TITLE:

EVALUATION OF STRATEGIES INSTITUTED TO IMPROVE THE TUBERCULOSIS CONTROL PROGRAM WITHIN SCOTT HOSPITAL HEALTH SERVICE AREA, LESOTHO

RESEARCHER: **DR. L. MAKAKOLE BSC, MD, MPH**

Submitted in partial fulfillment of the requirements for the M Med (Family Medicine) degree in the department of Family Medicine and Primary Health Care, University of Limpopo (Medunsa Campus), South Africa.

SUPERVISOR: **PROFESSOR GA OGUNBANJO**
MBBS, FCFP (SA) M. Fam Med (Medunsa)
FACRRM, FACTM, FAFP (SA)

Declaration:

I, Dr. Lipontso Makakole hereby declare that the work on which the research is based is original (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being or is to be submitted for another degree at this or any other university.

Signed: ……..

Dr. Lipontso Makakole

Date: .....

Dedication:

This work is dedicated to many dedicated health workers, the unsung heroes of human development who despite their relentless efforts to safe lives have themselves succumbed to tuberculosis and to my brother Paul also a victim of this unrestrained killer that terminates daily 4384 lives prematurely.

This is done with the sincere hope that some of the findings and recommendations of this dissertation will contribute to the removal of barriers to access to diagnosis and treatment and to reducing the spread of tuberculosis.

Acknowledgements:

It is a privilege to have been able to carry out this project under the supervision of Professor G.A. Ogunbanjo. I am grateful to Prof. “O” for his many years of academic stimulation, encouragement, support, guidance and help with data analysis. His belief in my ability to complete the project, his contagious energy and confidence were the guiding principles that paved the way for the successful completion of this work. It has been an enriching experience to finally be able to embrace research and evidence-based medicine as a cornerstone of modern medicine.

My gratitude also goes to Dr L.H. Mabuza for his patience, his friendly inputs and dedication to professional training. His ability to simplify even the most complex concepts for quicker understanding was well appreciated. His supervisory visits pointed me in the right path and the many hours spend in doing journal critique contributed immensely to this work.

I gratefully acknowledge the following: Drs J.M.Tumbo, H.I. Okonta and V.J. Ndimande for their valuable contribution in my training, not forgetting Mrs. L. Erasmus for her valuable assistance in literature search. This work would not have been possible without the commitment of Mrs. M. Ntsihlele and her laboratory technologists’ colleagues who diligently did sputum microscopy. I would also like to acknowledge Miss Nyane Makara the statistician who helped

me with data analysis and Mrs. K. Phoku the TB coordinator and other frontline TB nurses for their part in improving literacy among patients and recording all patients' details in the TB register.

It has been a great pleasure to get to know and work with Dr P. Saranckuk and Dr H. Bygrave who were very instrumental in training health workers about early TB detection and integrated TB/HIV activities. I sincerely thank the TB patients of Scott Hospital HSA for graciously having provided us with the study sample for this project.

I deeply thank my colleagues at Scott Hospital for their support during the study. I think of my family with thankfulness and love, my deep gratitude and love goes to my son Dr W.L. Brumskine for his support and understanding. I thank God for life and strength given to me to enable me to complete this project.

Acronyms and Abbreviations

AIDS	Acquire immunodeficiency syndrome
AFB	Acid fast bacilli
ART	Antiretroviral therapy
CDC	Center for disease control and prevention
CPT	Co-trimoxazole preventive therapy
DOT	Directly observed treatment
DOTS	Directly Observed Treatment, Short course
DST	Drug susceptibility testing
FM	Fluorescence microscopy
GDP	Gross domestic product
GFATM	Global fund to fight AIDS, tuberculosis and malaria
HIV	Human immunodeficiency virus
NTP	National tuberculosis control programme
HSA	Health service area
IPT	Isoniazid preventive therapy
ISTC	International standards of tuberculosis care
KNCV	Tuberculosis foundation
MDGs	Millennium development goals
MDR-TB	Multidrug resistant tuberculosis
MOHSW	Ministry of health and social welfare
NGO	Non governmental organization
NTP	National tuberculosis control programme

PPM	Public private mix
REPC	Research ethics and publications committee
SCC	Short course chemotherapy
TB	Tuberculosis
VCT	Voluntary counseling and testing for HIV infection
WHO	World Health Organization

Definition of Terms

Bias:

Bias in research is defined as any effect at any stage of a research process, or influence that tends to produce results that depart systematically from the true values.

Conversion rate:

Proportion of new sputum smear-positive cases that converted at two or three months after starting TB treatment

Interrupted treatment:

When doses of TB treatment have been missed for less than two months

Reliability:

Reliability refers to the consistency of measurement or the degree to which an instrument measures the same way each time it is used under the same condition with the same subjects. It does, in short, refer to the reproducibility and consistency of information.

Sensitivity:

The proportion of people with the disease that have a positive test result. A sensitive test will rarely miss patients who have the disease

Specificity:

The proportion of people without the disease who have a negative test result. A specific test rarely incorrectly classifies people without the disease as having the disease.

TB suspect:

Any adult who has coughed for two weeks or more.

Validity:

Validity refers to the accuracy of the study; it is the strength of the conclusions, inferences or propositions. It is also the degree to which the measurement reflects the true value of the characteristic.

Variable:

A characteristic of interest in a study that has different values for different subjects or objects.

Abstract

Background:

In spite of the substantial progress made in the development and implementation of many strategies necessary for effective tuberculosis control, the disease continues to be the leading cause of death, and in Africa, because of the expanding HIV epidemic, there has been an increase of HIV associated TB. In 2005 African health ministers declared TB a regional emergency. Although TB treatment is free and Lesotho has 100% DOTS coverage, the country still reported an incidence of 485 per 100,000 population (2005) and a treatment success of 74%, which is still lower than 85% WHO target.

Objective:

This six-month study at Scott Hospital Health Service area in Lesotho was undertaken to assess the outcome measures of strategies instituted to improve the tuberculosis control programme and determine the effect on TB treatment outcome indicators and TB/HIV integration.

Methodology:

The study design was a quantitative, descriptive study. The principal researcher and a research assistant used a questionnaire to collect data from the outpatient, TB suspect and treatment registers.

Study population and sample:

The subjects of the study were all adult new sputum- smear positive TB patients enrolled and registered in the Scott Hospital Health Service area TB register from 1st January to 30 June 2006.

Results and discussion:

A total of 100 new sputum smear positive adult TB patients presenting at Scott Hospital during the research period formed the sample group of this study. This included 47 female and 53 male patients. Their ages ranged from 18 years to 84 years with the mean age of 42 years. Majority 52 (52%) were in the age group 20-39 years, followed by 27 (27%) in age group 40-59 years and 19 (19%) in the age group 60-79 years. There was a high TB/HIV co-infection of 40 (81.6%) among the 49 (49%) who accepted HIV counseling and testing. Active screening of patients for TB resulted in 378 (86.3%) of the 438 TB suspects having their sputa tested. Of these, 100 (26.5%) were new sputum smear positive. Good

adherence and treatment supervision resulted in sputum conversion rate of 89 (89%). Rigorous implementation of the DOTS strategy showed increased treatment outcomes: cure rate of 76 (76%) and treatment success of 85 (85%). These results were similar to findings of other studies carried out in Cambodia, Tanzania and Rwanda to assess TB programme performance following introduction of improvements.

Conclusion:

This study demonstrates that implementation of activities consistent with new stop TB DOTS strategy to improve TB control is possible in a rural setting and leads to improvement in TB case detection and treatment success and a decrease in both defaulter and death rates.

TABLE OF CONTENTS

List of tables and figures **Page**

1. INTRODUCTION

Lesotho is a small country (30,355 square kilometers) situated in the south eastern part of southern Africa. The country is completely surrounded by the Republic of South Africa and its economy is intrinsically dependent on its more industrialized neighbour. Lesotho boasts of its highest altitude in Southern Africa and a spectacular view of high peaked mountains with abundance of water. Its scenic beauty has earned it the name “The Kingdom in the sky”. The population of Lesotho has declined from 2.2 million in 2003 (BOS, 2003:2) to 1.9 million in 2006 (BOS, 2007:2) probably due to the crippling impact of HIV infection. Lesotho has ten administrative districts and is a primarily subsistence farming country with gross domestic product (GDP) of 8,832 million Maloti (Lesotho Demographic and Health Survey, 2004:1).

1.1 Current Health Status

In Lesotho, the advent of the HIV/AIDS epidemic, the burden of suffering and economic loss caused by the increased prevalence of a complex of diseases associated with AIDS such as tuberculosis has already begun to erode the health gains of recent years as demonstrated by the declining health indicators. For instance, life expectancy has declined from 58 years in the 1990s to 35 years (MOHSW, 2002:1). Infant mortality rate is 91 deaths per 1000 live births (MOHSW, 2004:114). This figure is up from 75 per 1000 live births in 1999, while

the under five mortality has increased from 90 to 113 deaths per 1,000 live births over the same period (MOHSW, 2004:114). Lesotho has one of the highest maternal mortality rates of 762 per 100,000 live births. The fertility rate is 3.5 (BOS,2006:2) and adult HIV prevalence rate in the age group 15-49 years has soared to a high rate of 23.2 percent (Lesotho Demographic and Health Survey, 2004:239). Unfortunately majority of these people also have Tuberculosis.

1.1.2 Health Care Provision: Tuberculosis program in Lesotho

Lesotho is divided into eighteen Health Service Areas (HSA) demarcated around each of the seventeen hospitals with the exception of the Highlands Flying Doctor Services that is not attached to any hospital. The Health Service Area of Scott Hospital is the second largest in the country with a population of 220,000 (Scott Hospital profile, 2006:1). Because of the ongoing implementation of the Health Sector Reform Program, this demographic division of the country is also in the process of being functionally changed into the District Health System. The National Tuberculosis Programme (NTP) is responsible for co-ordination and management of free tuberculosis treatment in all the eighteen HSAs in Lesotho. Each HSA has a nursing assistant who has been trained as a Tuberculosis (TB) Co-coordinator, responsible for all TB activities in her area of assignment and is supervised by the District Medical Officer. Case detection is mainly by sputum microscopy and the treatment is Short-Course Chemotherapy (SCC) with Directly Observed Treatment (DOT).

1.1.3 Country Profile – Lesotho

Each year the Ministry of Health and Social Welfare, assisted by International Development Partners produce a report on Health Services. The following data about Lesotho was compiled from the Ministry of Health and Social Welfare annual joint review report (Source: Compiled from MOHSW annual report 2006-2007: 38-44).

1. 2005 new TB smear positive cases: 4280
2. New TB case rate: 485/100,000 population
3. TB smear positive case rate: 281/100,000
4. People living with TB: 11404
5. TB prevalence rate: 513/100,000 population
6. TB death rate: 107 deaths/100,000
7. DOTS coverage 100%
8. DOTS detection rate: 86%
9. DOTS treatment success: 74%
10. TB incidence in HIV positive adults (all forms): 5713
11. TB incidence in adults (HIV) all forms: 318/100,000
12. TB prevalence all forms in HIV + adults: 2857
13. TB prevalence all forms in HIV+ adults: 159/100,000
14. TB mortality all forms HIV+ adults: 1087
15. TB mortality all forms in HIV+ adults: 61/100,000
16. HIV prevalence in adult incident TB cases: 76%

1.1.4 Tuberculosis

Tuberculosis (TB) is an infectious disease caused by *mycobacterium tuberculosis*. The disease is transmitted from person to person by airborne droplet nuclei transmission. Although in the past substantial progress has been made in the development of strategies necessary for effective tuberculosis control, tuberculosis continues to be one of the major causes of illness and death in many countries and a significant public health problem worldwide (Blanc et al, 2007:326).

In 1991 the World Health Assembly approved targets of 70% TB case detection rate with treatment success of 85% of the detected cases for 2005. However these targets were not reached by all WHO regions, especially in the African region where the tuberculosis case rate continues to increase both due to HIV epidemic in Sub-Saharan countries and lack of primary health care services in some parts of the region (WHO, 2005:331). Until 2007 Lesotho Laboratory Service was unable to provide drug susceptibility testing and hence experienced difficulty in diagnosing drug resistant forms of tuberculosis.

It is estimated that one third of the world's population is infected with *mycobacterium tuberculosis*, mostly in developing countries where 95% of cases occur (Dye et al, 1999:677). In 2005 there were an estimated 8.8 million new incident TB cases and 14.1million prevalent cases (217/100000) on average (WHO, 2007:1). An estimated 1.6 million people (24/100000) died from TB

(WHO, 2007:1). Globally, TB incidence, prevalence and mortality are reported to be in decline since 2003. However, there is a small increase in prevalence in the African region, reportedly driven partly by emergence of multi- drug resistant strains of bacteria (WHO,2007:1) and HIV as this is the strongest predictor of progression of latent TB infection to active disease (Laserson, 2007:377). Africa accounts for 25% of the global TB burden (Sampaio, 2007:333); and the Sub-Saharan region has the highest TB burden per capita. Over the years TB has been associated with the disadvantaged populations, the economically deprived vulnerable and marginalized groups. It is widely recognized that universal access to high quality health care, early diagnosis and treatment will therefore save lives and curb the spread of the disease.

