A Cost-Effectiveness Analysis of the Clinical Curative measure as an alternative to Tuberculosis Management in the Pietermaritzburg-Msunduzi Council Area

Leabiloe Rampa-Molapo

Submitted as the dissertation component in partial fulfilment of the requirements for the Master of Social Science (Economics) degree.

Department of Economics
University of Natal

1999

Abstract

This research examines the treatment of Tuberculosis in South Africa, focussing particularly on the Pietermaritzburg-Msunduzi Council Area in the Natal province.
Two alternative measures of TB control are examined, the clinical curative regime and in-patient treatment, that is, the hospitalisation of patients. The samples used are a random selection of patients treated through the Pietermaritzburg Clinic and SANTA Hospital.
As this research entails a cost-effectiveness analysis determining the most cost-effective way of treating TB, much of the analysis and conclusions are derived from the costs entailed in the two aforementioned control measures. Cost analysis of the alternative measures of treatment reflects that the clinical outpatient alternative to TB treatment is more cost-effective than the hospitalisation option. A closer examination of the costs reveals the cost savings that can occur if an efficient use of resources is established. Furthermore the results reflect a cost effective drug use by the hospital at R173.65 per patient cured compared to R403.51 per patient cured through the clinic. Analysis of results showed institutional costs as the reason for the cost-ineffectiveness of hospital care. Overall, the clinical measure to the treatment of TB was more cost-effective at R490.34 per patient cured compared to the R7502.66 per person cured through hospitalisation.
The sample sizes yielded cure rates of fifty-eight for the clinic and eighty-five percent for the hospital.

Acknowledgements

An initial word of thanks to George Oldham, for his supervision of this paper. Dr.Nkosi and Dr.Dyer of the Pietermaritzburg-Msunduzi TB Clinic deserve a special mention of thanks for making all information accessible and from whom the initial encouragement came. Not forgetting Sister Nock, Sister van Wyk and the Boom Street Clinic and Staff. Mrs.Gold, Mr.Bonginkosi Ndlovu and the Doris Goodwin SANTA Hospital staff provided their assistance even at the most awkward times, and for this I am immensely grateful. Thank you to Thabo Khojane and Dr.Refiloe Matji for the initial information they provided Tsalikoe Ntoampe, Mmabatho Seeiso and the Wits University Library Staff.

A special thank you to my family- 'Maleabiloe and Ratau Rampa for their financial and emotional support throughout my entire academic career, this would not have been possible without them. 'Maseoehla and Seeiso Molapo for their encouragement and finally my husband Jonathan for being the eternal optimist.

The usual proviso naturally holds, any errors and omissions are entirely my own.

Declaration

Unless specifically indicated to the contrary, I declare that this dissertation is my own original work.

It has not been submitted simultaneously at any other University or at any other time for another degree.

Leabiloe Rampa-Molapo

Pietermaritzburg

1999

List of Figures and Tables **Page**

Table of Contents **Page**

Introduction

The quality of a nation's health overwhelmingly is a response to the nature of its political, social [and economic] environment. (Savage: 1979: 140). This has been highlighted recently by a number of authors as issues of health changes and development are being linked. "Health is much more than the absence of diagnosed physical disease..." according to Phillips and Verhasselt (1994:3). This invariably makes health an extremely elusive concept, equally so, to development.

The World Health Organisation (WHO) made its *Alma Ata Declaration* in 1977, to provide "universally accessible, appropriate and affordable health services for all by the year 2000"(WHO: 1978). Since then, governments of less developed and developing countries, international aid agencies and non-governmental donors have focused their attention on the development of health systems with the hope of ultimately improving health outcomes.

Health outcomes have been measured by health indices such as mortality and morbidity rates, and have often been associated with the level of development in transition economies and third world countries. Cullis and West (1979) looked at the relationship between health and development. Much as this use of health indices still remains the most popular way of measuring overall economic development, there are some drawbacks to their use, as has been addressed by Feldstein (1970).

The use of health indices in this study will be limited because analysis focuses on determining effectiveness and the determination of that lies in calculation of costs and cure rates. Sorkin (1975:2) states,"one measure of output or effectiveness of the health industry is selected indicators of health levels such as mortality rates..."

Incidence rate comparisons provide information useful in making judgements or providing insights about the relative health levels of various sub-populations. These rates will help in measuring the effects of Tuberculosis (TB) on sub-populations taken from the hospital and clinic.

Background to the Problem

The restructuring of health systems in developing countries has come under much debate, with assertions being made that inefficiencies of health systems begin with inefficiencies in health planning.

In most African countries, the inefficient health care systems can be attributed to the colonial era. "...Large urban hospitals, designed to provide *Western* acute care for colonial rulers, have been preserved to service the equally privileged elite in developing countries...[yet] remain inaccessible to the rural population "(Cullis and West: 1979: 278). In South Africa presently the problem is sustaining health programs implemented by the Department of Health, and in this particular study, the Tuberculosis Control Program.

The inadequate diagnosis and management of Tuberculosis (TB) is a major problem facing the Department of Health countrywide. Based on historical statistics, at any one time there may be a demand for over 15,000 specialised TB beds in South Africa. This figure is a conservative one given that the incidence of TB grows every year. During 1996 there were approximately 160,000 new TB cases in South Africa. Based on this information one can see that there will be a growing need for resource allocation to inpatient care. However, hospitalisation is not deemed as the only alternative.

The Directly Observed Treatment – Short Course (DOTS) or what will be referred to as the clinical outpatient treatment method in this study is a TB management method whereby TB patients are treated as outpatients from Clinics. They receive prescribed drugs and carry out a self-monitored treatment programme. The onus is on the patients to return for more medication when required, for regular check-ups and to see to it that the Treatment is completed. This is meant to be a low-cost alternative to the in-patient care of hospitals.

This study will investigate the effectiveness of the DOT course of tuberculosis in terms of the cure rates attained as well as the number of patients that default and also in terms of costs. Investigating cost effectiveness will shed light on assertions made regarding its potential cost-effectiveness.

Recognising the seriousness of the TB Problem, the Department of Health implemented the DOTS Strategy in 1996. The main focus of this strategy "...is on patient-

centred care, identification of infectious patients through smear microscopy, effective standardised treatment regimes, supporting patients through directly observed treatment, and monitoring treatment outcomes through cohort analysis using the tuberculosis register." (Department of Health: 1996).

The assertion is that, being based on internationally-recommended principles, this strategy, if implemented properly, will result in considerable savings, both financial and in terms of human life.

Hospitalisation was for a long time the National Strategy for TB management, but given the rising numbers of TB cases-most of which are now due to growing HIV/AIDS cases, it has now become a costly alternative.

Given the rising number of TB cases each year, the issue raised by this study is whether measures that entail hospitalisation would, in the long run, be more cost-effective. This is based on the assumption that hospitalisation ought to yield higher numbers of cured patients given that prescribed drugs are strictly administered and patients well monitored. Whereas with the Clinic measure lower costs are offset by higher failure rates.

Treatment of patients that default is associated with higher costs. Firstly because, they have to start their treatment from the beginning and secondly, some patients develop a resistance towards the drug treatment course. According to the principles of the South African TB Control Program, all Multi - Drug Resistant (MDR) patients require hospitalisation for at least the first two months of re-treatment.

The costs of preventive activities such as health education, mass screening campaigns and the general dissemination of information on TB will not be considered in the analysis. The assumption made here is that education programmes affect the 'marginal' cases and often enough these marginal cases are left untreated. So this preventive measure will not necessarily reduce future costs. McIntyre (1986:108), in her assessment of the effectiveness of health education in TB management states that, "[I] t is difficult to determine the effectiveness of health education as it does not directly 'prevent' notifications." In her analysis she includes health education as part of the costs of curative care. Feldstein (1970) inadvertently addresses the issue of preventive measures and how they affect the costs of treatment. He states that, "...[b]ecause of the contagious nature of the disease the vaccination of one person can prevent more than one future case"(1970:147).

According to Sorkin (1975:114), "...[with a cost-effectiveness analysis], the costs are calculated and alternative ways are compared for achieving a *specific set of results*." The objective is not only that the funds are used efficiently, but that a specified output must be achieved.

The objective in the treatment of TB is to improve treatment outcomes and in the long run improve mortality and morbidity rates associated with TB. The results should indicate the cheapest form of treatment that yields the highest returns.

The difficulty that arises in valuing human life makes Cost-effectiveness Analysis (CEA) more appropriate than Cost-Benefit Analysis (CBA).One of the problem areas for CBA is health because there is a problem in quantifying the benefits that accrue to the recipients of a health project. One can not rule out the fact that it can be done, as Cullis and West (1979) have illustrated, but if so, only with great difficulty.

CBA entails a process where all the costs and benefits of potential projects are expressed in monetary terms. The cost-benefit value of each project is assessed, after having discounted[1] the value of the ratios. There are various arguments that can be entered into regarding the welfare implications of CBA (Perkins: 1994). However, because CBA will not be the method of analysis in this study, much of the discussion will be confined to CEA.

A cost analysis alone would not provide any insight into how appropriate the TB management strategies are. The effectiveness has to be estimated through assessment of costs and with the help of data on the cure rates of patients treated.

Klarman et.al. (1968) applied CEA to the treatment of chronic renal failure. They provided their rationale for the use of CEA in stating that cost-effectiveness, rather than cost-benefit is employed when various benefits are difficult to measure. Dunlop (1975) in his review of the applicability of CBA in policy analysis also provides various rationales for the use of CEA.[2]

---

[1] *Discounting*-costs and benefits accruing in future periods are scaled down to take account of the preference for present consumption over future consumption.(Cullis and West:1979:173)

[2] See also Fendick (1972) and Cohen (1974).

Scope and method of the study

The purpose of this study is to determine the most cost-effective measure of alternative tuberculosis treatments. The focus is on two alternatives, outpatient clinic care and inpatient hospital care. The hospital is the SANTA hospital, which is categorised as specialised sanatorium care. Wilkinson et.al (1996) in a similar study established that public hospitals are the most ineffective measure of treatment. This is still the case as the cost per patient per bed in a public hospital has been estimated at R800 per day (Department of Health: 1996). The SANTA hospital has been seen as a more attractive option as it costs an estimated R46.63 per day and specialises in the treatment of TB treatment.
Comparing the Boom Street Clinic alternative to the SANTA hospital means making a comparison on the basis that the two centres specialise in TB treatment. The drug costs, as well as the staff and maintenance costs incurred in the treatment of patients will be calculated, with the measure of effectiveness defined as the **cost per patient cured**.

The study will be confined to TB patients using the PMB-Msunduzi Clinic Services, using data from the PMB Boom Street Clinic and the SANTA hospital in Edendale. These are the only specialised TB centres present in the area. The other health centres in the area; Greys, Northdale and Edendale Hospitals carry out testing and refer patients that test positive to TB to the SANTA hospital for inpatient care and Boom Street Clinic for outpatient care. The only other specialised centre is the Richmond Chest hospital. This however is a privately managed hospital whose cost structure differs from that of government hospitals.

Random samples of TB patients have been selected from the patient registers from both centres. Because analysis will base itself on the costs of treatment of all TB patients, the age groups considered will be from the infant age to the mature adult age. Primary sources of data will be from the hospital and the Clinic centre, observations and interviews with members of staff. Secondary sources will be articles from journals and any published and unpublished material that is related to the area of study.

This dissertation is divided into five chapters, which are summarised as follows. Chapter One discusses the extent of the Tuberculosis problem in South Africa, projections of

future incidence, control and management and the contribution economics can make to health policy in respect of TB. More detailed information covering the treatment and case management of Tuberculosis in South Africa is presented in appendices A to C.

Chapter Two is the Literature Review concerning economic analysis in health care. Cost Benefit as well as Cost-Effectiveness studies are reviewed. This chapter contains a review of the principles of economic appraisal in health as an introduction to the methodology that will be used in the Third and Fourth Chapters.

Chapters Three and Four are the core chapters of the dissertation as they detail the cost-effectiveness analysis of the clinical and hospitalisation treatments.

Chapter Five will contain the summary of results, discussion and conclusions.

Chapter One

1.1 The Incidence of Tuberculosis in South Africa

In South Africa, Tuberculosis (TB) has been a notifiable disease since 1919. Notifiable meaning that health authorities are bound by law to report TB cases to health departments. Only since 1961 has the incidence of TB been so high that it is considered a continual epidemic. Despite dramatic advances in detection, limitation and treatment in the years since, it still remains the main public health problem.

Presently there are 35 public TB hospitals countrywide with a total of nearly 10,000 beds. Of the 35 facilities, the South African National Tuberculosis Association (SANTA) manages 22 with approximately 5,000 beds. The management strategy for SANTA hospitals is strictly in-patient care. Six of these hospitals are managed by Life Care Special Health Services (LSHS) - a private company which like SANTA, is subsidised by the government, on a contract basis, to provide the service to all those who are referred by general public hospitals. The government manages seven TB hospitals with approximately 1,600 beds. The prescribed management strategy here is not strictly specified, but bases itself on the South African TB Control Program Guidelines.

The expenditure on TB still surpasses that of other infectious diseases. A Cost Analysis of the South African TB Control Program estimated the cost of TB control activities in 1995 at R500 million. (Department of Health: 1996). The extent and severity of TB is generally assessed according to the notification rate, and the case fatality rate for this disease. Since it is not possible to determine to what degree the actual incidence of this disease is reflected by the notification of newly diagnosed cases, the notification rate remains relatively unreliable. This naturally also applies to the mortality rate, as well as the case fatality rates for this disease. Despite these defects, all three indicators are generally employed to determine the incidence of TB. These issues compound on the problems of the misdiagnosis of TB.

In 1995, TB accounted for more than 80% of communicable disease notifications in South Africa according to Department of Health (1996) statistics. 21,222 TB cases were

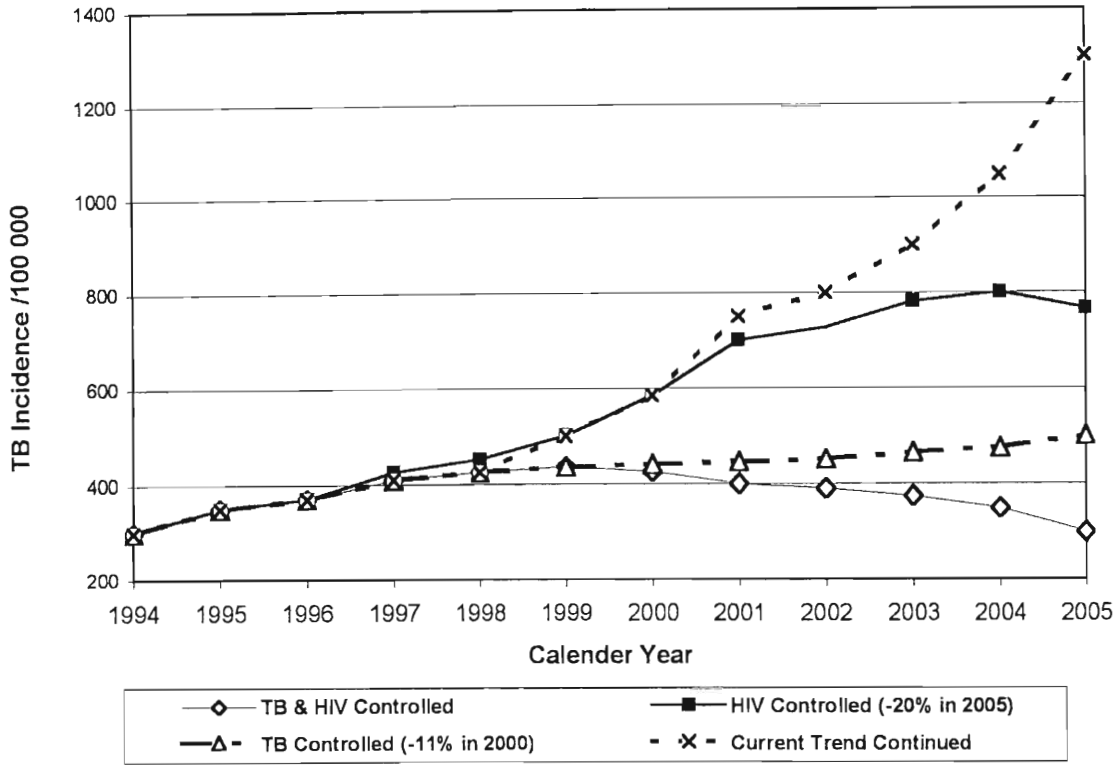
notified. Many smear positive cases remain undiscovered and from the discovered smear-positive cases many are not cured. Each uncured case infects about ten new people with TB. Current trends according to the Department of Health (1996) show increasing rates, which will only decrease with effective, HIV Control Programs. According to the 1996 Health Department's Epidemiological Comments,"[o]f these, at least 25% were attributable to infection with the Human Immuno-deficiency Virus (HIV) and 1% were harbouring multi-drug resistant tuberculosis organisms."

