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Evaluation of Tuberculosis treatment outcomes and the determinants of treatment failures in the Eastern Cape Province, 2003 -2005

By

Eric Maimela

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Faculty of Health Sciences

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DECLARATION

I declare that this dissertation submitted in partial fulfillment of the Master of Science in Epidemiology degree requirements, is my own work in accordance with the University of Pretoria academic regulations. It has not been submitted for any degree or examination in any other university, and all the sources I have used or quoted have been indicated and acknowledged by complete references.

Signed: Eric Maimela Date:

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Acronyms and Abbreviations

AIDS	Acquired Immunodeficiency Syndrome
ARV	Antiretroviral
CBO	Community-based organization
CDC	Communicable Disease Control
DoH	Department of Health
DHIS	District Health Information System
DHS	Demographic and Health Survey
DOTS	Directly Observed Therapy, Short Course
EC DoH	Eastern Cape Department of Health
ECP	Eastern Cape Province
EC TCP	Eastern Cape Tuberculosis Control Programme
EPTB	Extra-pulmonary Tuberculosis
ETR	Electronic TB Register
GBD	Global Burden of disease
HAART	Highly Active Antiretroviral Treatment
HBC	Home-based care
HCW	Health care workers
HIV	Human Immunodeficiency Virus
LSA	Local Service Area
MDR-TB	Multi-drug Resistant Tuberculosis
NGO	Non-governmental organization
NDoH	National Department of Health
NIAID	National Institute of Allergy and Infectious Diseases
NGO	Non-governmental organization
NTCP	National Tuberculosis Control Programme
PHC	Primary health care
PPS	Proportional Probabilities Size
PTB	Pulmonary Tuberculosis
SA	South Africa
SADC	Southern Africa Development Community
SCR	Smear Conversion Rate
StatsSA	Statistics South Africa
TB	Tuberculosis
UATLD	International Union Against Tuberculosis and Lung
VCT	Voluntary counselling and testing
WHO	World Health Organization
XDR-TB	Extensively Drug-Resistant Tuberculosis

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ABSTRACT

Background: This paper describes the performance of the Tuberculosis (TB) control programme in the Eastern Cape Province. The aim of the study was to evaluate the tuberculosis treatment outcomes as well as to identify factors that contribute to treatment failures in health districts of the Eastern Cape Province from 2003 to 2005. TB can only be controlled and eventually eliminated in the context of a National Tuberculosis Control Program (NTCP). Such a program must operate within the general health service of each country. Although considerable progress has been made with TB control efforts in South Africa since 2000, there is still little sign that the epidemic is abating in the Eastern Cape Province.

Method: The study was a descriptive study and the methodology employed in this evaluative study took cognizance of the main approaches used globally (World Health Organization and the International Union Against Tuberculosis and Lung Disease) to assess the performance and quality of Tuberculosis Control Programs. 152 336 records from the Electronic TB Register for the period 2003 – 2005 were systematically reviewed and a random sample design of 252 primary health care facilities with probability proportional to size was used to collect information on health system related factors that contribute to treatment failures with emphasis to input, process and output indicators for the TB Control programme including proper implementation of DOTS strategy.

Results: Overall TB treatment outcomes in Eastern Cape Province did not reach the national targets for the period 2003 – 2005. A cure rate of 39.7% for new smear positive patients in 2005 was reported. Only Chris Hani district reached a national target of 70% for smear conversion rate in 2005. The successful treatment outcomes were below 85% threshold suggested by the World Health Organization. Cure rates never reached 50% for the three-year study period. Defaulting from treatment remained a challenge for the TB control programme in the Eastern Cape Province. There has been an increasing number of patients with treatment outcome not evaluated in 2005 from 20.1% to 24.7% in new smear positive cases and in re-treatment smear positive cases, this increased from 21.2% to 27.3%.

Conclusion: The findings of the study reveal that, despite considerable efforts made by the NTCP, little change was noted in treatment outcomes. Efforts to provide effective TB treatment using DOTS at district and facility level in the province are constrained by failure of most districts to reach a 100% DOTS coverage. Patients are accurately diagnosed, recorded into the register, drug supply is regular and uninterrupted but there has been a slow increase in the proportion of patients cured and there are an increase number of defaulter rates and patients with treatment outcomes which are not evaluated. An improved base of information is needed to assess the TB morbidity impact more accurately. Human resources were among the most important resources, which were found lacking and health system managers have the responsibility and challenge of ensuring that maximum benefit is derived from these to maintain and expand health services.

CHAPTER 1

INTRODUCTION

Tuberculosis (TB) is, by any estimation, an important global health problem: it is estimated by the World Health Organization (WHO) to be among the leading causes of death and disability among the economically active segment of the world's population.[1] WHO estimates that the toll of TB mounts annually to 3 million deaths and till 2020 the global burden of TB infections will reach to more than one billion. Surprisingly more than 80% of the disease burden comes from the poor resourced countries where the rate of reemergence is faster due to poor TB control and spending extremely inadequate.[2, 3]

The disease adversely affects child health directly and indirectly as most of the victims of TB are parents of young children. It primarily impacts low income countries where resources for dealing with health are severely restricted. Nevertheless, TB control merits priority as an intervention in the health sector, as National Tuberculosis Control Programs (NTCP) are among the most cost-effective of any health intervention in low income countries.[1] TB can only be controlled and eventually eliminated in the context of this programme which must operate within the general health service of each country.[4] Therefore in Eastern Cape (EC) Province this programme is operating in the general health services.

The contribution of national and international non-governmental organizations is important. The advice of the International Union Against Tuberculosis and Lung Disease (IUATLD) to such organizations is simple: support TB control in the context of, or in close cooperation with NTCP.

There are three priority strategies that are fundamental to the prevention and control of TB.[5] These involve health programs directed at decreasing morbidity and mortality for TB, which are:

1. Identifying and treating persons who have active TB; this priority entails identifying persons who have TB, ensuring that they complete appropriate therapy, and, in exceptional circumstances, using confinement measures.[5]

2. Finding and screening vulnerable persons who have been in contact with TB patients to determine whether they have TB infection or disease and providing them with appropriate treatment (prophylactic). This approach is applicable to child family contacts of patients with pulmonary TB. [5]
3. Screening high-risk populations to detect persons who are infected with M. tuberculosis and whose early treatment would prevent further spread of the infection to the uninfected persons. [5]

The overall fundamental strategies to prevent and control TB encompass the Promotion of good environmental conditions, the availability of adequate and healthy nutrition; and the provision of programmes directed at reducing exposure to TB.

To implement the comprehensive health service interventions, public health TB Control Programs should coordinate its efforts with those of health-care providers from several community organizations to ensure the provision of comprehensive health care services for TB patients. Health departments are responsible for providing centralized coordinated systems for many activities extending beyond individual patient care (e.g., identifying TB cases; ensuring that patients complete therapy; performing contact investigations; screening high-risk groups; and collecting, analyzing, and publishing epidemiologic and surveillance data). [5]

The goal of TB treatment is not only to cure the disease, but also prevent its transmission and the development of drug resistance. This can be achieved with Short Course Chemotherapy (SCC) regimens. Ninety five per cent of the estimated eight million TB cases occur annually in the developing world, where health care dollars are severely limited. Nevertheless, the model of the NTCP, designed by Karel Styblo of the IUATLD and adopted by the WHO, delivers SCC and cures 85% of cases. NTCP's are a cost effective means of TB control, but they require government commitment, uninterrupted TB drug supplies, a microscopy network for diagnosis, and treatment centers using directly observed therapy (DOT) and evaluation of case outcome as a quality assurance measure. [6]

During the 17th century the massive TB epidemic had swept Europe and North America resulting with colonialists, settlers and missionaries bringing TB into South Africa. Many sufferers came seeking a cure from the sun and fresh air. The previously unexposed, non-

immune indigenous populations of South Africa rapidly developed TB. In the late 1800s, workers were exposed to silica dust, overcrowded hostel living, poor nutritional status and stress, all of which were major contributors to the development of TB when the gold mines started on the Reef. When they became sick, they returned to their families in rural areas and spread the disease to them. By 1930, it was estimated that over 60% of the black population of South Africa was infected. In 1953 the rate of active disease was measured to be 780 per 100 000 of the population of the northern and eastern parts of the country[7].

One of the worst TB epidemics in the world is witnessed in South Africa with disease rates more than double those observed in other developing countries and up to 60 times higher than those currently seen in the USA or Western Europe[8].

There are many factors which contributed to South Africa's TB epidemic. Among them are[7]:

- poor living conditions
- unjust laws that restricted legal movement and dangerous working environments
- the practice of banishing those with the disease to their original homes
- poor health service provision in both city and country
- High HIV prevalence in the country.

The Eastern Cape Province borders the Indian Ocean to the east, the Western Cape to the south, KwaZulu-Natal to the north – east and Lesotho and Free State to the North. The province is home to an estimated 7 million people (15% of the South African population). In the year 2000, it notified 24 057 cases of pulmonary tuberculosis (PTB) which was 20% of national total. During the same year, the reported incidence of smear – positive PTB was 222 per 100 000 with huge variations between localities[9].

A provincial breakdown of NTCP data on case finding shows that three provinces being KwaZulu-Natal, Eastern Cape and Western Cape have the highest incidence of TB cases. These provinces, together with the Northern Cape, also have TB incidences which are higher than the national average. The proportion of pulmonary new smear positive cases out of all pulmonary cases is an indicator which measures the extent to which the diagnosis and treatment of new smear positive patients is prioritized. Although sputum microscopy results

should be available on all patients with suspected PTB (i.e. bacteriological coverage should be 100%), a certain proportion of patients with PTB will be smear negative[10].

All provinces with the exception of the Eastern Cape and KwaZulu-Natal reached the current target of 50-70% set by the NTCP. The extremely low case detections rates for smear positive cases found in these provinces are likely to reflect ongoing reliance on chest X-rays rather than smear microscopy in the diagnosis of pulmonary TB, whilst the fall-off in the national figure since 2000 is likely to reflect both failure to rely on smear microscopy and the effect of the maturing human immunodeficiency virus (HIV) epidemic[10].

Within the Department of Health in South Africa, TB has been identified as one of the priority areas. Therefore additional information on the effectiveness of the TB control and the impact on TB epidemiology in South Africa is critical for planning and management purposes. This study intends to describe the operation of the TB program in the Eastern Cape in reducing TB mortality and giving rise to high cure rates which was never assessed. The findings of the study provide insight on the TB treatment outcomes and thus on some aspects of the evaluation of the TB control programme. Identification of factors associated with the high treatment failure rates, which will assist the Eastern Cape Health Department to make adjustments in the programme in order to reduce the high TB treatment failures. Again this study intends to describe human resources and skills for TB- control in the Eastern Cape; attempts to quantify the human resource gaps; and the main constraints related to human resources, their reasons and possible solutions.

CHAPTER 2

LITERATURE REVIEW

2.1 Introduction

The national South African burden of tuberculosis (TB) and the rate per population are among the worst recorded in the world. South Africa has been in the top seven of all high burden countries (HBC) with more than 300, 000 cases per annum, only surpassed by numbers from several highly populated countries such as India, China, Indonesia, Nigeria, Bangladesh and Pakistan.[11] TB is eminently treatable, and the epidemic can be controlled despite the very high morbidity rates and significant mortality. A good national tuberculosis control programme (NTCP) should focus primarily on the early identification of cases and immediate and unfailing treatment with appropriate drugs.[12]

World Health Organization (WHO) reports that infection with the human immunodeficiency virus (HIV) is the main reason for failure to meet TB control targets in regions with high HIV prevalence, and this is driving the TB epidemic worldwide. However, other risk factors have contributed toward the persistent increase in the burden of TB in developing countries. In some countries political strife and war have displaced communities, putting them at increased risk of acquiring TB, and have weakened governments' ability to adequately address health issues. Lack of political commitment from government for TB control programme, lack of resources to effectively manage and deliver healthcare, and poverty have been reported as reasons for failing TB control programme initiatives in other countries.[13]

TB control programme aims to reduce mortality and morbidity due to tuberculosis, while preventing the development of drug resistance. The proportion of cases with a successful treatment outcome is therefore a key indicator to assess the effectiveness of the national tuberculosis control programme.[14] However; treatment completion is often delayed or unsuccessful because it requires that patients adhere to taking medication for at least 6 months.[15]

2.2 Directly Observed Treatment, Short-course (DOTS) and Global strategy,

World Health Organization declared tuberculosis in 1993 a global emergency and developed a five-point strategy known as Directly Observed Treatment, Short-course (DOTS) in order to combat the increasing incidence of the disease. The main aims of the strategy were to achieve the desired control objectives being to reduce mortality and morbidity; reduce transmission; and decrease the emergence of drugs resistant strains. The World Bank has lauded DOTS as one of the most cost-effective measures in controlling the disease.[16] [17] The strategy had improved worldwide cure rates, but there are situations in which the implementation of DOTS programmes was difficult. This was true among refugee and displaced populations and in areas of civil conflict.[18]

The Millennium Development Goals (MDG) for TB call for halting and beginning to reverse the incidence of TB by 2015, while the Stop TB Partnership goals call for halving prevalence and death rates by 2015 relative to 1990 rates. These goals are thought to be achievable if at least 70 percent of new infectious (smear-positive) cases worldwide are detected and at least 85 percent of those cases are treated successfully.[19]

The strategy is underpinned on the following five components that guide its successful implementation: [16, 17, 20 – 22]

1. Obtaining sustained political commitment from the authorities. This commitment takes the forms of policy, advocacy, human resource, financing etc that are vital for the program implementation
2. Guaranteed accessibility to quality assured tuberculosis sputum microscopy for case detection
3. Standardized short course chemotherapy for all cases of TB under DOTS
4. Uninterrupted supply of quality assured drugs with reliable procurement and distribution systems
5. Proper recording and reporting systems, thus enabling individual patient outcome assessment and overall program performance.

These principles inform the National NTCP's that are implementing DOTS and ensure proper detection, diagnosis and treatment of TB cases. Individual countries could modify the implementation process according to their specific country circumstances so long as they adhere to the general guiding principles and technical quality.

Only 187 of 193 WHO member states with high level population coverage have adopted DOTS strategy: WHO estimates that 89 percent of the world's population was living in areas implementing DOTS by the end of 2005. While such administrative data do not necessarily reflect the proportion of all tuberculosis cases detected or the realities of patient access to care in developing countries, DOTS remains at the policy level one of the most widely-implemented and longest-running global health interventions in history. Given that DOTS will likely continue to occupy a central place in global tuberculosis control efforts in coming years, the question of what DOTS has or has not accomplished over the past 15 years is a central technical question; it is also critical to global health transparency and accountability.[23, 24]

Most countries have reported some encouraging results in controlling the TB epidemic and demonstrated significant successes in implementing the DOTS strategy.[17, 25] However, much still remains to be accomplished if the epidemic is to be controlled. In the face of dwindling resources particularly in the high burden countries where the TB case load is outstripping the available resources, this issue has taken center stage as a priority public health concern.[6,26, 27,

Effective community participation is one such component that is very vital for a successful implementation of the DOTS strategy.[23, 28, 29] Therefore it is imperative to explore various models aimed at successfully integrating the community resources into the TB control program. This is an elusive ideal; and no wonder, the implementation processes have not been without failures. However, these challenges should serve as learning avenues through which best practice models could be drawn in the effort to harness the community's multi-sectoral strengths in combating the disease. [26, 27]

2.2.1 DOTS classification

When a country is considered to be implementing the DOTS strategy, the country should have a national TB control policy based on the WHO recommendations, which complies with the technical elements of the strategy, and reports on notifications and treatment outcomes from DOTS areas. The country is also classified as implementing DOTS, if DOTS is implemented only in some districts (or equivalent administrative units) on the initiative of local authorities, but endorsed by national authorities. If a country reports that DOTS was newly implemented during the past year, so that the results of cohort analysis are not yet available, it is also classified as implementing DOTS, provided that case notifications from DOTS areas are supplied. DOTS coverage within a country is calculated as the fraction of the population living in administrative units that provide all elements of the DOTS strategy. [30]

Full DOTS coverage in a given country does not mean that all health care providers in that country follow the DOTS strategy, but only that all governmental health services can provide it. Furthermore, in some countries, only TB specialized clinics actually provide DOTS, leaving out a range of facilities including both outpatient and hospital primary health care services. An analysis in nine HBC's with low DOTS detection rates demonstrated that the relationship between DOTS coverage and the detection rate under DOTS is below the expected ratio that would allow countries to reach the 70% case detection target for 100% DOTS coverage.[25]

More than 180 countries had been helped by WHO to implement DOTS. 14 years of data have revealed the limitations of the program despite its successes. Globally, only 45% of the estimated cases of active TB were treated under DOTS in 2003. This is partly because DOTS was originally aimed at patients whose smears test positive; those with extra-pulmonary or smear-negative TB (i.e., half of patients) miss inclusion in treatment programs. Although DOTS has now been expanded to include some of these people, "low-priority" patients such as those with chronic TB or multi drug-resistant (MDR) TB still fall outside the program's recommendations for treatment priority. [25]

DOTS is widely accepted and practiced, with some TB high-burden countries achieving almost full coverage of their populations. DOTS is equally effective in curing TB patients with HIV co-infection and hence, its importance in the era of the HIV/AIDS epidemic. [25]

2.3 Outcome of Tuberculosis treatment

The goal of TB treatment is not only to cure the disease, but also prevent its transmission and the development of drug resistance. This can be achieved with short course chemotherapy (SCC) regimens.[6] Detection of TB disease as early as possible and to ensure that those diagnosed complete their treatment and get cured are the key elements in TB control. WHO target for treatment success is 85% of all detected smear-positive cases. Even where free medication is available, many patients are not successfully treated. Death (while on treatment or before start of treatment) and loss to follow-up are the main reasons for non-success. Incomplete treatment may result in prolonged excretion of bacteria that may also acquire drug resistance, cause transmission of disease and lead to increased morbidity and mortality.[28]

It is essential to monitor the outcome of treatment in order to evaluate the effectiveness of the intervention. Recommendations on how to evaluate treatment outcomes using standardized categories have been issued by the WHO in conjunction with IUATLD. An agreed set of six possible and mutually exclusive categories of treatment outcome in high-incidence countries are being used. These categories are cured; treatment completed, treatment failure, death, treatments interrupted, and transfer out. Ideally, treatment outcomes in all patients should be routinely monitored by the epidemiological surveillance system. This would make it possible to recognize and amend system failures before the incidence and proportion of resistant isolates rise.[29]

High morbidity and mortality rates are reported after treatment default, but estimates differ. Mortality after default was 4% in Singapore and 27% in Mexico. Failure after default was 28% in South Africa and 54% in the USA. All studies, except the study from Mexico were carried out in urban settings and follow-up time differed greatly between studies. [31]

Treatment outcomes were excellent and improved over time following the implementation of DOTS in China, There were about 4.1–4.9 million active tuberculosis patients (367/100 000 population) in 2000, of which 1.33–1.68 million (122/100 000 population) were smear-positive. Overall, the cure rate was 95% and 90% for new and previously treated (relapse and other re-treatment) cases, respectively. The cure rate for both new and previously treated cases

improved, while the treatment failure rate and death rate both decreased from the first to the sixth year of DOTS implementation. The percentage of treatment failure among new cases declined from 2.8% to 0.5% over the first six to eight years of DOTS implementation, but this percentage declined from 2.8% to 1.2% during the first year alone. [29]

2.4 Factors that contribute to Treatment Failures

Tuberculosis is a stigmatized disease and the lack of support from health workers, family members and friends, as well as the length of the treatment period; all contribute to the temptation to discontinue TB therapy. Many studies showed that the reasons for non-adherence to TB treatment are multifaceted, ranging from the personalities of patients to their social and economic environment. [32] As such, ensuring successful treatment of completion might require addressing multiple factors beyond simple supervision of drug intake. [33]

The global caseload is almost certainly rising, driven upwards in sub-Saharan Africa by the spread of HIV/AIDS and in Eastern Europe by the deterioration of health in general and of TB control in particular. One of the reasons for the persistent burden of tuberculosis is a failure to address the principal risk factors. [2]

WHO has been promoting the integration of NTCP's within general health services in order to increase access to effective TB care. While integration has gone a long way to increase access to TB services as expected, the generally limited coverage of public health services has continued to impede accelerated access to TB control services. This has partly been due to inadequate health service infrastructure, insufficient decentralization of both diagnostic and treatment services and inadequate human, material and financial resources. [27, 34]

Today, the reality however is that, many studies have shown that decentralizing the provision of TB care beyond health facilities and into the community can contribute to effective NTCP performance. [34] In all the studies, the intervention is the introduction of trained and supervised members of a community organization in supporting tuberculosis patients and directly observing their treatment. Implementing this intervention involves addressing the following issues:[27, 34]

I. how to identify and mobilize the appropriate community organization;
II. how to develop links between general health services, NTCP and the community organization;
III. how to train and supervise community members;
IV. how to develop and introduce recording and reporting systems in the community,
V. how to distribute anti-tuberculosis drugs and prevent potential abuse (particularly of rifampicin);
VI. how NTCP's can face the challenge of extending their current management responsibilities when harnessing community contribution to TB care.