In recent years failure to treat tuberculosis adequately and poor adherence to treatment have led to the development of multi- drug resistant TB defined as tuberculosis that is resistant to the two most important anti-tuberculous drugs, Rifampicin and Isoniazid. In March 2006 WHO reported extensively Drug Resistant Tuberculosis (XDR-TB), resistant to Rifampicin, Isoniazid as well as to any Fluoroquinolone and at least one of the three second line injectable drugs: Kanamycin Amikacin and Capreomycin (WHO, 2007:330) as a serious emerging threat to public health and to TB control in all regions but more common in former Soviet Union and Asia. Global survey carried out by WHO and CDL in 25 Supranational TB Reference Laboratories revealed a prevalence of MDR-TB and XDR-TB of 20% and 2% respectively (Stop TB, 2007:80).

1.1.5 Transmission of Tuberculosis

Tuberculosis is transmitted when an infected person coughs or sneezes into the air and the airborne droplet nuclei that contain *mycobacterium tuberculosis* are inhaled by a susceptible individual. The droplet nuclei can remain airborne for several hours and the likelihood of infection depends on the infectiousness of the person with TB, the duration of exposure and the prevailing surroundings. In 90% of the time, the bacilli are destroyed without causing disease but remain dormant in the host and cause latent TB. However in 5% of cases the bacilli can also cause primary TB within one to two years or in another 5% recrudescent TB may develop several years later.

Individuals with latent TB have a 10% chance of developing active TB during their lifetime, while immune- compromised individuals especially those with HIV infection have a 10% chance of developing TB per year. It is therefore imperative to decrease the burden of tuberculosis in people living with the Human Immuno deficiency Virus and Acquired Immune Deficiency Syndrome (HIV/AIDS) by establishing intensified TB case finding in all HIV testing and counseling settings and providing prompt referral for tuberculosis diagnosis and treatment.

Studies have established that since intensified TB case finding is feasible (Nachega et al, 2003:1398) not time consuming and can be done at little additional cost in existing Health Services (WHO, 2004:331), it should be

practiced in all clinics, hospitals, household contacts, populations at high risk for HIV and in congregate settings (e.g. hospital workers, hostels, prisons, police and military barracks,). In these congregate settings, administrative and environmental measures should include maximizing natural ventilation and ultraviolet irradiation (if applicable) including early recognition, diagnosis and treatment of TB suspects and separation of pulmonary tuberculosis suspects from others, until a diagnosis is confirmed or excluded (Paul et al, 2005:75). Personal protective measures aimed at reducing exposure to *Mycobacterium tuberculosis* of workers should be implemented in all health facilities.

1.1.6 Diagnosis of Pulmonary Tuberculosis

Persistent productive cough is the most common symptom of pulmonary TB, accompanied by fever, night sweats and weight loss. Microbiological diagnosis of tuberculosis can only be confirmed by culturing *mycobacterium tuberculosis* or by identifying specific nucleic acid sequences in a clinical specimen (ISTL, 2006:19). In practice, in many resource limited high prevalence countries, microscopic examination of Ziehl–Neelsen (Zn) stained sputum is still the most common and feasible test in nearly all settings (Ridderhof et al, 2007:355). In high prevalence areas, finding acid fast bacilli in stained sputum is the equivalent of a confirmed diagnosis (ISTC, 2006:19). In resource limited areas it is used as the most rapid method of identifying a person who has TB, one who is the most likely transmitter of the infection and is at the greatest risk of dying from the disease. Microscopy

therefore remains the mainstay of rapid TB case detection, while access to culture and drug susceptibility testing (DST) are scarce or non existent.

Developed countries use modern techniques that provide rapid detection and identification of *Mycobacterium tuberculosis;* fluorescence microscopy (FM), liquid culture for isolation and DST. These technologies have helped in hastening the decline of the prevalence of the disease (Drobniewski et al, 2003:141). The lower sensitivity of (ZN) smear in those with HIV infection who are often confirmed with TB has led to the use of concentrated smears and FM, a combination showing high yield in both industrialized and HIV high prevalence countries (Munyati et al, 2005:1818).

In order to reach the health related MDGs, active TB case detection employing both of the two commonly used methods of TB suspect identification must be used at every contact with the patients especially in high burden countries. Protracted cough lasting for two or more weeks is the most common symptom of pulmonary tuberculosis and is present in 95% of all sputum smear positive cases. It is therefore imperative that health workers ask each patient at the point of contact whether he/she has a cough and about the duration of the cough and other TB symptoms (fever, chest pains, hemoptysis, and loss of weight). Any patient with cough lasting two or more weeks is a TB suspect and warrants investigation for the disease. Data from India demonstrated that by using a threshold of ≥ 2 weeks to prompt collection of sputum specimens, the number of

patients with suspected tuberculosis increased by 61% and the number of tuberculosis cases identified increased by 46% compared with the threshold of > 3 weeks (Santha et al, 2005:61).

A combination of the following symptoms has also been shown to be highly predictive at identifying TB in HIV infected patients: cough persisting for more than three weeks, fever for more than one month, lymphadenopathy and body mass index (BMI) less than 18 had a sensitivity of 99%, a specificity of 66% and a negative predictive value of 100% for TB (Were, 2007:8). This screening of patients is a public health activity intended to detect and cure the source of infection. The other method of TB case detection is for the doctors to have a high index of suspicion, take relevant history, perform diagnostic tests and make early diagnosis for those patients consulting spontaneously.

1.1.7 International Standards of Tuberculosis Care (TBCTA, 2006:6)

The following are the recommended standards of TB case detection (ISTC, 2006:6).

Standard 1:

All persons with otherwise unexplained productive cough lasting for two-three weeks or more should be evaluated for tuberculosis.

Standard 2:

All patients who are capable of producing sputum, and are suspected of having pulmonary tuberculosis should have at least two, and preferably three, sputum specimen obtained for microscopic examination when possible; at least one early morning specimen should be obtained.

Standard 3:

For all patients suspected of having extra-pulmonary TB, appropriate specimens from the suspected sites of involvement should be obtained for microscopy and where facilities and resources are available for culture and histopathological examination.

Standard 4:

All persons with chest radiographic findings suggestive of TB should have sputum specimens submitted for microbiological examination.

Standard 5:

The diagnosis of sputum smear-negative pulmonary TB should be based on the following criteria: at least three negative sputum smear (including at least one early specimen); chest radiography findings consistent with tuberculosis; and a lack of response to a trial of broad spectrum antimicrobial agents (Flouroquinolones should be avoided as these are used in the treatment of MDR-

TB). Sputum for culture should be obtained, in patients with HIV infection; the diagnostic evaluation should be expedited.

1.1.8 Principles of Tuberculosis Care

Provision of care to individuals with tuberculosis does not only entail treatment of individual patients but also encompasses a high level of responsibility to the community and plays an important public health role. The basic principles of care for persons with tuberculosis therefore entail prompt and accurate diagnosis, the use of standardized treatment regimens of proven efficacy and a provision of appropriate treatment support and supervision. Because the above are the key elements in the public health response to tuberculosis and form a cornerstone of tuberculosis control, the response to treatment should be closely supervised and monitored.

A balanced approach concentrating on both individual patient care and public health principles of disease control is essential to reduce the burden of tuberculosis. Hence the patients' charter for tuberculosis care and international standards for tuberculosis care were developed to complement local and national tuberculosis control policies that are consistent with World Health Organization recommendations (ISTC, 2006:7) and to facilitate engagement of all health care providers in delivering high quality care for patients with all forms of tuberculosis in an effort to realize population based tuberculosis control.

1.1.9 Treatment of Tuberculosis

The following drugs are used to treat category I tuberculosis: Rifampicin 10 (8-12) mg/kg daily, Ethambutol 15 (15-20) mg/kg daily, Pyrazinamide 25 (20-30) mg/kg daily and Isoniazid 5 (4-6) mg/kg daily for the first two months of intensive phase and the remaining four months Rifampicin and Isoniazid are used. Treatment varies from country to country ranging from daily, three times a week and twice a week schedules.

Lesotho uses daily supervised treatment recommended by WHO. For category II, streptomycin 15 (12-18) mg/kg daily is added to the category I regimen during the intensive phase of 3 months and the continuation phase lasts for five months. For MDR-TB the following drugs are used: Pyrazinamide 20-30mg/kg daily, Ofloxacin 800mg daily or Ciprofloxacin 1500mg daily, Kanamycin 12-18mg/kg daily or Amikacin 12-18mg/kg daily, Ethionamide 10-20mg/kg daily, Cycloserine 10-20mg/kg daily or Terizidone10-20mg/kg daily and PAS 10-12mg/kg daily (MOHSW, 2007:9). Globally WHO recommends implementation of directly observed therapy, short course (DOTS) strategy because it ensures that the prescribed treatment is taken, it guarantees adherence, social support and globally, it is responsible for the success that has been achieved in TB control over the years.

In 2000 the Stop-TB partnership covering the years 2001-2005 was launched. This strategy set two key global targets: 70% case detection of acid fast bacilli smear positive TB patients under the DOTS strategy and 85% treatment success of those detected (WHO, 2002:202). The second global plan Stop-TB 2006-2015 to meet these targets and also to achieve target 8 of Millennium Development Goal (MDG) 6 “to have halted by 2015 and begin to reverse, the incidence of all forms of TB was formulated and disseminated (WHO, 2006:362). It is estimated that the implementation of this plan will also meet the Stop-TB partnership’s 2015 targets which are to halve the TB prevalence and death rates from the 1990 baseline and eliminate TB(incidence < 1/100000) as a global public health problem by 2050 (Laserson et al, 2007:377).

1.2 Problem Statement

Lesotho faces a major public health threat from the twin epidemic of Tuberculosis and Human Immunodeficiency Virus and Acute Immunodefiency Disease Syndrome (HIV/AIDS). In 2007 the National TB programme reported that of the 4,039 TB patients who undertook HIV test, 3257(81%) were HIV positive (MOHSW, 2008:23). In 2002 Lesotho had one of the highest tuberculosis case notification rate in the world at 634 per 100,000 population, and new smear positive cases at 176 per 100,000 population (MOHSW, 2002:12). Case detection for the latter was 61% and the treatment success was 71 % (MOHSW,

2002:12). Because of co-infection with HIV and late diagnosis, 13% of smear positive patients died during treatment while there was a defaulter rate of 5%.

In 2005 the National TB program had significant management and co-ordination issues. The program had no manager; supervision was not done from the central level and was sporadically done in the districts. There was limited human resource capacity and monitoring and evaluation had not yet been fully established to the extend that it was noted that during the global fund grant implementation the NTP had collapsed and there was lack of capacity to run the program at all levels (MOHSW, 2005:19). TB is still the leading cause of death in persons who are HIV positive and the NTP quality remains a challenge as smear positive patients were only 26% of the total TB notification (MOHSW, 2008:20) against the expectation of 35%, range 30%-40% in a high HIV prevalence area (Dye et al, 2005:365). At Scott Hospital, the HSA TB program reported 68% cure rate and a treatment success of 71% compared to the national treatment success of 74%. Both defaulter rate of 13% and death rate of 14% were significantly higher than the national figures of 4% and 8% respectively (Scott Hospital, 2005:1).

1.3 Justification for the Study

In an effort to address the deficiencies identified in the NTP, the Lesotho government developed a five- year strategic plan for DOTS expansion for the

effective implementation of the Stop-TB strategy and to meet the global targets of 70% case detection rate and 85% of treatment success, the following strategies were introduced for NTP (MOHSW, 2003:7-9):

- There was increased political and financial commitment demonstrated by massive ejection of funding at the program to ensure availability of reagents used for diagnosis of tuberculosis, strengthening of laboratory capacity to diagnose TB by introducing external quality assurance system and ensuring uninterrupted supply of quality TB drugs
- Strengthening of the health system including training and management capacity for drug storage and distribution
- Improved response to MDR-TB through a training programme and procurement of second line anti TB drugs through Global Fund to fight AIDS, Tuberculosis and Malaria (GFATM)
- Introduction of TB/HIV collaborative activities
- Providing Cotrimoxazole preventive therapy (CPT) to HIV positive TB patients
- The main intervention in improving the quality of TB services however, was directed at the training of all levels and cadres of health workers in TB case detection and management (MOHSW, 2003:20). The WHO/KNCV/CDC Stop-TB partners training modules were adapted for Lesotho and used for training of HSA's TB coordinators, medical officers and nurses in both public and private sector, thus introducing the public-private mix (PPM) as a strategy for TB control

- Targeted in the training also were teachers, agricultural extension workers, community health workers and traditional healers; all of them were expected to play an active role in the community based TB care.

At Scott Hospital and in its Health Service area, the trainings took place in 2005. TB treatment was decentralized to all clinics where trained personnel were assigned. In both public and private sectors, drugs were supplied to these facilities and community health workers entrusted with the supervision of drug intake. To date there is no study done in Lesotho to monitor the performance of TB control. Health workers continue to worry about the increasing numbers of TB patients and the disease continues to cause a serious public health concern. It is therefore imperative that monitoring and evaluation of implemented strategies is done to determine whether they have made any impact on TB indicators.

CHAPTER 2:

LITERATURE REVIEW

Introduction

The re-emergence of old communicable diseases such as Tuberculosis in Sub-Saharan Africa has been worsened by HIV/AIDS epidemic. The impact of these two epidemics has devastated many countries especially in an area also plagued by Malaria and it is indeed responsible for many health crises that embattle many health systems around the globe. Several strategies have been implemented and many achievements have been gained to help turn the tide around. While the world as a whole seems to be on track to achieve the MDG Target 6.c, African countries with low prevalence of HIV are reported to be lacking behind. This literature review will enhance the appreciation of the progress achieved thus far and the steps that have to be taken to achieve the 70% TB detection rate and the 85% treatment success.