1.2 Projections of Future Incidence

If current trends continue (in the absence of effective control programs), 3.5 million new cases of TB will occur in South Africa over the next decade. However, with effective tuberculosis and HIV control put in place now, this burden would be halved; at least 1.7 million cases and more than 50,000 tuberculosis deaths would be prevented. Figure 1 illustrates the TB trends that could be seen in South Africa under different TB and HIV Control Programs. With the current trend whereby the ineffectiveness of TB Control Programs continues, the incidence rate could spiral on an upward trend indefinitely. Under an effective HIV Control Program, this could result in the incidence of TB continuing to increase but at a decreasing rate. Socio-economic issues have to be addressed to ensure the effectiveness of Control Programs. Common characteristics of poverty, including a poor diet and crowded living conditions, contribute to increases in the size of the infectious pool and thus the incidence levels of TB. If a combination of effective TB and HIV Control Programs is put into place TB incidence rates decrease.

The extent and trend of the tuberculosis epidemic is not accurately known, mainly because of a lack of standardized case definitions. Most importantly, the size of the infectious pool (those responsible for sustaining and spreading the epidemic) is not known. According to various assumptions and initial results from the new recording and reporting system of 1994, the overall incidence estimated by the Medical Research Council was 311 per 100,000, with 80% of these occurring in the 15 – 49 year age group. (Department of Health: 1996).

Figure 1: Future Trends of TB in South Africa (1995 - 2005)



Source: Department of Health, Epidemiological comments, 1996.

The projections made are based on data that has been extrapolated from earlier systems of recording and reporting TB cases. Although not as standardized as the system established in 1994, extrapolations made for the non-European majority of the population are based on higher infection rates due to socio-economic differences.

In 1995 South Africa had lower HIV prevalence rates than most African countries, according to the Department of Health (1996), however rising rates are beginning to have a significant impact on the prevalence of tuberculosis. Projections made in a study by Fourie and Weyer (1996) indicated rising TB prevalence rates accompanied by rising TB cases. The study pointed out that the HIV epidemic has amplified the TB epidemic by shortening the period between TB infection and disease, as well as between disease and death. Dually infected individuals have a 25 times greater chance of dying due to TB unless they are properly treated. "Because of the extraordinary vulnerability of those infected with HIV, very

high rates of clinical disease follow quickly after infection," according to Iseman et al (1993:576).

South Africa's HIV Control Program has to work in parallel with the TB Control Programs for there to be a significant stabilization and ultimately decline of the TB trends. This means that the major challenge of the Tuberculosis Control Program is to stay committed to the implementation of the most effective strategy. (Department of Health: 1996).

Table 1 :

Reported TB case rates (all forms) and estimated smear positive pulmonary TB incidence

Province	Rate per 100,000 total population	
	Reported all forms[3]	Estimated positive smears[4]
Western Cape	737	221
Eastern Cape	241	193
Northern Cape	442	133
Free State	513	103
Kwazulu-Natal	120	129
North West	112	102
Gauteng	164	142
Mpumalanga	84	101
Northern Province	44	102

Source: Epidemiological Comments. Department of Health, 1996.

1.3 Perspectives on TB Control Services

Tuberculosis services are provided along three general lines: integrated with primary

3 Source: Directorate Epidemiology, Department of Health, 1995

4 Estimated of SM+ tuberculosis

-30% of notified for WC and NC: WC case registration data, 1995

-80% of notified for EC: reporting already largely based on smear microscopy

-20% of notified for FS: Steenekamp survey(Dept. of Health, 1992/3) and policy of X-ray diagnosis

-50% of notified for NW and NP: MPL case registration data 1995/6 as proxy KZN: published data from Hlabisa

health care services, dedicated TB clinics as part of local government services, clinics and hospitals run by non-profit non-governmental organisations (NGOs) and the private sector. Within health facilities outside large cities, or even in large cities, clinic services are often taken over by the nursing staff. Whilst in rural areas where access to clinics restricts patients from going in for daily treatments, the community takes over the 'clinic services'. This is the basis of the Directly Observed Treatment (DOT), not just the nursing staff duties, but the community participation as well. These support structures enable the TB management system to function in rural areas.

This is particularly relevant to this study, where the PMB-Msunduzi area faces over-crowding and large patient loads, and no direct access to microscopy facilities (except through the King Edward Hospital in Durban).

On a national level, TB services fall under the Communicable Disease Control but is in effect part of the National Tuberculosis Control Program. Services provided by this national umbrella include the Directorate for Laboratory Services "which has the task of formulating a strategy for a Public Health Laboratory Service." (Department of Health: 1986).

Essential Drug Lists and pharmaceutical supplies are the responsibility of the Directorate for Pharmaceutical Services. According to the Department of Health, international cooperation is achieved through an organization comprised of 12 nations in the region, called the Southern African Tuberculosis Control Initiative (SATCI). SATCI aims to standardize management of tuberculosis in the region and ensure the proper care of patients across international borders.

1.4 The Contribution of Economics to Health Policy

Development is generally understood as the process of improving the quality of all aspects of human life. Many economic definitions see development as being a phenomenon measurable by increasing per capita income or gross national product (GNP). While it does, undoubtedly, have a quantifiable fiscal element, it has many more subtle elements, to do with the distribution of resources, access to opportunities (services, jobs, housing, and education), political and human rights.

---

used as proxy. MPL and GT: case registration data, 1995/6.

A complex interrelationship exists between health and development. It has long been acknowledged that the health status of the population in a particular space or country influences development. It can be a limiting factor, as generally poor individual health can lower work capacity and productivity and in aggregate, in a population, this can severely restrict the growth of economies.

On the other hand, economic development can make it possible to finance good environmental health, sanitation and public health campaigns – education, immunisation, screening and health promotion – and to provide broader-based social care for needy groups.

Issues over how much countries should spend on health services, how such expenditure is to be financed and the contributions that better health makes to the growth of GNP[5] and the quality of life have become a significant part of policy debates. These issues are determined by the economic policies that are followed. A country's budget may choose not to allocate gross amounts to the Health sector. The implications of this decision can have adverse effects on the economy as a whole.

The association of HIV infection with the resurgence of TB has been well-documented (Barnes et al: 1991). The repercussions of the Department of Health's decision not to administer the drug AZT to pregnant mothers will not only be the number of HIV babies born but also the number of increasing TB cases. An effective economic policy that positively impacts on the health policy of a nation can inadvertently bring under control the incidence of TB.

[5]For a discussion on the positive relationship between health and GNP see Wells and Klees (1980).

Chapter Two

2.1 Economic Analysis in Health Care

The definition of Health can take on diverse dimensions. Varying from the holistic to the official definitions. The holistic definition implies that health is something that is entrenched within the norms of society. As Aggleton (1990:10) puts it, "ill health is something that is intrinsically bad for society". Official definitions are often the views of doctors and health professionals. Definitions given by societies tend to lie between the holistic and official. To them health is a relative quality – relative to the surroundings and circumstances in which people find them.

In 1946 the World Health Organisation (WHO) defined health as "a state of complete physical, mental and social well-being and not merely the absence of disease and infirmity" (1958). While this definition is rather idealistic for specifying a state of being which is impossible to attain, it somehow manages to incorporate both the holistic definitions – that of health relating to a wide range of human capacities and qualities and the official definition of those professionally involved in health issues.

As regards the measurement of health however, there is a certain norm attached, which is not disputed. Instead of measuring health directly in the presence of certain qualities within the population, they measure it more obliquely in terms of the extent to which disease and illness are detected. Morbidity and mortality rates have become the general indicators of the state of health in a country. The accuracy of morbidity rates on their own is questionable because they provide an incomplete picture about the seriousness of disease in a population. Their use in conjunction with mortality rates has become the more popular measurement. Valuable statistical data about morbidity can be obtained from hospital records, consultations between patients and doctors, from records detailing the causes of absence from work, as well as from special surveys. It is for this reason that it is also important to distinguish between the incidence of disease, that is, the number of new cases occurring over a period of time and the prevalence; the number of people who actually have the disease or illness at a particular time.

The most popular (and most widely criticised) one line definition is that provided by

the World Health Organisation in 1946, that health is "a state of complete physical and mental social wellbeing" (Cullis and West: 1979). This does not in any way imply that other definitions are of no consequence, but that this particular definition is one that people have an everyday understanding of without digressing to technical terms. After all, the definition that is chosen has widespread consequences. For instance, starting from the premise that health is defined in terms of mortality and a treatment has to be undertaken. The success of the treatment will be an increase in life expectancy, and resource allocation will consequently be directed to treatments or health policies that save and extend life rather than those that simply alleviate pain.

Because every commodity needs to be looked at in terms of the costs of its attainability, health also has to be looked at within the confines of an economic environment. Medical care decision-makers therefore have to devote considerable attention to the economic environment in which they find themselves. Health Economics is essentially the application of economic theories and practices to the health field. For instance, methods of resource allocation, cost-effective measures of treatment and even the basics such as the determinants of demand for health care.

2.2 Cost-Benefit Analysis versus Cost-Effectiveness Analysis – An Overview.

Cost analysis with respect to health issues has resulted in the use of project appraisal theories such as cost-effectiveness and cost-benefit analysis. Because benefits are not easy to decipher when carrying out a cost-benefit analysis in the health care area, efficiency becomes a more important indicator. If the objective of a hospital is to minimise its operating costs, then efficiency is defined as the point at which the least-cost method of operation is attained. Cost-Benefit Analysis sets out to discover whether the benefits of a particular project outweigh its real resource (opportunity) costs. Only those projects for which there is a surplus of benefits over costs are recommended. (Cullis and West: 1979).

Classification of costs and benefits in health care projects becomes time consuming and complicated. Whilst the costs can be effectively compiled through the use of data on costs and vigorous documentation of each and every expenditure, benefits can not be classified as easily. It is possible to undertake such an exercise if one has access to data

detailing every aspect that will show the accrual of benefits and be able to measure them accurately. The reason being those distinctions can be made between direct and indirect costs and benefits and tangible and intangible costs and benefits. One may consider the distinctions arbitrary but in cost-benefit analysis they are the crux of the economic analysis. As reiterated by Cullis and West (1979:171), "[t] he difference between direct and indirect hinges on whether the effect under consideration is directly related to the health project objectives or is a subsidiary consequence".

Klarman (1965) in his study of the benefits of a program to eradicate syphilis illustrated the differences between direct and indirect benefits (which are averted costs). The indirect tangible benefits are the production gains that result from a reduction in lost working hours resulting from diagnosis and treatment. According to Cullis and West (1979:172),"in this instance, an allowance is made for the reduction of gross earnings that resulted from the reduced mobility and employability [resulting from] the social stigma of having been treated for syphilis should it become general knowledge"

Clearly therefore, estimates of these benefits can not be accurately accounted for and would call for extrapolations of data and inferences from other forms of data. For instance, calculating the working hours gained would have to be taken from the hours of absence from work as a result of the treatment, assuming that all hours are accounted for. Difficult as it may be to quantify all benefits, arbitrarily excluding intangibles fosters erroneous results and can lead to inaccuracies that can affect entire studies and policies. One can see that while cost-benefit analysis may justify why certain health projects are undertaken, it is not the best method to use when one considers the rigorous, complicated procedure and considerations.

Drummond (1980) outlines a framework for economic analysis in health care. Firstly, one needs to have clearly outlined all objectives of the project in question, such that they adhere to the policy under consideration. Because there must be a possibility of choice before cost-benefit analysis can be undertaken, this inadvertently implies that all projects under consideration should be of an optimal size. That is, an increase in resources allocation (costs) should generate additional benefits, that way the results of the analysis are not misleading. From the possibility of choice, it ensues that the analyst should be able to address the following questions:

i) What treatment should be available

ii) When should the treatment be available (i.e. is the concern curative or preventive treatment)

iii) Where should the treatment be given, that is, should it be institution based or community based.

iv) To whom should the treatment be given, that is, what is the criterion for making treatment available to some patients before others

v) How the treatment should be given, that is, the input combinations or technique.

Identification of outcomes associated with alternate treatments should be possible. Health experts provide such information. The analyst then generates useful conclusions by simply making different assumptions about health care outcomes. Valuation of the outcomes that have been identified must be possible. Much as this may entail value judgements, the assertion is that all policy entails subjective opinion at one point or other.

Measurement of the costs of providing each service must be possible to convert into a common unit of value so that their relative magnitudes can be compared. "Crude attempts to value benefits are extremely hazardous", according to Culyer (1976). The reason being that classifying benefits requires great caution and subtlety. Allocative efficiency according to Mooney (1986) is addressed by cost-benefit analysis, which concerns itself with how to maximise benefits from available resources. He also emphasises that the objective that can be implemented in the least cost manner will be the one that is adhered to. Accordingly he asserts that, "...objectives are not pre-determined, and each objective has to fight with all others to be implemented...all costs and benefits arising as a result of implementing a particular project, no matter on whom they fall are relevant". (1986:15). His view regarding benefits, therefore, falls within the scope of what constitutes benefits according to Cullis and West (1979).

Cost benefit analysis and its applicability to a project comes with limitations that can be overcome by valuation using alternative techniques. It therefore has all the virtues and requirements of cost-effectiveness analysis plus the capacity to assist in decisions about whether or not a project is worthwhile. Mooney states that, "[b] enefit measurement is one of the major issues involved in cost benefit analysis in health care, and indeed, in all health care evaluation."(1986:49).

One measure of benefit that is frequently used is that of cost saving, where cost saving is a negative cost rather than a benefit per se. Culyer (1976) went further with his analysis of the benefits of health preventive treatment policies on the macro-economy.

Cost benefit analysis one can therefore say entails a great deal more than the mere assessment of how the benefits of a project outweigh the costs.

"[With a cost-effectiveness analysis] the costs are calculated and alternative ways are compared for achieving a 'specific set of results'". (Sorkin: 1975:114). The objective is how to use funds more effectively; the constraint is that a specified output must be achieved. Valuing and defining the output of health care provision gives rise to some difficulties as is illustrated by the simple definition of health benefits. Cost-effectiveness analysis is a simpler technique, in that it holds the output or benefit constant, i.e. simply defining it in physical terms and looking for the least cost way of achieving it.

Cost-effectiveness studies range from the treatment of varicose veins (Piachaud and Weddell: 1972) to treating chronic renal failure (Klarman: 1968). Because benefits are not the main consideration in this technique, the essential point is to define the output, hold it constant and establish the least cost method of treatment. "The results of cost-effectiveness analysis simply give the least-cost way to achieve the desired end" (Cullis and West: 1979:180).

The issue of whether even in the least cost method the costs actually outweigh the benefits is not even examined. This associates a fairly severe restriction or drawback with cost-effectiveness analysis because the knowledge of whether the provision of a given health care technique is efficient or not is lost. Another drawback is that it is not easy to hold the output constant. For instance, if a subsequent investigation suggests that a cost-effective measure of treatment does not have as long lasting results as a cost-ineffective method. This is similar to identifying and making a provision for indirect costs. In the treatment of tuberculosis, the indirect costs of unsuccessful treatment are a higher general incidence of drug resistant forms of tuberculosis. The resources that have already been expanded into the treatment, as well as those that will have to be made use of in treating a drug resistant form of TB are indirect costs that affect the cost-effectiveness of a treatment.