Community participation in TB treatment delivery, as part of routine NTCP activities has the potential to overcome at least some of these limitations imposed by an inadequate health service infrastructure, an insufficient level of decentralization to ensure adequate access to health care, and a paucity of locally available human and financial resources. [35]

Globally, one of the major barriers to effective TB control is defaulting on TB treatment and this poses serious challenge to TB control programmes. [6] Nine of the world's 22 TB high-burden countries are in the African region and the treatment success rate in this region is said to have remained more or less unchanged at around 70% since 1998, considerably short of the 85% target. Treatment default is one of the factors blamed for the low treatment success rate in the region. [38]

South Africa is one of the nine TB high-burden countries in Africa and the 2003 statistics for the country gave a treatment success rate of 67% among new cases and 52% among re-treatment cases, and a treatment default rate of 12%.[39] TB treatment default results in inadequate treatment of the disease, which is a major factor in the development of multi-drug resistant TB (MDR-TB). [40, 41] In 1999, MDR-TB in South Africa was estimated at 1% among new TB cases and at 4% among re-treatment TB cases. [34] The figures rose to 1.8% among new cases and 6.7% among re-treatment cases in 2004, as reported by the WHO. [38]

2.5 National Tuberculosis Control Programme (NTCP) and Targets for TB control Programme

The National Tuberculosis Control Program (NTCP) or its equivalent is organized in many countries to set the policy and ensure the prevention and proper management of tuberculosis cases.[36] For effective control of Tuberculosis, certain key outcomes have been identified as crucial for programme effectiveness and success. Specific targets have been set for these outcome measures; and NTCP's are to strive to achieve them if they are to be successful in controlling TB in their respective countries.[16, 17, 20 – 22, 25, 37]

The targets for TB control in South Africa are to:[21]

1. achieve sputum smear conversion rates of at least 85% among new sputum smear positive patients and 80% among re-treatment cases at the end of the intensive phase of treatment[15, 17, 21, 36]
2. cure 85% of the sputum smear-positive TB cases detected by the programme. The achievement of high cure rates is the highest priority of any NTCP since it is expected to give rise to the following results that are fundamental for successful TB control.[6,7,10,12]
    - Rapid decrease in the TB mortality, prevalence and hence transmission in the community
    - Gradual decrease in the incidence due to decreased transmission rates
    - Due to better cures rates (and by inference treatment completion rates) the emergence of drug resistance in expected to decrease
3. detect 70 % of existing cases of the sputum smear positive cases in the population. This expansion is expected to capture most of the infectious cases in the population and decrease the disease burden. However, it must be emphasized that only when the cure rates are satisfactory, should efforts be made to expand the coverage.[16, 20, 22] Failure to observe this would lead to more sputum positive treatment failures and increased transmission of drug resistant strains and hence the disastrous consequences that would render the epidemic to become untreatable.[16, 20]
4. ensure accurate measurement and evaluation of programme performance.[21]

2.6 The Eastern Cape Tuberculosis Control Programme

The EC Tuberculosis Control Programme (NTP) has a similar administrative structure to other Provincial Government departments in South Africa and is also supported by National Department of Health. TB treatment and control activities in the province follow the South African NTP guidelines.[21] The government of the Eastern Cape is politically committed to the programme and provides an annual budgetary allocation of funds to the TB directorate and districts within the province. The central TB unit (TB directorate) coordinates the programme at a provincial level, and TB officers have key roles in evaluating the programme. District TB officers are responsible for registration and case holding as well as coordination with other programmes, especially primary health care. Some hospitals under South African National Tuberculosis Association (SANTA) participate as treatment centers within the NTCP. These facilities follow NTCP guidelines for diagnosis and treatment of TB patients, and fulfill their recording and reporting requirements.

TB incidence has increased by more than 50% from 424 TB cases per 100,000 people in 2001 to 645 cases per 100,000 people in 2005. Three-quarters of South Africans with TB live in four of the country's 9 provinces, the Eastern Cape, Gauteng, KwaZulu-Natal and Western Cape provinces.[42] In the year 2000, Eastern Cape had notified 24 057 cases of PTB (20% of national total). During the same year, the reported incidence of smear – positive pulmonary tuberculosis (PTB) was 222 per 100 000 with huge variations between localities.[10]

There are several challenges, which affect the population of the Eastern Cape Province, which includes amongst other things unemployment. There are only 20.4% of people who are employed, 24.6% unemployed and 55% economically inactive population.

2.7 Relevance of the study

The IUATLD has played a pivotal role in the development of its model for the national tuberculosis program, a model generally applicable for health service delivery in low-income countries, which has been demonstrated to be feasible and sustainable. The WHO as the basis of their Global Tuberculosis Programme has adopted this model described by the World Bank as highly cost-effective. Tuberculosis control program may be considered to be a system with inputs, process, outputs and outcomes

The current global tuberculosis (TB) epidemic has pressured health care managers, particularly in developing countries, to seek for alternative, innovative ways of delivering effective treatment to the large number of TB patients diagnosed annually and better control the epidemic.

The Department of Health, South Africa, has introduced a comprehensive TB treatment programme that is endorsed by the WHO. The success of the TB program in the Eastern Cape in reducing mortality and giving rise to high cure rates have not been assessed. Finally the outcome of the study will provide the information necessary for the strengthening TB control programme for comprehensive interventions such as the roll out of antiretroviral (ARV) drugs and changing epidemiology as seen in emerging and re-emerging diseases. This study is aimed at influencing priority setting on the improvement of TB treatment outcomes and thus on some aspects of the evaluation of the TB control programme. And finally describing factors associated with the high treatment failure rates in order to assist the Eastern Cape Health Department to make adjustments in the programme such that high TB treatment failures can be reduced in the Province.

CHAPTER 3

AIMS AND OBJECTIVES

3.1 Introduction

Four of the countries with the highest global tuberculosis incidence rates are in the Southern Africa Development Community (SADC) region, and South Africa is one of them.[43] According to the World Health Organisation, South Africa remains one of the 22 countries worst affected by the tuberculosis epidemic and recently the country has been in the top seven of all high burden countries.[44, 45] Although tuberculosis treatment guidelines had been circulated for management of the disease at primary health care facilities, DOTS was the only best means of increasing compliance among TB drug-taking patients.

3.2 Aim of the study

The aim of the study was to evaluate the tuberculosis treatment outcomes as well as to identify factors that contribute to treatment failures in health districts of the Eastern Cape Province from 2003 to 2005.

3.3 Objectives of the study

3.3.1 Primary Objectives

To determine the TB treatment outcomes in different health districts of the Eastern Cape for period 2003 – 2005 against the National standards for TB control. The indicators which were used to determine the TB treatment outcomes in this study were as follows: Bacteriological Coverage, Smear Conversion rates, Cure rates, Treatment success rates, Defaulter rates, treatment failures, and Patients not evaluated.

3.3.2 Secondary Objectives

Determine the factors that contribute to TB treatment failures in the Eastern Cape Province. Focus was on Health System related factors with emphasis on input indicators, process indicators and output indicators for the TB Control programme including proper implementation of DOTS strategy.

CHAPTER 4

METHODOLOGY

The provision of accurate data and tools for surveillance, program management and supervision has become increasingly essential. The “Electronic TB Register” (ETR.Net) is a Microsoft.net–based computer software program, inspired on the WHO and IUATLD recording and reporting formats. Many of the features of ETR.Net are derived from the “Electronic TB Register” software, a TB surveillance project in southern Africa supported by USAID and Centers for Disease Control (CDC). It was developed to provide for more efficient and useful collection, compilation, and analysis of TB data on an ongoing basis. This software was chosen over the disease notification data surveillance system because it captures patient based information including the treatment outcomes of individual patients. This dataset is validated for accuracy and completeness of the data at a district level before its forwarded to the Provincial and National levels.

TB Surveillance data in the ETR.net database included the following non-identifiable information on persons with newly reported cases of PTB and re-treatment patients: dates of disease onset and treatment initiation; methods of diagnosis; treatment outcomes; and selected demographic characteristics. Standardized treatment outcomes of treatment completion, default, treatment failures, and patient not evaluated were assessed on the basis of the TB case definition and treatment outcome classification format outlined in DOTS guidelines issued by WHO. Denominator data to calculate rates were obtained from the Statistic South Africa, an office which provides National Census of South Africa. Logistic regression was employed to investigate factors associated with treatment outcomes using the STATA 8.2 software.

By law, TB is a reportable disease in South Africa. A standard notification form is completed by the treating physician or primary health care nurse and then entered into an electronic database when a patient receives a TB diagnosis in any TB treatment facility. In the Eastern Cape Province, the national TB surveillance database contains nonidentified information on cases from all 7 administrative health districts (25 LSA’s). During 2003--2005, a total of 152 336 extrapulmonary and pulmonary cases were registered in the database and these cases were used for the descriptive analysis.

The IUATLD has played a pivotal role in the development of its model for the national tuberculosis program, a model generally applicable for health service delivery in low-income countries, which has been demonstrated to be feasible and sustainable. The WHO as the basis of their Global Tuberculosis Programme has adopted this model described by the World Bank as highly cost-effective. Tuberculosis control program may be considered to be a system with inputs, process, outputs and outcomes therefore figure 4.1 below illustrates a management model, which focuses on these four main aspects. Finally, a program review is an important management tool for promotion of the program within the health services; therefore, involvement of key persons from within the health services is important.

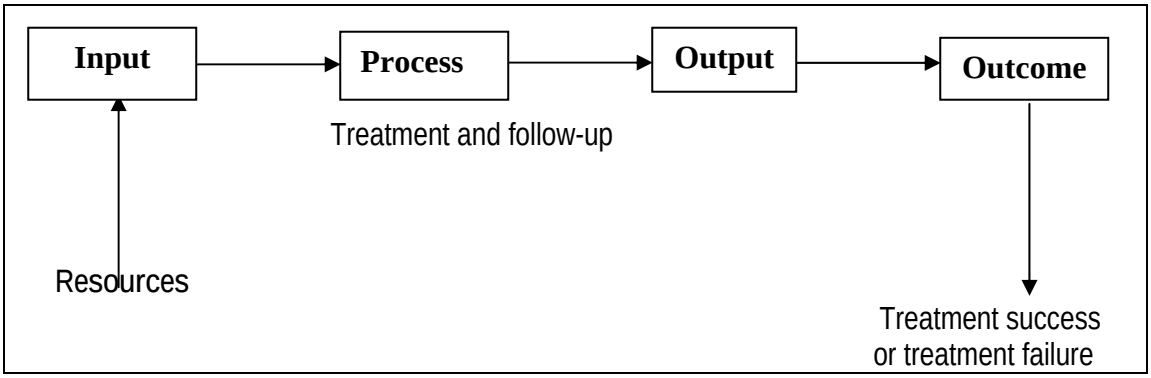


Figure 4.1: Management model for tuberculosis control activities

4.1 Definition of terms:

- Treatment outcomes[7, 21, 38, 39, 47]

  The treatment outcomes of interest in this study were:

i. Smear Conversion rates at 2 months, - Percentage of new smear positive PTB cases who are smear negative after two months of anti-TB treatment and are therefore no longer infectious.

ii. Smear Conversion rates at 3 months, - Percentage of new smear positive PTB cases who are smear negative after three months of anti-TB treatment and are therefore no longer infectious.

iii. Bacteriological coverage – measures the percentage of pulmonary tuberculosis patients on whom bacteriological investigation was requested at diagnosis.

iv. TB Cure rates – percentage of TB patient who are smear-negative at/or one month prior to, the completion of treatment and on at least one previous occasion.

v. Treatment success rates – percentage of patients who are cured plus those who complete treatment but without laboratory proof of cure, of new smear positive patients

vi. Defaulter rates – percentage of TB patients, whose treatment was interrupted for two months or more.

vii. Treatment failures rates – percentage of TB patients who, while on treatment, remained or became again smear-positive five months or later after commencing treatment. It is also a patient who was initially smear-negative before starting treatment and became smear-positive after the second month of treatment.

viii. Patients not evaluated- patients with information on treatment outcome not available.

TB case definitions[21, 38, 39, 44, 46, 47]

I. New case: A patient who has never had treatment for TB or who has taken anti-tuberculosis drugs for less than four weeks.

II. Relapse: A patient who has been declared cured of any form of TB in the past, after one full course of chemotherapy, and has become sputum smear-positive.

III. Pulmonary TB, smear-positive: A patient with at least two sputum specimens which were positive for acid-fast bacilli (AFB) by microscopy, or a patient with only one sputum specimen which was positive for AFB by microscopy, and chest radiographic abnormalities consistent with active pulmonary TB, or a patient with only one sputum specimen which was positive for AFB by microscopy, and a culture positive for M. tuberculosis.

IV. Pulmonary TB, smear-negative: A patient with symptoms suggestive of TB, with at least two sputum specimens which were negative for AFB by microscopy, and with chest radiographic abnormalities consistent with active pulmonary TB (including interstitial or military abnormal images), or a patient with at least two sputum specimens negative for AFB by microscopy, and a culture positive for M. tuberculosis, or a patient with two sets of at least two sputum specimens taken at least two weeks apart, and which were negative for AFB by microscopy, and radiographic abnormalities consistent with pulmonary TB and lack of clinical response to one week of broad-spectrum antibiotic.

V. Pulmonary TB smear positive re-treatment cases: A patient who completed at least one month of treatment and returned after at least two months' interruption of treatment.

VI. Extrapulmonary TB: A patient with TB of organs other than the lungs. Pleurisy and mediastinal lymphadenopathy are classified as extrapulmonary TB.

- Inputs: In this study, inputs refer to the resources provided by the Government in the commitment for the implementation of the DOTS strategy, and these includes:
  i. The availability of competent, well trained and well resourced health workers for the effective management of all aspect of TB control at the facility level, district and provincial level.
  ii. Facilities, equipment and tools essential for the management of TB.
  iii. Anti-TB drugs and a system for monitoring monthly drug supply
- Processes

  For the purpose of this study, processes refer to all the systems and activities undertaken to implement and support the implementation TB treatment in TB patients. This includes

  i. Overseeing of TB treatment DOTS supporters – the average monthly reports made on activities of TB DOTS supporter, logistical support services in place to facilitate the supervision of DOTS supporters

ii. Capacity to follow up patients who default from treatment – health education and alternative follow-up recommendations when medications are refused or not tolerated.

iii. Supervisory visits – frequency of supervisory visits made to the health care facilities by the provincial/district TB coordinators and to the DOTS supporters by the clinic staff.

iv. Referral systems between the health-care facilities in a district and between the districts – Existence of a system for patient referrals between health care facilities in a district and between the districts.

4.2 The study setting

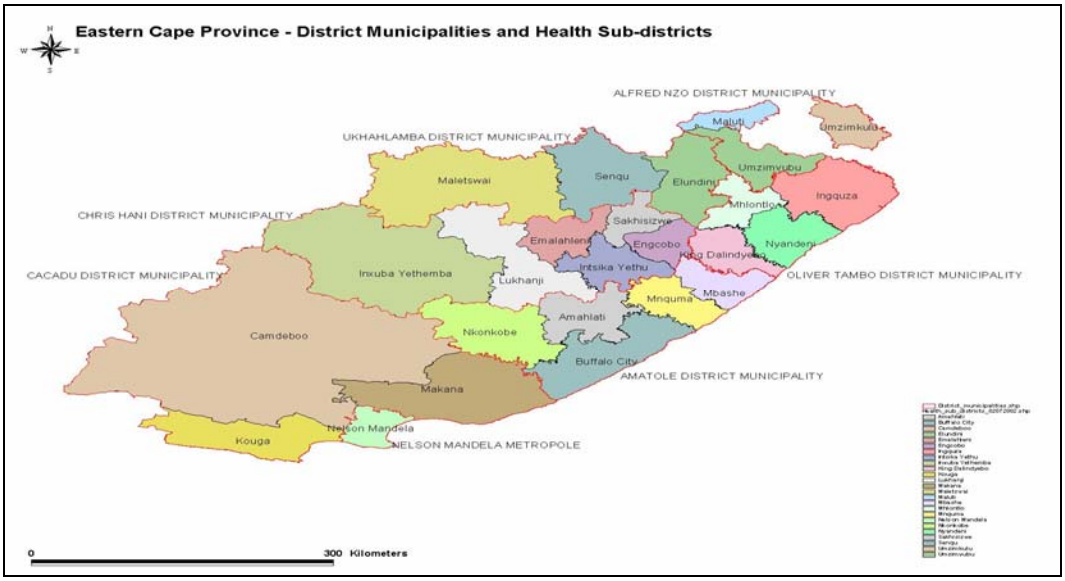


Figure 4.2: Map showing the geographical boundaries of the Eastern Cape Province

The Eastern Cape Province has an area size of 169, 580 km^2, which constitutes 13.9% of the total land area of South Africa. The Province is bordered by the Indian Ocean in the east, the Western Cape in the south, KwaZulu-Natal in the north-east and Lesotho and Free State in the North. The Eastern Cape Province has just below *7* million people *(6 906 200)* which is nearly 14.4% of the population of South Africa and has the 3rd largest population in the country. The Province is divided into 6 health districts and one metropolitan municipality. These 6 health districts and one metro are further divided into 25 sub-districts. The study covered all the 6 districts and 1 metropolitan municipality.

4.3 Study design

This study is a descriptive study and the methodology employed in this evaluative study took cognizance of the main approaches used globally (World Health Organization and the International Union Against Tuberculosis and Lung Disease) to assess the performance and quality of Tuberculosis Control Programs.[6] The study has been done in two phases; the first phase being a descriptive study comparing treatment outcomes in health districts and the second phase which is a further analysis to determine factors that contribute to treatment failures in the Eastern Cape Province looking at Health System related factors with emphasis to input indicators, process indicators and output indicators for the TB Control programme including proper implementation of DOTS strategy. Also describe programmatic problems with regard to human resources, patient management and management of TB Control programme in the Eastern Cape in an attempt to quantify the human resource gaps; and the main constraints related to human resources, their reasons and possible solutions.

4.3.1 Phase one: Record review of ETR data

Cure rates and treatment success rates for the new smear positives, as well as treatment completion rates for all TB cases are some of the crucial indicators that are used globally in evaluating the effectiveness of TB Control Programs. However, other important indicators which are not routinely used in this regard (as measures of effectiveness), but often constitute a vital evidence based on the performance of such programs have been included in this study to give a more comprehensive picture. These include but are not limited to bacteriological coverage, smear conversion rates, as well as the proportions of patients not evaluated.

In the phase one of data analysis, the Electronic Tuberculosis Register was used to generate program reports for Eastern Cape Province. The data was then manually extracted from the ETR reports and entered in Microsoft Excel software were a trend analysis over the three year period (2003-2005) was done using the STATA 8.2 software.

4.3.1.1. Inclusion criteria

All TB patient records captured in ETR.net program for the period 2003 – 2005 were eligible for inclusion in the sample.

4.3.1.2 Exclusion criteria

- All TB patient records which were captured in the National Notification system were excluded in the sample because the system did not have features contained in ETR.net for monitoring of the TB control programme.

The variables of interest that were taken into consideration in this phase of the study were as follows:

- Bacteriological coverage
- Smear conversion rates
- Cure rates
- Treatment success rates
- Defaulter rates
- Patients not evaluated

4.3.2 Phase two: Administration of questionnaires

Multistage sampling technique was used to select 252 from the 690 primary health care facilities (PHC's) for participation in the questionnaire. The Eastern Cape provincial population estimates for the drainage areas of each of the health districts was used to calculate on the basis of probability proportional to size (PPS), the proportion in the sample, of primary health care facilities to be studied

4.3.2.1 Inclusion criteria

The criterion that was applied in identifying sites eligible for inclusion in the study was that the facility had to be one that routinely provides TB services.