2.1 Modifications in the Treatment of Tuberculosis over the Years

The first anti tuberculosis drug was Streptomycin, introduced in 1944, followed by Thiacetazone in 1946, Isoniazid in 1952, Pyrazinamide in 1952, Ethambutol in 1961 and then Rifampicin in 1966 (Toman, 2004:99). Introduction of Rifampicin and Pyrazinamide made highly efficacious and effective 6 to 9 month long

treatment possible (Fox et al, 1999:5231). This paved the way for short course chemotherapy consisting of the combination of isoniazid, rifampicin, pyrazinamide and Ethambutol in the initial two months of treatment, followed by four months of Rifampicin and Isoniazid. This combination acknowledged as one of the most cost effective of all health interventions, estimated that effective tuberculosis control cost US$ 20-57 per death averted and US$ 1-3 per DALY saved (World Bank, 1993:247).

2.2 Introduction of DOTS

DOTS originally stood for directly observed treatment short course. Now the acronym refers to political commitment, case detection through quality assured bacteriology, standardized treatment with supervision and patient support, an effective drug supply management system and systems to monitor treatment progress and evaluate programme performance (Zolotova, 2007:331). Although a Cochrane systematic review synthesized six controlled trials comparing DOT with self administered therapy (Volmink J et al, 2000:1345) and concluded that the direct observation of ingestion of medication did not improve TB outcomes; The Risk ratio (RR) was 1.06, 95% C I 0.98, 1, 14 and rates of cure plus treatment completion had a RR of (1.06, 95% CI 1, 00; and 1.13), Other reviews found DOTS to be associated with a high cure and completion rates (Sbarbano, 2004:183).

2.2.1 Global Effectiveness and Success of DOTS

Although TB incidence increased globally in 2003, incidence, prevalence and death rates remained stable or decreased in 7 of the 9 WHO regions the exception being the regions of Africa and Europe (Blondal, 2007:387). DOTS programme reported an increase in the detection rate of new smear positive cases from 11% in 1995 to 45% in 2003 with the lowest rates in Eastern Europe and the highest in the Western Pacific (Dye et al, 2005:2790). The Global treatment success rate was 82%, the highest 89% in the Western Pacific region, the lowest 71%in African countries with high HIV infection rates and 74%in African countries with low HIV infection rates. Europe reached the treatment success rate of 77% while Eastern Europe reported 75% success rate Dye et al (2005) report in their paper that globally DOTS programmes must reduce incidence rate by at least 2% annually to reach MDGs.

Dye et al (2007) in their paper report that in 2005, the global case detection rate was 10% below the target at 60% (5% C.L. 52% to 69%). Only WHO Western Pacific region reached both the case detection and treatment success rates of 76% and 91% respectively driven mostly by China (WHO, 2007:37). The South East Asia reached the treatment success target with a rate of 87%, driven principally by India (WHO, 2007:37). In Africa only DR Congo reached the 85% treatment success while South Africa reached a case detection for new sputum smear positive of 108% and treatment success of 70% (WHO, 2007:30).

Based on the achievements to date, it is estimated that the world as a whole is on track to achieve MDG Target 6.c; Trends in incidence, prevalence and death rates are reported to be falling in all other WHO epidemiological sub regions with the exception of African countries with a low prevalence of HIV (WHO, 2009:1). The achievement in the reduction of the disease burden followed intensified implementation of DOTS strategy and its successor , the Stop TB strategy as indicated by 36 million people who were cured in DOTS programmes (between 1995 and 2008), with as many as 8 million deaths averted through DOTS (WHO, 2009:1). The 87% global treatment success rate exceeded the 85% target in advance of the target year of 2015 with fifty three countries reported to have exceeded the 85% patient treatment target (WHO, 2009:1).

DOTS strategy is a proven cost effective means for reducing mortality in developing world. In China in 1990 TB was a major health problem responsible for 360 deaths. Following implementation of DOTS in 1991, mortality declined by 36% in areas where the program was implemented compared to 12% in non DOTS areas (Levine, 2007:31). In India a study showed that the average cost for public private mix (PPM) DOTS and public sector DOTS was similar at US $120-140 per patient successfully treated compared to US $218-338 for non DOTS (Floyd et al, 2006:437). The analysis of these studies shows that PPM DOTS can improve effectiveness while also lowering cost.

2.2.2 The Effectiveness of the Directly Observed Therapy Short Course Strategy (DOTS) in the Americas

In the WHO region of the Americans, DOTS coverage and treatment success rose steadily form 1994 to 2005 with 88%of the population covered under DOTS by 2005 and 80% treatment success rate by 2004 (Ramon-Pardo et al, 2009:969). The region has seen a steady decrease in the TB incidence, prevalence and mortality rates from 1994 to 2010. In 2007 the Americans reported a treatment success rate of 92% and a case detection of 78% (Van Maaren, 2010:9). The success of the regions performance in TB control achieved through implementation of the DOTS strategy has already surpassed the MDGs of Stop TB programme.

2.2.3 The Effectiveness of DOTS in Eastern Europe

Following the collapse of the Soviet Union in 1991, there was a tuberculosis epidemic across the Russian Federation. DOTS was introduced as a strategy following WHO recommendation in 2003, and by 2006 Kazyenny (2007:329) reported that incidence had decreased by 26.5%, mortality by 48.3%and prevalence by 44.5% in the Russian region of Orel. This region has now become a model of Russian tuberculosis control success. In 2007 TB case detection in this area had increased to 55% in contrast to the national average case detection of 30% (Kazyenny, 2007:330). Social support for tuberculosis patients was

identified as very instrumental to their treatment success. Tuberculosis is still heavily stigmatized in the Russian society and adherence to treatment in a DOTS programme is the critical factor in determining treatment success (WHO, 2003:37).

2.2.4 The Effectiveness of DOTS strategy in Africa

In Rwanda approximately 183,558 adults live with HIV/AIDS and through expansion of DOTS strategy and integration of services treatment success rates have increased from 58% in 2003 to 81% by the third quarter of 2006; however case detection was an estimated 24% in 2005 (Gasana et al, 2007:383). The improvement of the integration was achieved after intensive training of health workers throughout the country. Similarly in Kenya the training of health workers started in March 2005. In the third quarter of that year 32% of TB patients were tested for HIV and this had increased to 64% by the third quarter of 2006 (WHO, 2007:46). Of those who were found positive 80% were given Cotrimoxazole (CPT) and 30% started on ART (WHO, 2007:46).

2.2.5 The Effectiveness of DOTS strategy in South Africa

DOTS strategy has been implemented on a national level in South Africa. TB indicators have gradually improved in case detection from 1997 when only 5% was notified to WHO, to 2005 when case detection in South Africa reached 103%

surpassing the WHO target of 70%. Treatment success however still hovers around 70% lower than the 85% target set by WHO (WHO, 2007:30).

Adherence to TB treatment is pivotal to the success of the DOTS strategy. In South Africa lay health workers called DOTS supporters are responsible for this very important job. A randomized controlled trial found that treatment completion rate in new smear-positive adult TB patients on farms was 19% higher under the DOTS strategy than in the control group (Clarke et al, 2005:5). Another study in South Africa showed that DOTS was 2.8 times cheaper than conventional treatment, costing US $890.50 per patient cured compared with $ 2095.60 for the latter (Floyd et al, 1997:1407).

2.2.6 DOTS-Plus for MDR-TB in South Africa

Despite efforts made to control TB through DOTS strategy in South Africa, TB incidence and case fatality rates have continued to increase three fold over the ensuring decade (WHO, 2006:1). TB mortality is high and MDR-TB cases are increasing. There are 10,000 incident cases of MDR-TB per year (Zignol et al, 2006:479). These represent the largest MDR-TB burden in Africa and further point towards a failure of TB control (Weyer, 2007:391). Treatment success for MDR-TB is 80% but the death rate at 20% is also high with up to 25% of patients defaulting treatment (Weyer, 2007:391).

The effectiveness of MDR-TB programme is reduced to 50% by high rates of around 10% treatment failure (South African Medical Research Council 2002-2004 unpublished data)(Weyer, 2007:391). Sixty (60%) of TB patients in South Africa are estimated to be co-infected with HIV (WHO,2006:362) and if serious infection control measures are not put in place, serious consequence may follow, as demonstrated by the 2005 XDR-TB outbreak in Kwazulu Natal (Gandhi, 2006:1554). TB control will be lost as MDR-TB and XDR-TB patients mix with vulnerable patients in congregate areas of Public service. Generic studies have confirmed both nosocomial and community transmission of drug resistant TB in South Africa (Gandhi, 2006:1554). Infection control and ART are mandatory if this scourge is to be successfully halted.

2.2.7 The Global Integration of TB/HIV services

The highest HIV testing rates for TB patients were in the European Region which has the lowest incidence rate of HIV positive cases; the lowest rates were in Africa where the incidence is the highest (WHO, 2007:1). In the Americas in 2005, 66% were detected; in the African Region 13% were detected while only 4% were found in the Western Pacific Region (WHO, 2007:2). Globally the African Region has 51% of the TB patients who tested positive for HIV, against 23% worldwide (WHO, 2007:2). Because HIV infection is a powerful risk factor for the development of active tuberculosis in co-infected people and in Sub-Saharan Africa, It is responsible for approximately 30% of mortality of HIV

infected smear positive TB patients (Raviglione, 1997:s115). Integration of these services is urgently needed to save lives.

2.2.8 The Effectiveness of TB/HIV integration in Asia

Cambodia serves as an example of success in TB/HIV integration in Asia as in 2006 this country was reported to have one of the most serious HIV infections estimated at 123,100 adults living with HIV/AIDS (WHO, 2006:362). The Cambodian Ministry of health (2001) estimated that 64% of Cambodians were infected with *mycobacterium tuberculosis* and that as the number of HIV cases increased so would the TB cases. Faced with these two epidemics, Cambodia embarked on integration of TB/HIV services and in 2005, Tan Eang et al (2007:382) in their paper report that 70-100% of all newly diagnosed HIV infected persons were screened for TB but only 14-83% of TB patients were tested for HIV co-infection and the rate of active disease found during screening ranged from 9% to 26%. Early treatment was provided for these people and TB/HIV activities expanded to 15 additional districts.

2.2.9 The Effectiveness of TB/HIV integration in Africa

The integration of TB/HIV services has steadily increased in African countries. In Zambia, for example the percentage of TB patients tested for HIV rose from 2% in 2005 to 52% in the third quarter of 2006. Twenty nine percent of this was given

CPT, while 33% started ART (WHO, 2007:46). Malawi was one of the countries to pilot the WHO ProTEST initiative (1999-2002), which promoted HIV counseling and testing as an entry point to HIV services for TB patients (Stop TB, 2004:336). The integration plan aimed at scaling up HIV testing through testing TB patients and providing Cotrimoxazole preventive therapy (CPT) and facilitating access to antiretroviral therapy. Seventy percent of TB patients in Malawi are infected with HIV (Chimzizi et al, 2007:385). By 2005 the proportion of TB patients tested had increased from 15% in 2003 to 47% and 90% of HIV positive patients had started Cotrimoxazole preventive therapy (Kwajana et al, 2001:7).

2.2.10 The Integration of TB/HIV services in South Africa

South Africa participated in WHO's ProTEST initiative between 1999 and 2002, establishing four TB/HIV/STI prevention care and support including VCT and rapid testing, Isoniazid preventive therapy (IPT) and the Cotrimoxazole preventive therapy. The success of this initiative resulted in intensified case finding, training of communities on HIV, scaling up VCT, home based care and collaboration with NGO's was stimulated (Hausler et al, 2004). The SAPIT trial showed that mortality among TB/HIV co-infected patients can be reduced by 55% if ART was provided with TB treatment at the same time (Hausler et al, 2004).

The Khayelitsha project managed by Médecins Sans Frontières has showed a successful integration of TB and HIV services. In 2005 ninety one percent of TB

patients had accepted HIV testing and 76% were positive. Prior to integration, only 19% of TB patients were on ART but since integration, 68% of the people on TB treatment in Ubuntu clinic (Khayelitsha) have been enrolled on ART (Odendal, 2010:2).

Chapter 3
Methodology

3.1 Aim

To assess the outcome measures of the strategies instituted to improve tuberculosis control program within Scott Hospital Health Service Area during January to December 2006.

3.2 Specific Objectives

1. To determine the proportion of TB suspects tested who were sputum smear positive.
2. To determine the proportion of new sputum smear positive TB cases that converted at 2 or 3 months
3. To determine the proportion of new sputum smear positive cases that were cured or completed treatment in 6 months
4. To determine the proportion of those who defaulted treatment.
5. To determine the state of TB/HIV integration.

3.3 Research Question

What is the effect of the strategies instituted to improve the tuberculosis control program within the health service area of Scott Hospital, Lesotho?

3.4 Study Design

This is a quantitative, observational, descriptive study.

3.5 Study setting

This is a hospital based study taking place in a small 120 bed rural district hospital in Lesotho. The hospital is situated 45km south of Maseru, the capital city of Lesotho. It is a non-government health facility that manages 14 clinics belonging to Government, Red Cross and three other faith based organizations. TB patients come from and are managed in the entire health facility complex known as the Health Service Area.

3.6 Study Population

Adult male and female TB patients (aged 18 years and over) registered in the Scott hospital health service area TB register from January 1, 2006 to June 30, 2006 constituted the study population (n=254 patients).