Much as the framework for cost-benefit analysis in health care (Cullis and West: 1979) asks the five possible questions, the more restricted classification now distinguishes alternative types of care, alternative places of care and alternative times of care. The distinctions are not

mutually exclusive; that is, different types and places of care are likely to go together. Mooney et al. (1980) assert that what is important in cost-effectiveness analysis is the specification of the objective in some detail.

Clearly the question of the definition of the objective in cost effectiveness analysis studies is very important if for no other reason than that the absence of a careful initial definition may result in an irrelevant study (Mooney et al: 1980). Further, in so far as the objective influences which costs are included, the definition should include as many of the relevant costs as possible. Whilst it is implicitly understood that the evaluation of benefits entails some value judgements at one point or other, Mooney (1986:17) explicitly asserts that "[b]oth costs and benefits are subjective concepts." He states further that it is frequently possible to assume that the costs of, say, nursing time are represented fairly accurately by the wages and overheads associated with the employment of nurses. Other costs may be difficult or even impossible to value, for example, the time spent by a son or daughter in looking after an ageing parent. However, even when value can not be assigned, at least noting these intangible costs means that they are less likely to be lost sight of in any decision taken.

The literature reviewed has already discussed some of the most obvious differences between cost benefit analysis and cost effectiveness analysis. As has been established, cost benefit analysis requires a great deal more information and rigorous calculations. Cost effectiveness analysis on the other hand is a 'costing' procedure which in effect makes a comparison between the costs of alternate projects and the decision maker then opts for the project with the least costs. With cost effectiveness analysis, decisions are made based on what the present observations are and what the results yielded by the analysis are.
The more obvious difference between the two is that of discounting. Because costs and benefits are incurred and accrue in different time periods, they have to be discounted. Discounting "...takes account of the fact that costs are typically incurred now while benefits accrue in the future". (Cullis and West: 1979:173). Selection of the appropriate discount rate is crucial in discounting, further adding to the complications that can arise in cost benefit analysis because, and an inappropriate rate can either overvalue or undervalue a project[6].

6 A guide to selecting the appropriate discount rate can be found in Perkins (1994).

2.3 Cost-Effectiveness Analysis- Introduction

Efficiency within the public sector is crucial as most services provided by this sector are not bought or sold on the open market. Efficiency however requires evaluation techniques in this sector. Cost -effectiveness analysis is one of such techniques. It [along with Cost-benefit analysis] has aptly been described by Klarman (1965) as attempting to do [within] the public sector what supply and demand analysis does in the competitive private sector.

The initial assumption made in this review is that all information regarding costs and tangible benefits is readily available, from either medical professionals or the patients themselves. The intangibles are extrapolated from given data. The main reason that economic analysis is undertaken in health is often to illustrate that it can complement epidemiological work in planning an efficient service.

2.3.1 Cost-Effectiveness Analysis – Theory and Applications

Economic appraisal alone is not enough to provide the answers to all questions of choice in health care. This is, according to Drummond (1980), because while it addresses efficiency, it is highly dependent on technical appraisal and often does not address questions of equity.

Here 'technical appraisal' refers to the assessment of costs and benefits of alternative health treatments. The assessment requires details of the costs and benefits, resource requirements for each alternative and results (or outcomes) produced by each alternative. Thus the economist relies on the expertise of relevant technical experts.

Equity is a rather elusive concept, which even in welfare economics is a criterion viewed as the trade-off with efficiency. "For instance, in health care one could have several notions of equity: equal access to care by geographical area, equal shares between client groups; equal access irrespective of income; and equal access for equal need." (Drummond: 1980:5).

Effectiveness is not necessarily efficiency. An effective treatment can be seen as one that alters the natural history of a disease. Taking this particular study as an example if the clinic alternative towards the treatment of tuberculosis is found to be not only less costly but

as yielding better results (less notifications, less default cases and more cures) it will in effect be deemed as more cost-effective. It will not only reduce the incidence of the disease, but will ultimately alter prevalence rates in future, assuming all other factors are held constant. Even with these distinctions however, effectiveness, efficiency and equity all influence the specification of alternative courses of action, which will ultimately influence the decision-making process.

2.3.2 Theory

Drummond (1980) states that assessment of medical effectiveness is normally an important preliminary stage in the assessment of efficiency. While this may seem to inadvertently lend a higher level of importance to cost-benefit analysis, what it does is reiterate the fact that in the provision of health care, there are considerations other than efficiency.

One used in the appraisal of alternatives is cost-effectiveness analysis. "For example, if two treatments are found to be equally medically effective, then the changes in resource use brought about by them can be assessed and the least costly treatment preferred on economic grounds." (Drummond: 1980:18). However, this is not as clear cut as it sounds as will be seen in the discussion of relevant case studies. Problems that may arise could be that the objective of medical intervention may not be clear-cut or the 'success' of the treatment may not be easily measurable.

The importance of clearly defining health indicators and their relevance becomes clearer as one probes into the assessment of medical effectiveness[7]. Whilst all these are relevant from the economists' view-point, since all relate to the benefits, or costs of care, a number of interpretation problems may arise.

Firstly, it may be that one treatment may not be superior on all counts – for example, it may have a higher case fatality rate but better long-term characteristics for survivors. Secondly, the 'outputs' to which indicators relate may not be homogeneous – one complication may be of lower quality than that gained by another.

[7] For instance, a number of indicators of the relative success of two treatments could be considered, if a comparison of effectiveness was being made between alternative treatments for a given acute condition. For example immediate indicators such as case fatality rate and complication rate, long-term indicators such as a five-year survival rate and recurrence rate.

Clearly the assessment of 'success' of alternative therapies is often ambiguous, but these are minor issues often cleared up in the early stages of the analysis, that of defining the questions to be answered by the problem and concisely articulating the alternatives to be considered.

In cost effectiveness analysis, the cost effectiveness index expresses the results in terms of the cost to obtain a unit of the desired benefit, for example, cost per year of life gained. An alternative with a lower cost effectiveness index (CEI) is preferred. This is the first decision criterion. This criterion also applies to projects that are mutually exclusive, where mutually exclusive means that if one of the two options is selected, then the other is automatically precluded.

The simple cost effectiveness approach, therefore, can only be applied when two alternatives produce an equivalent medical outcome or when there is one clear objective of medical intervention and the success of that intervention can be measured unambiguously.

2.3.3 Applications

Although a choice often exists in the treatment illnesses, not all treatments are equally effective. For this reason, therefore, the application of cost effectiveness analysis attempts to determine the least-cost effective method of treatment if one is given a choice between two-health programme and types of treatment.

Evaluative studies have been conducted into transplantation and dialysis in the treatment of renal failure. (Mooney et.al: 1980).

While this can be a fairly complex issue, in that very often there is not a straight choice between these two forms of treatment but a number of combinations of the two, Klarman et al (1968), directly compared transplantation and dialysis. One interesting aspect of the study revolves around the question of what to do in circumstances where the nature of the output differs. Both dialysis and transplantation prolong life and it is possible, given the relevant cost data, to compare the two in terms of the cost per year of life extension. It might then be argued that the treatment, which yields the lesser cost per year of life extension, should be preferred. (Mooney et al: 1980).

Klarman et al (1968) implied that although the quality of life for transplant patients is judged by experts to be usually better than those on dialysis, to allow for this, that is, a year

of life extension on dialysis is equivalent to three quarters of a year of life extension by transplantation.

Clearly, the use of value judgement in this one is evident. Cost benefit could not have been applied to this particular study because the issue of the distribution of benefits would have complicated matters. The valuation of benefits can also be avoided where the treatments do not produce equivalent medical effects, but where there is one clear objective of medical intervention and the 'success' of that intervention can be measured unambiguously. For example, if the objective of medical intervention in the case of a given disease were to prevent death, then alternatives could be compared on the basis of cost per year of life gained. The logic here being that for a given budget, the number of years of life gained would be greater if the more cost-effective treatment were selected. Klarman et al (1968) used this approach in their comparison of transplantation, hospital dialysis and home dialysis alternatives for the treatment of chronic renal failure. They argue that one feature of all these treatments is their capability for prolonging lives that otherwise would be cut short. Thus the three treatments were compared in terms of their cost per life gained.

Although their study of renal failure showed that transplantation was more cost-effective, it provided no guidance as to whether it was worth pursuing at all. Since the constraints of cost effectiveness are not necessarily how to use funds more efficiently, but that a specified output must be achieved, Klarman's study was still on the mark even with the use of value judgement, and despite the fact that it does not present information about how much transplants compared to dialysis can be undertaken.

According to Mooney et al (1980:98), "...[t]hese questions can only be answered if absolute rather than relative values are attached to the outputs involved".

The use of value judgement by Klarman et al (1968) in their study implies the use of relative values.

Piachaud and Weddell (1972) in their study entitled, 'The economics of treating varicose veins' compared the treatment of varicose veins by surgery involving in-patient stay with injection compression sclerotherapy, which involves only out-patient treatment. This study has similarities with the core of this dissertation – that of comparing in-patient treatment to outpatient clinic treatment.

A random controlled trial was set up under which the patients involved were randomly

allocated to surgery or to injection –compression. The costs of the treatment under the two regimes were then calculated, as was their effectiveness. This study showed that either form of treatment was approximately the same, which means the issue centred on which was cheaper, with effectiveness being equal.

One criticism that has been made of this study, is that while Piachaud and Weddell supported outpatient, injection-compression treatment, and the more expensive treatment that of surgery was more effective over a longer period. (Mooney et al: 1980).
However, it should be noted that the criticism was unfounded because, the fact that one treatment is more effective does not constitute a sufficient criterion for it to be accepted as a preferable policy. Since surgery has now been shown to be more effective in the longer term, it was not until the follow-up study by Hobbs (1974), that it was found that the two treatments are not medically equivalent. Which brings up the second point that the fact that at the time the study was conducted, it showed injection-compression treatment as more effective is no fault of Piachaud and Weddell (1972), but of medical knowledge.

Mooney et al (1980:99) state that, "...[s]ince decisions are frequently made in health care-indeed have to be made-on the basis of the medical knowledge existing at the time, the application of cost effectiveness analysis in no way creates additional 'hazards' to planning resource allocation. It does perhaps help to highlight the need to try to build uncertainty or at least sensitivity into health planning as well as cost effectiveness and cost-benefit studies."

Mass screening of populations at risk to certain diseases enables for the identification of cure for patients in the early stages. For instance, cervical smear programmes, amniocentesis with abortion for women carrying Down's syndrome foetuses and resting for high blood pressure are much talked about screening procedures.
The best known screening programme has got to be the Mass Miniature Radiography (MMR) for detection of pulmonary tuberculosis. (Culyer: 1976).
Today technological developments imply that drug therapy is almost completely effective, irrespective of the stage of the tuberculosis. This was not the case in the 1960s however, where the notification of tuberculosis meant several alternatives to treatment even though one would have worked, whether or not notification was in the early or late stages.

Pole (1971) found the range of potential benefits from finding a case of tuberculosis. He assumed that MMR worked with maximum effectiveness by completely eliminating the

infectious phase of the disease. Although the study by Pole uses the word 'benefit', it cannot really be counted as a cost benefit study, for the benefit here is the cost of alternative treatment avoided. Effectively, he was comparing the cost of one procedure (preventive care) with another, (remedial care).

In effect what he was doing was carrying out a cost effectiveness analysis. Along the same line as Pole's study, Crowe and Hailey (1989) carried out a cost effectiveness of diagnostic technology.

According to them, "the concept of cost effectiveness in medicine has been defined as producing an existing benefit at reduced cost or a new benefit at an acceptable cost. "(Crowe and Hailey: 1989:301). Thus they assert that with this background, health economists often have difficulty in coming to terms with modern diagnostic technology which seems to produce no discernible benefit at greatly increased cost.

In therapeutic technologies or treatment processes, a proven remedy is applied to a known disease, for example, penicillin to pneumonia. The cost of a drug or therapy in this case can be measured.

None of these circumstances apply to diagnostic technology. The process of diagnosis involves uncertainty as opposed to a therapy or treatment process. In this process, many steps are taken which can overlap. It is for this reason therefore that modern diagnostic technology can be extremely costly.

Crowe and Hailey (1989:301) give an example as to how these costs are incurred. "The diagnostic process involves a number of parties, typically a diagnostician (such as a pathologist or a radiologist) and a clinician (physician or surgeon) who has the responsibility for the treatment of the patient. Therefore the diagnostician, who passes information (the result of a test) to a clinician, has no control over the use made of the information and may not have any knowledge of the effect of the information on the treatment of the patient, or of the subsequent outcome of the patient following the treatment."

Ultimately an ill patient without a diagnosis will need further tests to dispel the contradictions, uncertainty and confusion among the medical personnel. Implications of this are that further tests are incurred. Crowe and Hailey stress that under such an environment, there is a clear need for expensive diagnostic tests to be used appropriately. This according to them, "...leads to considerations of efficiency and effectiveness" – where efficiency

represents the best result that can be expected from the application of technology.

Granted that much of the literature does not illustrate the way in which cost effectiveness and cost-benefit analysis can be applied in a straight forward manner such as will be the case in this study, one can see the broad diversity of its applications in other areas of health. In attempting to establish the costs and benefits of treatment of illnesses and in a quest to attain not only effectiveness but equity as well, health economics reveals itself as more than the mere application of the *science* to the health field.

As Drummond (1980:108) puts it, economic appraisal in health care has its benefits as "it embodies a systematic approach to decision-making, as opposed to 'muddling through', and thus enables decision-makers to test the implications of each decision against all the objectives that they have set themselves."

The principles of economics still have a great deal of significance on the need for appraisal in health. Scarcity being the overriding reasons –that is, decisions should depend upon benefits foregone as well as benefits obtained. Scarcity brings into the equation a wider perspective, which makes purely technical or medical frames of reference insufficient.

The decision-making process involves a great deal of value judgements, and economic appraisal makes them more explicit. "There is no objective way of making policy decisions, merely more systematic ways of articulating the judgements involved" is according to Drummond (1980:108).

It is for this reason that the debate regarding the restructuring of the South African health system still continues. Objectivity has to be met with subjectivity in order for effectiveness and the elusive equity to be attained. Thus the need for economic appraisal remains crucial as long as it takes decision-makers that one step closer to the improvement of health outcomes.

Chapter Three

3.1 Cost Analysis of the Clinic Alternative to TB Management

The analysis uses a sample size of sixty patients. The patients are a random sample taken from the Boom Street Clinic Patient Register. This Clinic was chosen because it caters for the Pietermaritzburg-Msunduzi Local Council Area. In 1996 the total number of TB attendances at the Local Council Clinics was 9266. The Boom Street Clinic is the main TB Clinic catering for this area and making most of its referrals to the SANTA- Edendale Hospital. The sample is taken from the end of 1995 to the beginning of 1996. The reason being that the costs of maintenance, staff and drugs were all provided in 1995/96 prices.

3.1.1 Methodology

The objective of this study is to calculate the relative costs entailed in treating TB patients through as outpatients and to assess the cost effectiveness of the two methods of treatment, outpatient and inpatient care. That is, taking into consideration the costs incurred by the clinic and hospital with its expenditure on maintenance, salaries of staff and the costs of the drugs supplied to patients. Presently the treatment of TB is highly cost ineffective. (Department of Health: 1996). Statistics indicate a trend in incidence rates that is on the rise while the Department is struggling to find cost-effective methods of treatment while managing the disease.

According to Wilkinson and Davies (1997:451), "the redesign of tuberculosis control in South Africa is to be welcomed as the previous fragmented and uncoordinated approach was unsatisfactory...treatment completion rates are generally considered inadequate."

The Provincial Medical Supply Centre (PMSC) which is in Durban and supplies the Public Institutions in the Kwazulu-Natal province caters for the Boom Street Clinic and the SANTA hospital. Using the unit costs of drugs that they supply to the clinic and

that are used in the treatment regimes, the costs of treating TB patients who have successfully completed treatment, have defaulted and have been transferred to hospitals are calculated.