The focus of questions in the questionnaire was on Health System related factors that contribute to treatment failure and performance of DOTS strategy. Responses to the questionnaire provided data that was used for describing perceived programmatic problems with regard to human resources, patient management and management of TB Control programme in the Eastern Cape.

Data on TB services provided by facilities was collected through a questionnaire and variables of interest that were taken into consideration in this phase of the study were as follows:

- Availability of human resource
- Capacity of health care workers and TB patients including communities
- Patient management
- Information dissemination
- Policy guidance and protocols

Data collection questionnaires were developed and approved by the study supervisor and the University of Pretoria Ethics committee. The questionnaire was piloted at Walmer 14th Avenue Clinic in Port Elizabeth during the month of October 2006, after getting the approval from the Directorate Epidemiological Research and Surveillance Management through the office of the Superintendent General – Health. The purpose of the pilot was to determine the feasibility of the methodology of the study with regard to questions contained in the data collection tool. It was then discovered that the collection tool was feasible and needed no modifications, see Annexure 1 and 2.

4.4 Ethical Considerations

The research proposal was submitted to the University of Pretoria Ethics Committee. Ethical approval was granted during the month of April 2006, see annexure 3.

Permission to use the Eastern Cape Provincial TB data and administer questionnaires in the public health facilities on health personnel providing TB care to patients was also requested in writing from the Superintendent General of the Department of Health and District Health Managers of the entire 7 districts within the province. Permission was granted to conduct the study by all relevant managers within the province, see annexure 5 to 12.

TB is strongly associated with HIV/AIDS because of the perceived mode of transmission, which stigmatizes and discriminates patients. TB becomes difficult to discuss in public. The names of the health officials who responded to the questionnaires were not collected but only the level of occupation. Confidentiality on information for each study participants was maintained and respondents were informed that this information would not be made available to persons outside the study team. Respondents were further assured that no persons-identifiers would be used for publication.

4.4.1 Amendments to the protocol

A request to have amendments on the protocol was submitted to the University of Pretoria Ethics committee during the month of January 2007. Amendments were with regard to as follows:

i. The period of the study changing from 2000 – 2003 to 2003 – 2005.
ii. The sample size changed to focus on only the public health facilities.

The amendments were then approved by the committee, see annexure 4.

4.5 Data collection and management

4.5.1 Phase one: Record review for ETR data

The routinely collected ETR TB data was received from the Eastern Cape provincial Department of Health, TB Directorate as a secondary data. This data was extracted from the Electronic TB Register (ETR) and then manually extracted from the ETR reports and exported into Microsoft Excel software were a trend analysis over the three year period (2003-2005) was done using the STATA software.

4.5.2 Phase two: Administration of questionnaires

The principal investigator collected data on TB services from a staff member in charge of each of the TB services in the primary health facilities which were sampled using a designed questionnaire. The process was directly interactive with the registered nurses who were directly involved in the TB service of the health facilities. Data collection was done during the visits to the health facilities for monitoring of the HIV/Syphilis survey and during planned meetings with health care providers to discuss disease surveillance activities. Quality control of data collection was done via 10% re-examination of the questionnaires by the principal investigator. Double data entries of the collected data were done using Epi data software but the analysis of the data was done using STATA 8.2 for Windows and Epi Analysis software's.

4.6 Statistical methods for data analysis

The following statistical methods of data analysis were used:

1. Continuous variables were analyzed using summary statistics such as the mean, median, standard deviation, the coefficient of variation, box and whisker plots, graphs, and one-sample t-tests
2. Chi-square tests of association was used to assess the strength of association between variables

3. Binary and multinomial logistic regression analyses were used to identify influential variables to treatment outcomes and factors that affect implementation of the programme.
4. Sensitivity and specificity tests as well as ROC (receiver operating characteristic) plots were done to assess the reliability of the data, and the classification table and the Hosmer-Lemeshow goodness of fit test was used to assess the adequacy of the fitted logistic regression model.

4.7 Limitation of the study - Part of methodology

I. The study is reliant on routinely collected TB data (secondary data) which was not originally designed for a study purpose, hence some data elements required for the study, may be found lacking
II. Routinely collected data is likely to be incomplete particularly in health care facilities that have staff shortages.
III. The findings of the study cannot be generalizable to the general population of the EC province due to the selection bias of using data obtained from health facilities only.
IV. This study is only confined to the users of the public health facilities in the Eastern Cape Province. The study results will thus be biased towards the findings relevant to lower income and rural communities, but not to the users of the provincial or regional, private sector hospitals and public sector tertiary hospital care facilities in the province.
V. The fitted logistic regression model has an overall percentage of correct classification that is less than 75%. It is also poorly specific. According to the Hosmer-Lemeshow goodness of fit test, the fitted model is not reliable. Hence, results from this study should be taken with caution.

CHAPTER 5

RESULTS

5.1 Introduction

Table 5.1: The number of TB cases reported and percentage of TB cases per district, 2003- 2005

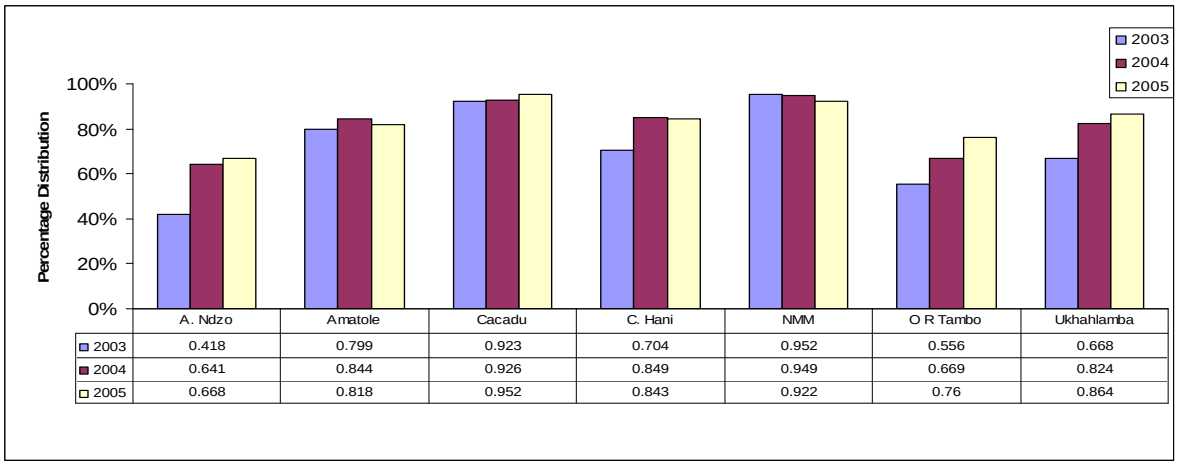
Health district	Number of TB cases reported in 2003 (% of cases reported that year)	Number of TB cases reported in 2004 (% of reported cases that year)	Number of TB cases reported in 2005 (% of cases reported that year)	Total cases
Alfred Ndzo	1909 (7.0%)	5172 (8.6%)	5217 (8.0%)	12298 (8.0%)
Amatole	5820 (21.4%)	14258 (23.7%)	15986 (24.7%)	36064 (23.7%)
Cacadu	2541 (9.3%)	5231 (8.7%)	6147 (9.5%)	13919 (9.1%)
Chris Hani	2528 (9.3%)	4715 (7.8%)	5206 (8.0%)	12449 (8.2%)
Nelson Mandela Metro	7531 (27.6%)	15041 (25.0%)	16499 (25.5%)	39071 (25.6%)
O. R Tambo	5890 (21.6%)	13551 (22.5%)	13515 (20.9%)	32956 (21.6%)
Ukhahlamba	1035 (3.8%)	2298 (3.8%)	2246(3.5%)	5579 (3.7%)
TOTAL	27257 (100%)	60374 (100%)	64828 (100%)	152336 (100%)

(%) is the percentage of all the provincial TB cases reported in the ETR database for that particular year of reporting.

5.2 Tuberculosis treatment outcomes

5.2.1 Bacteriological Coverage

In this study it was found that the provincial bacteriological coverage rose steadily from 2003 to 2005 but never reached the national target of 90%. Respectively, the bacteriological coverage increased from 71.7%, 81.5% and finally to 83.2% for the years 2003, 2004, and 2005. The bacteriological coverage rate has been above 90% in only two districts of the Eastern Cape Province being Cacadu and Nelson Mandela Metro. The other districts never reached 90% since 2003.



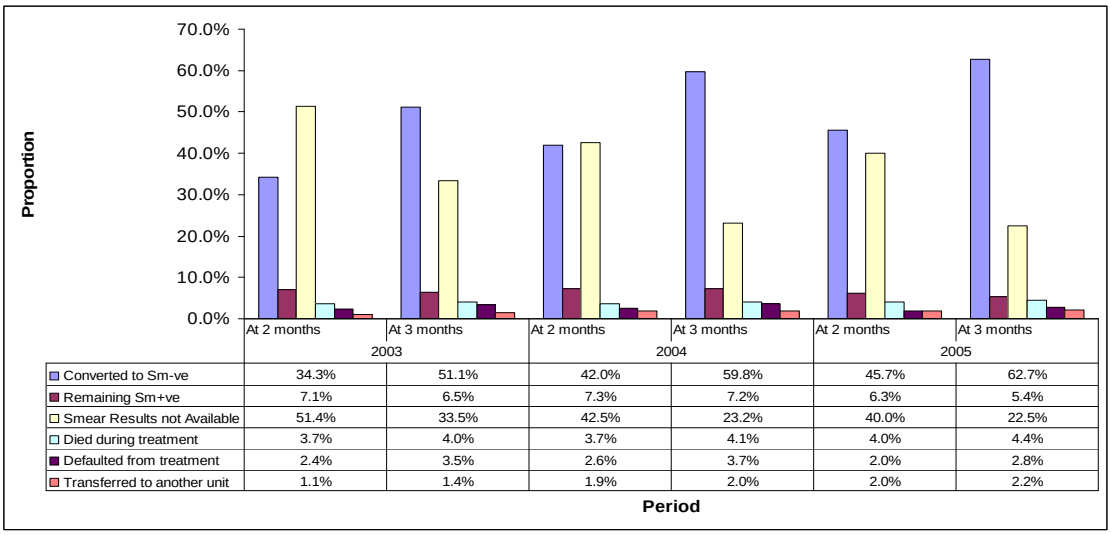
	A. Ndzo	Amatole	Cacadu	C. Hani	NMM	O R Tambo	Ukhahlamba
2003	0.418	0.799	0.923	0.704	0.952	0.556	0.668
2004	0.641	0.844	0.926	0.849	0.949	0.669	0.824
2005	0.668	0.818	0.952	0.843	0.922	0.76	0.864

Figure 5.1: Bacteriological Coverage per District in Eastern Cape Province, 2003 - 2005

5.2.2 Smear conversion rates

In the current study, the provincial proportion of smear conversions for new TB cases increased at 2 months from 34.3% in 2003 to 45.7 in 2005. A similar increase was witnessed at 3 months from 51.1% in 2003 to 62.7 in 2005. The percentage of patients who remained smear positive at 2 months decreased from 7.1% in 2003 to 6.3% in 2005. Again at 3 months these decreased from 6.5% in 2003 to 5.4% in 2005. The percentage of patients with smear results not available at 2 months was 51.4% in 2003 then decreased to 42.5% and 40.0% for the years 2004 and 2005 respectively. At the end of treatment period, large proportion patients did not have their treatment outcomes evaluated.

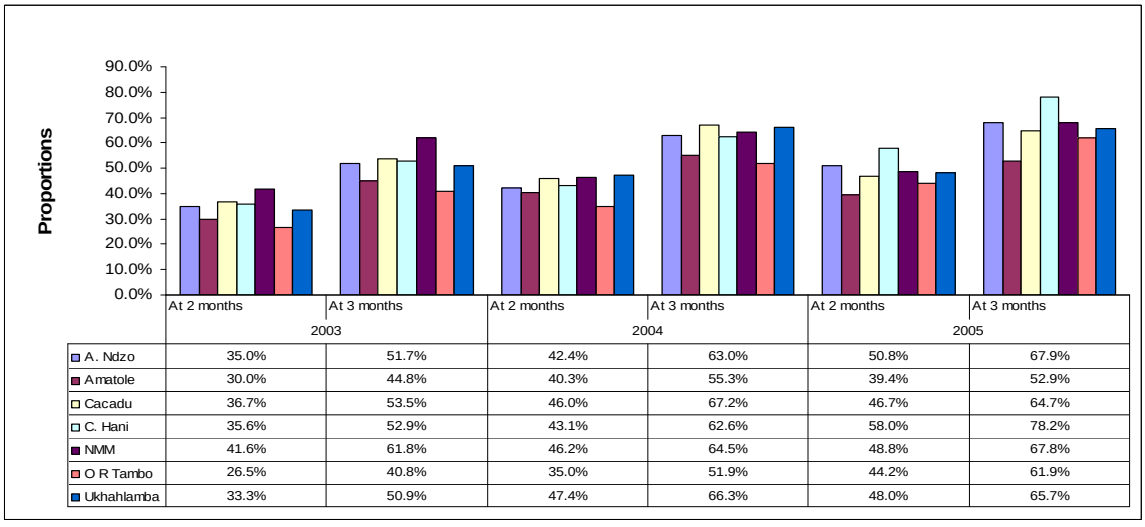
The proportion of TB patients who died during treatment at 2 months was 3.7% in 2003 and 2004 then increased to 4.0% in 2005. At 3 months, the proportion of TB patients who died during treatment increased from 4.0% 2003 to 4.4% in 2005. Patients who defaulted from treatment at 2 months accounted for 2.4% in 2003, 2.6% in 2004 then decreased to 2.0% in 2005. An increase in patients who were transferred to another unit was reported at both 2 months and 3 months in all the study period.



	At 2 months	At 3 months	At 2 months	At 3 months	At 2 months	At 3 months
	2003		2004		2005	
Converted to Sm-ve	34.3%	51.1%	42.0%	59.8%	45.7%	62.7%
Remaining Sm+ve	7.1%	6.5%	7.3%	7.2%	6.3%	5.4%
Smear Results not Available	51.4%	33.5%	42.5%	23.2%	40.0%	22.5%
Died during treatment	3.7%	4.0%	3.7%	4.1%	4.0%	4.4%
Defaulted from treatment	2.4%	3.5%	2.6%	3.7%	2.0%	2.8%
Transferred to another unit	1.1%	1.4%	1.9%	2.0%	2.0%	2.2%

Figure 5.2: Proportion of new TB cases smear conversion, Eastern Cape 2003 – 2005

From the figure 5.3 below, it is clear that the NMM performed well (became the highest, 41.6% at 2 months and 61.8% at 3 months) in 2003 as compared to 2004 and 2005 with regard to smear conversion rates. It is encouraging to note that Chris Hani has achieved the highest SCR in the Eastern Cape Province in 2005 but Amatole district has been the worst performing district. (Chris Hani district became the highest, 58.0% at 2 months and 78.2% at 3 months). The response to treatment should be monitored and microbiological examinations performed after the initial intensive phase of treatment, after 5 months and at the end of treatment.



	At 2 months	At 3 months	At 2 months	At 3 months	At 2 months	At 3 months
	2003		2004		2005	
A. Ndzo	35.0%	51.7%	42.4%	63.0%	50.8%	67.9%
Amatole	30.0%	44.8%	40.3%	55.3%	39.4%	52.9%
Cacadu	36.7%	53.5%	46.0%	67.2%	46.7%	64.7%
C. Hani	35.6%	52.9%	43.1%	62.6%	58.0%	78.2%
NMM	41.6%	61.8%	46.2%	64.5%	48.8%	67.8%
O R Tambo	26.5%	40.8%	35.0%	51.9%	44.2%	61.9%
Ukhahlamba	33.3%	50.9%	47.4%	66.3%	48.0%	65.7%

Figure 5.3: Proportion of new TB cases smear conversion per district, Eastern Cape 2003 - 2005

5.2.3 Cure rates

The cure rates for both new smear positive and re-treatment smear positive cases have not improved up to satisfactory level over the three-year study period. For new smear positive cases, the cure rates rose from 31.9% in 2003 to 39.7 in 2005 and re-treatment smear positive cases increased from 24.25 in 2003 to 29.4% in 2005.

The worst performing district in the Eastern Cape with regard to achieving better cure rates is Amatole district. The proportion of cured patients has been the lowest since 2003 to 2005. On average, Amatole district reached 30.4 as the highest in the study period. Chris Hani district had an increasing proportion of cured TB patients and is the only district which did not experience a decline in cure rates for the years 2003 – 2005. Other districts experienced a decrease in cure rates during the year 2005 in both new smear positive and re-treatment smear positive cases.

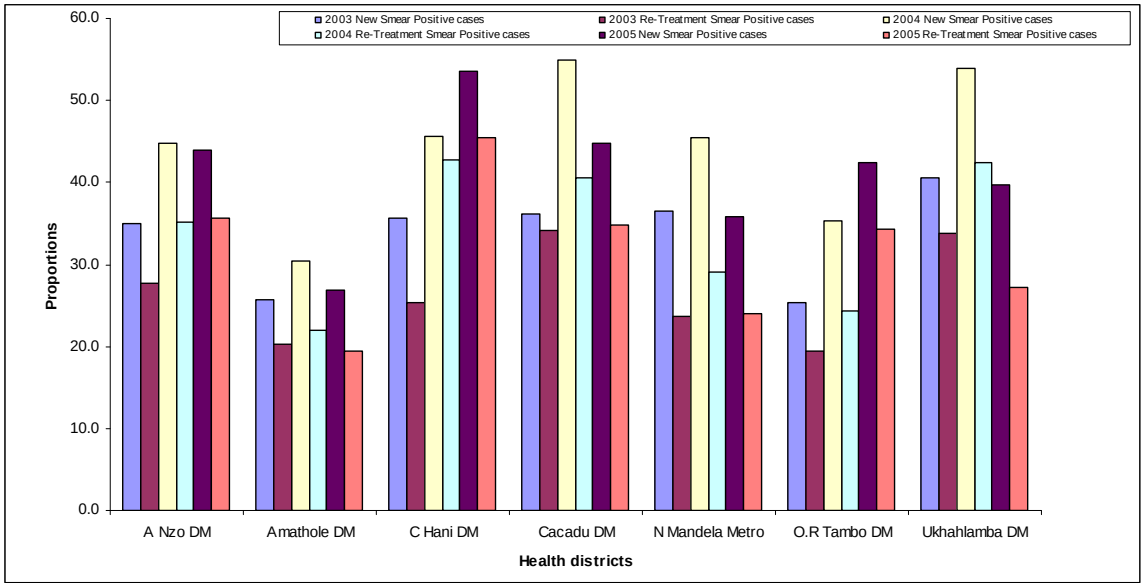


Figure 5.4: Cure rates for both New cases and Re-Treatment cases, per health district 2003 - 2005

5.2.4 Treatment success rates

Figure 5.5 below fairly explains that proportion of treatment success was high in 2004 for both new smear positive and re-treatment smear positive cases being 64% and 49.4% respectively. A drop in treatment success was noticed in both categories of smear positive cases for the year 2005.

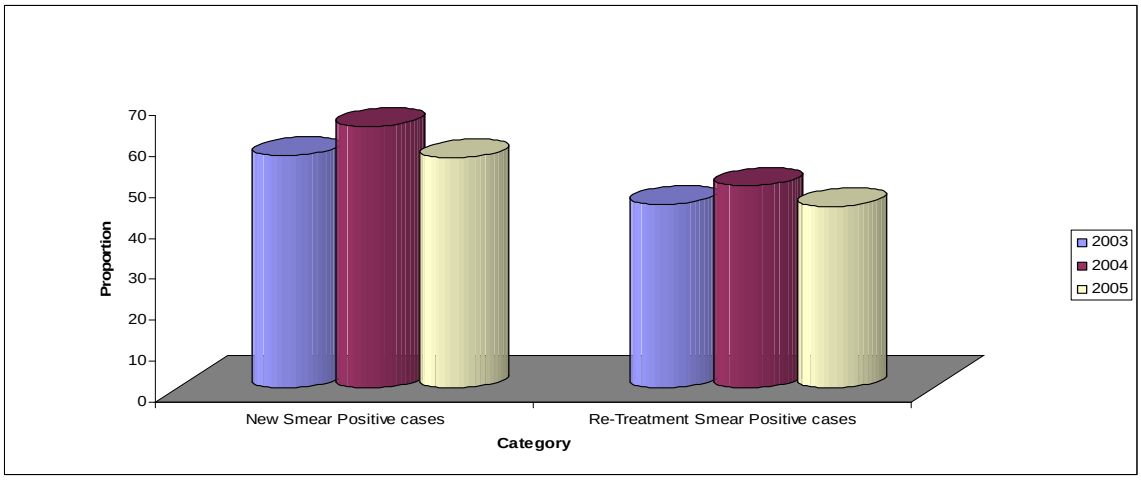


Figure 5.5: Proportion of treatment success in Eastern Cape, 2003 - 2005

The current study shows that, O.R Tambo district in the Eastern Cape performed very badly as compared to the other 6 districts during the year 2003 with regard to treatment success. There was a great improvement in all the districts during the year 2004 and 2005 but all districts failed to the reach the 85% target. Treatment success rate was high among the new smear positive cases than that among the re-treatment cases. Alfred Nzo district, reported a drop of 2% in 2004 (59.2% to 57.2%) and again a drop of 5.9% in 2005 (57.2% to 51.3%) in treatment success of new smear positive cases. Amatole district had an increase of 3.3% in 2004 (61.9% to 65.2%). But a dramatic drop of 9.7% in 2005 (65.2 to 55.5%) was reported. During 2005, Nelson Mandela Metro and Ukhahlamba districts also reported a significant drop in treatment success of new smear positive cases, 18.3% (64.3% to 45.7%) and 20.7% (70.6 to 49.9%) respectively.