3.7 Study Sample

Records of All new smear positive adult (aged 18 years and over) male and female TB patients registered in the Scott hospital health service area TB register

from January 1st 2006 to June 30th 2006 were reviewed. These formed the study sample (n= 100 patients).

Inclusion criteria

Records of adult male and female cases (18 years and over), newly diagnosed TB cases with sputum microscopy positive for Acid Fast Bacilli (AFB), registered in the Scott Hospital TB register, diagnosed and started TB treatment between January 1 and June 30, 2006 and completed TB treatment on or before December 31,2006.

Exclusion criteria

Records belonging to TB cases younger than 18 years old, diagnosed before January 1, 2006 or after June 30, 2006. Records of cases diagnosed by other method other than sputum microscopy, sputum negative cases, retreatment cases and those whose treatment extended beyond the study period were also excluded from the study.

3.8 Variables and Measurement of variables

Questionnaires were completed by the researcher with the aid of a research assistant. The information collected included the age, sex and whether the case

was newly diagnosed or not. The variables included methods of diagnosis; chest x-ray or sputum microscopy. Sputum results; whether sputum-smear positive or negative at diagnosis. Date of TB treatment initiation; The date of sputum smear conversion following completion of two months of treatment, the date of completion of treatment, the results of sputum analysis at the end of the TB treatment; whether sputum-smear positive or negative and the outcome of TB treatment; whether cases were classified as cured, completed treatment, died, defaulted, failed or transferred out. Information about the HIV status: positive, negative or not tested was also recorded for all cases. Information was obtained from the 2006 TB registers.

3.9 Data Collection

Documents of patients who took TB treatment during the study period were reviewed. The researcher and the trained research assistant independently collected recorded data from Scott Hospital TB registers; only information from those records that met the inclusion criteria for the study was collected. All entries were double checked to ensure the correctness of the information. The questionnaire, data collection sheet was used to record data (Appendix 2). Collected also was the total number of outpatients' consultations and TB suspects. Documents used included Scott Hospital HSA TB register, laboratory TB register, TB suspect register and the out- patient register.

3.10 Data Analysis

Epi Info was used to analyze the data and Microsoft Excel was used to generate graphs and tables. Comments were made as written text

3.11 Reliability and validity of the study

Reliability refers to the consistency of measurement or the degree to which an instrument measures the same way each time it is used under the same condition with the same subjects. It does, in short, refer to the reproducibility and consistency of information. This was ensured by repeating data entry (double) from the registers for the same smear positive adults to ensure the reliability of the results and again by engaging two doctors to independently enter the data to minimize human error. Stability and consistency of information is maintained as the official TB registers, laboratory register and TB suspect register will be available to confirm the collected information. These registers are kept in a safe place to ensure that data is not lost and can be retrieved whenever needed.

Validity refers to the accuracy of the study; it is the strength of the conclusions, inferences or proposition and it is also the degree to which the measurement reflects the true value of the characteristic (De Vos et al, 2002:351). The indicators used in this study (sputum conversion rate, cure rate, treatment success and treatment defaulter rate) are " gold standard" used widely to assess

the TB control programs throughout the world and the desired WHO performance levels have been established. The use of data triangulation was employed to enhance the validity of the findings. The same laboratory was used for sputum examination and the same method of analysis was performed by the same laboratory technicians. External quality assurance on sputum microscopy was done monthly and calibration of the laboratory equipment was supposed to be done regularly. Patients had been given the same instruction for sputum production and collection and two to three sputum collections were checked at each level. Peer examination by two general practitioners working in this HSA was sought to enhance the validity of the whole process and the scores of the instruments used in this study. The researcher's supervisor was involved in her guidance throughout all the phases of the research process.

3.12 Bias

Bias in research is defined as any effect at any stage of a research process, or influence that tends to produce results that depart systematically from the true values (Ogunbanjo, 2001:35).

3.13 Sampling bias

This may occur when the study population does not have an equal chance of selection in the sample and this should be recognized. Elimination of this bias is

not easy especially where a different method of diagnosis is used. This was minimized since the sample included all records of sputum smear positive patients.

3.14 Selection bias

Selection bias is observed when there is an error caused by differences in characteristics between those who are selected for the study and those who are not. This was minimized by selecting all adults, 18 years and above who had sputum smear positive results recorded in the TB register during the period mentioned.

3.15 Observer bias

Due to differences in true value and that was observed as a result of observer variation was minimized by the data collection being rechecked doubly by the researcher and the research assistant concerned.

3.16 Bias in the presentation of data and **bias of interpretation of data**

These were minimized by utilizing the expert opinion of a statistician and that of my supervisor.

3.17 Ethical Considerations

Approval to conduct the study was given by the Ministry of Health and Social Welfare in Maseru. Permission was also obtained from the Scott hospital health service Area management team. The research protocol was submitted to the Research, Ethics and Publications Committee (REPC) (now MREC) of The University of Limpopo-MEDUNSA campus for clearance, approval and registration. Protocol was accepted and Clearance certificate was obtained; clearance certificate number: MCREC/M/16/2007:PG. Confidentiality, beneficence and non maleficence were respected.

DEFINITIONS OF TUBERCULOSIS CASES AND TREATMENT OUTCOMES

3.18 Definitions of Tuberculosis Cases (WHO, 2007:15)

3.19 Case of Tuberculosis

A patient in whom tuberculosis has been confirmed by bacteriological or diagnosed by a clinician.

3.20 Definite Case

A patient with positive culture for the *Mycobacterium tuberculosis* complex. In countries where culture is not routinely available, a patient with two sputum smears positive for acid –fast bacilli (AFB+) is also considered a definite case.

3.21 Pulmonary Case

A patient with tuberculosis disease involving the lung parenchyma.

3.22 Smear Positive Pulmonary Case

A patient with at least two initial sputum smear examinations (direct smear microscopy) AFB+; or one sputum examination AFB+ and radiographic abnormalities consistent with active pulmonary tuberculosis as determined by a clinician; or one sputum specimen AFB+ and culture positive for M. tuberculosis.

3.23 Smear Negative Pulmonary Case

A patient with pulmonary tuberculosis not meeting the above criteria for smear-positive disease. Diagnostic criteria should include: at least three sputum smear examinations negative for AFB; and radiographic abnormalities consistent with active pulmonary tuberculosis; and no response to a course of broad-spectrum antibiotics; and a decision by a clinician to treat with a full course of anti-tuberculosis chemotherapy; or positive culture but negative AFB sputum examinations.

3.24 Extra-Pulmonary Case

A patient with tuberculosis of organs other than the lungs (e.g. pleura, lymph nodes, abdomen, genitourinary tract, skin joints and bones, meninges). Diagnosis should be based on one culture-positive specimen, or histological or strong clinical evidence consistent with active extra-pulmonary disease, followed

by a decision by a clinician to treat with a full course of anti- tuberculosis chemotherapy. A patient in whom both pulmonary and extra-pulmonary tuberculosis has been diagnosed should be classified as a pulmonary case.

3.25 New Case

A patient who has never had treatment for tuberculosis or who has taken anti-tuberculosis drug for less than one month.

3.26 Relapse Case

A patient previously declared cured but with a new episode of bacteriologically positive (sputum smear or culture) tuberculosis.

3.27 Re-Treatment Case

A patient previously treated for tuberculosis, undergoing treatment for a new episode, usually of bacteriologically-positive tuberculosis.

3.28 Definitions of Treatment Outcomes

(Expressed as a percentage of the number registered in the cohort)

3.29 Cured

A patient who was initially smear-positive and who was smear-negative in the last month of treatment and on at least one previous occasion.

3.30 Completed Treatment

A patient who completed treatment but did not meet the criteria for cure or failure. This definition applies to pulmonary smear-positive and smear-negative patients and to patients with extra-pulmonary disease.

3.31 Died

A patient who died from any cause during treatment.

3.32 Failed

A patient who was initially smear-positive and who remained smear-positive at month 5 or later during treatment.

3.33 Defaulted

A patient whose treatment was interrupted for two consecutive months or more.

3.34 Transferred out

A patient who transferred to another reporting unit and for whom the treatment outcome is not known.

3.35 Successfully treated

A patient who was cured or who completed treatment.

3.36 Cohort

A group of patients in whom TB has been diagnosed, and who were registered for treatment during a specified time period. This group forms the denominator for calculating treatment outcomes.

CHAPTER 4

RESULTS

Records of one hundred adult patients (100%) who were new sputum smear positive and met the criteria set for the study were eligible for inclusion in the study. The study sample included 47(47%) records belonging to female patients and 53 (53%) for male patients. The cases were classified into five age groups: less than 20 years (1%), 20-39 years (52%), 40-59 years (27%), 60-79 years (19%) and 80 or more years (1%). Out patient TB –suspect register was used to document 438 (6.1%) patients' entries identified as TB suspects from January 1st to June 30th 2006 while the outpatient register documented the total number of patients (7207) seen over the same period. Laboratory tuberculosis registers were used to verify the sputum results recorded in the Patients TB register.

4.1 Selection of records to be included in the study

Records to be included in the study were selected using the strict inclusion criteria set for the study. A total of 254 records of TB patients registered in Scott Hospital TB register and started on TB treatment between 1st January and 31st June 2006 were reviewed. Of the 254 records reviewed only 100 records met the inclusion criteria set for the study and were thus considered to form the study sample. Table I shows the monthly distribution of the reviewed records and those that met the selection criteria.

Table I

Monthly distribution of TB records as registered in hospital TB register

Month	All TB records	Records of New sputum-smear positive adults
Jan	23	12
Feb	41	18
Mar	50	15
April	29	11
May	43	17
June	68	27
Total	254	100

4.2 Distribution of TB cases according to sex

Table II shows the distribution of patients' records according to sex. Fifty three (53%) of the new sputum smear positive patients were males and 47 (47%) were females. There were no significant differences in age in the two groups. Both the youngest, 18 years old and the oldest 84 years old were females.

Table II

Distribution of TB patients' records according to sex

Age Group	Males	Females	Total
< 20	0	1	1
20 -39	24	28	52
40 -59	17	10	27
60 -79	12	7	29
≥ 80	0	1	1
Total	53	47	100

4.3 Distribution of patients' records according to age

Records of 100 (100%) patients were reviewed. Their ages ranged from 18 years to 84 years with the mean age of 42 years. A significant number of patients 52 (52%) were in the age group 20 – 39 years; 27 (27%) were in the age group 40-59 years, 19 (19%) were in the age group 60-79 years. Of the remaining two patients, one was 18 years old and the other 84 years old (Table III).

Table III

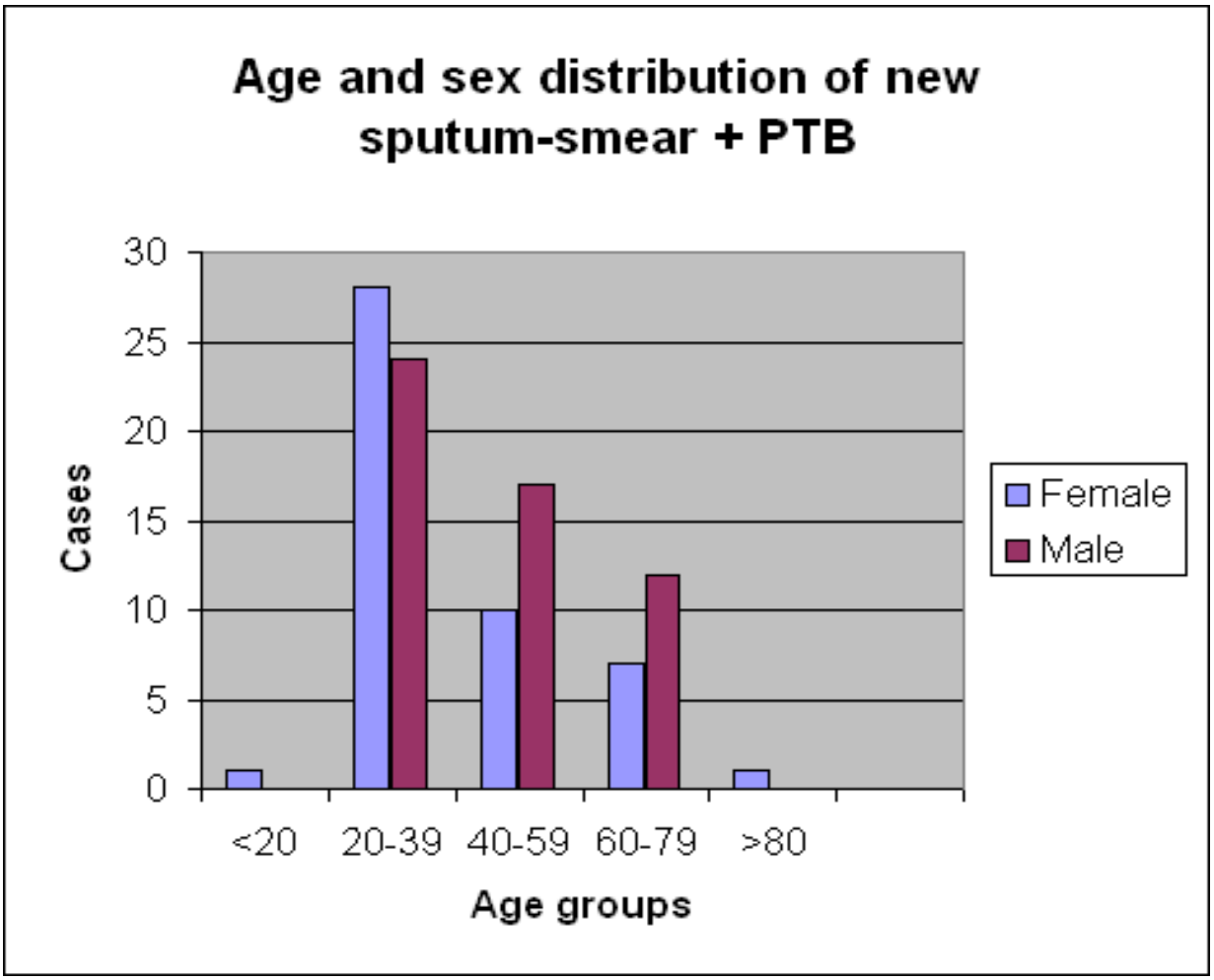
Distribution of patients' records according to age

Age Group	Cases
< 20	1
20 -39	52
40 -59	27
60 – 79	19
≥ 80	1
Total	100

4.4 Age and sex distribution of new sputum-smear positive PTB cases

Fifty two (52%) of the new sputum smear positive patients were in the age group 20-39 years, 28 (28%) of those were females while 24 (24%) were males. In the age group 40-59 years 17 (17%) were males and 10 (10%) females. In the older age group 60-79 years there were 12 (12%) males and 7 (7%) females. The youngest 18 year old and the oldest of the patients 84 year old were both females (Figure 1).