The measure of cost-effectiveness is in this case the cost per patient cured and this will be the main indicator. However, marginal costs are also calculated. These will provide insight into how much hospitalization is worthwhile given that it is inevitably the more expensive treatment alternative. As planning is crucial in decision-making, for the already cash-strapped Department of Health, knowing how extensive a particular service should be –in this case, hospitalization of TB patients is as important as knowing the total costs entailed in treatment. These are calculated using the sample of sixty patients selected randomly from the clinic and hospital database.

The way in which the study is carried out; the sampling method used makes it a descriptive, and in part, testimony case study. Descriptive studies according to St.Leger (1992:76), "involve the evaluator's understanding of the context within which the service operates."

The research part of these types of studies involve service providers, that is, identifying the people involved in the actual provision, in this case health workers or nurses. This particular study can also be classified as a testimony study because as part of the research, the nurses were interviewed to provide information that is not normally obtained from databases. The information gathered from nurses and doctors provided some insight into why in some cases the delivery of TB services is not always cost-effective. For instance, in this study it was easy to elicit information about the extent to which the participation, or lack thereof, from nurses made the Direct Observed Therapy (DOT) ineffective. This was not necessarily because of any unwillingness to participate, but the difficulties entailed in fully coordinating the efforts of all health workers and the patients involved.

The random sampling used is referred to in some studies as Random Controlled Trials (RCT). According to St.Leger (1992:95), "the use of RCTs has become increasingly common in the evaluation of the clinical procedures aimed at individuals and it can, in principle, also be applied to services as a whole and mass health promotion activities."

The simplified basics of a Randomized Controlled Trial are that:

i) a comparison is made between two groups and

ii) there is a random allocation of treatment to the groups, i.e. Treatment A or Treatment B.

In this study however, much as the comparison is between in-patient and outpatient groups, the selection of patients is random but not the treatment.
In as far as, it being a 'controlled' trial, the treatment of TB patients in outpatient clinics makes them the comparison group. The outpatients are therefore the standard against which to judge the efficacy of the drugs used and their cost-effectiveness.
The selection was random so as to eliminate even the slightest hint of bias that may suggest that some factor, known or unknown influenced the effects of treatment due to their either having or not having certain characteristics fitting a particular profile.

Much of the bias is eliminated by the nature of the study because the treatment regimes are not stipulated by the health workers and nurses but by a higher body within the Department of Health. Patients who are still undertaking treatment have no knowledge of their selection so they can not lend any form of bias to the analysis.

3.1.2 Assumptions

Statistics on the number of attendances to the TB Clinic were used to estimate the costs entailed in the treatment of patients.

i) The monitoring costs are not included in the calculation of costs because such information was impossible to get. The staff at the clinics are considered to be the monitors or supervisors that would otherwise be responsible for TB patients if the Directly Observed Therapy (DOT) was effectively implemented. Geographical constraints make the effective functions of monitors extremely difficult because for patients that are in rural areas – some do not receive any form of monitoring whilst others may.

ii) The same two inputs are used. Personnel and equipment are categorized as a single input and drugs used as another. These are used in different

combinations to produce the same level of output, that is, a cured patient.

iii) Effectiveness in this study will define a *cured* patient. The effectiveness levels of the alternatives will therefore be held constant, that is, the number of patients cured and the costs incurred to attain the cured level.

3.2 Costing

The costs of drugs were obtained from the Provincial Medical Supply Centre (PMSC) and the TB Province List for 1996 is presented in table B-I in the Appendix. Given this drug list, the costs incurred in the treatment of the random patients selected from the patient register are calculated. This information is extrapolated to calculate the costs incurred by the TB Clinic in the treatment of all its TB attendances. From the patient register, the ratio of cured patients to default cases can be calculated.

3.2.1 Cured Patients

The National TB Control Program's Practical Guidelines (1996), specify that the first two months of treatment is the Intensive Phase of treatment and the treatment regime after that is the Continuation Phase which is four months long. However, when the research was carried out for this study, the treatment regime followed in Kwazulu-Natal did not adhere to the Guidelines. In fact, not many provinces had implemented the new strategy in 1996. For this reason therefore, the treatment regime followed was not *standard* as is prescribed by the Department of Health (1996).

From the random patients selected, it was easy to decipher what constituted a standard treatment for patients from the majority of patients who received specific treatments. There were still six different types of treatment regimes followed, prescribing the *standard* TB Drugs, but in different combinations. For the purpose of the calculation of costs, the different types of treatments were differentiated.

Treatment A prescribed the following drugs, Rifampicin 450mg, INH 300mg, Pyrazinamide (PZA) 500mg and Ethambutol 200mg. In some cases this treatment was combined with Vitamin B.Complex supplements and antibiotic treatments of Tetracycline 250mg.

As the Vitamin supplements and antibiotic prescriptions are not standard in the treatment of TB even though they were common in many of the patients' treatment regime, their costs are not included in the calculation of the total costs of treatment.

Treatment B prescribed INH 400mg, Ethambutol 800mg and in some cases the Vitamin B.Complex supplement.

Treatment **C** prescribed INH 400mg, Rifampicin 450mg, Pyrazinamide 500mg and Ethambutol 200mg.

Treatment D which was recommended to one of the patients prescribed Rifampicin 600mg, INH 900mg, Pyrazinamide 500mg and Ethambutol 200mg. This seemingly rather intensive course of treatment was followed by one of the standard treatments mentioned above.

Children followed a different course of treatment but for them too the treatment regimes varied. There was **Treatment E** that prescribed INH 100mg, Rifampicin 100mg and Pyrazinamide 250mg. Then there was **Treatment F** which prescribed the same drugs but in the following combinations, 200mg/200mg/500mg.

From the total sample size of sixty patients, a total number of thirty-five patients were cured after having successfully completed their treatments. As can be seen in the table, some of the patients' treatment ran over a period of more than the recommended six months. Many defaulted and were treated as new cases while others continued with their initial course of treatment. Specifications are that retreatment cases be hospitalized after a two-month period has elapsed since they received treatment. In all of the retreatment cases from this sample however, none were hospitalised before the continuation of their treatments. As has already been mentioned the length of time it takes for radiology reports to be returned from the laboratory results in some patients undergoing treatment even though their sputum comes back negative. This will explain why some of the patients were on a course of less than six months yet were given a clean bill of health. Some ran their course of treatment over periods of more than six months without defaulting. This is a result of treatment failure. There were Multidrug Resistant cases, and this was rather surprising considering the number of retreatment cases and the patients that ran courses of treatment over the standard six months.

Table 2: The Costs of Cured Patients

Treatment	No. of patients[8]	Avg.Cost/month (R)	Total Cost[9] (R)
A	33	37.34	8021.93
B	7	18.65	932.45
C	1	35.19	211.12
D	1	49.59	297.53
E	2	15.97	212.69
F	1	27.35	164.07
		30.68	**9839.79**

From the patient register, the number of days the drugs were to be taken, the length of the course of treatment and the treatment regime followed were all available. Using the price list from Table B-I in the Appendix the cost of drugs were calculated using the following formulae found in Appendix D.

The percentage of cured patients was fifty-eight percent. This is not a good rate because the national goal according to the Department of Health (1996) is eighty-five percent. In a study carried out by Wilkinson and Davies (1997), a 'best-case' scenario of a ninety-one percent cure rate was assumed. This was based on the fact that some IUATLD (International Union against Tuberculosis and Lung Disease) model programs on which the Department of Health's TB Control Program is based has achieved this number.

The cure rate for this study is the ratio of cured patients to the sample size, which is sixty. The percentage cure rate can be explained by the fact that of the sixty patients, ten of these patients did not have Tuberculosis but were investigation cases.

Excluding these ten patients, this brings the sample of patients with tuberculosis to fifty, making the cure rate seventy percent.

The new cure rate still falls short of the best-case rate of 91% and the national goal 85%, but gives a better indication of what may be the cure rate if the strategy was followed completely and all data-bases complete enough to corroborate this assumption. The total cost of drugs of treating thirty-five patients, who are cured after their treatment is **R9839.79.**

---

8 Number of patients for each treatment means the number of patients who were prescribed the treatment even if they may have changed to an alternative one. See Appendix E for further information on the total number of cured patients.

3.2.2 Default Patients

Because of the strategy of treating patients who do not have TB but might have had it clinic costs are increased. Of the sixty random patients, ten of which did not have tuberculosis, fifteen were default cases. Some of these patients defaulted several times, returned for treatment and yet still failed to complete their treatment. Others however defaulted after the first course of treatment was prescribed and never completed the first six months of the recommended treatment. The fact remains however that even thought they did not complete their courses of treatment, the clinic still incurred costs from the first-course drugs that were prescribed and for those that returned for further treatment, even more costs were incurred.

Default cases raise the issue of whether or not these costs would have been incurred had the patients been hospitalised after they had defaulted the first time. As has been mentioned, policy requires that patients who default for a period of two months be hospitalized when they become retreatment cases. Geographical logistics on the part of the patients and resource logistics on the part of the service providers make this an infeasible feat however, which explains why even some of the cured cases that were retreatment cases were not hospitalized after having defaulted for periods of up to four months.

To bring into light the resource savings that could have occurred had some of the default cases been hospitalized, the costs of drugs given were calculated. Table 3 below summarizes the costs. The same formulae as the one in the preceding section were used.

Table 3: The Cost of Default Patients

Treatment	No. of patients	Avg.Cost/month (R)	Total Cost (R)
A	18	37.34	3424.08
B	7	18.65	615.40
C	1	35.19	35.19
D	1	49.59	99.18
F	1	27.35	109.38
		30.68	**4283.23**

9 Inclusive of relapses, with treatment periods ranging from two to twelve months.

3.3 Cost Effectiveness

The calculation of the total costs incurred by the Boom Street Clinic, is the costs of drugs dispensed to the thirty-five cured patients, fifteen default patients, misdiagnosed patients and the staff and maintenance costs. Boom Street Clinic is one of the clinics catering for the Pietermaritzburg-Msunduzi local council area. The patient register that provided the statistics for this study was for patients attending this clinic.

Effectiveness has been defined, as the number of cured patients. For analysis purposes, the costs of treating default patients will be calculated independently to bring insight into the resource savings.

Using the numbers on the TB Clinic Attendance, the costs have been calculated using the patient register as a reference as well as the costs of Staff and Maintenance of Boom Street Clinic. The costs of treating TB Patients through outpatient care can be calculated. The research for this study focussed on the year 1996.The costs of Outpatient TB Services for the Clinic were as follows.

Table 4: Staff and Maintenance Costs of Outpatient TB Services

Year	Costs (R)
1994/1995	396 356
1995/1996	444 558
1996/1997	511 629

Source: Pietermaritzburg-Msunduzi Local Council City Health Division: 1997

The financial year is from July to June. As the research was for 1996, the average between the 1995/1996 and 1996/1997 costs is taken to get a figure that is closer to what the costs would have been if the financial year was taken from January to December. This average gives a total cost of **R478, 094.**

The total number of TB Attendance from the period July to December 1995 and June to and January to June 1996 for the Pietermaritzburg Clinic were **4765** and **4584** respectively. The total therefore for the Financial Year for 1996 was **9349.**

The drug costs for the treatment of the thirty-five random patients who were cured came out to R9839.79. These costs are for the different regimes under which patients were placed irrespective of the length of treatment they underwent.

The **average total costs** of drugs per patient cured is:

$$= \frac{\text{Drug costs}}{\text{Cured patients}}$$

$$= \frac{9839.79}{35}$$

$$= \mathbf{R\ 281.14}$$

The **effective cost** of drugs per patient cured is:

$$= \frac{\text{Drug costs (all patients)}}{\text{Cured patients}}$$

$$= \frac{9839.79 + 4283.23}{35}$$

$$= \mathbf{R\ 403.51}$$

Calculating the "institutional cost" of staff and maintenance costs:

$$= \frac{478.094^{10}}{9439}$$

$$= \mathbf{50.65} \text{ per patient.}$$

Adding this to the equation for calculating the effective cost gives:

$$= \frac{\text{Drug costs + Institutional costs}}{\text{Cured patients}}$$

$$= \frac{14123.02 + (50.65 * 60)}{35}$$

$$= \mathbf{490.34}$$

The underlying assumption here is that of the random sample of sixty patients; seventeen percent were investigation cases, twenty-five percent default cases and fifty-eight percent were the cured cases.

Granted that investigation cases are not prescribed any TB medication, the calculations of drug costs exclude this 17 percent. They are however included in the TB Attendance because it is only after one or more consultations that the patients are ruled

10 This figure is calculated from Table 4 on the page 33.

out as TB cases. Patient registers are however not updated to accommodate this new information; hence, in the compilation of statistics the investigation cases are noted as part of the TB attendances.

This total does not include the costs of sputum examinations or x-ray costs. If these costs were included, this would undoubtedly raise the costs of treatment, as would the inclusion of antibiotic costs given to investigation cases. Monitoring costs would also contribute to higher costs if there were sufficient data on them for their inclusion.

In their study Wilkinson and Davies (1997) included costs incurred for a community clinic visit, costs of community health worker visits, supervision costs, Program management costs as well as sputum examination and x-ray costs.
As four different strategies were examined in this Wilkinson study, the costs per patient cured ranged from R151 to R223.
In this study however, the proxy for supervision costs are the staff and maintenance costs. The fact that this study takes the perspective of the service provider means that, unlike with Wilkinson's study, the costs of treatment incurred directly by the patients are not calculated. Of more relevance are the drug costs as well as staff and maintenance costs. The comparison of these costs to hospitalization costs will provide an indication of how cost-effective the outpatient alternative to TB management is.

Chapter Four

4.1 Introduction

In much the same way that the Pietermaritzburg-Msunduzi TB Clinic attempts to adhere to the guidelines set for the TB Control Program by the Department of Health (1996), the strict adherence that the Department of Health strives for is impossible to attain.

Given the Health Budget cuts that the Health Department has had to deal with, the implementation and sustenance of Health Programs has been incapacitated in many respects. This has not only affected the running costs of Clinics and Hospitals, but has overall affected the number of patients that can be treated in a given time.
Prior to the 1997 Budget Speech, The Doris Goodwin SANTA Centre had a capacity, both in space and costs for one hundred and sixty patients, which was reduced to one hundred and seventeen after the Budget Speech, which decreased funding by up to forty percent. Much as the period that the study focuses on is 1996/97 and the 1997 Budget cuts did not affect the costing of treatment options; this information is sufficient in providing a reflection on the status of the TB management program in South Africa. If projections were to be made, they would indicate a certain decrease in a projection that should for be increasing.

The Doris Goodwin SANTA Centre in Edendale Pietermaritzburg has had to deal with problems of Budget cuts as well as the increasing numbers of patients due to HIV/AIDS. The Centre does not carry out any notifications or screenings, but because it is a specialized TB Centre, its patients are referrals from either the Edendale or Richmond Chest Hospitals. Their patients also include those that are referred from the Greys and Northdale Hospitals.

All patients are TB patients and all subject to a mandatory two-month long hospital stay. The focus at this Centre is extended to the compulsory six-months according to the Department of Health Guidelines with treatment being strictly monitored. The SANTA Hospital does not experience problems of misdiagnosis and rising costs due to delays between investigations and laboratory results because

investigations are carried out by other institutions.

The noticeable difference between the treatment regime carried out by hospitals and that by clinics is adherence to the guidelines by the hospital. Four different types of treatment regime for adults were carried through Outpatient care and two for children. This diversity not only affected the costs of drugs dispensed as can be seen in the Third Chapter but also the uniformity of treatment.

The SANTA Hospital however has established uniformity in treatment that can be applauded by the Department of Health. Once a patient is referred to the Hospital for treatment, before treatment is undertaken a sputum sample is taken- more as a confirmation of the need for treatment than an investigation. The patient then undergoes treatment.

As with Clinic Treatment cases, retreatment cases and new cases undergo the same treatment once it has been established that they are coughing up live TB Bacilli. If after the two-month investigation period a patient still has positive sputum, they are given a Streptomycin injection that is only administered at the discretion of the doctor monitoring the treatment. This is administered according to weight; where patients weighing less than 50 kg receive 750mg and those over 50kg are prescribed 1gram. This can continue for two months until such time that the patient's sputum turns negative. The toxicity of Streptomycin makes it inappropriate for regular use and is only administered if patients do not respond to treatment.