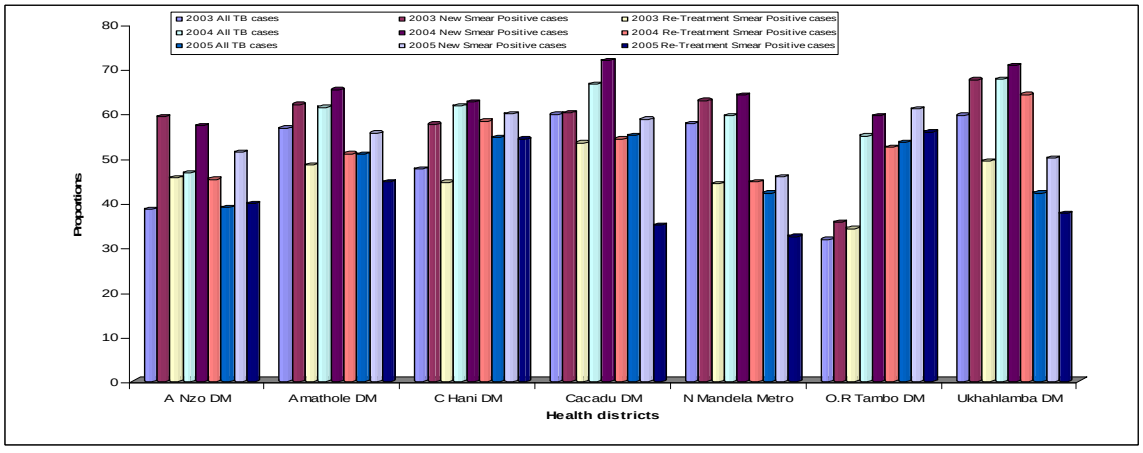


Figure 5.6: Proportion of treatment success per health districts in Eastern Cape, 2003 - 2005

5.2.5 Defaulter rates

Defaulter rates decreased for the three-year study period in Eastern Cape Province for all patient categories. A decrease of 3.1% was noticed in all TB cases from 2003 to 2005. In the new smear positive cases a decrease of 3.9% was noticed from 2003 to 2005. A huge decrease of 6.4% was noticed in the re-treatment smear positive cases for the study year period; this is best illustrated in figure 5.7 below.

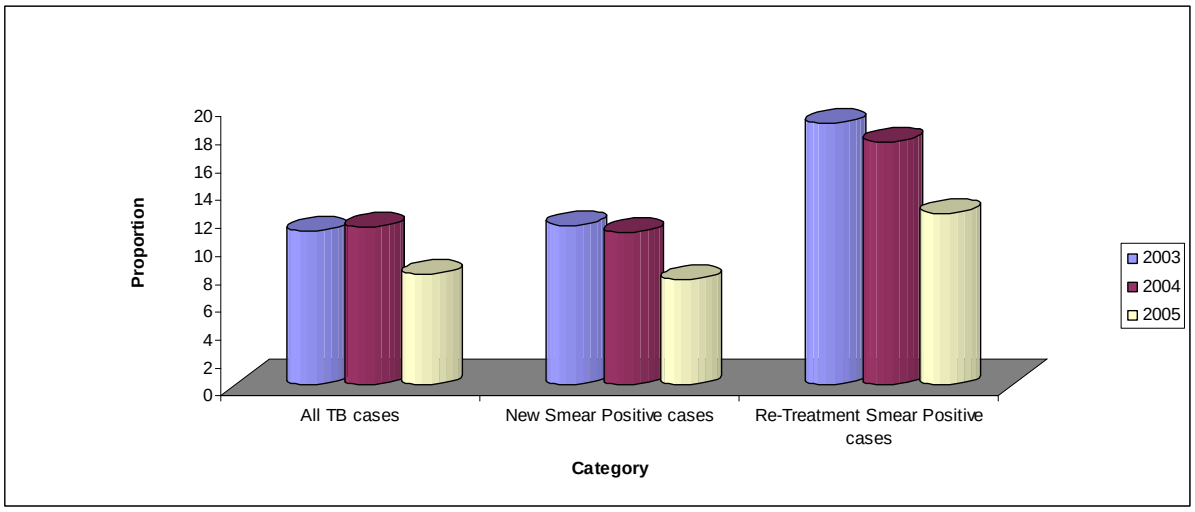


Figure 5.7: Proportion of patients defaulted from treatment in Eastern Cape, 2003 - 2005

The provincial average for defaulter rates in smear positive cases for the years 2003, 2004 and 2005 was 20.1%, 15.9% and 30.3% respectively; and for re-treatment smear positive defaulter rates were 18.7%, 17.4% and 12.3% respectively. The overall rate of TB treatment interruption or defaulters was found to be high in the Nelson Mandela Metro in comparison to other districts. This was most significantly seen in the re-treatment patients smear positives and it was above the provincial average 8.8%, 9.4% and 7.1% respectively for the years 2003, 2004 and 2005.

The rate of defaulting was lower in O.R Tambo district in all patient categories for the study period. With the available data which was used, it was not possible to categorize the defaulters in terms of duration of treatment and if whether they were successfully traced. But improvement was noticed from almost all health districts in terms the reduction of the proportion of TB patients who default from treatment.

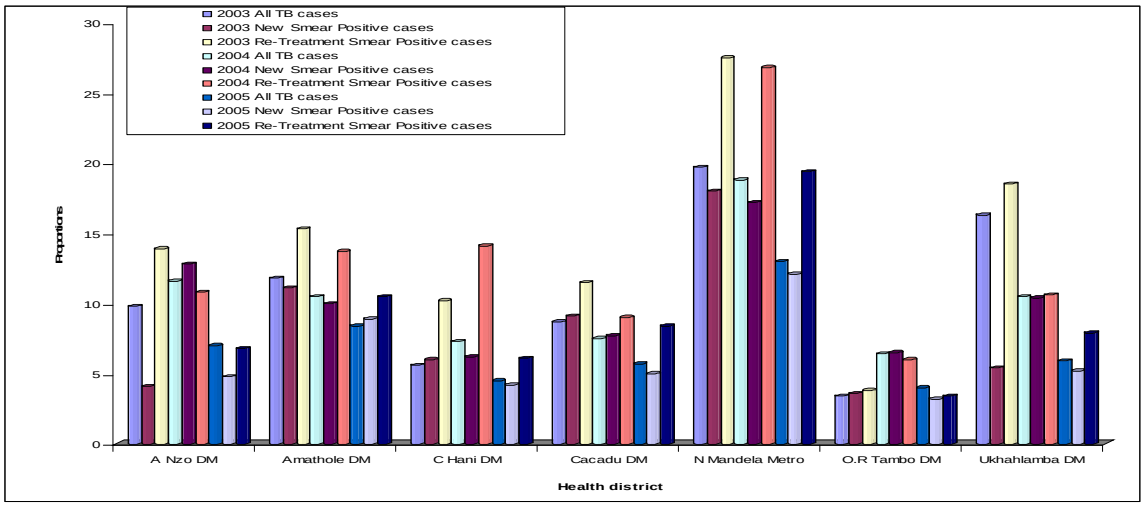


Figure 5.8: Proportion of patients defaulted from treatment per health districts in Eastern Cape, 2003 - 2005

5.2.6 Treatment failure rates

In the Eastern Cape Province, proportion of treatment failures has improved such that a decrease of 0.6% from 2003 to 2005 was noticed in new smear positives and 0.5% decrease in the re-treatments. The high percentage of treatment failures was noticed in the re-treatment smear positive patients above that of the new smear positive patients in all the health districts for the year 2003 except for Amatole district. Chris Hani district had reported a significant improvement in the proportion of treatment failures during the years 2004 and 2005.

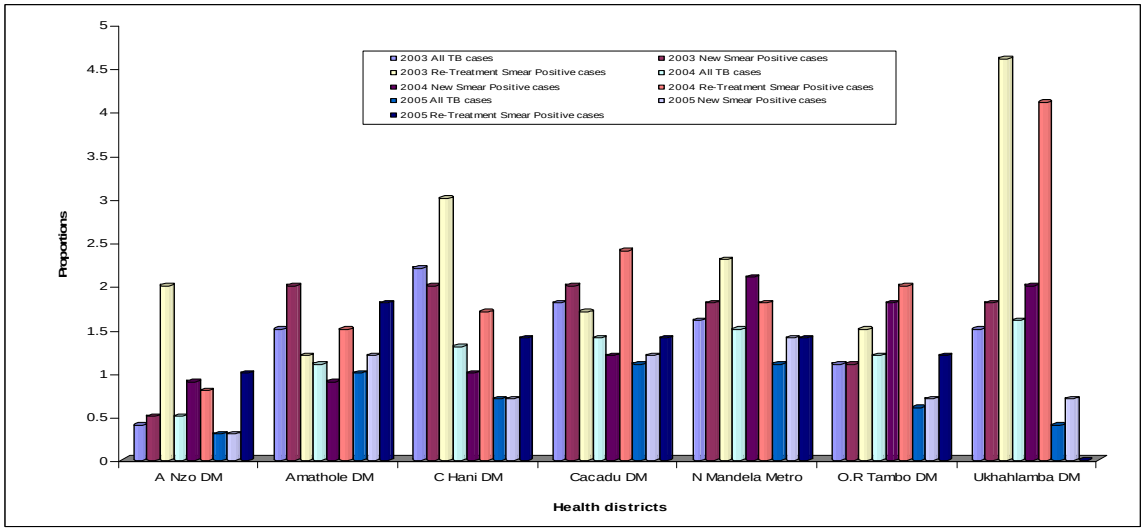


Figure 5.9: Proportion of treatment failures per health districts in Eastern Cape, 2003 - 2005

5.2.7 Patients with treatment outcomes not evaluated

The proportion of TB patients with treatment outcomes, which are not evaluated for all categories, has increased. For all TB cases, this increased by 2% (from 28.3% in 2003 to 30.3% in 2005), then for new smear positive cases this increased by 4.6% (from 20.1% in 2003 to 24.7% in 2005). The major increase has been seen in the re-treatment smear positive cases were it increased by 6.1% (from 21.2% in 2003 to 27.3% in 2005); this is best illustrated in figure 5.10 below.

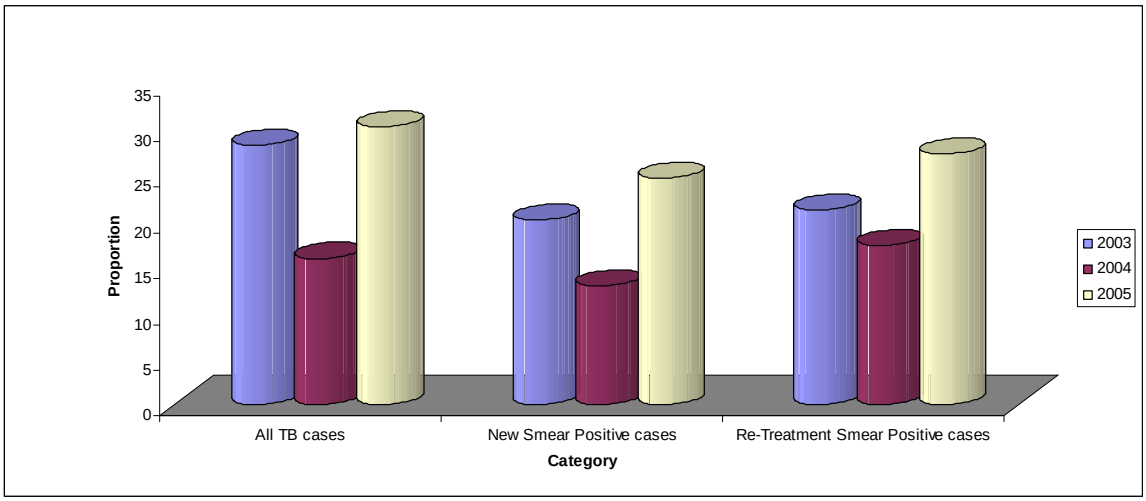


Figure 5.10: Proportion of patients with treatment outcomes not evaluated in Eastern Cape, 2003 - 2005

O.R Tambo, Chris Hani and A. Nzo districts are the districts contributing high proportions of patients with unevaluated treatment outcomes in all categories of patients. The proportion of patients which has treatment outcomes not evaluated shows the poor management of TB Control programme including supervision of the health system.

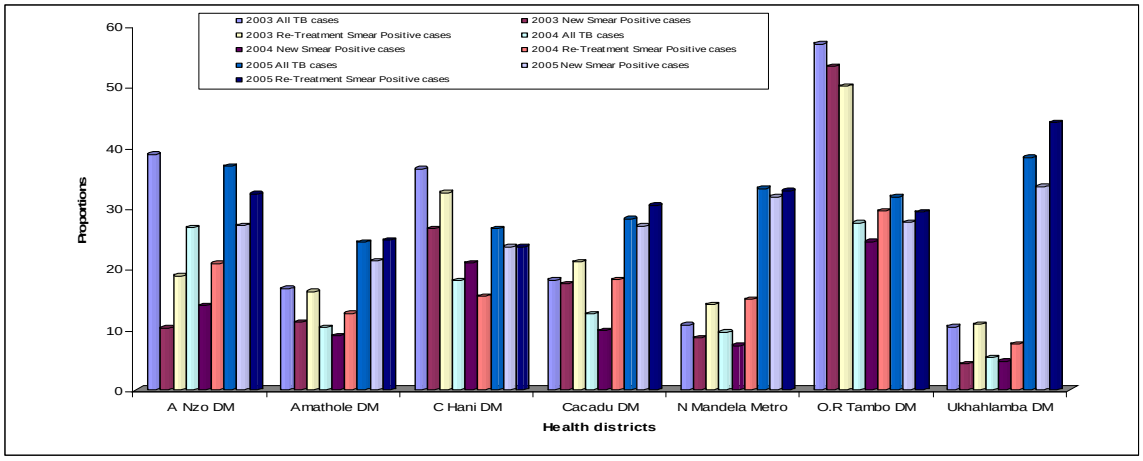


Figure 5.11: Proportion of patients with treatment outcomes not evaluated per health district in Eastern Cape, 2003 - 2005

Multinomial logistic regression was used in the current study for five-category outcome analysis: Treatment Completed and cured, Died during treatment, Treatment failed, Interrupted or transferred out and not evaluated or treatment outcome unknown to determine the influential variables to treatment cure rates. It was found that, when controlling for age and sex, patients who were transferred to another unit were more likely to have their treatment outcome unsuccessful, 1.242171 (CI= 1.21 – 1.27) than those who interrupted/defaulted from treatment 1.217594 (CI= 1.71 – 1.27) and those whom treatment failed 1.158814 (CI= 1.01 – 1.33),

The odds ratio of the variable sex or gender is equal to 1.03 (CI= 1.01 – 1.05) and this figure is fairly close to 1. This shows that males and females are equally vulnerable to not being cured from TB. The odds ratio of age category is 1.05 (CI= 1.04 – 1.05) and this figure is fairly close to 1, which also therefore denotes that the various age categories are equally vulnerable treatment failures, thus conclusive that, there is no specific age category that is particularly more vulnerable to treatment failure. The odds ratio of the variable new cases is 0.42 (CI= 0.39 – 0.44) and the estimated odds ratio is less than 1, suggestive that, the variable “new cases” has a higher likelihood of being cured compared to the re-treatment cases by a factor of 58% (1 – 0.42 = 0.58). = 58% to be cured in comparison with re-treatment cases.

Table 5.2: The Hosmer-Lemshow goodness-of-fit test

Number of observations	=	152451
Number of covariate patterns	=	465
Pearson chi2(456)	=	1354.39
Prob > chi2	=	0.0000

- H0: Fitted model is reliable
- H1: Fitted model is not reliable

  P=0.00 < 0.05. Reject H0.

The P-value from the Hosmer-Lemeshow goodness-of-fit test is 0.0000 > 0.05. This shows that the fitted model is not reliable at the 5% level of significance. Hence, results obtained from binary logistic regression analysis should be taken with precaution.

The mean age was 35.07 and the standard deviation of 16.4 was observed. These data illustrates the notion of Skewness being 0.24 and the notion of kurtosis 3.08 which shows that there was a positive kurtosis and indicates a relatively peaked distribution. Normal distributions produced a kurtosis statistic of about zero, therefore the distribution here was normal

Table 5.3: Summary statistics for mean, median, standard deviation, coefficient of variation

	Percentiles	Smallest		
1%	1	0		
5%	5	0		
10%	16	0	Obs	152451
25%	24	0	Sum of Wgt.	152451
50%	34		Mean	35.07122
		Largest	Std. Dev.	16.44969
75%	45	98		
90%	57	98	Variance	270.5923
95%	64	99	Skewness	.2402525
99%	76	99	Kurtosis	3.08537

The figure 5.12 below, illustrates the Box and Whisker plot of age groups for TB patients registered in the ETR data set. The box encloses 50% of the data; the line inside the box indicates the mean age group. The vertical lines enclose 100% of the data; the circles above indicate statistical outliers. In the presence of outliers, any statistical test based on sample means and variances can be distorted. There might have been errors in data recording or entry errors.

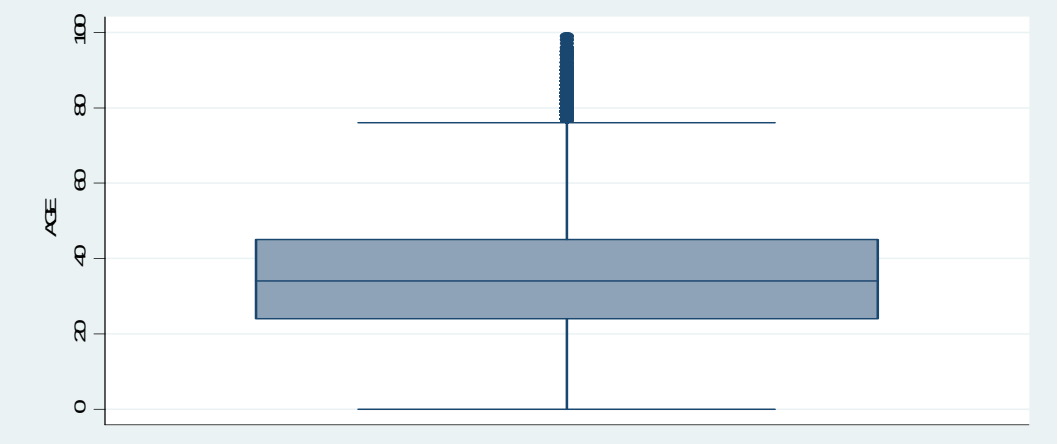


Figure 5.12: Box and Whisker Plots

5.3 Factors that contribute to treatment failures

Table 5.4: Number of Primary Health Care facilities per district

Health district	Number of PHC facilities	Number of sampled PHC facilities
Alfred Ndzo	61	28
Amatole	210	54
Cacadu	60	20
Chris Hani	134	44
Nelson Mandela Metro	35	25
O. R Tambo	148	63
Ukhahlamba	42	18
TOTAL	690	252

5.3.1 Human resource factors

5.3.1.1 Availability of human resource

The data collected using questionnaires in the 252 health facilities participated in the study revealed that Primary Health Care (PHC) facilities have officials responsible for detecting and diagnosing Tuberculosis cases. The study also revealed that there are officials responsible for maintaining recording and reporting forms of TB patients. Most of the staff members in the health facilities were Professional Nurses (96%); Enrolled Nurses and Doctors contributed 2% each. In some Community Health Centers some doctors did sessions in order attend to patients.