Figure 1



4.5 Tuberculosis diagnosis

Sputum microscopy was used as a leading criterion for selection into the study as well as meeting other requirements; all the records included in this study had positive acid fast bacilli results 100 (100%). One hundred (100%) cases included in the study were diagnosed using sputum microscopy (Table IV).

Table IV

Tuberculosis Diagnosis

CXR	Sputum Microscopy
0	100

4.6 Classification of TB patients' records

All 100 (100%) records selected for the study were classified as newly diagnosed sputum smear-positive cases who met the inclusion criteria for the study (Table V).

Table V

Classification of TB Patients' records according to sputum results

Newly Diagnosed	Re-treatment
100	0

4.7 Sputum Monitoring during Treatment

Sputum was used to monitor the response to treatment for all cases that had started TB treatment. Although there were 100 (100%) cases at diagnosis, records show that four (4%) of those were transferred out to another reporting unit before completing the initial intensive phase of treatment and hence the treatment outcome was not known. At two months of treatment there were only 96(96%) cases, as indicated by the sputum results after two months of treatment. Records indicated that nine (9%) patients died while on treatment and did not complete treatment, while two (2%) defaulted treatment. The records for those two groups showed the treatment outcome as death and defaulted respectively. There were only 85 (85%) cases recorded as having completed treatment, of whom 76 (76%) had negative sputum results at the end of the treatment, hence the cure rate of 76%, while nine (9%) had completed the TB treatment, but sputum results were not recorded and therefore the treatment outcome was recorded as completed. Treatment success was defined as the sum of the cure rate (76%) and the completion rate (9%) hence the treatment success of 85 % (TableVI).

Table VI

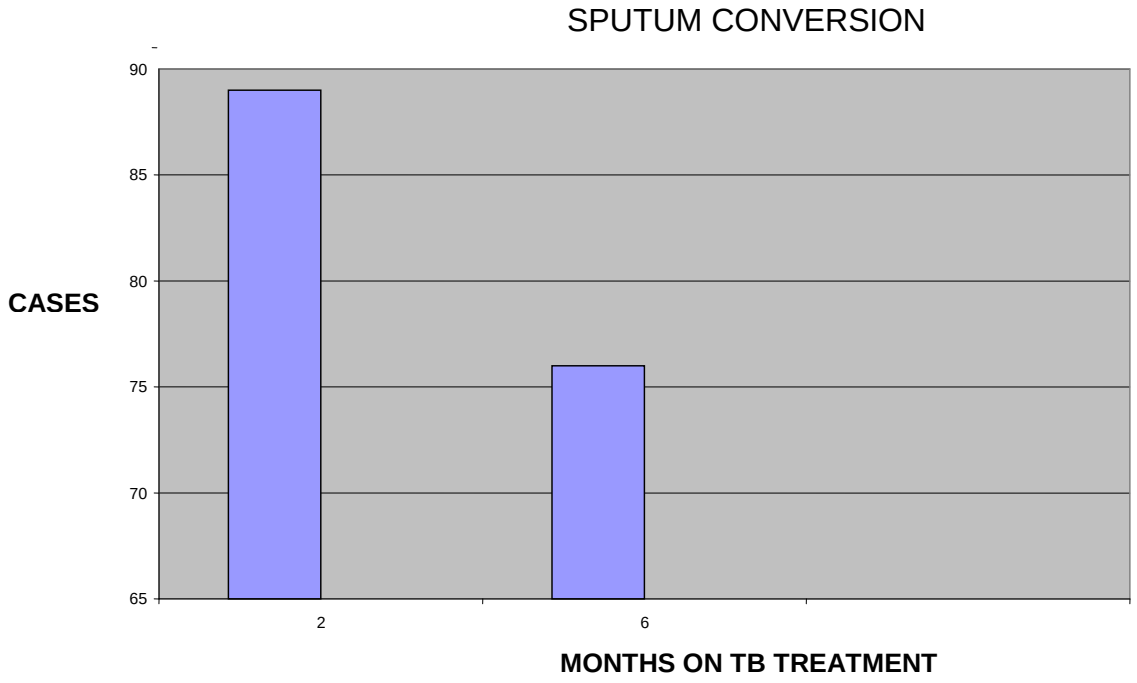
Sputum Monitoring during Treatment

	Smear positive	Smear negative	Sputum results not recorded	Total
At diagnosis	100	0	0	100
2 months of treatment	7	89	0	96
Completion of treatment	0	76	9	85

4.8 Sputum conversion

There were 100 (100%) records with positive sputa at the beginning of treatment. Four cases (4%) were recorded as transferred out before sputum was due for analysis hence at two months of treatment only 96 (96%) had recorded sputum results. Sputum conversion at two months was 89 (89%), seven (7%) had positive sputum results. Of the 96 (96%) remaining in care, nine (9%) was recorded as dead while two (2%) was recorded as having defaulted during the course of the treatment and hence did not complete treatment. At the end of treatment 76 (76%) records had negative sputum results and were recorded as cured while 9 (9%) had no sputum results recorded but were registered as having completed treatment (Figure 2).

Figure 2



4.9 Duration of TB treatment

Eighty two (82%) of the patients were recorded as having completed the Tuberculosis treatment in 6 months but 3 (3%) of the cases who had been initiated on TB treatment in February had been switched to category two treatment in April apparently because of high sputum positive results. Their treatment therefore took longer than six months. They were recorded as having completed treatment in November 2006 (Table VII).

Table VII

Duration of TB Treatment

	6 months	**> 6 months**	**Transferred out**	**dead**	**Defaulted**	**Total**
Cases	82	3	4	9	2	100

4.10 TB treatment outcome

Records showed that of the 100 (100%) cases that started TB treatment, 76 (76%) had negative sputa at the end of their treatment and had been classified as cured, while 9 (9%) had completed their treatment but had no sputum results. 9 (9%) of patients had died while on treatment, 2 (2%) had defaulted treatment, and 4 (4%) had been transferred out (Table VIII).

Table VIII

TB Treatment Outcomes

Cured	Completed	Died	Defaulted	Failed	Transferred out	Total
76	9	9	2	0	4	100

4.11 HIV status of TB cases

One hundred TB records were reviewed. Forty nine (49%) of those showed that counseling and testing had been accepted and there were 40 (40%) HIV positive results and 9 (9%) negative results while 51 (51%) had no entries in the HIV counseling and testing column and were assumed not counseled (Table IX).

Table IX

HIV Status of TB cases

Proportion of TB cases counselled	Proportion accepted testing	Proportion tested HIV positive	Proportion tested HIV negative	Proportion not counselled	Total TB cases
49 (49%)	49 (49%)	40 (40%)	9 (9%)	51 (51%)	100 (100%)

4.12 Age and sex distribution of TB cases with HIV

Forty nine (49%) of the cases were tested for HIV, 16 (32.7%) of cases who had been tested were females in the age group 20-39 years, 8 (16.3%) were males. In the age group 40-59 years 6 (12%) were females while 4 (8.2%) were males. In the age group 60-79 years 3 (6.1%) females and 3 (6.1%) males had been tested. Percentage TB/HIV co-infection among those who had been tested was 81.6%, nine patients had tested negative for HIV (Figure 3).

Figure 3

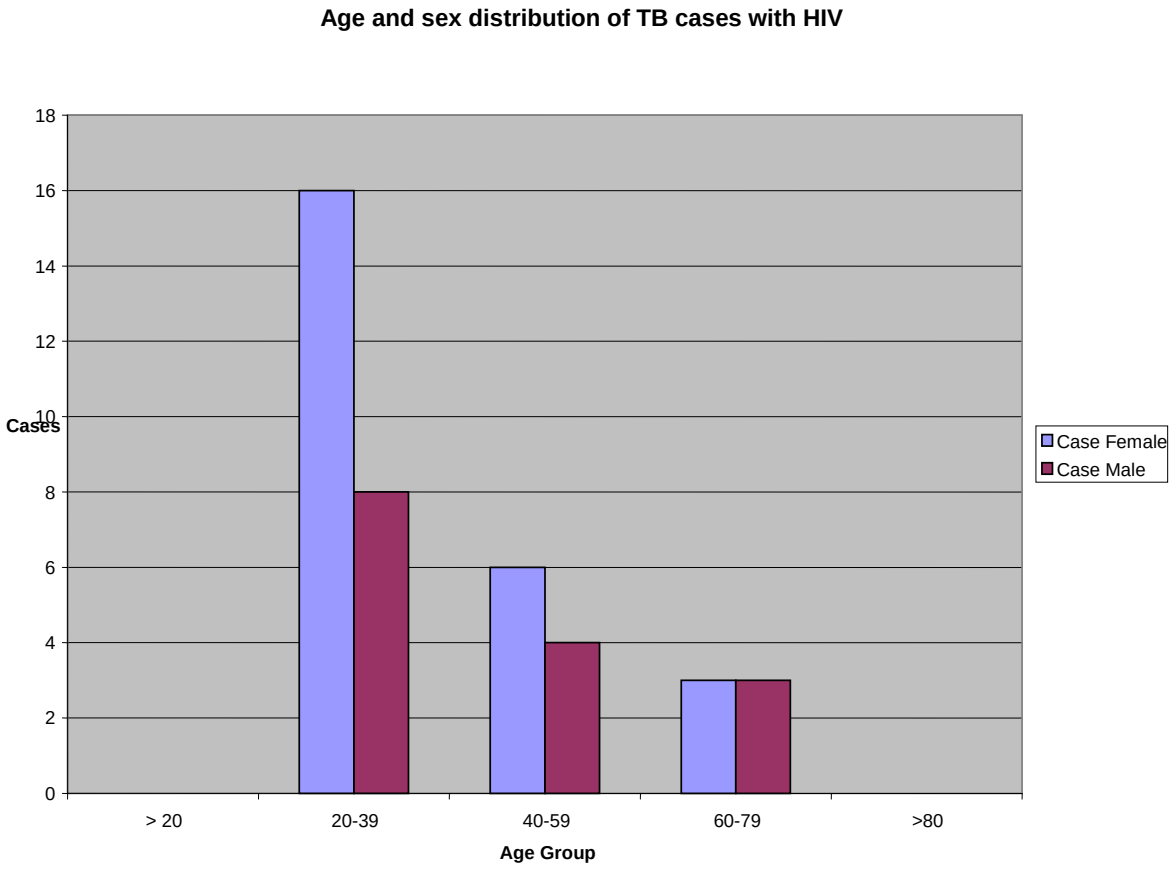


Table II Indicators to monitor TB case detection and treatment

To monitor:	Indicators	Time frame	How to calculate (numerator/denominator	Result
TB case detection (*using data from Register of TB suspects)*	Proportion of outpatients aged 18 years and over who were identified as TB suspects	Jan – June 6 months	Number of TB suspects identified = 438 Total outpatients aged 18 years and over 7207	6.1%
	Proportion of TB suspects whose sputum was tested for TB	Jan – June 6 months	Number TB suspects whose sputum was tested = 378 Number TB suspects identified 438	86.3%
	Proportion of TB suspects tested who were sputum smear-positive	Jan – June 6 months	Number smear-positive case detected Number TB suspects whose sputum was tested = 100 378	26.5%
TB treatment (*using data from Register of TB suspects and TB Treatment Register*)	***Conversion rate:*** Proportion of new sputum smear-positive cases that converted at 2 months	Jan – June 6 months	Number new smear-positive cases that converted at 2 months = 89 Number new smear-positive cases put on treatment 100	89.0%
	Treatment outcomes: Proportion of new sputum smear positive cases that: were cured	Jan – June 6 months	Number new smear-positive cases cured = 76 Number new smear-positive cases put on treatment 100	76.0%
	- completed treatment	Jan – June 6 months	Number new smear-positive cases that completed treatment = 9 Number new smear-positive cases Put on treatment 100	9.0%
	- defaulted	Jan – June 6 months	Number new smear-positive cases that defaulted = 2 Number new smear-positive cases put on treatment 100	2.0%

Treatment Success = Cure rate (76) + Completed (9) = 85%

4.14 Monthly Distribution of TB cases during the study period

This table shows the summary of the records of patients who were started on TB treatment each month, the number that completed treatment each month and those who died, defaulted or were transferred out and hence by definition had no recorded outcome. In April records of three patients who started treatment in February showed that because sputum results were still highly positive the treatment was switched to category two, and was recorded as completed in November for those cases. Four cases had been recorded as transferred out before completing the initial phase of the treatment, one in each of the following months, February, April, May and June. Records showed that two patients who started treatment in January died, one who started treatment in February also died, and similarly two patients were recorded as having died in each of the following months: March, May and June (Table XI).

