced. From the previous numbers the hospital was no longer full to capacity. The bed capacity was 350 but from 2009 the number of patients admitted on average was 200 per month. This prompted the Executive authority to decide that it is best to have TB wards in general hospitals as a cost saving measure rather than a TB Hospital.

This study did find that many patients were referred back to general hospitals after admission to the TB Hospital possibly for further management. Thus, some advantage of having the TB wards in general hospitals is that patients can then have access to other services and disciplines in the facility, without having to be moved between institutions. The fear, however, is that TB patients might be discharged when they have not yet fully recovered as the general hospitals are always full.

3. RECOMMENDATIONS

The recommendations made below are done in light of the closure of the hospital in which the study was conducted, but are important considerations that should be accounted for with any in-patient or out-patient TB control programme

- There must be an improvement in the management of TB/HIV co-morbidity, especially in relation to the provision of ARV therapy. This must be accessible to all admitted patients as this study found that most of the admitted patients who were eligible for therapy were not on treatment.
- The NTCP criteria are written in a very broad format. As TB Hospitals have been closed, the criteria need to change to accommodate TB wards in general hospitals.
- The length of stay recommended needs to be reconsidered and possibly revised for different categories of patients admitted.
- Provisions need to be made available in general hospitals for the long-term hospitalization of TB patients. This includes issues like infection control, management of the TB wards, budget and resource allocation.

Other partners:

- There is a need to strengthen linkages with the Department of Social Development, and to find ways to assist patients in accessing grants during this time.

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APPENDIX A: CHARLES HURWITZ TB HOSPITAL: PROFILE OF ADMITTED TB PATIENTS

Sex	Male……1 Female……2
Age in years	_ _
Employed	Yes.....1 No.....0
Grant Receiver	Yes.....1 No.....0 If yes: type of grant: _____
Location (Extension name)	
Admission date (yyyy / mm / dd)	_ _ _ _ / _ _ / _ _
Patient category	New case.....1 Retreatment after failure.....2 Retreatment after default.....3 Retreatment after cure.....4
TB Confirmed	Yes.....1 No.....0
Diagnosed by	X-ray……1 Sputum ……2 LP……3 Biopsy……4 Clinical……5 Other……6 _____
State on Admission	Stable……1 Unstable……2 Cause of being unstability: _____
HIV	Positive.....1 Negative.....0 If yes, latest CD4 count: Date of result (yyyy / mm / dd): _ _ _ _ / _ _ / _ _ Result: _ _ _ If yes, is patient on ARV: Yes.....1 No.....0 Date when ARV started: _ _ _ _ / _ _ / _ _
Other Co-Morbid Conditions	Diabetes.....1 Hypertension .....2 CNS .....3 Other:.....4 List other:_____
Drug abuse	Yes.....1 No.....0
Alcohol abuse	Yes.....1 No.....0
Date of Discharge (yyyy / mm / dd)	_ _ _ _ / _ _ / _ _
Outcome	Death ……1 Discharge……2 Referred ……3 Transferred out (Clinic or Province) ……4

APPENDIX B: ETHICS APPROVAL CERTIFICATE

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Ms Maranyane R Lesele

CLEARANCE CERTIFICATE	**M10640**
PROJECT	The Profile of Patients Admitted at Charles Hurwitz Tuberculosis Hospital in the Gauteng Province
INVESTIGATORS	Ms Maranyane R Lesele.
DEPARTMENT	School of Public Health
DATE CONSIDERED	25/06/2010
DECISION OF THE COMMITTEE*	Approved unconditionally

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

DATE 28/06/2010 **CHAIRPERSON** .....
(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable
cc: Supervisor : Dr R Jina

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 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...