5.3.1.2 Health education for TB Patients

Community and facility health education sessions were the most mechanisms used to provide knowledge to TB patients on TB symptoms management and prevention of the spread of TB infection, followed by the use of posters and talks in waiting rooms then lastly by conducting individual health talks to patients having the proportions of 50%, 46.4 and 1.6% respectively.

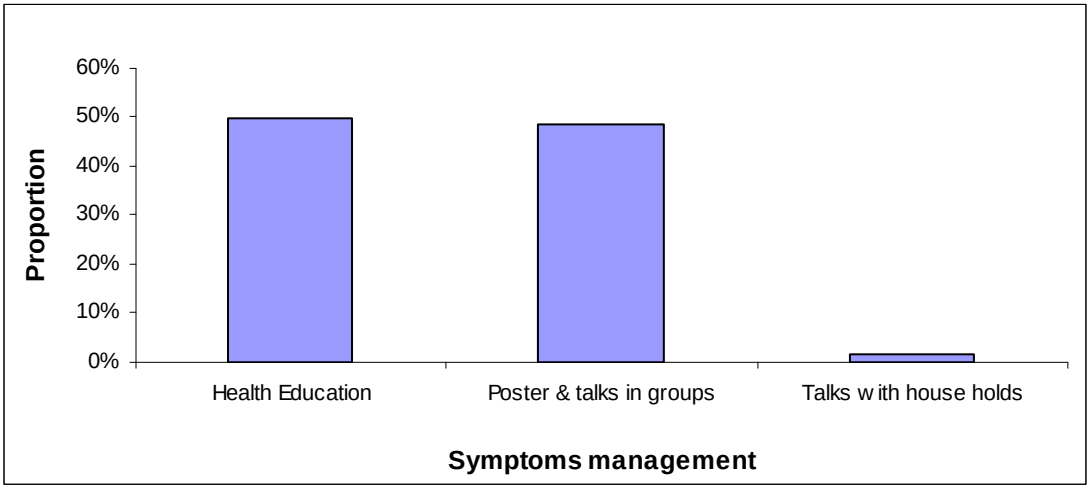


Figure 5.13: How clients are given information on knowledge of symptoms management and prevention of TB spread

5.3.1.3 Trained treatment supporters

In the Eastern Cape Province, most of the facilities of DOTS management structures are supported by training workshops on recording and reporting of TB cases. Only 1.2% of health facilities participated in the study did not have health care workers (HCW) trained on DOTS. Proportions of trained HCW's per facility were 1 HCW (23.4%), 2 HCW's (34.9%), 3 HCW's (31.0%). Those with above 4 HCW's trained contributed 7.5% and only 3.2% did not know how many trained.

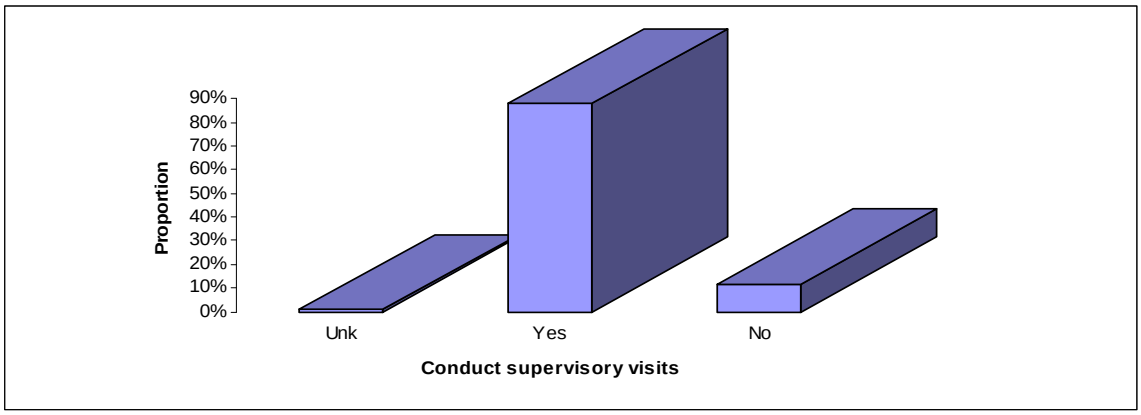
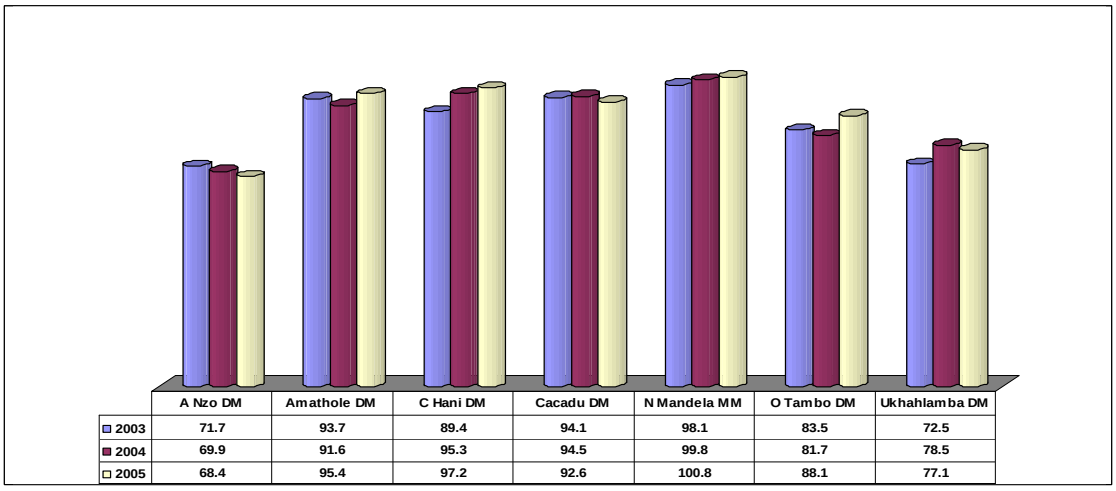


Figure 5.14: Staff capacity at health facility level to conduct supervisory visits to DOTS supporters

It was also found that evaluations on the performance of the TB Control programme at district level was never done in the province and although the DOTS strategy has been widely accepted in the Eastern Cape Province, there was no district which has reached 100% DOTS coverage except NMM in 2005. The results of the low coverage was evident in those districts which have been unable to expand coverage as rapidly as needed and have failed to achieve the targets of detecting 70% of infectious cases and curing 85% of those detected.



	A Nzo DM	Amathole DM	C Hani DM	Cacadu DM	N Mandela MM	O Tambo DM	Ukhahlamba DM
2003	71.7	93.7	89.4	94.1	98.1	83.5	72.5
2004	69.9	91.6	95.3	94.5	99.8	81.7	78.5
2005	68.4	95.4	97.2	92.6	100.8	88.1	77.1

Figure 5.15: DOTS Coverage in Eastern Cape, 2003 – 2005

5.3.1.4 Mechanisms for monitoring of drugs and other suppliers

Figure 5.16 below illustrates mechanisms used at health facility level on monitoring of drug supplies. Stock control cards was the most used mechanism with 43.7% followed by the use of clinic supervisors reports, community health workers reports, pharmacists reports and lastly TB coordinators reports respectively having a proportion of 25.4%, 15.9%, 8.3% and 1.2%.

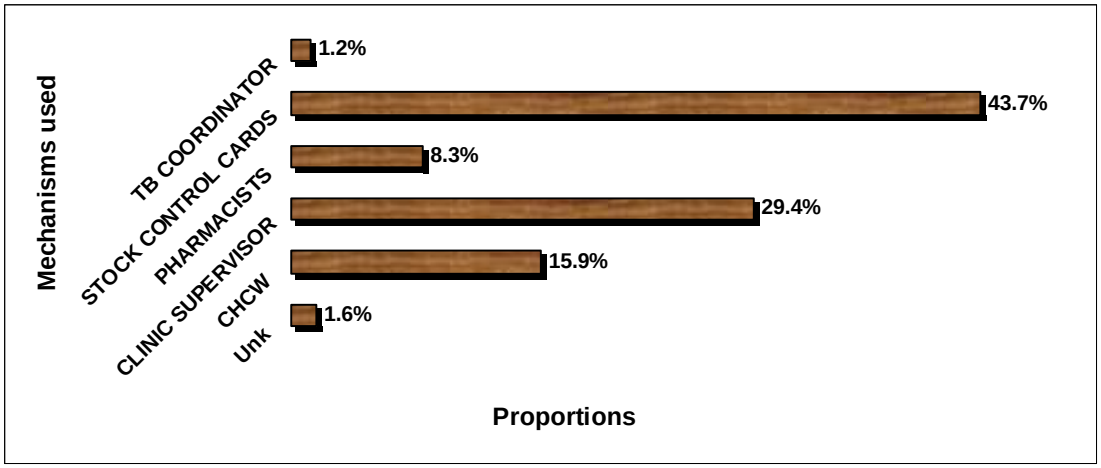


Figure 5.16: Mechanisms used to monitor Drug Supply at health facility

5.4 Patient management

In the Eastern Cape Province, 98.8% of the health facilities participated in the study had a system in place to recall TB clients with positive sputa from the community for commencement of treatment. Only 0.4% did not have and 0.8% did not know how TB patients are recalled. In health facilities with this system in place, a large proportion (85.7%) recall clients immediately and only 13.5% recall clients on a weekly basis due to shortage of staff. DOTS are not mostly used to recall patients with positive sputa to the health facilities. The findings therefore show that in most health facilities there is no delay in diagnosis and initiation of TB treatment.

Most of the health facilities which participated in the study (52.8%) confirmed that patients are not deferred and only 46.8% confirmed that patients are ever deferred. Facilities who ever defer patients mostly did not know how often followed by those who did it rarely (32.9%) then daily or weekly (11.9%). Only 28.6% of the participated facilities had an appointment system in place for deferred patients and majority of the health facilities (40.1%) did not know if there was a system in place or not.

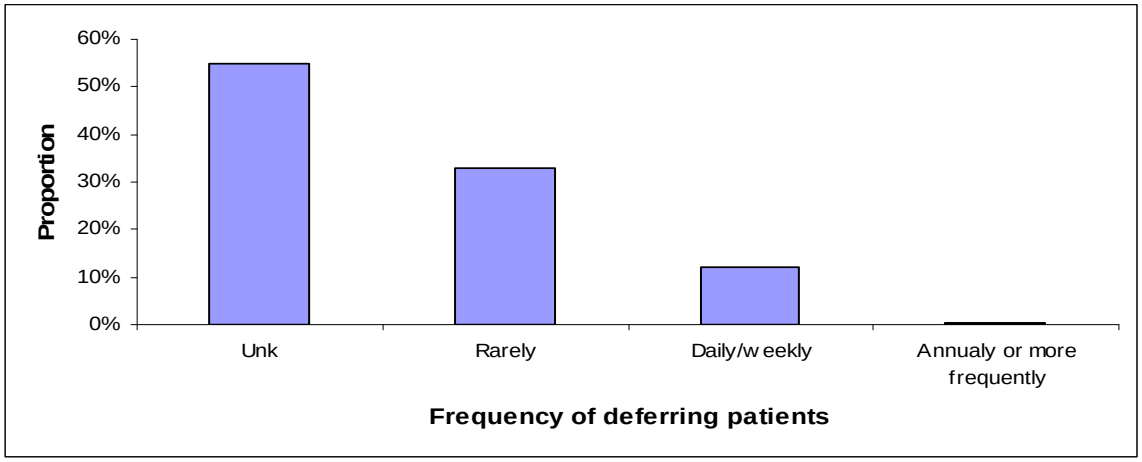


Figure 5.17: How often are patients deferred

The study findings revealed that 91.3% of the participated health facilities had a referral system to home based care in place as another intervention used for management of TB patients at community level whereas 5.6% did not have referral system. Community health care workers were mostly used as illustrated in figure 5.18 below for referral system to home based care.

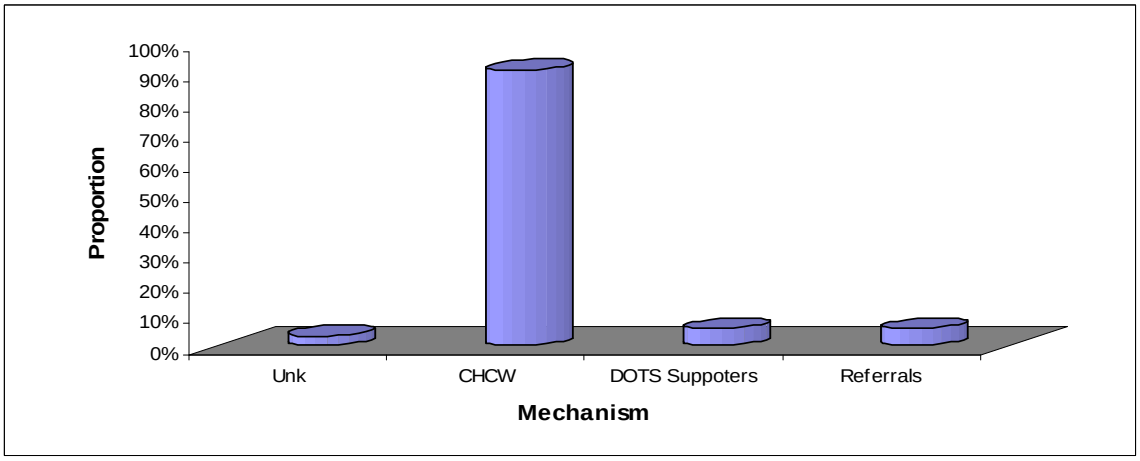


Figure 5.18: Mechanisms used for referral system of patients to home based care

Patient transfer system between health facilities is a crucial element of TB control programme which needs good management but only 24% of the health sub-districts reported that the system is efficient whereas 76% reported that the system is not efficient. But in contrary 80% of the health sub-districts reported that TB services are integrated into a comprehensive primary health care programmes.

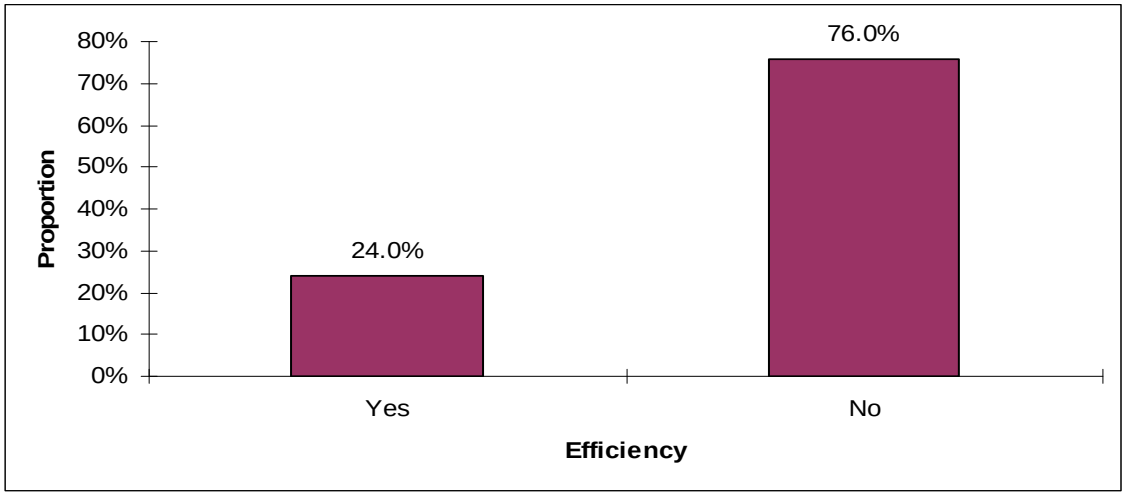


Figure 5.19: **Efficiency of** patient transfer system between health facilities

5.4.1 Infection control

The current study revealed that, there is no proper triage system in place to arrange patients in the waiting rooms in most of the health facilities (86.9%) such that those with chronic cough's can be isolated from other patients while waiting to be seen by the health professionals to reduce the spread of the disease. 13.1% of the health facilities which participated in the study had a triage system for all patients and only 1.6% for patients with chronic coughs. This might be the basis to initiate further studies to determine the rate of Nosocomial TB in health facilities in the Eastern Cape Province.

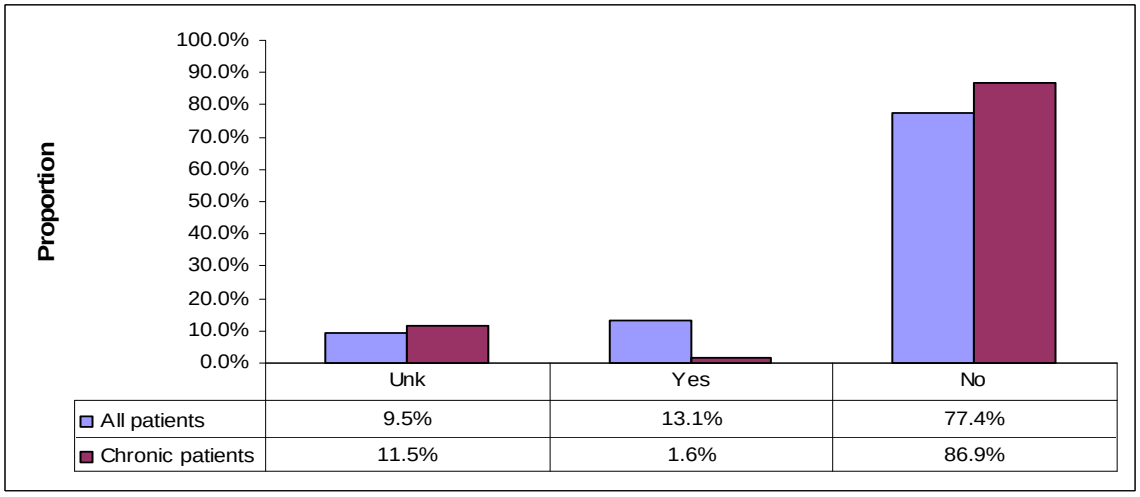


Figure 5.20: Triage system in place for patients at health facilities

5.4.2 Community DOTS, Tracing of Contact and defaulters

The findings of the current study revealed that, 69.4% of the health facilities which participated in the study used DOTS for tracing of TB patients who defaulted from treatment. Clinic nurses who reported to be conducting home visits to trace defaulted patients contributed 27.4%. Shortage of transport in health facilities was the major reason why TB defaulters and TB contacts were not traced in communities, which contributed 86% and in some health facilities is not done due to shortage of staff. This leads to an increase in defaulter rates and poor treatment success rates of less that 85%.

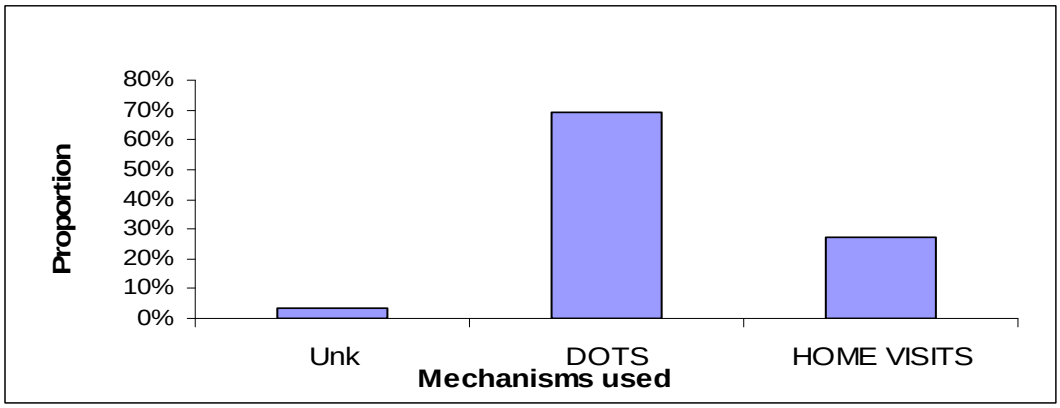


Figure 5.21: Mechanisms used for tracing of TB defaulters

The current study findings also revealed that 69% of the participated health facilities provide TB patients with community DOTS option with DOTS follow ups for patient management whereas 21% were mainly advising patients to use family members to monitor treatment adherence and lastly, 9% did not know how to advise patients with regard to DOTS.