Table XI

Monthly Distribution of TB cases during the study period

Month	No. started on treatment	No. completed treatment	No. died	No. transferred	No. defaulted
Jan	12	0	2	0	0
Feb	18	0	1	1	0
Mar	15	0	2	0	0
April	11	0	0	1	0
May	17	0	2	1	0
June	27	0	2	1	2
July	0	10	0	0	0
Aug	0	13	0	0	0
Sept.	0	13	0	0	0
Oct..	0	10	0	0	0
Nov.	0	17	0	0	0
Dec.	0	22	0	0	0
Totals	100	85	9	4	2

4.15 Identifying TB suspects

A total of 7207 patients with a variety of diseases were recorded in Scott Hospital out patients' clinic register, from among whom 438 (6.1%) had been identified as TB Suspects. Records showed that 378 (86.3%) of the suspects were screened for TB using sputum microscopy, 100 (26.5%) had positive sputum smear results. Those 378 patients were not confirmed TB cases; they were TB suspects who did not form part of the study population.

Part of the training of health workers in an effort to improve TB control programme was to increase TB case detection by actively asking all who visited out patient services about TB symptoms. If they had a cough lasting for two or more weeks, they had been recorded as TB suspects and subsequently investigated for TB. Records showed that 100 of the patients that visited the health facility some for non TB related consultation were none the less diagnosed with TB because of the screening method (Table XII).

Records of the 100 identified through the screening method were not necessarily the same as those that formed the study sample as some of them did not meet the criteria to be included in the study, but they formed part of the study population.

Table XII

Number of patients identified as TB Suspects-January to June 2006

General outpatients	TB Suspects	suspects with tested sputum	Patients with positive smear results
7207	438	378	100

CHAPTER 5

5.1 DISCUSSION

Despite the great TB treatment success, that is, the fall in prevalence and mortality rates achieved by the global TB control in eight (8) WHO epidemiological sub-regions in 2009, TB still remains a significant public health problem in African countries and Lesotho is no exception. The most efficient method for preventing TB transmission is its identification through case detection, diagnosis and cure of the most potent sources of infection: pulmonary tuberculosis patients excreting tubercle bacilli (Rouillon et al, 1976:275). Case finding in patients attending health facilities is an essential component of the control of tuberculosis. Active TB case detection reduces treatment delay and identifies infectious patients who are a risk to the community, other patients and health workers at every health facility. The ability of the health workers to identify tuberculosis suspects, investigate them, arrive at a diagnosis and initiate appropriate treatment if suspects are sputum smear positive is the cornerstone of TB case detection.

In this study, sputum microscopy examination of samples from 378 TB suspects identified during screening of patients attending outpatient clinic at Scott Hospital diagnosed 100 (26.5%) new sputum smear positive tuberculosis (Table X). This result is comparable to a similar study in Cambodia that identified 9% - 26% active tuberculosis during screening of patients (Eang, 2004:382). In the United Republic of Tanzania, direct examination of sputum smears for acid fast bacilli

from 61,580 patients with suspected tuberculosis revealed an average proportion of smear positive cases of 18.9% while Malawi, a country with a high HIV prevalence like Lesotho had a high sputum positive rate. In a study of 402 suspected tuberculosis cases, 230 patients of those who had sputum smears done, the smear positivity rate was 43% (Harries, 2004:616).

The proportion of positive smears is an indicator of the impact of the TB programme in reducing the prevalence of tuberculosis in the community (Luelmo, 2004:9). A study in Peru which has a well established DOTS programme, the rate of smear positivity in persons with respiratory symptoms was 18.7% in 1990, and fell to 2.7% in 1999 (Luelmo, 2004:8). Following implementation of DOTS strategy Luelmo (2004:9) also reports that in Chile the smear positivity rate fell from 10% to less than 2% in two decades. Based on the experiences of these two countries, with rigorous implementation of the DOTS strategy, it is feasible that the TB programme at Scott Hospital will also see the rate of smear positivity in persons with respiratory symptoms declining significantly within a decade.

Once diagnosis of tuberculosis has been made, an appropriate treatment regimen should be started. The aims of the treatment are to: cure patients and prevent continued transmission of infection in the community, prevent death and emergence of drug resistant forms of tuberculosis organisms and minimize relapse. The initial intensive phase of the treatment, usually rifampicin-containing is designed to kill actively growing and semi-dormant bacilli. This

phase is directly observed and closely monitored and when adherence is good, the duration of infectiousness is shorter, with rapid sputum smear conversion of (80 – 90%) after 2 – 3 months of treatment (Harries, 2004:124). Sputum smear microscopy has played a critical role in monitoring the response to TB treatment. The sputum conversion rate, defined as the proportion of new sputum smear positive TB cases that converted at 2 or 3 months, is a good indicator that shows the capacity of the TB programme to maintain patients on treatment, monitor treatment through sputum analysis and eliminate the source of infection. This important measure is therefore an early surrogate of the treatment outcome indicator. In this study the sputum conversion of 89% (Table x) compared favourably with the expected 80-90% in a well run DOTS programme (Harries, 2004:124) In the Madras study Toman (2004) also reports that sputum conversion of 90% was achieved after four months of treatment.

Treatment success rates by DOTS programmes varied from 74% in Europe and Africa to 87% in South East Asia and 91% in the Western Pacific, the latter two regions having exceeded the 85% target (WHO, 2007:2). In this study, treatment success of 85% (TableVI) compares favourably with findings of other studies: TB programme improvement has increased treatment success rates in Rwanda from 58% in 2003 to 81% in 2006 (Gasana et al, 2007:383). In 2006 fifty seven countries reached 84% treatment success, slightly lower than the target (Laserson et al, 2007:377). In Mali, the treatment success rate for new sputum

smear positive patients improved from 61% for 2002 Cohort to 77% for mid-2005 Cohort (Dara et al, 2007:403).

Tuberculosis is a very serious disease, untreated; 50-80% of patients with smear-positive tuberculosis will die of their disease (WHO, 2002:210). In a poorly implemented tuberculosis programme, as many as 30% of patients with smear positive tuberculosis die (Datta et al, 1993:186). In contrast, good DOTS programmes throughout the world report death rates of less than 5% (WHO, 2007:37). Results in this study show the death rate of 9% (Table VIII). Though an encouraging improvement and a 5% decrease from the previous year's 14% reported by the Scott hospital TB control programme, it is still less than 5% expected in a good DOTS programme. The high death rate in this study may probably have been influenced by a high HIV co-infection rate among TB patients and a delay in initiating ART in HIV positive TB patients. While a high death rate is a concern to the reseacher, it is comparable to death rates among TB patients in the region; Mozambique, South Africa, Tanzania and Zimbabwe reported death rates higher than 7% (WHO, 2007:46).

A high defaulter rate and transfers without follow up are responsible for continued spread of the infection in communities. However with improved DOTS implementation these are often also decreased. The defaulter rate in this study was 2% (Table VIII), eleven (11%) decrease from the previous year, indicating the success of the TB programme following improvements and much lower than the 9% defaulter rate reported by most African countries (WHO, 2007:46). Other

studies in Africa also report decrease in defaulter rates: following improvements in the TB programme the defaulter rate in Mali significantly decreased from 29% in 2002 to 7% in mid 2005 (Dara et al, 2007:403).

HIV associated TB is often difficult to diagnose, and has led to an increasing incidence of smear negative and extra-pulmonary tuberculosis which often has a worse progress than smear positive TB (WHO, 2006). Although only 49 (49%) of patients in this study accepted counseling and testing (Table IX) this is consistent with the results of baseline evaluation of access to and acceptance of HIV counseling and testing among TB patients in other countries. In Rwanda of the 482 patients registered for TB treatment in the fourth quarter of 2004, 52% had documented HIV test results (Gasana et al, 2007:383). A high TB/HIV co-infection rate of 40 (81.6%) Table IX, in this study is also found in other high burden HIV countries: In Malawi 70% of TB patients are infected with HIV (Chimzizi, 2007:384). In Khayelitsha, South Africa 76% of TB patients also tested positive for HIV (Medecins Sans Frontieres, 2007:9).

5.2 Study Limitations

This study is hospital based. Therefore findings may not be generalized to non hospital based population. The TB programme at Scott Hospital does not do contract tracing. Therefore it is possible that patients reported as defaulters may have self transferred themselves to another treatment site or they may have died.

Culture is not available to confirm TB diagnosis, hence some of the patients may have been wrongfully diagnosed as having tuberculosis because only microscopy was used in diagnosing patients. Some re-treatments could have posed as new patients due to lost records.

CHAPTER 6

CONCLUSION AND RECOMMENTATIONS

6.1 Conclusion

Strengthening and introduction of improvements for the TB program at Scott Hospital empowered the trained frontline TB workers through support and supervision to provide recommended TB care and treatment according to the national guidelines. They enforced DOTS strategy implementation and by so doing improved TB case detection through active screening of patients attending outpatient clinic, monitored the effects of TB treatment at recommended two, five and six months of treatment thereby achieving 89% sputum conversion rate and 85% treatment success, a significant improvement from the 71% treatment success reported in 2005. There was also an increase in the cure rate from 68% in 2005 to 76% in 2006. Both the defaulter rate and the death rate decreased to 2% and 9% respectively from 13% and 14% in 2005. Counseling and testing of TB patients, introduced in 2006, achieved 49% acceptance. In general the strategies instituted to improve TB programme at Scott Hospital significantly improved case detection and all the TB treatment outcome indicators. The challenges remain for provision of IPT, CPT, ART and sustained political commitment to support the required activities in the context of evolving health trends.

6.2 Recommendations

1. Construction or renovation of existing TB clinics to accommodate TB/HIV services taking into account improved infection control measures to reduce the risk of facility acquired infection.
2. Training and increasing of laboratory staff to reduce fatigue, turnaround time for results and errors and to increase quality assurance.
3. Capacitating clinic staff through continuing education to manage both TB and HIV
4. Given the increasing workload of co-infected patients, strengthening administrative support to the clinics to deal with data management is highly recommended.
5. Improving cure rates for both the TB/HIV co-infected and TB patients through treatment literacy in TB among patients and their communities, through patient centered approach to adherence and by removing pre-diagnosis charges which are a barrier to access to services.
6. Introduction of TB/HIV electronic registers which will integrate monitoring of both TB and ARV programs and facilitate identification of patients who have missed their scheduled appointments.

References

Blanc L., Martinez L.,2007. *The International TB control targets*. Bulletin of the World Health Organization, 85(5), pp.325-420.

Blðndal K.,2007. *Barriers to reaching the targets for tuberculosis control: multidrug-resistant tuberculosis.* Bulletin of the World Health Organization, 85(5), pp. 387-389.

Bureau of Statistics.,2003. *Statistical report no. 17 (2003)*. Maseru: Bureau of Statistics. 1.

Chimzizi R., Harries A.,2007. *Joint tuberculosis/HIV services in Malawi: progress, challenges and the way forward.* Bulletin of the World Health Organization, 85(5), pp. 385-386.

Clarke M., Dick J., Zwarenstein M., Lombard C.J., Diwan V., Forthcoming,2005. *Lay workers improve TB treatment outcome in commercial farming area of South Africa: Cluster randomized control trial*. In: Operations research results: The effectiveness of TB DOTS supporters in South Africa. USAID. ; 5-6.

Dara M.,Naco A.,2007. *DOTS expansion and TB control: the case of Mali*. Bulletin of the World Health Organization, 85(5), pp. 402-403.

Datta M., Radhamani MP., Selvaray R., Paramasivan C.N., Gopalan B.N., Sudeendra C.R.,1993. *Critical assessment of smear-positive pulmonary tuberculosis patients after chemotherapy under the district tuberculosis programme*. International Journal of Tuberculosis and Lung Disease, 74(3), pp.180-6.

De Vos A.S., Strydom H., Fouché C.B., Delport C.S.L., 2002. *Research at grass roots for the social sciences and human science professions.Pretoria:* Van Schaik.pp.351-352.

Dye C., Hussein M., Watt C., 2007. *Did we reach the 2005 targets for tuberculosis control?* Bulletin of the World Health Organization, 85(5), pp.364-369.

Dye C., Watt C.J., Bleed D.M., Hossein S.M., Ravigleone M.C., 2005. *Evolution of tuberculosis control and prospects for reducing tuberculosis incidence, prevalence and deaths globally*. Journal of American Medical Association, 293(22), pp. 2790-3.

Dye C., Scheele S., Dolin P., Pathania V., Raviglion M.C.,1999. Global burden of tuberculosis: estimated incidence, prevalence, and mortality by country. *Journal of American Medical Association,* 282, pp.677-86.

Floyd K., Arora V.K., Mary K.J.R., Lonurath K., Singla N., Akba Y., Zignol M., Uplekar M.W.,2006. *Cost and cost effectiveness of PPM-DOTS for tuberculosis control: evidence from India. Bulletin of the* World Health Organization, 84(6), pp. 437-445.