If however after the two months treatment that includes Streptomycin the patient still coughs up positive sputum, then they remain on the Intensive Phase of Treatment. As long as MDR-TB has not been established, this intensive phase is sometimes extended over longer periods. Most patients' drug regime is supplemented with a twice-daily weekly administration of multi-vitamins.

4.2 Cost Analysis of Hospitalisation

The TB Patient Register for the SANTA Hospital was not implemented until January 1998. It was still possible to discern information from the existing patient registers through to the effective implementation date. This made the calculation of

costs incurred in the treatment of patients possible.

Unlike with the Clinic Patients, the treatment that was followed did not alter from patient to patient. The fact that hospital stay for the first two months of treatment is mandatory ensured that the treatment was adhered to during the months of hospitalization. Patients that are released before their two-month stay are referred to TB Clinics where they undergo their treatment through the outpatient services. This means that the follow-up treatment required for these patients was not assured as long as they were not closely monitored. For those patients who remained hospitalized throughout the course of their treatment however, the costs incurred were calculated for the length of their stay, up until their diagnosis attested to their Tuberculosis having been arrested.

To provide a reflection of the cure rates in the Hospital, Table E-I in the Appendix E provides the numbers of improved, default, transferred and dead patients per month over the 1996 Period. The capacity for patients in this year according to the hospital administrator was one hundred and sixty-five patients with the actual numbers being closer to two hundred patients. This number is taken as an average of the capacity (165) and the actual numbers (200).

Thus the total number of beds is:

$(165 + 200)/2 = 183.$

4.3 Costing

The most crucial cost calculation is that of the cost per patient cured. Other costs that are calculated to make inpatient treatment comparable to outpatient treatment will be the costs of treating patient who default during the course of their treatment.

The costs of patients who are transferred to clinics to undertake their treatment through outpatient care are not included, as neither are the costs of treating patients who die. These costs are excluded so as to avoid garnering information that will prove superfluous in the final analysis.

The drug list from Table B-I in the Appendix provides the drug costs in 1997

prices and is used in the cost calculations.

4.3.1 Cured Patients

The standard course of treatment shown in Table 3 is prescribed to every patient undergoing TB treatment. The variations are made according to weight. The formulae can be found in Appendix C.

The Intensive Phase of this treatment regime; known as Regime I is similar to that classified as Treatment A in outpatient treatment. Having established the cost of drugs for one month for the Intensive and Continuation Phases of Treatment, the costs of cured patients are calculated.

Table 5: The Drug Costs of Cured Patients

Treatment	No. of patients	Avg. Cost/month (R)	Total Cost (R)
Regime I	28	37.43	4873.80

The cost of treating 28 patients with varying treatment periods from two months to six months is R4873.80. On average the treatment cost per patient is R179.98 for patients who complete the six-month treatment period, R164.85 for those who have their TB arrested after five months and for those who were hospitalized for two months only the cost of medication is R74.86.

Taking the random sample of sixty, the percentage of cured patients is forty-seven (n = 28), thirteen percent (n = 8) are default patients, thirty-percent (n = 18) are those who were transferred to clinics to continue their treatment as outpatients and the remaining ten percent (n =6) are those patients that died.

Including the number of patients who died in the calculation of costs does not contribute to the calculation of the most cost-effective measure of TB management. The reason for this is that the clinics or family members refer most patients that die in the last stages of the disease. Treatment in such instances is futile.

The patients that are transferred to clinics to carry out their treatment will be

classified as cured. This assumption is made on the basis that patients released to clinics are classified as having arrested TB even if their course of treatment is not completely over. Even with the reluctance from the staff to classify them as cured, their sputum tests are negative and their TB arrested. The sentiment among the medical personnel at SANTA is that 90% of patients transferred to clinics are in the final stages of their treatment and often remain on their treatment course until its completion.

Excluding the patients that die in the calculation of a cure rate means that the sample size is reduced to n = 54. The cure rate with this sample size is eighty-five percent. This rate is higher than the fifty-eight percent cure rate of patients, excluding investigations, who were treated as outpatients in the third chapter are.

4.3.2 Transferred Patients

Table 6: The Drug Costs of Transferred Patients

Treatment	No. of patients	Avg. Cost/month (R)	Total Cost (R)
Regime I	18	37.43	1983.79

The patients had to stay in hospital for the mandatory two months before they could be transferred. Most were transferred after three months of hospitalization. The transferred patients' hospital stay ranged from two to seven months.

4.3.3 Default Patients

From the initial sample size of sixty, there were eight default patients. This figure is lower than that found in the sample taken from clinics providing outpatient TB services. The SANTA hospital and other hospitals that take in TB patients can not force patients to stay in the hospitals but can ensure compliance to treatment if patients remain hospitalized. The lack of compliance to treatment can affect the Department of Health's aim of improving the effectiveness of Programs. Default cases add to the costs of treating TB but do not yield any benefits in the long run. Calculating these costs gives a perspective of the resources that are lost due to the low levels of

compliance. Table 7 summarizes the costs.

Table 7: The Drug Costs of Default Patients

Treatment	No. of Patients	Avg.Cost/month (R)	Total Cost (R)
Regime I	8	37.43	606.19

The proxy for staff and maintenance costs in this chapter is the cost per patient per day of hospital care. The SANTA hospital incurred a cost of R46.63 per patient per day in 1996. Adding the costs of hospitalization to the drug costs gives the total costs incurred in treating TB through inpatient care.

For the twenty-eight cured patients, the total costs are calculated from the total number of days that they were hospitalized up until they were released with arrested TB. The costs are calculated using the formulae found in Appendix D-II.

The costs incurred by treating patients who later default on their treatment was R606.19 for the eight patients. The default rates are lower for inpatients than they are for outpatients because compliance is greater for patients that are hospitalized as a stricter monitored environment is assured.

4.4 Cost Effectiveness

Looking at the drug costs only gives the impression that inpatient treatment is a cheaper measure of treatment. This alone is not sufficient to make recommendations because of the costs of a hospital stay that make the clinic alternative cheaper.

Of the thirty-five cured patients that were outpatients, the cost of drugs per patient cured on average was calculated as R281.14 per patient. This is taken as an average cost because there were six different drug regimes that were followed by the clinic TB services. The hospital yielded better results in terms of drug costs. The average cost of drugs per patient cured was calculated as R149.08.

The **average total costs** of drugs per patient cured is:

$$= \frac{\text{Drug costs (Cured + Transferred)}}{\text{Cured patients}}$$

$$= \frac{4873.80 + 1983.79}{28 + 18}$$

$$= \frac{6857.59}{46}$$

$$= \textbf{R 149.08}$$

The **effective cost** of drugs per patient cured is:

$$= \frac{\text{Drug costs (all patients)}}{\text{Cured patients}}$$

$$= \frac{4873.80 + 1983.79 + 606.19 + 524.02}{46}$$

$$= \frac{7987.80}{46}$$

$$= \textbf{R 173.65}$$

The hospital cost per patient per day at SANTA is R46.63. This cost thus constitutes the 'institutional' costs. Staff and maintenance costs are covered by this patient cost. The formulae in D-II of the Appendix were used to calculate the costs of hospitalization for the cured, transferred and default patients. For all three categories, the lengths of hospital stay ranged from one to seven months. The total institutional costs were **R337 134.90.** Table 8 breaks down the costs into four categories.

Table 8: **Institutional Costs**

No. of days	Cured	Transferred	Default	Dead
30	1398.9 (1)	1398.9 (1)	6994.5 (5)	2797.8 (2)
60		16786.8 (6)	5595.6 (2)	8393.4 (3)
90		33573.6 (8)		
120			5595.6 (1)	
150	27978.0 (4)	6994.5 (1)		
180	193 048.2 (23)	8393.4 (1)		8393.4 (1)
210		9792.3 (1)		
	222 425.1 (28)	76939.5 (18)	18185.7 (8)	19584.6 (6)

The numbers in brackets are the numbers of patients treated per category.

The average total cost per patient cured is:

$$= \frac{6857.59 + (222425.10 + 76939.50)}{46}$$

$$= \frac{6857.59 + 299364.6}{46}$$

$$= \mathbf{R\ 6657.0}$$

Adding this to the equation for calculating the **effective cost** gives:

$$= \frac{\text{Drug costs (all patients)} + \text{All Institutional costs}}{\text{Cured patients}}$$

$$= \frac{7987.80 + 337134.9}{46}$$

$$= \mathbf{R\ 7502.66}$$

The high institutional costs are due to the "free hospitalisation" that is provided by SANTA. This makes the hospitalisation alternative less cost effective in terms of institutional costs. In terms of the drug costs, however, it is more cost effective than the clinic alternative.

Chapter Five

The objective of this study was to carry out a cost effectiveness analysis of the alternative treatments to TB management. The alternatives to management being clinical treatment or hospitalization. Health system cost data were obtained from a variety of sources including the clinic superintendent, the hospital administrator and medical supply companies.

The analysis focuses on average costs (drug and institutional) which are the total costs expended divided by the number of patients cured. The average total costs (ATC) are thus the ATC per patient cured. In calculating cost effectiveness, it was assumed that patients discharged by medical personnel from the hospital completed their treatment and were thus considered cured.

5.1 Summary of Results

Table 9: Cost-effectiveness of Alternative TB management Strategies

Strategy	**Clinic**	**Hospital**
Total **Drug** Costs	14 123.02	7987.80
Cured	9839.79	4873.80
Transferred		1983.79
Default	4283.23	606.19
Dead		524.02
Total **Institutional** Costs	3039.00	337 134.90
Average Drug Costs per patient cured	281.14	149.08
Effective Drug Cost per patient cured	403.51	173.65
Total **effective cost** per patient cured	490.34	7502.66

The implicit assumption is that monitoring and supervision costs are accounted for in the institutional costs. Reason being that reliable and complete information was not available for a thorough breakdown of those costs.

Analysis of the institutional costs reinforces the need to evaluate the justification for the hospitalisation of patients. The high drug costs incurred in treating TB patients as outpatients illustrate the need for a well-organised health infrastructure that can support a program of directly observed therapy. Merely stating which strategy is the most cost-effective overall is not enough to be the foundation of future recommendations without identifying the areas and reasons of ineffectiveness.

5.2 Discussion

In both case studies, a sample size of sixty patients was used. This size is sufficiently representative because it establishes a pattern in the course treatment of patients. From this sample it was possible to decipher the most common treatment regime as well as corroborate this information with that given by the clinic staff. The fact that ten out of sixty patients in the clinic sample were investigation cases is also reflective of the costs incurred with outpatient care when patients have to be screened before they can be prescribed a treatment course. These investigation cases are as important to the study as the established TB cases. Of the sample of sixty patients treated at the SANTA hospital the institutional costs were R337 134.90 compared to the R3039.00 it cost the clinic to treat the same number of patients. The clinic costs included staff and maintenance costs and took into account the minimal supervision and monitoring costs which were not explicitly identified. Analysis of the average and effective costs provides a clearer picture of the differences in inpatient and outpatient care as alternatives to TB management.

The clinic cure rate was 58.3%, an extremely poor rate by National standards which puts the National goal at 85%. The low cure rate can be attributed to the fact that outpatient treatment does not encourage high compliance rates. The monitoring of patients after completion of the intensive phase of their treatment is not assured as long as patients receive their treatment as outpatients. It is cases such as these that health education would have a positive effect on the *marginal* cases that McIntyre (1986) mentions in her study. A treatment course that not only includes the drug therapy but also disseminates information regarding the stages of tuberculosis and its treatment could have an effect on the costs incurred in treating patients. If treated in the same

manner that Feldstein (1970) regards preventive therapy, health education would affect the number of potential default cases by making them aware of the dangers of defaulting on treatment and consequences of developing multi-drug resistant strains of tuberculosis. Granted that health education would incur costs, the potential benefits far outweigh the costs. Default cases would be minimised and in the long run so would the retreatment costs. The incidence of the disease can also be affected by the reduction in the number of patients that default. If a default patient infects another with a TB resistant strain, the costs in terms of lost income, hospital treatment and other costs may be relatively high. A default patient thus, does not only raise the cost per patient cured but increases the spread of the disease.

Raising compliance through health education would perhaps have the same effect as ensuring compliance through hospitalisation, though not a guaranteed result. The cure rate for the hospital was 77%, based on the assumption that all transferred patients completed their treatment course. This rate is higher than the cure rate but still falls short of the National goal rate. The percentage of default cases yielded by the hospital was thirteen. This is half the number of default cases from the clinic alternative. The high cure rates and low default rates provide an argument for the need to hospitalise TB patients in spite of the high institutional costs. Much as hospitalisation reduces the number of default cases and reduces the infectious pool, in light of the costs the argument for hospitalisation is one that can not be easily won.

This study has its limitations in terms of ascertaining the number of patients who actually complete their treatment as outpatients after being hospitalised for their intensive phase of treatment. For this reason therefore, the low drug costs for inpatients can be attributed to a couple of factors, the excluded costs of transferred patients and the default cases.

Firstly, the total drug costs for all inpatients were R7987.80, half the cost of those treated through the clinic. If an assumption is made that all transferred patient complete their treatment at the hospital and within the specified treatment period, then this raises the hospital drug costs. Those patients who die at the hospital also generate costs to the system, although they can not be reflected in the cure rate. However, even if the drug costs of transferred patients are included the hospital drug costs are still

considerably lower.

One way in which these excluded drug costs can be accounted for is if they are included in the calculation of costs.

= No. of transferred patients * Average Drug costs per patient cured

= 18 * 149.08

= R2683.44

Added to the drug costs for the other categories of patients, the total drug costs come to, R8687.45. Despite the extrapolations the hospital drug costs are still lower although not by the same margin.

The second and most important factor that explains the lower hospital drug costs is the number of default cases. Eight patients defaulted from their hospital treatment compared to the fifteen who were outpatients costing R606.19 and R4283.23 respectively. Although clinic default cases were twice the number of hospital cases the cost was seven times more. The reason for this huge difference is that outpatients can default for a month or more and still return for treatment, lengthening their treatment to periods of longer than the standard six months thus incurring more costs in the process. With inpatients however default cases often do not return for further treatment and for those that do, retreatment periods last as long as the standard requirement thus reducing the excess retreatment costs.

The Average Drug Costs per patient cured for the clinic was R281.14 compared with the R149.08 for the hospital. Compliance to treatment in the hospital is greater and explains the lower drug costs. Through the clinic there was not a strict adherence to a single Treatment regime. The treatment A that was prescribed by the clinic and the regime followed by the hospital are both the Standard Treatment Course for TB patients. This treatment, " is well established in many countries and has been endorsed by the World Health Organisation (WHO)" according to McGregor et al. (1996). The breakdown of the costs of drugs in Appendix D illustrates that this was not the cheapest treatment regime even though it was the standard one. Establishing the most cost-effective regime was not possible because of the lack of uniformity with outpatient treatment. This however did not lend any bias to the outpatient system because the patients that were put on the more expensive treatment were prescribed the standard

treatment after their condition had been stabilised. That is, before they had completed their six-month treatment. Even for the seriously ill and drug resistant patients the standard course was still favourable though for longer periods of treatment.

The clinic incurred higher drug costs because there was a lack of consistency in the treatment prescribed for each patient. Personal communication with members of staff at the clinic (Nkosi – Boom Street Clinic) explained the reason for this. The rotations that different doctors make to the clinic as well as administrative inefficiency mean that patients' treatment changed when a different doctor was in attendance if it was not clearly noted in the patient register which treatment the previous doctor had prescribed. Compounding to this is the fact the clinic is often forced to dispense alternative TB medication to the one prescribed depending on the availability of medication at the time. Inefficiencies like these emphasise the need for a well-structured health system infrastructure before the DOTS alternative can be completely effective.