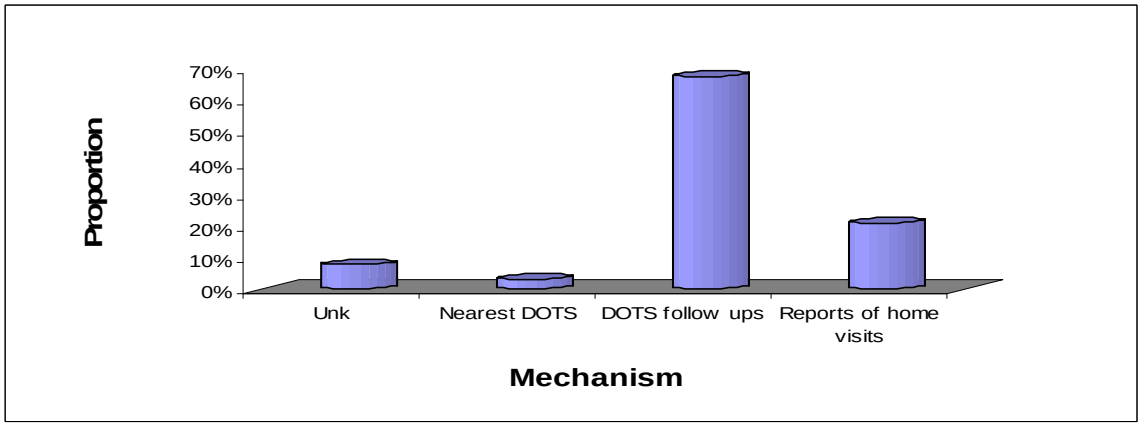


Figure 5.22: Community DOTS option for TB patients

5.5 TB control programme management, policy guidance and protocols

The findings of the current study reveals that, TB district coordinators are not supported by the Provincial TB coordinators for supervision of TB activities and at a sub-district level they are not part of the strategic plans development to combat TB. The sub-district TB coordinators conducts supervisory visits to health facilities mostly on a monthly basis (52%) followed by quarterly (28%) and lastly six monthly or more frequently (20%) as illustrated in figure 5.23 below.

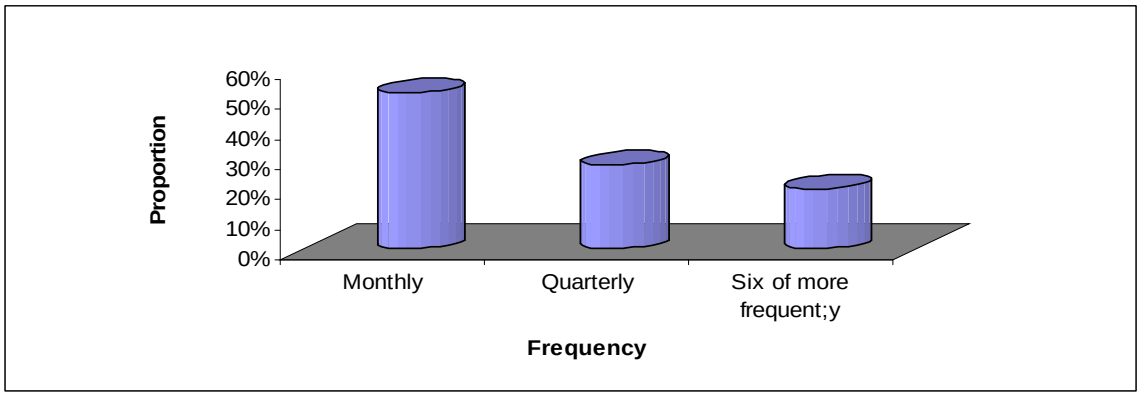


Figure 5.23: Supervisory visits to health facilities by TB coordinators

In the current study it was found that TB reports are written regularly and the elements which were mostly included in the written reports at health sub-district levels were performance on TB control goals; training activities and needs; clinical audits; active TB surveillance then lastly TB procedures with the proportions of 48%, 24%, 16%, 8% and 4% respectively.

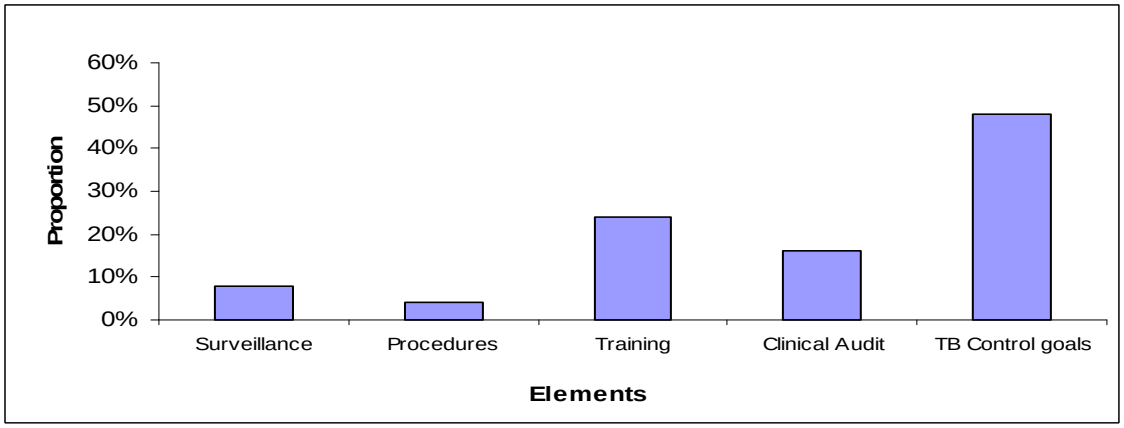


Figure 5.24: Elements which are included in the written TB report

In the current study, Electronic TB Register (ETR) was one of the tools used by the Eastern Cape health districts as part of the TB surveillance to monitor patients, and supervise TB program. This contributed 52% in activities which were frequently or regularly monitored at a health sub-district level followed by pharmacy prescription reports. Active TB surveillance was less monitored with only 28% while the adherence and management of TB policies was not monitored at all.

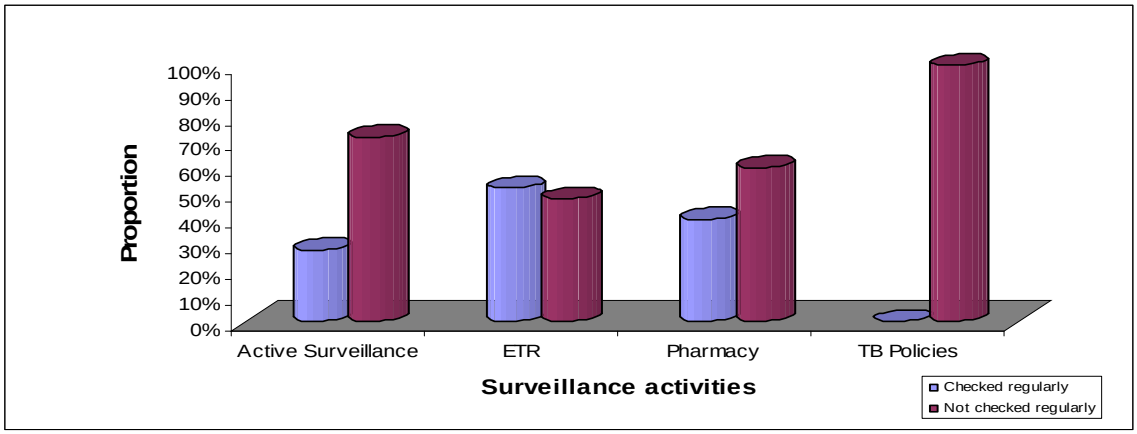


Figure 5.25: TB surveillance activities which are regularly monitored

TB policies which were available during the visits to the health facilities were found to be old and some health facilities did not have TB policy guidelines at all. Only 4% of the health sub-districts (NMM, Buffalo City Makana, Kouga and Sakhisizwe) reported that protocols with standard procedures were available. Protocols for management of immunocompromised patients were available in only 40% of the health sub-districts and about 24% of health sub-districts had protocols for TB contact tracing.

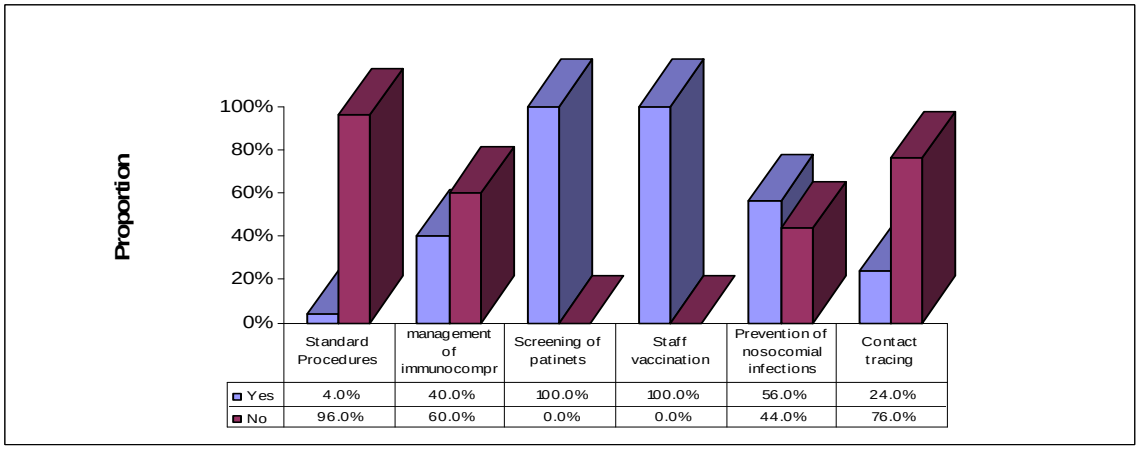


Figure 5.26: Availability of TB protocols at health district level

CHAPTER 6
DISCUSSION

The purpose of these discussions is to point out the various salient points that are emergent from the study findings and offer rational explanations for the various observations. However, this discussion does not seek nor claim to establish a conclusive cause and effect relationship; but demonstrates a strong evidence base that could generate questions for further in-depth research and investigation in the subject. Although the overall picture is probably correct, the figures need to be regarded with caution.

To determine the TB treatment outcomes, the current study was reliant on secondary TB data (routinely collected data for TB patient captured in the Electronic TB Register) and this data was not originally designed for a study purpose, hence some data elements required for the study were found lacking. It was not possible to get the main reasons why did patients default from treatment, at which stage was the treatment discontinued and whether the defaulted patients were traced. Evaluation of treatment results preferably becomes an inbuilt component of national monitoring of programme performance. Patients with definite pulmonary TB, notified during one defined calendar year were selected for analysis. Because envisaged treatment with short-course chemotherapy lasts for up to 9 months and patients are allowed to interrupt treatment for up to 2 months before being classified as such, analysis of treatment outcome can only take place 1 year after closure of the calendar year of notification and therefore a three year period was considered in this study.

An effective tuberculosis control programme detects at least 70% of new sputum smear-positive cases and successfully treats at least 85% of cases detected. This prevents the creation and spread of drug-resistant forms of tuberculosis by ensuring that cases are detected quickly and placed on proper regimens.[46]

The bacteriological coverage rate reflects the percentage of cases of PTB for which sputum microscopy results were available. As such, it reflects both the availability of laboratory services and compliance with the national TB guidelines, which stress the use of sputum microscopy in

the diagnosis of PTB. Sputum microscopy results should be available on all patients with suspected PTB (i.e. bacteriological coverage should be 100%).[47] The findings from this study explains that, in the Eastern Cape Province, the National TB guidelines are not properly followed by the health facilities and the TB coordinators, this therefore concludes that not all patients with suspected PTB have their sputum collected or sputum microscopy results available.

The smear conversion rate (SCR) measures the proportion of infectious people who no longer have the TB bacillus in their sputum after 2 months of treatment. This indicator is very important as it measures how effective the initial treatment is in helping to stop the transmission of TB. It is an important indicator to determine how well the health service is doing and makes information available to health workers much earlier than does the cure rate. For most patients this indicator should be available within 3 months of the diagnosis with TB. It is proper to evaluate the smear conversions of TB patients after 5 and 7 months. The target for TB smear conversion rate set by the National Department of Health is 70%.[48]

The average SCR for the Eastern Cape Province is 65.6%, which is below the set target and the current study findings are consistent with those of the study conducted by Health System Trust with regard to the SCR's. Thus, this may reflect inadequate treatment and failure to convert, but more commonly it might mean that a sputum smear was not taken or reported on at the end of the intensive phase as we have a high number of patients with treatment outcomes not evaluated in the Eastern Cape Province.

In a study conducted in Guangzhou, China, the cure rate for both new and previously treated cases improved, while the treatment failure rate and death rate both decreased from the first to the sixth year of DOTS implementation. [29] In contrast to the current study, cure rates for both new smear positive and re-treatment smear positive cases have not improved up to satisfactory over the three-year study period. Furthermore, contrary to what is happening in the Eastern Cape, in the 2008 WHO report, it was found that, the cure rate among cases registered under DOTS worldwide was 77.6%, and a further 7.1% completed treatment (no laboratory confirmation of cure), giving a reported overall treatment success rate of 84.7%, very close to the 85% target. This means that 49% of the smear-positive cases estimated to have occurred in

2005 were treated successfully by DOTS programmes. Among all the patients treated under DOTS, 9% had no reported outcome (defaulted, transferred, and not evaluated). [49] The performance of the Eastern Cape is amongst those which are dragging the globe in reaching the 85% target.

DOTS programs aim to detect 70% of incident cases and to successfully treat 85% of the cases for control of TB globally. Treatment success is based on end-of-treatment outcomes, and as there is no standardized system of monitoring patients after treatment to confirm cure or record recurrent TB, published data are scant on rates of recurrence from routine DOTS programs, particularly in settings of high drug resistance.[49] Successfully completed treatment of active cases of tuberculosis is the single most important way to control and prevent new cases. However, treatment completion is often delayed or unsuccessful because it requires that patients adhere to taking medication for at least 6 months.[15]

Treatment success has been increasing in Africa, although cohorts of DOTS patients in this region continue to have high death and default rates: one or other of these indicators exceeded 10% in Mozambique, Nigeria, South Africa, Uganda and Zimbabwe,[33, 49] but improvement in the Eastern Cape province is not sufficient to can quickly reach the expected targets. The findings of this study is inline with study findings of a study conducted in China were it was found that, the percentage of treatment failure among new cases declined from 2.8% to 0.5% over the first six to eight years of DOTS implementation, but this percentage declined from 2.8% to 1.2% during the first year alone.[29]

It is encouraging to note that there has been an improvement in the reduction of treatment failures amongst the new smear positive patients in all the health districts of the Eastern Cape Province. In general, during the 2003 and 2005 the proportion of treatment failures was high in the Eastern Cape Province. In contrast, some bacteriologically confirmed tuberculosis cases may in fact be due to re-infection rather than treatment failure.

The proportion of re-infections was not determined in this study due to the unavailability of this variable in the data set, therefore we cannot conclude about patients with default or transfer-out

as treatment failures due to the unavailability of information on tracing after default or transfer-out. A large proportion of treatment failures remain currently undetected by the NTP and those patients are not detected for further tuberculosis treatment. In a study conducted in Northern Vietnam, only two of eleven patients had started re-treatment and in northern Vietnam in 2003 this would be 105 undetected failure cases as compared to 48 cases who received re-treatment after failure.[31]

The greatest challenge in the Eastern Cape TB Control is an increase in TB patients with treatment outcomes, which are not evaluated for all categories. The reasons for patients to have treatment outcomes unevaluated were not possible to get from the data because the data set was not having this variable. In the Region of the Americas, deteriorating outcomes are explained, at least in part, by the expansion of DOTS coverage, often into regions of countries with weaker health services. No outcome was reported for 16% of patients in the region as a whole (18% in Brazil) and in Brazil, 44% of patients completed treatment without cure being confirmed (via a final, negative sputum smear).[33, 49]

Successful TB control strategies rely on functioning general health systems. Many NTP's today struggle to implement high-quality services in the context of health workforce crises, continuous low levels of public funding for health care, weak government stewardship functions and disintegrated health service networks. DOTS expansion itself is one facet of health systems development. To invest in DOTS means investing in improved health systems. However, DOTS expansion without strengthening of general health services is not sustainable. [22]

Human resource development has for many years been synonymous with organizing training courses. The realization that this is not enough has gradually developed, not only for TB control programmes but also for many of the other programmes and components of primary health care.

Human resources are among the most important resources in health care delivery. Health system managers have the responsibility and challenge of ensuring that maximum benefit is derived from these human resources to maintain and expand health services such as

tuberculosis case detection and management. Training which is properly focused, directed and managed is therefore an essential component of the comprehensive strategy for TB control.[50]

Patients placed on treatment should be registered in the TB Register within a month of the initiation of treatment. Information on follow-up sputum examination results and treatment outcomes should be transferred from the Treatment Card to the TB Register within a month of the event. All these can properly be done if there is enough human resource to cope with the increasing number of TB cases worldwide.

There is an African Dots Project (AFDOT) which is an ongoing research conducted in sub-Saharan Africa, (two geographical sites been selected for study, one in Burkina Faso in North West Africa and one in the Western Cape in South Africa). Its main aim is to evaluate the effectiveness of Directly Observed Treatment (DOTS) in tuberculosis patients. The study includes the development of a multi-faceted patient-centered package of care: which comprise of providing staff with training for improving consultation skills, providing patients with brief motivational interviewing, providing a patients with a health education booklet, providing user-friendly pre-packaging of TB medication and providing patients with an adherence chart. [51]

Therefore implementation of these interventions in Primary Health Care facilities will improve TB management and this will solely rely on the management of organizational change and providing supportive management-related interventions in the Eastern Cape Province.

Contrary to the WHO and IUATLD, training of lower staff members at health facilities was not prioritized by management in health sub-districts and provincial office because only 16% of the sub-districts had a capacity to conduct trainings and 84% did not have capacity. Frequency of trainings differed from health sub-district to another. Most were conducted on a quarterly basis (52%) followed by six monthly (28%) and lastly annually (20%).

Health education is a learning process through which an individual adopts a behavior that is beneficial to health. It is important to mention that one of the obstacles against tuberculosis control is a behavioral problem. Lack of community awareness leads to delay in diagnosis and

spreading of infection in healthy contacts. Health Education and Community Outreach - NGOs can sensitize, train volunteers, disseminate information, provide counseling to patients, families; sensitize, orient & advocate key groups, develop and revise IEC material according to local context.[52]

Lack of information can lead to delays in accessing treatment, increasing the potential for transmission of the disease. A study conducted in Tanzania found that only 42 percent of TB patients visited a health facility within three months of the onset of symptoms; the median duration between onset of TB symptoms and visiting a health facility was about eight months.[53]

In the Eastern Cape province, based on the study results, it is understood that without community and patients understanding of how TB is spread and that it can be cured, health care providers cannot fight the TB burden alone. By ignoring community awareness, an atmosphere of suspicion, fear, and hostility toward people with TB can easily develop. In Bangladesh, Bangladesh Rural Advancement Committee (BRAC) research has shown that "common people would not like to associate with TB patients for fear of transmission," making people with TB reluctant to seek diagnosis and care.[53]

It has proved in the province that trainings of these HCW's have provided capacity for health facility personnel to conduct supervisory visits to DOTS supporters. These resulted in good supervision of DOTS at facility level with 87.7% and those facilities with no personnel to conduct supervisory visits contributed 11.5% and those that did not know if there is supervision needed contributed 0.8%. the good supervision of DOTS decreases the lack of public awareness on TB and this contributes to an environment in which people living with TB are less likely to feel shame and don't face stigmatization and discrimination, even from health care workers, motivating them to seek treatment and care. The study findings also revealed that, those who were able to conduct supervisory visits to DOTS supporters mostly did that on a weekly basis (78.6%) followed by fortnightly with 6.3% and monthly with almost 2%.

An uninterrupted supply of good quality anti-TB drugs is one of the five components of the DOTS strategy being followed for the implementation of the RNTCP. The design and

implementation of a Drug Logistics Management Information System (LMIS) is an important technical intervention in supply chain management.[54] Strong procurement and logistics management with respect to drugs is essential to strengthen every link in the drug supply chain, from the manufacturer to the patient. With better management of the supply chain, one can stretch limited resources to serve more people with essential services and exceed programme objectives.[55]

India has developed a unique system of providing drugs in Patient-Wise Boxes (PWB's) which contain the drugs for the entire duration of treatment for a single patient. Once a patient is started on anti-TB treatment, a box is assigned to that individual patient, thus ensuring that when the patient starts on treatment, the entire course is available uninterrupted to him/her. This uninterrupted availability of drugs throughout the six- to eight-month treatment course is a key component of the DOTS programme. The effort in this direction was made possible by analyzing and improving existing systems.[53, 54, 55] By analyzing and improving existing systems to monitor drug suppliers in the Eastern Cape Province, could make a significant improvements in the inspection of patients on drug supply, storage and quality control practices and better cure and treatment success rates could also be achieved.