Floyd K., Wilkinson D., Gilks C.,1997. *Comparison of cost effectiveness of directly observed treatment(DOT) and conventionally delivered treatment for tuberculosis: experience from rural South Africa*. British Medical journal, 315(11), pp.1407.

Fox W., Ellard G.A., Mitchism D.A.,1999. *Studies on the treatment of tuberculosis undertaken by the British Medical Research Council Tuberculosis units 1946-1986 with relevant subsequent publications*. International Journal of Tuberculosis and Lung Disease, (3), pp.5231-5279.

Gasana M., Vandebriel G., Kabanda G., Mugabo J.,Tsiouris S.J., Ayaba A., et al.2007. *Tuberculosis in Rwanda: challenges to reaching the targets*. Bulletin of the World Health Organization, 85(5),pp.383.

Gandhi N.R., Mol A., Sturm A.W., Pawinski R., Govender T., Lallo U., et al.2006. *Extensively drug-resistant tuberculosis as cause of death in patients' co-infected with tuberculosis and HIV in a rural area of South Africa*. Lancet 368, pp. 1554-6.

Harries A.D., Chimzizi R.B., Nyirenda T.E., Van Gorkom J., Salaniponi F.M., 2003. *Preventing recurrent tuberculosis in high HIV prevalent areas in Sub-Saharan Africa: what are the options for tuberculosis control programmes*?, International Journal of Tuberculosis and Lung Disease, 7, pp.616-22.

Hausler H., Simelela N., Vilakazi K., Mvusi L., Naidoo P., Penrose A., Et al, 2004. *Scaling up TB/HIV collaborative activities in South Africa linked to antiretroviral implementation*. In; E Lab-medical. [On line]. International conference on AIDS Bangkok,Thailand. Available at: http://www.scientistlive.com . [Accessed 6 March 2010]

Kazyenny B.,2007. In: *Russian oblast is model in fight against* TB. Bulletin of the World Health Organization, 85(5), pp.329.

Kwanjana J.H., Harries A.D., Gausi F., Nyangulu D.S., Salaniponi F.M., 2001. *TB-HIV Seroprevalence in patients with tuberculosis in Malaw*i. Malawi Medical Journal, 13, pp.7-10

Laserson K.f., Wells C.D.,2007. *Reaching the targets for tuberculosis control: the impact of HIV*. Bulletin of the World Health Organization, 85(5), pp.377-386.

Levine R., 2007. *Case 3, Controlling TB in China*. In: Millions saved proven successes in global heath. Washington DC; Center for Global Development, pp.31-37.

Luelmo F.,2004. *What is the role of sputum microscopy in patients attending health facilities*? In: Frieden T. ed. Toman's Tuberculosis. Case detection, treatment, and monitoring. Second edition Geneva: World Health Organization, pp.7-10.

Medécins Sans Frontierès,2008. *Khayelitsha annual activity report 2008-2009*. [on line] Available at: http://www.msf.org.za [accessed 6 March 2010]

Medécins Sans Frontierès,2007. *Report on the integration of TB and HIV services in Ubuntu clinic (site B), Khayelitsha.* Cape Town: Medecins Sans Frontieres, pp.9

Ministry of Health and Social Welfare Lesotho, 2008. *Monitoring and Evaluation Report* 2008: Maseru, Ministry of Health and Social Welfare, pp.20-38.

Ministry of Health and Social Welfare Lesotho, 2007. *Lesotho MDR- Guidelines*. Maseru: Minisry of Health and Social Welfare, pp. 2-14.

Ministry of Health and Social Welfare, 2007. *Grant Scorecard LSO -202-G02-7-00, The Global Fund to fight AIDS, TB and Malaria Secretariat Phase 2 Recommendation*. Maseru: Ministry of Health and Social Welfare, pp. 2-12.

Ministry of Health and Social Welfare, 2007. *Annual Report 2006-2007.* Maseru:Ministry of Health and Social Welfare, pp.38-44.

Ministry of health and social Welfare, 2005. *Annual Joint review report 2005.* Maseru: Ministry of Health and Social Welfare, pp.19-24.

Ministry of Health and Social Welfare, 2004. *Lesotho Demographic and Health Survey.* Maseru: Ministry of Health and Social Welfare, pp. 4-248.

Ministry of Health and Social Welfare, 2003. *Five-year strategic plan for DOTS expansion in Lesotho*. Maseru: Ministry of Health and Social Welfare. 6: 5-47.

Ministry of Health and Social Welfare, 2002. *National Social Welfare Policy*. Maseru: Ministry of Health and Social Welfare, pp. 4-12.

Ministry of Health,2001. *HIV Sentinel Surveillance (HSS) in Cambodia, Phnom Penh:* national center for HIV/AIDS Dermatology and STD. Phnom Penh: Cambodian Ministry of Health, pp.616-622.

Ministry of Finance and Development Planning,2007. *2006 Lesotho census of population and Housing*. Preliminary results Report. Maseru: Bureau of Statistics, pp.3-16.

Munyati S.S., Dhoba T., Makanza E.D., Mungofa S., Wellington M., Mutsvangwa J., et al,2005. *Chronic cough in primary health care attendees, Harare, Zimbabwe: diagnosis and impact of HIV infection*. Clinical Infectious Diseases, 40, pp.1818-27.

Murray C.J.L., 1996. *Epidemiology and demography of tuberculosis*. In: Timaeus I.M., Chackiel J., Razieka L., (eds) Adult Mortality in Latin America. Oxford; Clarendon Press, pp.199-216.

Nachega J., ccoetzee J., Adendorff T., Msandiwa R., Gray G.E., McIntye J.A., Chaisson R.E.,2003. *Tuberculosis active case- finding in a mother to child HIV transmission prevention programme in Soweto, South Africa*. AIDS, 17(9), pp.1398-400.

Odendal L.*,2010. Integrating TB and HIV services: lessons from the field; Khayelitsha's integrated TB/HIV programme*. HATip 156(23), pp. 2-5. Available at www.aidsmap.com/hatip email bulletin at hatip@nam.org.uk
[Accessed 23 March 2010].

Ogunbanjo G.A., 2001. *Statistics for general practitioners: what is "bias" in research*? South African Family Practice Journal, pp. 23:35.

Prasad R., Nautiyal R.G., Mukherji P.K., Jain A., Singh K., Ahuja R.C.,2003. *Diagnostic evaluation of pulmonary tuberculosis: what do doctors of modern medicine do in India*?International Journal of Tuberculosis and Lung Disease, 7(1),pp.52-7.

Ramon-Pardo P., Del Granado M., Gerger A., Carela Soler J., Mer M., Arnengol R., Lopez Olarte R.A., Rodriguez R.,2009. International Journal of Tuberculosis and Lung Disease, 13(8), pp. 969-75.

Raviglione M.C., Uplekar M.W., 2006. *WHO's new Stop-TB Strategy*. Lancet, 367, pp.952-5.

Raviglione M.C., 1997. *Tuberculosis and HIV: current status in Africa. AIDS*, 11, pp.s115-s123.

Reider H.L., 1996. *Sputum smears conversion during directly observed treatment for tuberculosis*. Tubercle Lung Disease, 77, pp.124-129.

Ridderhof J., Van Deun A., Man Kam K., Narayanan P.R., Aziz M.A.,2007. Roles of laboratory systems in effective tuberculosis programme. Bulletin of the World Health Organization, 85(5), pp.354-357.

Rouillon A., Perdrizet S., Parrot R., 1976. *Transmission of tubercle bacilli: the effects of chemotherapy*. *Tubercle* 57(4),pp.275-299.

Scott Hospital of Lesotho Evangelical Church, 2005. Scott Hospital TB control report 2005. Scott Hospital.

Sbarbano J., 2004. *What are the advantages of direct observation of treatment* in: Frieden T.R ed Toman's tuberculosis. Case detection, treatment and monitoring 2nd Ed. Geneva; World Health Organization, pp.183-184.

Santha T., Garg R., Subramani R., et al., 2005. *Comparison of cough of 2 and 3weeks to improve detection of smear-positive tuberculosis cases among outpatients in India*. International Journal of Tuberculosis and Lung Disease, 9(1), pp.61-8.

Tan Eang M., Chheng P., Natpratan C., Kimerling M.E., 2007. Lessons from TB/HIV integration in Cambodia. Bulletin of the World Health Organization, 85(5), pp.382-383.

Toman K., 2004.*What were the main landmarks in the development of tuberculosis treatment?.* In Frieden T ed. Toman's Tuberculosis. Case detection, treatment, and monitoring. 2nd ed. Geneva: World Health Organization, pp.99-100.

Tuberculosis Coalition for Technical Assistance, 2006. *International Standards for Tuberculosis Care (ISTC).* The Hague: Tuberculosis Coalition for Technical Assistance, pp. 6.

Van Maaren P.J., 2010. *Fighting the tuberculosis epidemic in the Western Pacific region: current situation and challenges ahead*. Kekkaku ,85(1),pp.9-16.

Volmink J., Matchaba P., Gamer P., 2000. *Directly observed therapy and treatment adherence.* Lancet, 355 (9212), pp.1345-50.

Were W.A., et al., 2007. *Clinical predictors of active tuberculosis in HIV- infected people attending an antiretroviral treatment program in rural Uganda*. The 2007 HIV/AIDS implementers' meeting, Kigali, Rwanda, abstract1280.

Weyer K., 2007. Round Table discussion. Case study: South Africa. Bulletin of the World Health Organization, 85(5), pp. 391.

World Health Organization, 2009.Global Tuberculosis Control: a short update to the 2009 report. [Accessed 20 June 2010]. Available from World Wide Web:http://www.who.int/tb/publication/global_report/2009/update/en/index.html

World Health Organization, 2007.*Global Tuberculosis Control Surveillance, Planning, Financing*. Geneva: World Health Organization, pp.280.

World Health Organization, 2006. *Global Tuberculosis Control Surveillance, Planning, Financing.* Geneva: World Health Organization, pp.362.

World Health Organization, 2006. *The Global Plan to Stop-TB 2006-2015*. Geneva: World Health Organization Stop TB Partnership.

World Health Organization Stop-TB department, 2004. *Report of a lessons learnt working on the six Protest pilot projects in Malawi, South Africa and Zambia.* Geneva: World Health Organization, pp.336.

World Health Organization, 2003. *Adherence to long term therapies. Evidence for action. Geneva*: World Health Organization, pp. 212-289.

World Health Organization, 2003. *Management of Tuberculosis Training for Health Facility Staff. J Reference booklet.* Geneva: World Health Organization, pp.33-37.

World Health Organization, 2002. *An expanded DOTS framework for effective tuberculosis control*. Geneva: World Health Organization, pp 202-297.

World Bank,1993. *Investing in Health*: 1993 World Development Report. In: Frieden T. ed. Tomans' Tuberculosis, Case detection, treatment and monitoring, 2nd Ed. Oxford: Oxford university press in association with WHO, pp.246-247

Zignol M., Hosseinei M.S., Wright A., Weezenbeck C.L., Nunn P., Watt C.J., et al., 2006. *Global incidence of Multi-drug-resistant tuberculosis*. Journal of infectious Diseases, 194, pp.479-85.

Zolotova E., 2007. *Russian oblast is model in fight against TB*. Bulletin of the World Health Organization, 85(5), pp. 330.

Appendix 1

RESEARCH PROTOCOL

TITLE:

EVALUATION OF STRATEGIES INSTITUTED TO IMPROVE THE TUBERCULOSIS CONTROL PROGRAM WITHIN SCOTT HOSPITAL HEALTH SERVICE AREA, LESOTHO

RESEARCHER: **DR. L MAKAKOLE BSC, MD, MPH,**

SUPERVISOR: **PROFESSOR GA OGUNBANJO**
MBBS, FCFP (SA) M. Fam Med (Medunsa)
FACRRM, FACTM, FAFP(SA)

DEPARTMENT OF FAMILY MEDICINE & PHC,
UNIVERSITY OF LIMPOPO (MEDUNSA CAMPUS)

Table of contents

1. INTRODUCTION:

1.1Current Health Status:

In Lesotho the advent of the HIV/AIDS epidemic and the burden of suffering and economic loss caused by the increased prevalence of complex of diseases associated with AIDS e.g. Tuberculosis has already begun to erode the health gains of recent years as demonstrated by the declining health indicators. For instance, life expectancy has declined from 58 years in the 1990s to 35 years.[i] Infant mortality rate is now 91 deaths per 1000 live births (2004) up from 75 per 1000 live births in 1999, and the under five mortality has increased from 90 to 113 deaths per 1,000 live births over the same period.[ii] Lesotho has one of the highest maternal mortality rates of 762 per 100,000 live births. The fertility rate is 3.5. Adult HIV prevalence rates in the age group 15-49 years have soared to a high rate of 23.2 percent,[iii] unfortunately majority of these people also have Tuberculosis.

1.2 Health Care Provision: Tuberculosis program in Lesotho

Lesotho is divided into eighteen health service areas (HSA) demarcated around each of the seventeen hospitals with the exception of the highlands flying doctor services that is not attached to any hospital. The Health Service area of Scott Hospital is the second largest in the country with a population of 220,000. Because of the ongoing implementation of the health sector reform

program this demographic division of the country is also in the process of being changed into the district health system. The National Tuberculosis Program (NTP) is responsible for co-ordination and management of free tuberculosis treatment in all the eighteen HSA's in Lesotho. Each HSA has a nursing assistant who has been trained as a Tuberculosis (TB) Co-ordinator responsible for all TB activities in her area of assignment and is supervised by the district medical officer. Case detection is mainly by sputum microscopy and the treatment is short-course chemotherapy (SCC) with directly observed treatment (DOT).