The lack of adherence to treatment courses and inefficiencies in the health system contribute to the high drug costs of the clinic treatment. If an efficient monitoring system existed as part of the TB Control Programme enormous savings would be realised by the Department of Health. Hospitalisation of a TB patient costs R46.63 per day. This means that patients are kept under strict monitored conditions in hospitals to effectively ensure they complete their treatment. If an alternative system of ensuring that outpatients were monitored in the same manner from home, this would not only mean a saving of the R46.63 per patient per day but higher compliance rates of outpatients. A better system of monitoring and follow up by TB health workers could be put in place, with the cost savings from hospital costs. The broader implication of a better system of monitoring is that the loss of income that would have otherwise occurred if the patient had been hospitalised is avoided.

5.3 Conclusions

The effective cost per patient cured is the measure of effectiveness in this study. It is an important indicator that illustrates the effect of the cure rate on the costs of treatment. With an indicator such as this, emphasis of TB programs should be on

prevention and cure.

The formula for the Effective Cost is: $\frac{\text{Total costs (all patients)}}{\text{Cured patients}}$

High cure rates lower the effective cost; thus attaining a high cure rate effectively determines the cost effectiveness of a management strategy. For the two strategies in this study, the effectiveness of each can be compared on the basis of drug costs and institutional costs.

The hospitilisation strategy has yielded results that make its drug therapy more cost effective than the clinics. This is despite the fact that the hospital picks up the problem cases, while outpatient treatment goes more frequently to those who are more easily cured. At a cost of R173.65 per patient cured for the drugs, this cost is 2.3 times cheaper than the R403.51 per patient cured incurred by the clinic. This however is not a sufficient basis on which to make policy decisions that could affect the future of national management strategies. Taking into consideration the issues raised earlier regarding factors that could account for the hospital drug costs being underestimated, the hospital alternative is still seen as the alternative that makes a cost effective use of the TB drugs dispensed to patients. The fact that default cases are lower and retreatment cases comply with their treatment contributed to the effectiveness. Even more importantly is the fact that the Directly Observed Treatment Strategy (DOTS) is more evident in the hospital than with the clinic. The lack of follow-up treatments and monitoring combined with the absence of efficient community-based cared contribute to DOTS not being fully functional as part of outpatient care.

Despite the cost effectiveness in drug treatment alone, inpatient care can not be recommended as the national strategy. This is because the institutional costs make it the cost ineffective alternative. The effective costs per patient cured for the clinic and hospital are R490.34 and R7502.66 respectively. Recommending the hospital alternative to TB treatment is not justifiable given these results. The health system clearly expends too much of its resources on patients who have defaulted and then have to be hospitalised. The same resources could be allocated to outpatient care. The issue raised in the background to the problem was whether the hospitalization of TB patients yielded higher cure rates, less dafault rates and thus offset the higher hospital costs. The results depict a different picture, that is, compliance rates are expectedly lower but the

high hospital costs do not make the hospital alternative any more cost effective. What the clinics could learn from this is that there is a need to improve upon their existing monitoring and follow up procedures. The results illustrate that outpatient treatment of TB patients can and does yield relatively positive cure rates. The crucial point is to ensure that the treatment is complied with.

In their study Wilkinson and Davies (1996:455) concluded that "even relatively cheap institutional care is more expensive and hence less cost-effective than community-based care."

The results of this study support that conclusion. This is crucial if one were to make recommendations. Selecting one strategy on the basis of overall cost effectiveness is not necessarily the solution to TB management. The transferred patients completed the course of their treatment as outpatients, thus combining hospitalization with outpatient care. Because the clinic is regarded as the next best alternative to community-based care, what the results show is that a short hospital stay and community-based directly observed treatment can be successfully implemented.

This study showed that what can accurately be termed 'Directly Observed Treatment', that is, according to Iseman et al (1993:576), "the practice of giving patients their pills and seeing that they are swallowed" was more evident with inpatient than outpatient care. This adherence to DOT inadvertently affected the hospital default and cure rates and thus the cost effectiveness of drug therapy. A study by Iseman et al (1993) in which DOTS was practised yielded default rates of less than 10%, slightly lower than the 13% yielded by the hospital. This was in contrast with a multi-center that used self-administered treatment. The onus of ensuring that all medication is taken is on outpatients more than the clinic staff. This makes the clinic comparable to a multi-center using self-administered treatment. The default rates are also more comparable on this basis. According to Iseman et al (1993:577), "39% [defaulted] in the six-month regime and 49% in the nine-month regime." Default cases were a result of lack of responsibility in ensuring the completion of treatment.

These rates support Wilkinson's assertion that, "Although more patients with tuberculosis do require lengthy hospitalization in the HIV era, even with the high [rates], ninety percent of patients are successfully managed as outpatients" (1997:455).

If improvements to cure rates and costs effectiveness are to be made, the focus should be on improving the efficiency of the DOT strategy. Hospitalization is cost-ineffective, although the clinical alternative has proven to be ineffective in terms of drug costs. Obvious reasons such as the lower monitoring that patients receive accounts for the longer treatment periods and in some instances occurrences of MDR-TB. Resources could be allocated to strengthening community-based care in terms of making more health workers available to patients in rural areas, that way ensuring higher monitoring costs and even higher compliance rates.

Statistics from the Epidemiological Comments (1996) reveal that "...about one third of all TB cases are retreatment cases".

This goes further to reiterate the need for a complete bacteriological cure which can be ensured with prompt, accurate diagnosis and a strict monitored treatment regime – none of which have yet been established in South Africa.

Currently cure rates are between fifty to sixty- percent of all smear positive TB cases. The target rate is eighty-five percent. The cost analysis of the two strategies to TB management have provided an insight into not only which strategy is more cost-effective, but the different components of costs that reflect an inefficient use of resources.

Merely stating which strategy is more cost-effective is not enough to be the foundation of future recommendations without identifying the areas and reasons of ineffectiveness. For all intents and purposes however, DOTS is the future to all TB management, not only because of its cost-effectiveness but as the economically viable strategy towards treating the more productive proportion of the country's population, without the need to lower their productivity through hospitalisation.

Bibliography

Aggleton, Peter. 1990.Health. North Yorkshire: Cox and Wyman Ltd

Barnes, P.F., Bloch, A.B., Davidson,P.T., and Snider Jr.,D.E.1991. Tuberculosis in patients with immunodeficiency virus infection. New England Journal of Medicine. 324: 1644 – 1650.

Cohen, J.E. 1974. Some Potential Economic Benefits of Eliminating Mortality Attributed to Schistosomiasis in Zanzibar. Social Science and Medicine. Volume 8:383-398.

Crowe, B.L., and Hailey, D.M. Cost-Effectiveness of Diagnostic Technology: MRI-A Case Study. In Smith, C.S. (Ed.), Economics and Health: 1989. Proceedings of the Eleventh Australian Conference of Health Economists.

Cullis, J.G., and West, P.A. 1979. The Economics of Health - An Introduction. Oxford: Martin Robertson.

Culyer, A.J. 1976. Need and the National Health Service: Economics and Social Choice. London: Martin Robinson.

Department of Health. Health Trends in South Africa. Department of Health, 1994 – 1996.

Department of Health. *National Annual Reports.* Epidemiological Comments. Department of Health, 1990 – 1996.

Department of Health. Report on the Review of the Tuberculosis Control Programme of South Africa, June 1996. Pretoria: Department of Health, 1996.

Department of Health. The South African Tuberculosis Control Programme. Practical Guidelines 1996. Pretoria: Department of Health, 1996.

Drummond, M.F. 1980. Principles of Economic Appraisal in Health Care. Oxford: Oxford University Press.

Dunlop, D.W. 1975. Benefit-Cost Analysis: A Review of its Applicability in Policy Analysis for Delivering Health Services. Social science and Medicine. Volume 9: 133-139.

Feldstein, M.S. 1970. Health sector Planning in Developing Countries. Economica. May: 138-163.

Fenwick, A. 1972. The costs and a cost-benefit analysis on an irrigated sugar estate in northern Tanzania. Bulletin of the World Health Organisation. Vol 47:573-398.

Hagard,S., Carter,F., and Milne,R.G. Screening for spina bifida cystica, British Journal of Preventive and Social Medicine. In Mooney et al. (1980). Choices for Health Care.

Hobbs, J.T. 1974. Surgery and sclerotherapy in the treatment of varicose veins: a random trial. Arch. Surgery. 109: 793-6.

Iseman, M.D., Cohn,D.L., and Sbarbaw, J.A. 1993. Directly Observed Treatment of tuberculosis. We can't afford not to try it. New England Journal of Medicine. 328: 576 – 578.

Klarman, H.E. 1965. The Economics of Health. New York: Columbia University Press.

Klarman, H.E., Francis, J.O., and Rosenthal, G.D. 1968. Cost-effectiveness analysis applied to the treatment of chronic renal failure. Medical Care. Volume 6.pp 48-54.

Klarman, Herbert. E. 1965.Measuring the Benefits of a Health Programme-The Control of Syphilis. Paper delivered at the Brooking Institution Conference on Public Expenditures, Washington D.C.Noveber 8,1963.

Klees, S., and Wells, S. 1980. Health economics and Development. New York: Praeger.

Kochi, A. The global tuberculosis situation and the new control strategy of the World Health Organisation. Tubercle 1991: 72: 1–6

McGregor, M.M., Olliaro, P., and Wolmarans, L. 1996. Efficacy and Safety of Rifabutin in the Treatment of Patients with Newly Diagnosed Pulmonary Tuberculosis. American Journal of Respiratory and Critical Care Medicine. 154: 1462 – 1467.

McIntyre, D. 1986. A Cost-Effectiveness Analysis of the Tuberculosis Control Procedures Applied in the Cape Divisional Council Area. MA thesis. University of Cape Town.

Mishan, E. 1971. Evaluation of Life and Limb: A Theoretical Approach. Journal of Political Economy. Volume 79.No.4.pp 687-705.

Mishan, E.J. 1975. Cost-Benefit Analysis. Norwich: Page Brothers Ltd.

Mooney, G.H., Russel E.M., and Roy D, Wein. 1980. Choices for Health Care. Hong Kong: Macmillan Press.

Mooney, G.H. 1986.Economics, Medicine and Health Care. Sussex: Wheatssheaf Books Ltd.

Pearson, J.O. The Costs and Benefits of Intensive Short-course Chemotherapy for TB. In Westcott, G and Wilson,F.1980. Hunger, Work and Health. Economics of Health in South Africa. Volume 11.

Perkins, F.C. 1994. Practical Cost-Benefit Analysis. Melbourne: Macmillian.

Phillips, D.R. and Verhasselt, Y. 1994. Health and Development. New York: Routledge.

Piachaud, D., and Weddell,J.M.. 1972. The economics of treating varicose veins. International Journal of Epidemiology. Volume 1.pp 287-294.

Pole, D. 1971. Mass Radiography: A Cost-Benefit Approach. In G.McLachlan (Ed.), Problems and Progress in Medical Care. Oxford: University Press.

Savage, Michael. 1979. The Political Economy of Health in South Africa. Cited in Westcott, G., and Wilson, F. (Eds.),'Perspectives of the Health System'. Economics of Health in South Africa. Vol.1.

Sorkin, A.L. 1975. Health Economics. Toronto: D.C Heath.

Sorkin, A.L. 1995. Health Economics: An Introduction. Massachusets: Lexington Books.

St. Leger. 1992. Evaluating Health Services Effectiveness: A guide for health professionals, service managers and policy makers. London: Independent Press.

Van Rensburg, H.C.J. 1982. Profile of Disease and Health in South Africa. Pretoria: H and R Academica.

Viney, Rosalie. Cost Benefit Analysis of Non-Drug Treatment of Hypertension. In Smith, C.Selby (Ed.), Economics and Health: 1989-Proceedings of the Eleventh Australian Conference of Health Economists. Clayton, Victoria: Public Sector Management Institute.

Warner ,K., and Luce , B. Cost Benefit and Cost-Effectiveness Analysis in Health Care. Ann Arbor: Health Administration Press, 1982.

Weiss, K.B., Gergen,P.J., and Hodgson, T.A. 1992. An economic evaluation of asthma care in the US. New England Journal of Medicine. 326: 862 – 866.

Weyer, K., and Fourie P.B. Assessment of the Tuberculosis Epidemic in South Africa – Historical Perspective and Critical Evaluation of Current Information. Pretoria: Medical Research Council, 1996.

Wilkinson, D., and Davies G.R. 1997. The increasing burden of tuberculosis in rural South Africa – impact of the HIV epidemic. South African Medical Journal, Volume 87: 4

Wilkinson, D., and Davies,G.R. 1996. Costs and cost-effectiveness of alternative Tuberculosis Management Strategies in South Africa - implications for policy. South African Medical Journal. Volume 87: 451-455.

World Health Organisation. 1958.Constitution of the World Health Organisation Annex; The first ten years of WHO. Geneva :WHO.

World Health Organisation.1978. Fourth Report on World Health Situation 1965-68. Geneva: WHO.

Appendix A

A. Treatment and Case Management

The costs of drugs alone do not make up the costs that are incurred in the treatment of tuberculosis. The costs of drugs are provided as are all other expenses, and in situations where a near accurate estimation was not provided in the actual research process, the information is supplemented by information provided by alternate reliable sources such as official health reports.

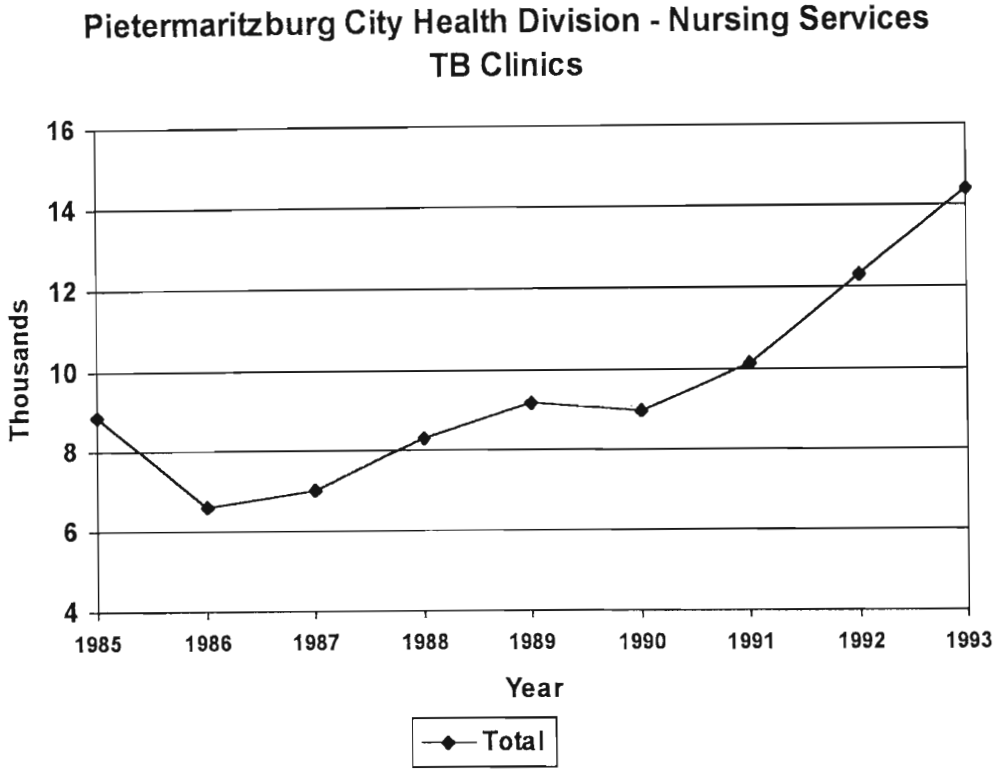
Statistics of the Pietermaritzburg-Msunduzi Clinic show a continuing decrease of tuberculosis patients in the years 1993 to 1996. This deviates from the trends of previous years, where the Tuberculosis clinic attendances have always shown an increasing trend. For instance, according to Figure 2, from the years 1985 to 1993 the total number of reported Tuberculosis cases declined initially only to be followed by an increasing trend that continued until 1993. The numbers include all race groups, according to the classification used when the statistics were compiled.