Delays in diagnosis and initiation of effective treatment increase morbidity and mortality from tuberculosis as well as the risk of transmission in the community.[56] The current study did not focus on the reasons why patients were deferred and this might be another interesting part to find out in the future on why are patients deferred in Eastern Cape in comparison to other studies.

The World Health Organisation (WHO) has proposed a number of interventions to deal with referral of patients to home based care. The interventions are aimed at providing coherent health response that involves all stakeholders in TB/HIV care. The goal is to exploit synergies between different stakeholders including tuberculosis programmes, HIV/AIDS programmes and Non Governmental Organizations (NGOs) in order to provide comprehensive care to people with TB and HIV/AIDS.[55, 57] Health facilities in the Eastern Cape Province have adopted some of these interventions to deal with referral of patients to home based care.

There is an urgent need to implement appropriate infection control precautions in health care facilities for Eastern Cape Province, with special emphasis on those facilities providing care for people living with HIV/AIDS. The implementation should be supported by practical guidelines drawing from the recently updated addendum to the WHO infection control guidelines for resource-limited countries[58], entitled *Tuberculosis Infection Control in the Era of Expanding HIV Care and Treatment*;

For patients presenting to the health care facility for care, screening for signs and symptoms of TB should be done in the initial triage locale. The detail and extent of this screening process should be determined based on the facility risk category. An example of a suitable screening methodology would be questioning the patient regarding cough lasting greater than three weeks, weight loss, night sweats and malaise.[59]

Several studies globally concurs that, Failure to complete treatment not only leads to morbidity and mortality in the individual patient but also to the spread of the disease to others in the community. In addition, partial treatment of TB can result in the dreaded complication of multiple drug resistance (MDR), a phenomenon that became widespread in several US cities during the 1980s and early 1990s.[22,33,49,55,60] Major efforts have been directed at controlling these public health problems with some success. Among the factors cited for improving the situation are better use of effective, short course treatment regimens, better institutional infection control measures, and perhaps, most importantly, the increased use of directly observed therapy (DOT).[29,46,55,60]

The findings of the current study are inline with other studies in showing that DOTS is widely used in the Eastern Cape Province. Even though there is a poor supervision of DOTS by health facility staff members including health district TB coordinators

The role of home visiting and supervision of directly observed chemotherapy, short course (DOTS) by a non governmental organization (NGO) in tuberculosis program was studied in Nepal. Information was collected on home visits to a cohort, of 205 smear positive patients, almost one third of new smear positive cases were visited, 14% of patients required home visits to ensure treatment completion.[61] Therefore transport is vital for supervised chemotherapy in the community, in order to find supervisors, to visit patients and supervisors, to chase non-

attendanders and for the transport of drugs to the clinics and to the supervisors. The findings of the current study is consistent with those of the study conducted in Sekhukhuneland in Limpopo Province were it was found that the nurses in all hospitals claimed that there was inadequate transport services.[62] In the current study, it was found that health facility personnel did not have adequate transport or did not have transport at all to conduct supervisory visits and other TB activities in the communities.

TB has reached crisis proportions in the country and in the Eastern Cape Province. The crisis plan in the Eastern Cape Province is focusing on three districts, i.e. Nelson Mandela Metro, Amathole and O.R Tambo Districts because of their high number of cases. All efforts to increase the cure rates should be made to mobilize all sectors of communities to increase awareness about TB, and the dangers of TB, especially the extreme-multidrug-resistant strain known as MDR or XDR. It is also important to emphasize that TB is curable.

Coordination of TB activities with partners was found to be poor also in the Eastern Cape Province. This study revealed that 88% of the health sub-districts did not have officials to coordinate TB activities with partners and NGO's then conduct TB support activities to the communities without the knowledge of TB coordinators. Therefore, there was no link between their work with the department of Health. Only 12% of the health sub-districts had enough capacity to coordinate TB activities with external partners.

Report writing and information dissemination in TB control programme serves as an important management tools to assess program performance and to determine future needs and direction. These reports also form the basis of ongoing TB surveillance, [63] and in the current study it was found that reports are written regularly on TB programmes and the major elements which were included in the reports were performance on TB targets, and TB surveillance.
Tools are needed to strengthen TB surveillance and TB program management in order to better track the epidemic and help prevent increases in drug-resistant TB. Electronic TB register (ETR) was developed in 1995 to improve surveillance and management of efforts, as part of collaboration between the Ministry of Health of Botswana and Centers for Disease Control and Prevention in the United States. Therefore it was found that the ETR is a potentially powerful

tool for surveillance, management, and supervision for countries with well-functioning paper-based recording and reporting systems.[63]

Availability of protocols helps health care providers to refer and adhere to the standards of patient management. [64] But contrary to this note, TB policies which were available during the visits to the health facilities were found to be old, not updated and some health facilities did not have TB policy guidelines at all. This is another contributory factor to the mismanagement of TB in the Eastern Cape Province.

CHAPTER 7

CONCLUSIONS AND RECOMMENDATIONS

7.1 Concluding remarks

Tuberculosis detection rate under dots is the proportion of estimated new smear-positive cases of TB detected (diagnosed and then notified to the TB control programme) by dots programmes provides an indication of the effectiveness of the TB control programmes in finding and diagnosing people with TB. This study highlights that there was an increase in the caseload registered in the Chris Hani district; and this could be explained by a variety of reasons. Some of the possible factors that could shed some light into this phenomenon include the high disease burden as a result of the HIVAIDS epidemic; better case finding systems as a result of community mobilization; population increase and mobility among others. In relation to this study, the most plausible among these factors, would be better case finding.

Efforts to improve treatment outcomes require a better understanding of the particular barriers to and facilitators of adherence to TB treatment, and of patient experiences of taking treatment. [65] Therefore these findings may be important beyond Eastern Cape Province to other provinces or countries with a similar tuberculosis epidemiology and reported treatment outcomes. A follow-up study among patients who did not complete treatment may be considered in settings with high default or transfer-out rates, or patients with treatment outcomes not evaluated.

The study shows that, despite considerable efforts made by the NTCP, little change was noted in treatment outcomes with average cure rates of 37.7% and interruption rates of 9.3%. Reported death rates are surprisingly low (approximately 7%) given the HIV epidemic. However, it is quite likely that a significant number of deaths might have been categorized as “treatment interrupters” as patients have been lost to follow-up and deaths not reported to health facilities. The death rates in re-treatment cases are almost above that of new smear positive cases with approximately 4%. Variation in treatment outcomes among districts raises important questions about the quality of treatment, the quality of the data and how quickly these will improve in future.

The 85% treatment success rate in the Eastern Cape Province has not been reached since reliable monitoring began, despite prioritization of TB in the province. The treatment outcomes of tuberculosis (TB) patients who move before completing anti-tuberculosis treatment have not been described in this study because such information was not available in the dataset that was received from the Provincial Department of Health in the Eastern Cape Province. Moreover, in the current study, the proportion of patients carrying multidrug resistant strains of those with culture positive tuberculosis is not known. Patients with primary multidrug resistance have a high risk of death and failure with the standard NTP treatment regimen. It was also found that Nelson Mandela Metro is the district with the highest defaulters in the Eastern Cape Province in all the patient categories.

If the proportion of patients with treatment outcomes that are not evaluated can be decreased in the Eastern Cape Province, then the cure rates for all smear positive cases can be improved and this may result in better treatment outcomes. Again sputum conversation and cure rates could have been better, had tracing of defaulters been intensified and full course of treatment under DOTS given to them.

The failure of DOTS as a TB control strategy does not mean this approach is without benefits. DOTS programmes that improve treatment outcomes and prevent the emergence of drug resistance should be developed further in the Eastern Cape Province. However, controlling TB will require much more than treating people diagnosed with smear positive disease. To substantially reduce TB Provincially, we will have to do much more than connect the DOTS. Involve the DOTS in defaulter tracing, contact tracing and recalling of patients with positive sputa. While continued improvement in case detection rates is encouraging, there has been a deceleration in the rate of progress in treatment success in the Eastern Cape Province.

New analytical work is also improving our understanding of the extent to which TB control programmes are driving trends in TB incidence, working with or against other biological, social and economic factors. The health system factors presented in this study suggests that while DOTS programmes are introduced in all the health districts of Eastern Cape, there is still limited capacity in handling the increased caseload and this is validated by the low bacteriological

coverage in most of the districts. This means that the program's capacity to offer quality sputum smear microscopy at diagnosis, was somewhat compromised; and thus by inference the capacity to offer regular and quality follow-up sputum smear microscopy. Follow-up microscopy is a necessary measure in tracking the progress made by patients on treatment, particularly the infectious smear positive cases. This argument suggests that community DOTS support systems can not singly fix a poorly performing TB control program.

The organizational and technical capacities of the central coordinating level need to be strengthened first before involving the complimentary support from the community whose main role is to increase program coverage and improve adherence to treatment. This discourse further asserts that, prior to increasing coverage through these community support initiatives, it is of paramount importance to have a functional laboratory system; reliable drug supply system; good referral systems and reliable recording and reporting systems, among others. Failure to observe this logical relationship would only lead to a disastrous performance in all programmatic aspects; particularly treatment outcomes. Obviously this is a recipe for the emergence of drug resistance which might be further catastrophic by rendering a treatable epidemic, untreatable.

As a province and contributing to South African success in TB control to go beyond the target of 70% case detection of new bacteriologically confirmed TB cases and to treat at least 85% of them successfully, continued efforts are needed to improve and sustain the quality of DOTS through improved programme management, strengthened human resources and improved supervision and laboratory services for sputum smear microscopy. Therefore the involvement of all relevant partners is essential to reach patients currently treated outside DOTS programmes as well as patients in whom TB is not diagnosed and treated at all.

Regular clinic attendance does not, however, translate into regular treatment. No treatment can be effective unless the patient takes the drugs prescribed and the only way to ensure this is by giving the drugs under direct observation. Mere availability of free medication under the previous TB control programme in India was associated with cure rates of only 40 percent.[66] Non-adherence to treatment is a universal human trait and can only be overcome by

establishing a human bond between the patient and the provider via directly observed treatment (DOT). Under the NTCP, any patient late for her/his treatment or having adverse drug reactions, can be easily identified and prompt remedial action taken because of DOT. [66]

It may in general be concluded that the results of the evaluation are positive, although it would be desirable to improve some of the programme's activities, such as early diagnosis, examination and tracing of contacts, acquisition of data about chemoprophylaxis recommendations, and on non-adherence to them. The effectiveness of the information system at the clinic level should be revised in terms of the functions, validity and data completeness. This will help in providing proper information on treatment outcomes more especially the defaulters' demographic and socioeconomic characteristics (to be used as predictors of defaulting). Clinics should also be evaluated on capability of handling data as a means of self evaluation, and utilization of generated information.

Table 7.1 below illustrates the programmatic challenges identified and highlighted by the study findings and the possible recommendations and solutions to them. Health Education was found not to be an integral part of the overall control process of TB and the degree of urgency (triage system) in Health facilities was found to be poor in deciding who investigate and treat/refer. Provision of enough transport in health facilities for DOT supporters to trace defaulters and TB contacts is highly recommended for proper control of TB in the Eastern Cape Province and NTCP supervision should be strengthened by reviewing of the supervisory system hierarchy. Lastly partnership with NGO's with regard to TB activities should be overseen by a dedicated.

Table 7.1: Programmatic problems identified and recommendations improvement

DOTS strategy	Problem	Solution
TB Knowledge	Non continuous education on TB infectivity	Health Education to be an integral part of the overall control process of TB
		Health education to target different groups
Infection Control in health faculties	No triage system in place	Degree of urgency in Health facilities to be introduced in order decide the order to investigate and treat/refer patients
Recall clients with	DOT supporters not regularly used	Patients need to be recalled by DOT supporters when lab results are positive
Defaulter and TB contact tracing	No transport	Provision of enough transport in health facilities for DOT supporters to trace defaulters and TB contacts
Community DOTS option	Poor supervision	Health facility staff or clinic supervisors should frequently supervise DOT supporters
NTCP Supervision	Poor supervision by provincial coordinators	Review of the supervisory system hierarchy and functions
		Training of supervisors more frequently
Programme Evaluations	No training evaluations	Ongoing evaluations linked to needs assessments
Strategic Plans	TB strategic plans are developed provincially or nationally	Strategic plans to control TB should be developed in consultation with the district coordinators and nurses who are responsible for TB activities
Training of lower level staff members	No enough capacity and training is not Prioritized	Management should prioritize training of TB health professionals
Partnership with NGO's	lack of coordination	A dedicated TB personnel should coordinate TB activities done by NGO's
Report writing	No reports written at sub- district and district levels	Health districts should learn how to produce TB surveillance and management reports
TB Policies	old or no policies available	Health facilities to be updated on new policies and new developments with regard to TB management
TB Surveillance	No active surveillance	TB active surveillance should be introduced in order to control and manage the spread of the disease

Finally it is recommended from the study findings, that, the entire TB control programme be subject to annual evaluation, as this would enable comparisons to be made and lead to improvements in effectiveness. The consequence of all this will be a reduction in treatment failures, and an improvement treatment success resulting in better cure rates not forgetting proper support to DOTS programme.

CHAPTER 8

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Annexure 1: Tuberculosis Control Programme review questionnaire used at facility level

District Municipality:……
Local Service Area:……
Name of Health facility:……
Type of facility:……

"The implication of completing the questionnaire is that informed consent has been obtained from you. Data that may be reported in scientific journals will not include any information that identifies you as a participant in this study. As all information or data are anonymous, you must understand that you will not be able to recall your consent, as your information will not be traceable. All information during the course of this study is strictly confidential."

Who should fill in this questionnaire?

This questionnaire is for the TB Control Coordinators.

By the TB control coordinators we mean health practitioners who have day-to-day responsibility for TB control in the health facilities, if not available any member of the TB control team or a nurse working in a health facility can fill it in, or a number can share the task.

Purpose: This study focuses on TB treatment outcome evaluation and the determinants of treatment failures. The findings will provide some aspects of the evaluation of the TB treatment outcomes and therefore these will help the government to make adjustments in the programme in order to reduce the number of new infections and plan for medical and social care needs.

Any queries?

If you are uncertain how to answer any question, or wish to discuss any aspects of the questionnaire, please contact Mr. E Maimela 083 378 0194 or 040 609 3792 or at: maimelae@impilo.ecape.gov.za

The level/position of the official filling the questionnaire……

1. INFORMATION ABOUT HUMAN RESOURCE

	Yes	No
1.1 Is there a staff member responsible for TB services in your facility?.....1	◯	2 ◯

If yes, what is the portfolio of this person

Professional Nurse…….....1 ◯
Enrolled Nurse……..2 ◯
Doctor…….....3 ◯
Other……4 ◯
Please specify_____

If your answer is NO on the above question who normally oversees the TB services in your facility?

_____

1.2 IS THERE STAFF CAPACITY TO DO THE FOLLOWING

		Yes	No
1.2.1	To detect and diagnose Tuberculosis cases…….....1	◯	2 ◯
	If No, explain:_____		
	_____		
1.2.2	Maintain recording and reporting forms……..1	◯	2 ◯
	If No, explain:_____		
	_____		
1.2.3	Provide health education to patients and communities…….....1	◯	2 ◯
	If No, explain why:_____		
	_____		
	If Yes, explain how is it done:_____		
	_____		
1.2.4	Oversee TB treatment supporters…….....1	◯	2 ◯
	If No, explain why:_____		
	_____		
	If Yes, explain how is it done:_____		
	_____		
1.2.5	Trace patients who default from treatment……..1	◯	2 ◯
	If No, explain why:_____		
	If Yes, explain how is it done:_____		
1.2.6	Monitor drugs and other suppliers……..1	◯	2 ◯
	If No, explain why:_____		
	If Yes, explain how is it done:_____		

Yes	No

1.2.7 Conduct supervisory visits to DOTS supporters ……..1 ◯ 2 ◯
If No, explain:_____
If yes, how often

Weekly or more frequently……..1 ◯
Fortnightly or more frequently…….2 ◯
Monthly or more frequently……..3 ◯
Bi – Monthly or more frequently…..4 ◯
Less frequently than Bi – Monthly…5 ◯
Don't know……..6 ◯

Yes	No

1.2.8 Are facility/DOTS TB management structures supported by training workshops?....1 ◯ 2 ◯
If yes, how many staff members from your facility have attended such trainings in the past six months_____
If , No explain:_____

2. INFORMATION ABOUT PATIENT MANAGEMENT

Yes	No

2.1 Are clients given knowledge about symptoms management .....1 ◯ 2 ◯
If No, explain:_____
_____
If yes, explain how is it done:_____
_____

2.2 Are patients given information on prevention of infecting others.....1 ◯ 2 ◯
If No, explain:_____
_____
If yes, explain how is it done:_____
_____

2.3 Are clients motivated to change and maintain the daily behaviors that can improve their health.....1 ◯ 2 ◯

2.4 Are clients equipped with skills to manage TB themselves and make best use of the support available……1 ◯ 2 ◯

2.5 Are patients ever deferred?.....1 ◯ 2 ◯

If Yes, please state how often

Rarely……..1 ◯
Daily/weekly……..2 ◯
Annually or more frequently…….3 ◯
Less frequently than annually……4 ◯
Don't know……5 ◯

	Yes	No

2.6 Is there an appointment system in place for all patients who are deferred?.....1 2

2.7 Is there a triage (degree of urgency to decide the order) system in place that investigates and treats/refers patients?

3.7.1 all patients?.....1 2

3.7.2 patients with a chronic cough (>2 weeks)?.....1 2

2.8 Is there a referral system in place to refer patients to home based care?

If yes, describe the mechanism used:_____

	Yes	No

2.9 Is there a system in place to recall clients with positive sputa?.....1 2

If yes, describe the mechanism used:_____

3.9.1 Who does the recall?_____

3.9.2 How often is recall done?_____

3.9.3 How do staff member know who to recall?_____

2.10 Is the a mechanism of defaulter tracing in place.....1 2

If yes, comment_____

_____

If no, explain_____

_____

2.11 Are patients out in register correlate with transfer slips?.....1 2

If no, explain_____

2.12 Are clinics where patients are transferred to noted in register?.....1 2

If no, explain_____

2.13 Are clinics where patients transferred to notified of the patients?.....1 2

If yes, comment on the mechanism_____

If no, explain_____

2.14 Are clients given community DOTS option?.....1 2

If yes, comment_____

If no, explain_____

2.16 Is there a mechanism of TB Contact tracing?.....1 2

If yes, comment on the mechanism_____

If no, explain_____

2.17 How often are TB contacts traced

Weekly or more frequently.....1

Fortnightly or more frequently.....2

Monthly or more frequently.....3

Quarterly or more frequently 4

Don't know.....5

Thank you for your time and effort. Please ensure that this questionnaire is returned to the address mentioned in the cover page.

Annexure 2: Tuberculosis Control Programme review questionnaire used at Sub – District (LSA) level

District Municipality:……
Local Service Area:……

"The implication of completing the questionnaire is that informed consent has been obtained from you. Data that may be reported in scientific journals will not include any information that identifies you as a participant in this study. As all information or data are anonymous, you must understand that you will not be able to recall your consent, as your information will not be traceable. All information during the course of this study is strictly confidential."

Who should fill in this questionnaire?

This questionnaire is for the TB Control Coordinators.

By the TB control coordinators we mean health practitioners who have day-to-day responsibility for TB control in the health facilities, if not available any member of the TB control team can fill it in, or a number can share the task.

Purpose: This study focuses on TB treatment outcome evaluation and the determinants of treatment failures. The findings will provide some aspects of the evaluation of the TB treatment outcomes and therefore these will help the government to make adjustments in the programme in order to reduce the number of new infections and plan for medical and social care needs.

Any queries?