2. THE PROBLEM AND JUSTIFICATION FOR THE STUDY

HIV infection has been the most potent risk factor for converting latent TB into active form, thus effectively accelerating the spread of the disease. Today TB is the leading cause of death in persons who are HIV positive. The incidence of TB for all cases is 696 per 100,000 population while that of new smear positive is 276/100,000 pop/year with estimated case detection rates of 91% and 86% respectively.[iv] Despite this improvement in case detection rates, treatment success for new smear positive cases has hovered around 70% for the past few years, while death rates have slowly increased to almost 14%, and 5% of the patients defaulted treatment. In Scott HSA these figures are far below the national norms. It is estimated that the prevalence of HIV in adult TB patients is about 76%. TB control supervision, monitoring and evaluation are still very poor in Lesotho. Interventions that help to curb TB epidemic are various. The root causes of the performance gap have been identified; interventions have been selected, designed and implemented. It is important that these should be monitored and evaluated so that needed corrections and adjustments can be made and integrated within the ongoing systems.

3. LITERATURE REVIEW:

Many studies have proven the effectiveness of some intervention strategies to improve the success of the TB control programs. Approximately one fourth of patients with active tuberculosis fail to complete the usual six months course of treatment within 12 months[v]. In the light of this, strategies have been used to promote adherence to treatment.

In Georgia USA, money has been used successfully and was highly effective in promoting adherence.[vi] The positive impact of health education on treatment adherence has also been demonstrated. In a retrospective survey to assess factors associated with compliance in TB treatment, the nursing assessment of patients understanding at the time of initial contact among 209 instances, showed that 57% of patients who were judged to have fair or poor understanding successfully completed therapy, compared to 73% of those rated to have good understanding.[vii]

Patient enablers or prompts have also been successfully used to improve adherence to tuberculosis treatment. Reminder letters sent to patients with tuberculosis soon after they had defaulted produced good results. Of the 29 patients who defaulted in the intervention group, 17(58.6%) returned, compared with 4 out of 31(12.9%) in the control group. This method was efficacious even among illiterate patients.[viii] The strength of the provider/patient relationship and the participation of patients who feel more motivated and accountable for their own treatment has improved on the success of the partnership between the health care worker and the patients and hence the success of the adherence to treatment.

The involvement of community in tuberculosis control has been used with success in programs in Bangladesh, the Philippines and South Africa. In Haiti, in rural and very poor conditions, treatment was observed at patient's home by former tuberculosis patients with 7% defaulter rate and 87%

treatment success among 138 patients.[ix] To reduce mortality rate in HIV positive TB patients in developing countries the use of Cotrimoxazole prophylaxis was introduced in the management of these people. In 1999, a Cotrimoxazole placebo-controlled trial in HIV positive smear positive pulmonary TB patient in Cote d'Ivoire showed a 48% reduction in deaths in the Cotrimoxazole group.[x] A study from South Africa produced further evidence showing that adjunctive Cotrimoxazole in HIV positive TB patient improved survival rates by 53%.[xi]

Although defaulter tracing is expensive, needs additional resources, transport and man power it has been used successfully to improve adherence and completion of TB treatment. In South Africa and in Uganda an intervention directed at monitoring and evaluation showed that patients with TB attending health centres with intense supervision of staff were more likely than those attending health centres with routine supervision of staff to complete treatment.[xii]. In South Africa, this intervention also had a positive effect on sputum conversion rate[11]. Directly observed treatment when used as part of a comprehensive effort to improve TB services has been associated with improvements in rates of adherence.[11]

4. Research Question:

What are the outcome measures of the strategies instituted to improve the tuberculosis control program within Scott Hospital health service area, Lesotho?

5. Study Aim and Objectives

5.1 Aim:

1. To asses the outcome measures of the strategies instituted to improve the tuberculosis control program within Scott Hospital health service area, Lesotho.

5.2 Objectives:

1. To determine the proportion of TB cases tested and who were sputum smear positive.

2. To determine the proportion of new sputum smear positive TB cases who became smear-negative at 2 months.

3. To determine the proportion of new sputum smear positive cases who completed treatment at 6 months.

4. To determine the proportion of new sputum smear positive who were cured.

4. To determine the proportion of those who defaulted treatment.

5. To determine the proportion of TB patients who were co-infected with HIV.

6. Methodology:

6.1 Study Design:

This will be a descriptive, retrospective study.

6.2 Study Population & sample:

All male and female TB patients (aged 18 years and over) registered for TB treatment within the Scott hospital health service area from **January 1 to June 30, 2006** will constitute the study population and sample simultaneously. The cut-off date of June 30, 2006 allows completion of the

6-month treatment in the last cohort of TB patients registered. From the TB register, the sample will be 250 participants.

6.3 Data Collection:

Data on patients registered for TB treatment within the Scott hospital health service area from **January 1 to June 30, 2006)** will be extracted from the official TB register and collated by the researcher using a designed questionnaire (see Appendix 1). The questionnaire will contain demographic characteristics of the participants and outcome measures of the strategies of the TB control program.

6.4 Data Analysis:

Simple descriptive analyses using EPI-Info version 3.3.2 2005 software will be done with the assistance of my supervisor, who is proficient in the use of the software, and presented as tables, frequencies and graphs. The graphs will be generated using Microsoft Excel. For association of variables, chi-square test or student T-test will be used where appropriate and applicable. Findings with p-values ≤ 0.05 will be considered statistically significant.

6.5 Reliability:

Reliability is the degree to which the questionnaire gives the same results when used on more than one occasion with the same respondents under the same conditions. Stability and consistency of information will be maintained as the official TB registers laboratory register and TB suspect

register will be available to confirm the required information. These registers are kept in a safe place to ensure that data is not lost and can be retrieved whenever needed.

6.6 Validity:

Validity is the degree to which the measurement reflects the true value of the characteristic that the researcher actually intents to measure. Implicit in this is that the measurements are also reliable. The indicators used in this study (sputum conversion rate, cure rate, treatment success and treatment defaulter rate) are " gold standard" used widely to assess the TB control programs throughout the world and the desired WHO performance levels have been established. The use of data triangulation will be employed to enhance the validity of the findings. Examination of the official registers and the questionnaire containing information extracted from these documents will be done by my peers; the two general practitioners working in this HSA. It is hoped that their participation will help ensure that the information collected is the true reflection of what is in the registers and that the instrument used measures what it is intended to. This will help in enhancing the validity of the whole process and the scores of the instruments used in this study. My supervisor will be involved in guiding me throughout all the phases of the research process.

6.7 Bias:

- **Sampling bias** may occur when the study population does not have an equal chance of selection in the sample and this should be recognised. Elimination of this bias is not easy especially where different method of diagnosis is used. This bias will be minimized by

including everybody registered in the TB register for treatment from January 1 to June 30, 2006 in the sample thus giving all an equal chance of selection.

- **Selection bias** is observed when there is an error caused by differences in characteristics between those who are selected for the study and those who are not. This will be minimised by systematically selecting those who had sputum smear positive results recorded in the TB register during the period mentioned.

- **Observer bias** due to differences in true value and that observed as a result of observer variation will be minimised by the participation of my peers in the whole process.

- **Bias in the presentation of data** and **bias of interpretation of data** will be minimised by using the expert opinion of my supervisor.

6.8 Ethical Consideration:

Since this is a retrospective study using patient files, there will be no need for completion of consent forms but approval to conduct the study will be sought from the Ministry of Health and Social Welfare in Maseru Lesotho. In addition, permission will also be obtained from the Scott hospital health service Area management team. Finally, the research protocol will be submitted to the Research, Ethics and Publications Committee (REPC) of the university of Limpopo- Medunsa

campus for ethical clearance and approval. Confidentiality of data collected and anonymity of the participants will be maintained by analyzing the data as “group” data.

References

[1] Ministry of Health and Social Welfare (2002) National Social Welfare Policy. Ministry of Health and Social Welfare Lesotho. Maseru.

[2] Ministry of Health and Social Welfare Lesotho/Bureau of Statistics Lesotho/ORC Macro Calverton, Maryland USA. Lesotho Demographic and Health Survey 2004 Maseru. P 114, 233, 266

[3] Global Tuberculosis Control: Surveillance, Planning, Financing. WHO report 2006. Geneva World Health Organization (WHO/HTM/TB/2006 362

[4].Ministry of Health and Social Welfare Lesotho. Five year Strategic Plan for DOTS expansion inLesotho. 2003. Maseru

[5] Sumartojo E. When tuberculosis fails. A social behaviour of patient adherence. Am Rev Respir Dis,1993;147:1311-1320

[6] Bock NN, Sales RM, Rogers T, Devoe B A spoonful of sugar …….: Improving adherence to tuberculosis treatment using financial incentives. Int J tuberc Lung Dis 2001 Jan; 5(1): 96-8

[7]Menzies R Rocher I, Vissandjee B. Factors associated with compliance in treatmnent of tuberculosis. Int J Tuberc Lung Dis 1993; 74: 32-7

[8]Paramasivan R, Parthasarathy RT, Rajasekaran S. Short course chemotherapy: A controlled study of indirect defaulter retrieval method. Indian J Tuberc 1993; 40: 185-90

[9] Olle-Goig JE, Alvarez J. Treatment of tuberculosis in a rural area of Haiti: directly observed and non-observed regimens. The experience of Hospital Albert Schweitzer. Int J Tuberc Lung Dis 2001 Feb; 5(2): 137-41

[10] Zachariah R, Massaquoi M. Cotrimoxazole prophylaxis for HIV positive TB patients in developing countries. Tropical Doctor 2006; 36: 79-82

[11] Volmink J Garner P. systematic review of randomised controlled tirals of strategies to promote adherence to tuberculosis treatment. BMJ 1997; 315: 1403-1406 (29 November)

[12] Nuhawa F. High compliance in an ambulatory tuberculosis treatment programmes in a rural community of Uganda. Int J Tuberc Lung Dis, 3(1):79-81

[i] Ministry of Health and Social Welfare (2002) National Social Welfare Policy. Ministry of Health and Social Welfare Lesotho. Maseru.

[ii] Ministry of Health and Social Welfare Lesotho/Bureau of Statistics Lesotho/ORC Macro Calverton, Maryland USA. Lesotho Demographic and Health Survey 2004 Maseru. P 114, 233, 266

[iii] Global Tuberculosis Control: Surveillance, Planning, Financing. WHO report 2006. Geneva World Health Organization (WHO/HTM/TB/2006 362

[iv].Ministry of Health and Social Welfare Lesotho. Five year Strategic Plan for DOTS expansion inLesotho. 2003. Maseru

[v] Sumartojo E. When tuberculosis fails. A social behaviour of patient adherence. Am Rev Respir Dis,1993;147:1311-1320

[vi] Bock NN, Sales RM, Rogers T, Devoe B A spoonful of sugar …….: Improving adherence to tuberculosis treatment using financial incentives. Int J tuberc Lung Dis 2001 Jan; 5(1): 96-8

[vii] Menzies R Rocher I, Vissandjee B. Factors associated with compliance in treatmnent of tuberculosis. Int J Tuberc Lung Dis 1993; 74: 32-7

[viii] Paramasivan R, Parthasarathy RT, Rajasekaran S. Short course chemotherapy: A controlled study of indirect defaulter retrieval method. Indian J Tuberc 1993; 40: 185-90

[ix] Olle-Goig JE, Alvarez J. Treatment of tuberculosis in a rural area of Haiti: directly observed and non-observed regimens. The experience of Hospital Albert Schweitzer. Int J Tuberc Lung Dis 2001 Feb; 5(2): 137-41

[x] Zachariah R, Massaquoi M. Cotrimoxazole prophylaxis for HIV positive TB patients in developing countries. Tropical Doctor 2006; 36: 79-82

[xi] Volmink J Garner P. systematic review of randomised controlled tirals of strategies to promote adherence to tuberculosis treatment. BMJ 1997; 315: 1403-1406 (29 November)

[xii] Nuhawa F. High compliance in an ambulatory tuberculosis treatment programmes in a rural community of Uganda. Int J Tuberc Lung Dis, 3(1):79-81

Appendix 2

QUESTIONNAIRE FOR PARTICIPANTS

Demographic information

1. Patient's Tuberculosis registration number _____Sex_____

2. Age in years _____

Information on Tuberculosis (please tick)

3. Was this the first time for the patient to be treated for Tuberculosis? □ Yes □ No

4. How was Tuberculosis diagnosed?

□ CXR □ Sputum □ other please specify _____

5. If the diagnosis was made with sputum what were the results?

□ Sputum smear positive □ Sputum smear negative

6. When was Tuberculosis treatment started? Date _____
YY-MM-DD

7. What were the sputum test results at the end of the two months of initial tuberculosis treatment?

□ Sputum smear positive □ Sputum smear negative

8. When was Tuberculosis treatment completed? Date _____
YY-MM- DD

9. What were the sputum test results at the end of the Tuberculosis treatment?

□ Sputum smear positive □ Sputum smear negative

10. What were the results at the end of the Tuberculosis treatment?

□ Cured □ Completed treatment □ Died

□ Defaulted □ Failed □ Transferred out of HAS

Tuberculosis and HIV co-infection

11. What was the patient's HIV status? (Please tick)

□ HIV Positive □ HIV Negative □ Not Tested