Table A-I: Total TB Attendance of all clinics

	1993	1994	1995	1996
Tuberculosis	**14396**	**10844**	**9551**	**9266**

Source: PMB-Msunduzi City Health Division, Nursing Services.

Figure A-II



Source: 1993. PMB City Services Health Division

A.I Treatment of New Cases

Treatment of new cases requires the same investigation protocol as retreatment cases. However the treatment regime differs between the new and retreatment cases. The underlying principle of Tuberculosis (TB) treatment is that in order to control its spread in a community, patients that are coughing up living TB Bacilli should be started on treatment as soon as possible. In order for the treatment to be effective, it is crucial that the correct drugs are given for the correct period of time.

In principle this appears straight-forward enough but as has already been mentioned in the first chapter, problems encountered between the time when sputum samples are taken and the length of time it takes for microscopy results to be relayed to the clinician creates a number of problems. The main one being the possibility of a

misdiagnosis, whereby patients are started on treatment sooner than the results are relayed back even though this may not be the requirement. In such instances, the protocol is that the decision to give TB treatment must be taken by an experienced clinician, and a full course of TB drugs given as for a new case.

All new cases are started on the Intensive Phase Treatment. By new cases is meant new adult patients who have never been treated before or those who have only been treated for less than four weeks before.

The Intensive Phase of Treatment lasts two months. According to the Department of Health's Epidemiological Comments (1996:9), "the national recommended regimen for new adult sputum smear positive patients during the intensive phase is isomiazid (400mg), rimampicin (1280mg), Ethambutol (1200mg) and pyrazinamide (1280mg)". Kwazulu-Natal, which is the province of interest, had not yet implemented the recommended standardized treatment regime when the research for this study was carried out. What they have continued to do is to prescribe the previously recommended or non-standardized treatment regime. Only six of the nine provinces are implementing the recommended standardized treatment regime.

Much as the number of tablets prescribed are for adults with weights below and above fifty kilograms, since the majority of adults weigh more than fifty kilograms the Provincial Medical Supply Centre assumes the requirement for The Intensive Phase in adults to be for adults weighing more than fifty kilograms. The health worker or clinician in cases makes adjustments accordingly where the adult weighs less.

In the first two months of the Intensive Phase of Treatment, the bactericidal effect of this treatment leads to the bacteriological conversion of sputum. This is the rationale behind the two-month investigations. In the Continuation Phase, the sterilizing effect of the treatment eliminates the remaining viable bacilli and prevents subsequent relapse. The results of the two-month investigations determine the modifications in the drugs prescribed in the treatment regime. If the sputum microscopy is not possible at two months, the Intensive Phase of treatment in continued for six months. If at the six-month investigation the results are smear positive then the patient is assumed to have Multi Drug Resistant Tuberculosis (MDR-TB).

A.II Retreatment Cases

Unless Multi Drug Resistance is diagnosed retreatment cases that have sputum positive results will be those that have, according to the TB Control Program's Practical Guidelines (1996:10):

i) been treated before and shown to be sputum negative by smear or culture at the end of the treatment**(cured)** or

ii) been treated before and **completed** treatment but were not shown to be sputum negative at the end of the treatment or

iii) been treated before but **failed** because the patient was still sputum positive at the end of the course or

iv) Been treated before but whose treatment was interrupted by missing a total of two months treatment during the six month course.

The six-month investigation will determine the results of the treatment. All treatment including that given in hospital is given as Directly Observed Therapy (DOT). This means that every single capsule or tablet is monitored and swallowed by health workers.

If the patient requires hospitalization, treatment is given seven days a week while in hospital, and the period of hospitalization is included in the total of six months.

In some patients, hospitalization may be necessary in order to ensure compliance. Other reasons for TB patients to be admitted to the general hospitals are for diagnosis, control of any medical condition or clinical reasons. The clinical reasons for admission are in cases where patients are sick and require a variable time of hospitalization. This includes patients with *miliary* TB and TB *meningitis* .TB institutions on the whole also do not have laboratory, diagnostic or X-ray facilities so admission to general hospitals is a necessity for diagnostic purposes.

All relevant TB investigations are completed at the referring hospitals. Admission to TB hospitals is for patients with specific needs:

i) Patients who are too ill for outpatient treatment but are clinically stable.

ii) Those with Extra Pulmonary TB – which in this case are selected cases only.

iii) Those with MDR-TB. Because this requires a different treatment regime, admission is to those hospitals that have appropriate drugs.

iv) Retreatment Patients. Those whose results show treatment failure after one course of TB treatment. In order to prevent MDR-TB, patients are admitted for the first two months until sputum conversion has occurred.

v) High risk groups, such as the very poor, alcohol dependants, substance abusers, previously non-compliant patients, neuro-psychiatric patients and those who refuse treatment.

vi) Small children, who are admitted with their mothers, if it is possible to do so.

The number of tuberculosis beds and the proportion of patients hospitalized vary from province to province according to the Department of Health (1996).
While in almost all provinces patients spend varying lengths of time in hospital, often for at least the first two to three months and sometimes for the whole duration of the treatment.

A.III Treatment of Children

Diagnosing TB in children is not very easy which is the reason preventive measures are taken as soon as a child is born. BCG is a TB vaccine given to infants as soon as possible after birth. Children between the age of zero to two years are put under preventive therapy called chemoprophylaxis. This prophylactic treatment is a course of INH and Rifampicin for three months. This is for children with close contact with adults that have smear positive cases of Pulmonary TB.
Chemoprophylaxis however is not considered to be a major component of the TB Control Program. Emphasis is on finding sputum positive cases and treating them effectively.

A.IV Multi-drug Resistant (MDR) TB Cases

There is a standardized policy for the treatment of multi-drug resistant tuberculosis patients, who usually receive treatment in hospital, although there are some who receive outpatient treatment.

Multi-drug resistant TB (MDR-TB)1 is a tuberculosis disease caused by strains of *Mycobacterium tuberculosis* that are resistant to at least both rifampicin and isoniazid (INH). This means that these drugs have less or no effect against many of the TB bacilli found in a patient's sputum.

There are two types of resistance, *initial* and *acquired* resistance.

Initial resistance is the presence of drug resistance to one or more TB drugs in a patient who has never received prior tuberculosis treatment (new patients). Acquired resistance develops during the course of treatment usually as a result of poor compliance or faulty prescription. The Department of Health (1996) notes that retreatment patients are more likely to have this type of resistance.

MDR-TB is diagnosed in the laboratory. Patients with ongoing symptoms, but who are culture negative, do not necessarily have MDR-TB. The diagnosis can only be made with appropriate culture and susceptibility testing. (TB Control Program in Kwazulu-Natal: 1996).

Patients are suspected of having MDR-TB if they;

i) relapse after the completion of treatment,

ii) have a poor clinical response to anti-TB therapy,

iii) have evidence of poor compliance with TB therapy,

iv) have persistently positive sputum after three months of treatment,

v) have contact with an MDR-TB case and

vi) are a family member of a patient who has died from TB.

---

1 MDR-TB is not the same as TB due to MOTT (Mycobacteria Other Than Tuberculosis). MOTTs are commonly resistant to INH and rifampicin, but is not to be confused with MDR-TB caused by resistant strains of *M.tuberculosis*.

Clearly the diagnosis of MDR-TB is not as straight forward as that of new TB cases. Only after susceptibility tests have been carried out is a treatment regime implemented.

There is the standardized regime for a new patient with two-drug resistance (INH and rifampicin) MDR-TB, which is also categorized into two phases, intensive and continuation.

The **Intensive Phase** prescribes the drugs stipulated in Table A-IV in the Appendix.

There is also an individualized regime for MDR-TB whose combination of drugs are determined by the health worker or qualified clinician. The standardized regime is the most commonly implemented, as the individualized regime is applicable in very rare cases, for instance, when the MDR-TB requires close monitoring and a cautious treatment. This is in cases where the MDR-TB is severe enough to warrant close attention.

For most MDR-TB patients, hospitalization is recommended because MDR-TB can be fatal if not effectively treated. Another reason for hospitalizing MDR-TB patients is that the treatment regimes of MDR-TB frequently entails the use of agents known to be toxic and difficult to tolerate. In-patient care in this case ameliorates the effectiveness of the treatment regime.

Compliance by patients together with strict monitoring and effective treatment by health workers is by far the only way to ensure that treatment is managed in a cost-effective manner. When these aspects are attained, it is the only way of ensuring lower levels of defaulting patients, who if left untreated will require retreatment at higher costs of treatment. Furthermore, they risk developing MDR-TB if treatment is not completed. Treating MDR-TB is far more expensive than treating new or retreatment cases because, other than the different types of drugs that are prescribed, the costs are incurred in the form of higher monitoring costs and of the hospitalization costs.

Community and hospital/clinic co-operation is a requirement that can ensure that treatment regimes are adhered to.

Appendix B

Table B-I : The Drug Price List

Description	Price as at Dec.1996(Rands)
I.N.H. 100mg – 30's	0.48
I.N.H. 200mg – 30's	0.80
I.N.H. 300mg – 30's	1.71
TB Unit Dose (intensive) – 20's(Pyrifin + Ethambutol 400mg)	44.71
Dapsone 100mg	39.44
Ethambutol 100mg – 500's	31.01
Ethambutol 400mg – 500's	62.12
Ethambutol 300mg + INH 100mg ("Tuberol") – 500's	56.56
Ethionamide 250mg – 250's	104.02
I.N.H. 100mg – 1000's	13.49
I.N.H. 200mg – 1000's	26.73
I.N.H. 300mg –100's	5.70
Rifampicin 120mg + PZA 250mg 100's ("Pyrifin")	36.06
Pyrazinamide 500mg – 1000's	140.53
Rifampicin 150mg – 100's	25.06
Rifampicin 450mg – 100's	76.12
Rifampicin 600mg – 100's	129.18
Rifampicin 150mg + INH 100mg ("Rifinah 150") – 20'S	9.34
Rifampicin 300mg + INH 150mg ("Rifinah 300") – 20's	10.77
Streptomycin 5g vial	3.33
Ethambutol Syrup 500ml	18.80
Rifampicin Syrup 180ml	44.13

B-II: Treatment Regimes as stipulated by the Department of Health

Table B-II: New Adult Patients

Stage of treatment	Drug	No. tablets	
		< 50kg	> 50kg
Intensive Phase **2 Months** *5 times per week*	Rifampicin/INH/Pyrazinamide 120/80/250mg* Ethambutol 400mg	 4 2	 5 3
Daily no. of tablets		6	8
Continuation Phase **4 Months** *3 times per week*	Rifampicin/INH - 150/100mg** Rifampicin/INH – 300/150mg** INH	3 - 300mg	- 2 400mg
Daily no. of tablets		3	2

Source: Department of Health: 1996

Table B-III: Retreatment Adult Patients

Intensive Phase 2 Months		**Over 50kg**
Rifampicin/INH/Ethambutol Combination tablet 150/75/300mg	3 tablets	4 tablets
Pyrazinamide 500mg	2 tablets	3 tablets
Streptomycinψ	750mg	1000mg

Third Month	**Under 50kg**	**Over 50kg**
Rifampicin/INH/Ethambutol Combination tablet 150/75/300mg	3 tablets	4 tablets

* Combination tablet: Pyrifin
** Combination tablet: Rifinah

ψ Streptomycin dose must be reduced to 750mg for those older than 45 years, and must not be given over 65 years or in pregnancy.

Pyrazinamide 500mg	2 tablets	3 tablets

Continuation Phase 4 months		**> 50kg**
Rifampicin/INH/Ethambutol Combination tablet 150/75/300mg	3 tablets	4 tablets

Table B-IV: Treatment of Children

Stage of treatment	**Drug**	**Number of tablets**		
		Weight5-10kg	**Weight 11-20kg**	**Weight 21-30kg**
Intensive Phase 2 Months *5 times per week*	Rifampicin/INH 150/100mgξ	Rifampicin syrup 5ml INH 50mg	1	2
	Pyrazinamide 500mg	1/2	1	2
Continuation Phase 4 Months *3 times per week*	Rifampicin/INH 150/100mgξ	Rifampicin syrup 5ml INH 50mg	1	2
	INH	50mg	100mg	100mg

Table B-V : Drugs for MDR-TB Patients

Drug	**Dose**
Streptomycin	750 – 1000mg daily or
Kanamycin	750 – 1000mg daily

ξ Combination tablet :Rifinah

Terizidone	750mg daily
Ethionamide	250mg tds
Pyrazinamide	1500mg daily

The **Continuation Phase** prescribes the following:

Drug	**Dose**
Ethionamide	259mg tds
Terizidone	750mg daily
Pyrazinamide	1500mg daily

Appendix C

C-I: TB Control Program in the Kwazulu-Natal Area

In Kwazulu-Natal pretreatment investigations follow the same protocol as the other provinces nationwide. The main reason for the upsurge of TB in Kwazulu-Natal is an unfocussed TB Control Program, which fails to cure a high proportion of smear positive cases. The high numbers of HIV positive cases that can be found in Kwazulu-Natal further exacerbates the situation. With the assertion that dually infected individuals have a 25 times greater chance of dying due to TB unless they are probably treated, the deadly link between TB and HIV will have catastrophic results unless it is urgently addressed. The failure to adhere to a prescribed treatment regime is often the primary reason for unattainable cure rates and the development of multi-drug resistance. Short course chemotherapy regimes have been proven to have very high cure rates and very low relapse rates, but they are fully successful when combined with a control program in which drug administration is supervised and facilities for sputum examinations are available.

The elements outlined by the Kwazulu-Natal TB Control Program are outlined by the Department of Health;

i) Integrating the TB Control Program into the existing health infrastructure with technical leadership and coordination from a central unit.

ii) Administering a standardized directly observed short course therapy to all confirmed sputum smear positive cases of TB.

iii) Case detection through passive case finding, primarily based on smear microscopy.

iv) An assured supply of all essential anti-TB drugs (isoniazid, rifampicin, pyrazinamide, and ethambutol).

v) Implementing an effective monitoring system using standardized registers, quarterly reporting and clear definitions of new and retreatment cases and treatment outcomes.

When Tuberculosis therapy is undertaken, the initial procedure is the determination of any previous anti-tuberculosis treatment, because patients who have undergone TB treatment before have a higher probability of developing drug resistant tuberculosis.

After which, it is then established whether the case is a new case, retreatment case or a chronic case. New cases are patients who have never been treated for tuberculosis before and retreatment cases are patients who have previously been treated for tuberculosis and have active tuberculosis again. With retreatment cases, the following distinctions are made.

i) retreatment after a previous cure

ii) retreatment after a previous treatment completion, where there are no results to confirm whether the patient was cured

iii) retreatment after a treatment interruption, where the interruption period was over a cumulative period of two months or longer over the six month treatment period

iv) retreatment after a previous treatment failure, for instance when a patient has developed multi-drug resistance.

Chronic cases are those that have had treatment for twelve months and are still smear or culture positive.

Diagnostic protocol for diagnostic tuberculosis in the Pietermaritzburg-Msunduzi clinic follows the same guidelines of the entire province. The hospitals that carry out testing are the Northdale, Greys and Edendale Hospitals, private institutions and hospitals as well as the Boom Street Clinic. Sputum tests are the essential way of establishing whether or not pulmonary TB is present in a patient, and this remains the most commonly used method at the Boom Street Clinic. This being the clinic that caters for the Pietermaritzburg-Msunduzi Clinic services. Hospitals are able to test for other forms of TB other than pulmonary tuberculosis. Testing is often carried out on the basis of referrals either from local clinics or from occupational nurses or supervisors working within factories, as it is in factories that a higher incidence of pulmonary tuberculosis can

be found.

Once new cases have been established, that is, referred then the pretreatment investigations begin. An initial sputum specimen is collected under direct supervision at clinics or hospitals. Thereafter, the patient is issued with two specimen containers with instructions on the correct procedure for obtaining early morning sputa. All specimens are then submitted or sent to the laboratory accompanied by a special request for a sputum examination. The Pietermaritzburg clinic sends its sputum specimens to the King George Hospital in Durban.

If the microscopy of one specimen is positive for (acid-fast bacilli) AFB, the patient is treated for active tuberculosis. Further specimens are not required to be collected or sent to the laboratory if the results are positive. It is only when the results are negative that microscopy is carried out on the other two specimens. If all three sputa are negative however, the obvious conclusion is that the patient does not have tuberculosis unless there is strong clinical and radiological suspicion of TB, in which case sputum can be sent for culture. An active case of tuberculosis refers to symptomatic disease due to infection with *Mycobacterium tuberculosis* according to clinical definitions. The diagnostic protocol therefore stipulates that a patient must be treated for active tuberculosis if the sputum culture is positive for *M.tuberculosis.*

Once the pretreatment investigations have been completed, the treatment regime for active tuberculosis cases is undertaken. To ensure that the treatment is working, sputum is collected routinely after two months of treatment. This is the two-month investigation. If the smear results are negative at two months, the Continuation Phase of the treatment is introduced. If they are positive however, then a further specimen is sent for culture and susceptibility testing and the Intensive Phase Treatment is continued until the results of these tests are available. Susceptibility results will indicate whether the TB is being affected by the treatment, and the treatment regime may require modification according to the results. If after two months sputum microscopy is not possible, then the Intensive Phase of the treatment is continued for six months.

The six-month investigation is carried out if the patient is still not doing well clinically. This specimen is then submitted for culture, and if the smear is positive for AFB then it is

sent for culture and drug susceptibility tests are performed. These investigations are for new cases alone, and they entail diagnostic costs being incurred before, during and after the treatment. The department of Health recognizes its limitations at the moment as regard the availability of resources for diagnostic purposes, for instance, laboratory services.

Retreatment cases also require pretreatment investigations, and the same treatment regime is undertaken, unless the patient has developed multi drug resistance. Because of the delay between the collection of sputum for microscopy and the dissemination of results from laboratories, retreatment cases are often started on therapy almost immediately, before results are received. According to the TB Control Program's Treatment Protocol (1996), "ideally, all retreatment cases, whether failed treatment cases – smear positive at the end of the first course of treatment – or relapsed – smear negative at the end of the previous treatment, now smear positive again – should have specimens submitted for culture and drug susceptibility testing before starting treatment again." Retreatment cases require the six-month investigations as well. An early morning sputum specimen is obtained at six months and submitted for microcopy. If it is positive for AFB it is cultured and drug susceptibility tests are performed.

The treatment regime may be modified according to the results of the investigations carried before, during and after the treatment depending on the various stages at which the patient begins his treatment.

Because diagnosing tuberculosis in children is not easy, the diagnostic protocol for childhood tuberculosis is different from that of adults. Furthermore, children are more susceptible to other severe forms of tuberculosis such as respiratory, miliary and meningitis tuberculosis.

A preventive measure that is undertaken for children is the BCG, which is a tuberculosis vaccination. This is given immediately after birth and repeated after six weeks if there is no scar as scarring is an indication that the vaccination has been effectively administered. Children who live in close contact with adults with tuberculosis undergo a preventive treatment called chemoprophylaxis. A TB treatment regime for children is undertaken if the results of a tuberculin test are strongly positive and the chest x-ray is abnormal.

The Pietermaritzburg TB Clinic has only just introduced the internationally recommended Tuberculosis Laboratory Register, which ensures that all diagnosed infectious patients are registered, started on treatment and evaluated. This is the most obvious method of preventing an overlapping of diagnostic costs because it ensures that all diagnosed patients are evaluated and that information on patients moving from one institution or area to another are fully taken into account. According to the department of Health (1996) it is only in Mpumalanga that such a good support structure existed. This study will therefore assume a co-ordination of information among institutions and among neighbouring areas so as to account for any discrepancies in the results that can be accounted for by an overestimation of diagnostic costs. However, as mentioned earlier the main emphasis is not on the costs of the diagnostic measures undertaken or the preventive measures. Much as they are costs incurred in the management and treatment of tuberculosis and therefore should be included as control activities, they will not contribute to the issue of whether or not inpatient or outpatient treatment is the more cost-effective for tuberculosis. What they will do is create incentives for the Department of Health as regards the improvement of support structures.

C-II: Case findings, diagnostic protocol and laboratory services.

Case finding by sputum examination, recommended by the Tuberculosis Control Program is rather passive. It is only in some provinces and certain sectors of the economy such as the mining and industrial that case finding is more active. The mining and industrial sectors for obvious reasons because the main type of TB that are a problem in South Africa is pulmonary tuberculosis.

Along with these sectors, the Free State and certain areas of the Northern Cape carry out active case finding procedures that include "routine radiographic screening of workers or household contacts of an index case of tuberculosis." (Department of Health: 1994)

Screened individuals with abnormal chest x-rays are investigated by a sputum bacteriology, but the norm is that suspects start tuberculosis treatment on the basis of chest x-rays alone.

Being in its infant stage, The Tuberculosis Control Program has not yet developed to such an extent that bacteriological confirmation of all suspects is possible in all the provinces, Such being the case, most suspected cases are treated on the basis of their radiographic or clinical suspicion only. Sputum tests entail microscopy laboratory results, and because there are often delays in obtaining such results, most patients are treated before results are received. This clearly adds to the diagnostic costs of TB treatment; another aspect of the Control Program that the health department has to take into consideration in its quest for a cost-effective Control Program.

Presently there has been little laboratory coordination as a result of the demand for services far exceeding the costs. According to the Epidemiological Comments by the Department of Health (1996:9), "[w]ith regard to tuberculosis laboratory services in particular, [a] wide variation is observed among the provinces. Microscopic examination of sputum specimens for acid fast bacilli (AFB) is performed in 208 laboratories. Microscopic services are, however, not distributed uniformly, ranging from four (Northern Cape) to 46(Kwazulu-Natal) per province. Nearly all microscopy centres are in urban areas or in rural district hospitals. Quality control and proficiency testing programs are largely absent. On average, less than 25% of laboratory time is devoted to tuberculosis bacteriology."

This state of affairs as regards the laboratory services devoted to tuberculosis may explain the delay in disseminating results. Since sputum microscopy is the basis for diagnosis of tuberculosis and monitoring of the treatment outcome, without fully functional laboratory services, case finding and hence diagnosis may remain a costly problem, other than actual treatment costs.

In the PMB-Msunduzi case, the provincial TB Control Program's guidelines are used. Case detection through predominantly passive case finding is base primarily on smear microscopy.

Appendix D

D-I: Clinical Treatment Regime

Calculation of the Cost of Drugs for a Cured Patient:

i) Treatment A, (Monday – Friday):

Rifampicin 450mg (100s) = R76.12

Cost per tablet = R76.12/100

Cost of tablets per day = R0.76*1 tablet

Cost of tablets per month = R0.76*20days

The monthly costs in all cases are multiplied by the standard treatment time period, which is six months.

INH 300mg (30s) = {[R1.71/30] * 3 *20}* 6

Pyrazinamide (PZA) 500mg (1000s) ={[R140.53/1000]*4*20}*6

For Ethambutol however, the number of tablets prescribed per day is three, so the cost is:

Ethambutol 400mg (500s) = {[R63.12/500]*3*20}*6

The total number of tablets taken each day is eleven, which is clearly not the eight specified by the recommended standard treatment. In combination, the number would be eight but the Pietermaritzburg-Msunduzi Clinic still prescribed the specified drugs in separate doses for the sample patients studied.

The total cost of Treatment A for an adult patient who completes the course of treatment in the stipulated period of six months is **R37.34** per month and **R224.04** throughout the treatment period. These costs are drug costs alone and those further costs incurred by the clinic in its maintenance, salaries are not included.

ii) Treatment B.

INH 400mg was given in combinations of INH 300mg+INH 100mg. The drugs shaded in were the most commonly used at the clinic as they were the ones in stock. This therefore means that the cost per tablet of both the 100mg and 300mg type have to be

calculated.

INH 300mg(30s) = R1.71

Cost per tablet = R1.71/30

Cost of tablets per day = R0.06*3 tablets

Cost of tablets per month = R0.18* 20days

INH 100mg(30s) = {[R0.48/30]*1*20*6}

Ethambutol 800mg is twice the dosage of Ethambutol 400mg, which is the particular one that was being prescribed.

Ethambutol 400mg(500s) = R62.12/500*3*20 per month

Ethambutol 800mg = [R62.12/500*3*20]*2 per month

This was the cheapest drug treatment but not the most commonly prescribed one even though at **R18.65** per month and **R111.90** per six-month treatment period it is twenty-five percent cheaper than treatment A.

iii) Treatment C

INH 400mg = INH 300mg+INH 100mg

Rifampicin 450mg

Pyrazinamide 500mg

Ethambutol 100mg(500s) = [R31.01/500*1*20]*6

Ethambutol 200mg is twice the dosage of Ethambutol 100mg.

Treatment C was not used on a regular basis and it may not be regarded as a standard treatment. Its cost came to **R211.12** for a treatment period of six months, which is slightly, less than treatment A.

iv) Treatment D

Rifampicin 600mg(100s) = R129.18

Cost per tablet = R129.18/100

Cost of tablets per day = R1.29* 4tablets

Cost of tablets per month = R5.16 * 8 days

INH 900mg. Since the cost of INH 300mg has been calculated as R0.06 per tablet. For INH 900mg, the dose is three times the INH 300mg which makes it R0.06 * 9 = R0.54 per day.

Pyrazinamide 500mg

Ethambutol 200mg

The total cost of Treatment D is **R297.53** for six months. This was clearly the most expensive treatment and its cost may be the reason why it was not used regularly as a standard treatment. The patient who was prescribed this treatment was put on Treatment A after the first six months has elapsed. The doses of the drugs are higher than is normal. Unlike the other treatments this particular treatment was prescribed to be taken twice a week and not the five times normally required. The number of days a week was calculated as two and eight for the month.

The treatments for children were also not standard but the dosages prescribed allowed for the calculation of their costs.

V) Treatment E

INH 100mg(30s) = R0.48

Cost of tablet = R0.48/30

Cost of tablet per day = R0.016*1 tablet

Cost of tablets per month = R0.02* 20 days

Rifampicin 150g is the widely used and available type, but given the drug price list and the dosage required for it, the cost of Rifampicin 100mg can be calculated.

Rifampicin 150mg(100s) = R25.06

Cost of tablet = R0.25

Cost of tablet per day = R0.25 * 2[γ]tablets

γ The recommended dose for Rifampicin 450mg is one tablet. For Rifampicin 150mg it is 3 tablets. If

Cost per month = R0.50 * 20days

Pyrazinamide 250mg can be calculated as half the dose of Pyrazinamide 500mg, making its total cost per six month treatment period = R67.45/2

The Total cost of Treatment E was **R95.79** for a six-month treatment coming out to **R15.97** per month.

The alternative **Treatment F** followed for children was calculated to cost:

INH 200mg(30s) = R0.80

Total cost = {[R0.80/30]*2tablets*20days}*6months

Rifampicin 150mg is the closest approximation of the cost of Rifampicin 200mg. The cost of Rifampicin 200mg is not provided, so throughout the calculations where the cost of Rifampicin 200mg is required, the cost of Rifampicin 150mg is used. The cost = R0.25*3 tablets

= R0.75 *20days *6months

Pyrazinamide 500mg cost R67.45/2 = R33.73. This is because the dose for children is half that of adults.

The total cost of Treatment F was **R164.07**.

It should be noted that this would not be the standard cost of treatment, as neither would Treatment E because the costs varied according to the weight of the child, which invariably affected the total costs of drugs.

Default cases cost more to the clinic because they are not only retreatment cases which means that their initial cost of treatment is added to a latter treatment, thereby increasing the costs that may have been incurred initially by the amount of the drugs dispensed in the first course. Whether the initial course lasted two months or five months does not take away from the fact that the patients have to begin an entirely new course treatment after they have defaulted.

100mg are required, then 2 tablets should be prescribed.

Clearly the problem here is that the Department of Health's Guidelines are not adhered as regards the retreatment cases.

The Guidelines stipulate that all retreatment cases are hospitalized for the first two months of treatment, after the decision to extend treatment has been taken on the condition that the patient is not Multidrug resistant. This decision to extend or alter treatment must be based on laboratory results (Department of Health: 1996). The problems of the time periods between the submission of tests and the return of results are once again reiterated by this study. Because there are no laboratory services at the Pietermaritzburg Clinic, this means that sputum samples are all sent to King George V Hospital in Durban. This means that crucial decisions regarding the treatment of new patients and that of retreatment cases is the sole decision of the clinician. These decisions may contribute to the high costs of treatment for retreatment cases. Compared to the R9839.79 it cost to treat and cure thirty-five patients, the R4283.23 it costs the clinic in drugs for default patients, who most likely received further treatment if they did return, the problem is clearly the way in which default cases are handled.

D-II: Treatment Regime for Hospital Patients:

Intensive Phase of Treatment (5 times per week)

Rifampicin 450mg (100s)= R76.12

Cost Per Tablet = R76.12/100 = R0.76

Cost Per Day = R0.76 * 1 tablet = R0.76

Cost Per Month = R0.76 * 20 days = R15.20

INH 300mg (100s)=R5.70

Total Cost Per Month = (R5.70/100) * 3 * 20

= R3.42

Pyrazinamide (PZA) 500mg (1000s)=R140.53

Total Cost Per Month = (140.53/1000) * 4 * 20

=R11.24

Ethambutol 400mg (500s)=R63.12

Total Cost Per Month = (R63.12/500) * 3 * 20

= R7.57

Total Cost of the Intensive Phase of Treatment Per Month:

R15.20 + R3.42 + R11.24 + R7.57

= R37.43

Continuation Phase of Treatment (3 time per week)

Rifinah (300mg * 2) 20s= R10.77

Total Cost Per Month = (R10.77/20) * 2 * 12

= R12.92

INH 400mg = (INH 300mg + INH 100mg)

INH 300mg(100s)=(R5.70/100) *3 * 12

= R2.05

INH 100mg (1000s)=(R13.49/1000) * 1 * 12

=R0.16

INH 400mg = R2.21

Total Cost of the Continuation Phase of Treatment Per Month:

R12.92 + R2.21 = R15.13

D-II: Formulae for the calculation of Institutional cost for hospitalized patients.

Cost Per Patient per 6 month treatment period:

Number of days = 180

Cost Per Day = R46.63

Total Cost Per Patient = 180 * R46.63

= R8393.40

Number of patients = 23

Total Cost = 23 * R8393.40

= R193048.20

Cost Per Patient per 5 month treatment period:

Number of days =150

Total Cost Per Patient = 150 * R46.63

= R6994.50

Number of patients = 4

Total Cost = R27978.00

Cost Per Patient per 2 month period:

Number of days = 60

Total Cost Per Patient = 60 * R46.63

Number of Patients = 1 * R2797.78

Total Cost = R2797.78

Total Costs per 28 patients = R223823.98

Appendix E:

Table E-I: 1996 SANTA TB Cases

1996	Improved		Defaulted		Transferred		Died		Total	
February	20	*63*	7	*22*	3	*9*	2	*6*	32	*17*
March	28	*80*	5	*14*	2	*6*	0	*0*	35	*19*
April	10	*59*	0	*0*	6	*35*	1	*6*	17	*10*
May	20	*49*	17	*41*	3	*7*	1	*2*	41	*22*
June	4	*50*	0	*0*	3	*37*	1	*13*	8	*5*
July	37	*48*	13	*17*	25	*32*	2	*3*	77	*42*
August	28	*76*	3	*8*	6	*16*	0	*0*	37	*20*
September	15	*79*	3	*16*	1	*5*	0	*0*	35	*10*
October	20	*59*	5	*15*	8	*23*	1	*3*	34	*16*
November	18	*58*	4	*13*	9	*29*	0	*0*	31	*17*
December	41	*80*	5	*10*	5	*10*	0	*0*	51	*28*
January	23	*53*	5	*13*	15	*35*	0	*0*	43	*23*
February	27	*60*	15	*33*	3	*7*	0	*0*	45	*25*
Total	291		82		89		8		470	
Avg./Year	24	*68*	7	*17*	7	*21*	0.7	*3*		