If you are uncertain how to answer any question, or wish to discuss any aspects of the questionnaire, or if you would like longer time to complete it, please contact us at: maimelae@impilo.ecape.gov.za
Telephone: 040 609 3792

The level/position of the official filling the questionnaire……

1. INFORMATION ABOUT HEALTH FACILITIES

i. How many facilities are in your LSA……. ☐

ii. How many are offering Tuberculosis services…… ☐

iii. How often are these facilities monitored by a District TB Coordinator

Weekly or more frequently…….....1 ◯
Fortnightly or more frequently……..2 ◯
Quarterly or more frequently……3 ◯

IV. How often are these facilities monitored by a Provincial TB Coordinator

Weekly or more frequently…….....1 ◯
Fortnightly or more frequently……2 ◯
Quarterly or more frequently……3 ◯
Not visited by provincial office……4 ◯

2. INFORMATION ABOUT HUMAN RESOURCE

IS THERE STAFF CAPACITY TO DO THE FOLLOWING

	Yes	No
i. Prepare decentralized Strategic plans……..1	◯	2 ◯
If No, explain:_____		
ii. Plan, manage drug supplies & equipments for health facilities……..1	◯	2 ◯
If No, explain:_____		
iii. Maintain treatment registers……1	◯	2 ◯
If No, explain:_____		
iv. Conduct supervisory visits to health facilities……..1	◯	2 ◯

If No, explain:_____

If yes, how often

Monthly or more frequently…….....1 ◯
Quarterly or more frequently……..2 ◯
Six-monthly or more frequently……3 ◯
Annually or more frequently…….....4 ◯
Less frequently than annually……5 ◯
Don't know……6 ◯

	Yes	No

v. Train lower-level staff……1 ◯ 2 ◯

If No, explain:_____

If yes, how often

Quarterly or more frequently……1 ◯
Six-monthly or more frequently……2 ◯
Annually or more frequently……3 ◯
Less frequently than annually……4 ◯
Don't know……5 ◯

	Yes	No

vi. Coordinate activities with partners……1 ◯ 2 ◯

If No, explain:_____

vii. Are district TB management structures supported by training workshops?.....1 ◯ 2 ◯

If No, explain:_____

If yes, how often

Quarterly or more frequently……1 ◯
Six-monthly or more frequently……2 ◯
Annually or more frequently……3 ◯
Less frequently than annually……4 ◯
Don't know……5 ◯

3. INFORMATION ABOUT INFORMATION DESSEMINATION

i. Is the district TB report written?.....1 ◯ 2 ◯

If No, explain:_____

_____

If yes, how often

Monthly or more frequently……1 ◯
Quarterly or more frequently……2 ◯
Six-monthly or more frequently……3 ◯
Annually or more frequently……4 ◯
Less frequently than annually……5 ◯
Don't know……6 ◯

ii. Who formally write the report

	Yes	No
a. District manager……..1	◯	◯
b. District Tuberculosis Coordinator……..1	◯ 2	◯
c. Other, please specify_____1	◯ 2	◯

iii. Which of the following elements are included in the report

	Yes	No
a. Implementation of surveillance programmes……1	◯ 2	◯
b. Programme for updating of procedures……1	◯ 2	◯
c. Training/education programmes……1	◯ 2	◯
d. Clinical Audit Programmes……1	◯ 2	◯
e. Setting of TB control goals……1	◯ 2	◯
f. Other, please specify_____1	◯ 2	◯

iv. To whom is the information disseminated?_____

_____

v. How is the information disseminated to other stakeholders?_____

5. INFORMATION ABOUT POLICY, GUIDANCE AND PROTOCOLS

i. Which of these is true?

	Yes	No
There is a complete TB Control Manual (hard copy and/or electronic) containing all the generic TB control policies for health facilities available for TB Control Coordinators……..1	◯ 2	◯

ii. Please show whether a protocol or procedure exists for each of the following and if it does, answer B and C

	A Does a protocol or procedure exist for this?		B Calendar year it was last updated	C Has it been audited in the last 12 months?	
	Yes	No		Yes	No
a. Standard Precautions	1 ◯ 2 ◯			1 ◯ 2 ◯	
b. Screening of patients	1 ◯ 2 ◯			1 ◯ 2 ◯	
c. Management of immunocompromised patients	1 ◯ 2 ◯			1 ◯ 2 ◯	
d. Staff vaccination policy	1 ◯ 2 ◯			1 ◯ 2 ◯	
e. Prevention and management of infection in hospital staff	1 ◯ 2 ◯			1 ◯ 2 ◯	
f. Investigation of contacts in the community	1 ◯ 2 ◯			1 ◯ 2 ◯	

Thank you for your time and effort. Please ensure that this questionnaire is returned to the address mentioned in the cover page.

Annexure 3: Ethical approval and permission to conduct the study by University of Pretoria

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

University of Pretoria

1 Soutpansberg Road
MRC-Building
Room 2 - 20

Private Bag x 385
Pretoria
0001

Faculty of Health Sciences Research Ethics Committee
University of Pretoria
Tel: (012) 339 8619 Fax: 086 6516047
E Mail deepeka.behari@up.ac.za
Date: 26/04/2006

Number : **S28/2006**

Title : Evaluation of Tuberculosis treatment outcomes and the determinants of treatment failures in the Eastern Cape Province, 2000 - 2003

Investigator : E Maimela, School of Health Systems and Public Health, University of Pretoria
(SUPERVISOR: PROF M J MATJILA)

Sponsor : **None**

Study Degree : **MSc Epidemiology**

This Student Protocol has been considered by the Faculty of Health Sciences Research Ethics Committee, University of Pretoria on 25/04/2006 and found to be acceptable.

Mr K P Behari	B.Proc. (KZN); LLM – (UNISA)
Prof J A Ker	Deputy Dean
Advocate AG Nienaber	(female)BA(Hons) (Wits); LLB; LLM (UP); Dipl.Datametrics (UNISA)
Prof V.O.L. Karusseit	MBChB; MFGP (SA); M.Med (Chir); FCS (SA): Surgeon
Dr M E Kenoshi	MBChB; DTM & H (Wits); C.E.O. of the Pretoria Academic Hospital
Prof M Kruger	(female) MBChB.(Pret); Mmed.Paed.(Pret); PhDd. (Leuven)
Dr N K Likibi	MBChB.; Med.Adviser (Gauteng Dept.of Health)
Dr F M Mulaudzi	(female) Department of Nursing
Mrs E.L. Nombe	(female) B.A. CUR Honours; MSC Nursing - UNISA
Snr Sr J. Phatoli	(female) BCur (Et.Al) Senior Nursing-Sister
Dr L Schoeman	(female) Bpharm, BA Hons (Psy), PhD
Prof J.R. Snyman	MBChB, M.Pharm.Med: MD: Pharmacologist
Dr R Sommers	(female) MBChB; M.Med (Int); MPhar.Med;
Prof TJP Swart	BChD, MSc (Odont), MChD (Oral Path) Senior Specialist; Oral Pathology
Prof C W van Staden	MBChB; Mmed (Psych); MD; FTCL; UPLM; Dept of Psychiatry

Student Ethics Sub-Committee

Mrs E Ahrens	(female) B.Cur
Dr L Schoeman	(female) Bpharm, BA Hons (Psy), PhD
Dr R Sommers	SECRETARIAT (female) MBChB; M.Med (Int); MPharMed
Mrs N Lizamore	(female) BSc(Stell), BSc (Hons) (Pret),MSc (Pret) DHETP (Pret)
Prof R S K Apatu	MBChB(Legon); PhD(Cambridge)
Dr S I Cronje	DD (UP) – Old Testament Theology
Dr M M Geyser	(female) BSc; MBChB; BSc HONS (Pharm); Dip PEC; MpraxMed
Dr D Millard	(female) Blur LLB LLM LLD (UJ)
Dr A.M Bergh	(female) BA (*cum laude*), Rand Afrikaans University BA (Hons) (Linguistics), University of Stellenbosch Secondary Education Diploma (*cum laude*), University of Stellenbosch BA (Hons) (German) (*cum laude*), University of South Africa (Unisa) BEd (Curriculum Research and Non-formal Education) (*cum laude*), University of Pretoria PhD (Curriculum Studies), University of Pretoria

PROF J R SNYMAN
MBChB, M.Pharm.Med: MD: Pharmacologist
CHAIRPERSON of the Faculty of Health Sciences Research
Main Ethics Committee - University of Pretoria

DR L SCHOEMAN
Bpharm, BA Hons (Psy), PhD
CHAIRPERSON of the Faculty of Health Sciences Research
Students Ethics Committee – University of Pretoria

Annexure 5: Approval for amendments of the study

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

University of Pretoria

Faculty of Health Sciences Research Ethics Committee
University of Pretoria
Tel: (012) 339 8619 Fax to E-Mail: 086 6516047
E-Mail: deepeka.behari@up.ac.za
Soutpansberg Road
MRC Building
Room 2 - 20
Private Bag x 385
Pretoria
0001

Date: 31/01/07

Amendment	:	**Title change, Change of period of study to 2003 – 2005** **Change of study population** **Change in sampling sizes for administering questionnaires**
Number	:	**S28/2006**
Title	:	Evaluation of Tuberculosis treatment outcomes and the determinants of treatment failures in the Eastern Cape Province, 2003 – 2005
Investigator	:	E Maimela, School of Health Systems and Public Health, University of Pretoria (SUPERVISOR: PROF M J MATJILA)
Sponsor	:	**None**
Study Degree	:	**MSc Epidemiology**

This Amendment: Title change; Change of period of study to 2003 – 2005; Change of study population and Change in sampling sizes for administering questionnaires have been considered by the Faculty of Health Sciences Research Ethics Committee, University of Pretoria on 30/01/2007 and found to be acceptable.

Mr K P Behari	B.Proc. KZN; LLM – Unisa; (Lay Member)
Advocate AG Nienaber	(female)BA(Hons) (Wits); LLB; LLM (UP); Dipl.Datametrics (UNISA)
Prof V.O.L. Karusseit	MBChB; MFGP (SA); M.Med (Chir); FCS (SA): Surgeon
Prof M Kruger	(female) MB.ChB.(Pret); Mmed.Paed.(Pret); PhDd. (Leuven)
Dr N K Likibi	MB.BCh.; Med.Adviser (Gauteng Dept.of Health)
Dr F M Mulaudzi	(female) Department of Nursing
Mrs E.L. Nombe	(female) B.A. CUR Honours; MSC Nursing – UNISA (Lay Member)
Snr Sr J. Phatoli	(female) BCur (Et.Al) Senior Nursing-Sister
Dr L Schoeman	(female) Bpharm, BA Hons (Psy), PhD
Prof J.R. Snyman	MBChB, M.Pharm.Med: MD: Pharmacologist
Dr R Sommers	(female) MBChB; M.Med (Int); MPhar.Med;
Prof TJP Swart	BChD, MSc (Odont), MChD (Oral Path) Senior Specialist; Oral Pathology
Prof C W van Staden	MBChB; Mmed (Psych); MD; FTCL; UPLM; Dept of Psychiatry
Dr AP van der Walt	BChD, DGA (Pret) Director: Clinical Services, Pretoria Academic Hospital
	Student Ethics Sub-Committee
Prof R S K Apatu	MBChB(Legon); PhD(Cambridge)
Dr A.M Bergh	(female) BA (*cum laude*), Rand Afrikaans University BA (Hons) (Linguistics), University of Stellenbosch Secondary Education Diploma (*cum laude*), University of Stellenbosch BA (Hons) (German) (*cum laude*), University of South Africa (Unisa) BEd (Curriculum Research and Non-formal Education) (*cum laude*), University of Pretoria PhD (Curriculum Studies), University of Pretoria
Dr S I Cronje	DD (UP) – Old Testament Theology
Dr M M Geyser	(female) BSc; MBChB; BSc HONS (Pharm); Dip PEC; MpraxMed
Mrs N Lizamore	(female) BSc(Stell), BSc (Hons) (Pret),MSc (Pret) DHETP (Pret)
Dr S A S Olorunju	B.Sc Hons; M.Sc; Ph.D
Dr L Schoeman	(female) Bpharm, BA Hons (Psy), PhD
Dr R Sommers	SECRETARIAT (female) MBChB; M.Med (Int); MPharMed

PROF J R SNYMAN
MBChB; M.Pharm.Med: MD: Pharmacologist
CHAIRPERSON of the Faculty of Health Sciences Research
Main Ethics Committee - University of Pretoria

DR L SCHOEMAN
Bpharm, BA Hons (Psy), PhD
CHAIRPERSON of the Faculty of Health Sciences Research
Students Ethics Committee – University of Pretoria

Annexure 5: Ethical approval and permission to conduct the study by Eastern Cape Department of Health

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Eastern Cape Department of Health

Enquiries: Zonwabele Merile
Tel No: 040 609 3408
Date: 25th January 2007
Fax No: 040 609 3784
e-mail address: merilez@impilo.ecape.gov.za

Dear Mr. Maimela

Re: EVALUATION OF TUBERCULOSIS TREATMENT OUTCOMES AND THE DETERMINANTS OF TREATMENT FAILURES IN THE EASTERN CAPE PROVINCE, 2003 – 2005; MR. E. MAIMELA

The Department of Health would like to inform you that your application for changing of your research period and the sample target is hereby approved as amendments to your protocol. All the health districts within the Eastern Cape Province will be notified of your changes and the following will still be expected from you if you decide to have other amendments:

1. During your study, you will follow the submitted protocol with ethical approval and can only deviate from it after having a written approval from the Department of Health in writing.
2. You are advised to ensure observe and respect the rights and culture of your research participants and maintain confidentiality of their identities and shall remove or not collect any information which can be used to link the participants. You will not impose or force individuals or possible research participants to participate in you study. Research participants have a right to withdraw anytime they want to. However, you shall be responsible in dealing with any adverse effects following the research treatment provided in your study.
3. The Department of Health expects you to provide a progress on your study every 3 months (from date you received this letter) in writing.
4. At the end of your study, you will be expected to send a full written report with your findings and implementable recommendations to the Epidemiological Research & Surveillance Management. You may be invited to the department to come and present your research findings with your implementable recommendations.
5. Your results on the Eastern Cape will not be presented anywhere unless you have shared them with the Department of Health as indicated above.

Your compliance in this regard will be highly appreciated.

DEPUTY DIRECTOR: EPIDEMIOLOGICAL RESEARCH & SURVEILLANCE MANAGEMENT

PGDP EASTERN CAPE 2004 - 2014

Ikamva eliqaqambileyo!

Annexure 6: Approval by Alfred Ndzo District municipality, Eastern Cape Department of Health

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Iphondo Lwempuma-Koloni Province of the Eastern Cape Lefapha La Kolone otshabela

ISEBE LEZEMPILO DEPARTMENT OF HEALTH
LEFAPA LA BO PHELO
Ingxowa Eyodwa/ Private Bag/ Mokotla wa poso
Alfred Nzo Health District
P/Bag X 3515, KOKSTAD 4700 SOUTH AFRICA
(BATHO PELE)
(PEOPLE FIRST, ABANTU KUQALA)

Ireferensi
Ref No.
Verwysings Nr.
Imibuzo
Enquiries Mr H.S.Magaqa
Dipotso

Ifoni
Telepho 039-7274002 / 4462
Mohala
Ifax
Facsimile039727 5725 / 1044
Fekese

TO: - MR E. MAIMELA
BISHO

Your correspondence dated 12 January 2007 bears reference

- This office acknowledge and appreciate that you would like to conduct a study on the "EVALUATION OF TIBERCULOSIS TREATMENT OUTCOMES AND THE DETERMINES OF TREATMENT FAILURES IN THE EASTERN CAPE PROVINCE"
- This office aligns itself with the Departmental approval of your research and will therefore inform the managers about your visit.
- Necessary arrangements will be made and the programme managers concerned will be informed
- All sampled facilities will be ready.
- This office therefore gives you this letter to submit in any Alfred Nzo facilities that you will visit.

Good Luck!

25/01/2007
ACTING DISTRICT MANAGER
ALFRED NZO HEALTH DISTRICT

Annexure 7: Approval by Amatole District municipality, Eastern Cape Department of Health

Isebe LeZempilo - Department of Health
Amathole Health District
Province of the Eastern Cape

Ingxowa Eyodwa
Private Bag X9015
East London. 5200

Enquiries E N PUTTA
Tel (043) 7220029
Fax (043) 7220418

Date: 17/01/07

SUBJECT : **PERMISSION TO DO RESEARCH.**

This is to confirm that Mr. Eric Maimela has been granted permission to conduct research, at Amathole Health District facilities and as such it is hereby requested that he be allowed to have an access to TB data from the year 2000-2003 for him to complete the research.

DISTRICT MANAGER AMATHOLE

Annexure 8: Approval by Cacadu District municipality, Eastern Cape Department of Health

0109

PROVINCE OF THE EASTERN CAPE
DEPARTMENT OF HEALTH
CACADU DISTRICT OFFICE / CORPORATE SERVICE CENTRE
P O Box 27156, Greenacres
PORT ELIZABETH 6057
Golden Mile Building 5th Floor, Govern Mbeki Road, Port Elizabeth

Enquiries	:	Mrs G. Nchukana	Our Reference	:	
Telephone	:	(041) 408 8153/8152	Your Reference	:	
Facsimile	:	(041) 408 8149	Date	:	2007/02/15
E-mail	:	gloria.nchukana@impilo.ecprov.gov.za			

To: Mr. E. Maimela

From: District Manager-Cacadu

RE: PERMISSION TO CONDUCT RESEARCH IN CACADU DISTRICT HEALTH FACILITIES

Thank you for your submission or request to conduct a research study in health facilities within the Cacadu district Municipality.

Please be advised that the clinics will not permit you entry for your research without this letter of introduction. Your research should not involve the use of clinic staff as research assistants/fieldworks.

The distribution of your questionnaires is part of data collection and the title of your research being "**Evaluation of Tuberculosis Treatment Outcomes and the Determinants of treatment Failures in the Eastern cape Province, 2000 – 2003.**

Hoping that the findings and the recommendations of the research will be utilized in the manner that could improve the TB situation in the province

The District Manager will be expecting presentation on feedback of the findings.

Yours in Health Service Delivery.

15/02/2006

Mrs N.G. Nchukana
District Manager: Cacadu Health

Annexure 9: Approval by Chris Hani District municipality, Eastern Cape Department of Health

Province of the Eastern Cape • Iphondo leMpuma-Koloni
ISEBE LEZEMPILO DEPARTMENT OF HEALTH
Private Bag / Ingxowa Eyodwa P.O. Box 664,Queenstown 5320
CHRIS HANI HEALTH DISTRICT OFFICE
BATHO PELE: PEOPLE FIRST: ABANTU KUQALA

Ref No:
Ireferensi:

Enquiries:
Imibuzo:
E-mail: nonkululeko.njaba@impilo.ecprov.gov.za

Telephone: 045-8074500
Ifoni:

Fascimile: 045-8074507
Ifekisi:

Mr Maimela E (Deputy Director)
c/o Department of Health
(Epidemiology Research & Surveillance Management)
Private Bag X 0038
BHISHO

16 October 2006

REQUEST TO CONDUCT A T.B STUDY AT CHRIS HANI HEALTH DISTRICT : YOURSELF

Sir

Permission is hereby granted that you conduct a TB study at the above Health District.

Kindly be reminded that the recommendation / outcomes of your study should be shared with the above Health District.

Please note that in future you are requested to also submit the approval letter (for you to conduct a study) from the Head of Department before you commence your study.

Wishing you success with your studies.

Yours in service.

DISTRICT MANAGER
CHRIS HANI HEALTH DISTRICT

N.R. NJABA
DISTRICT MANAGER
CHRIS HANI HEALTH DISTRICT

Annexure 10: Approval by Nelson Mandela Metro, Eastern Cape Department of Health

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

nelson mandela bay
MUNICIPALITY
PORT ELIZABETH | UITENHAGE | DESPATCH

HEALTH

tel: +27(41) 508 7417, fax: +27(41) 506 1247
PO Box 293, Port Elizabeth 6000
Republic of South Africa
e-mail: health@mandelametro.gov.za

16TH OCTOBER 2006

Mr. Eric Maimela
45 Mtati Drive Gardens
BHISHO
5605

Dear Sir,

POST GRADUATE STUDY;- MSC EPIDEMIOLOGY

Thank you for your submission of request to access Health Information for Academic Study purposes.

Permission is granted for such research to take place within the Nelson Mandela Bay Municipality(municipal) health services.

Please be advised that the clinics will not permit you entry for your research without this letter of introduction.

A copy of your research report must be made available to the Business Unit Health.

Your research should not involve the use of clinic staff as **"research assistants/fieldworks"**

The following contact persons will assist with the statistical data on T.B. for the period 2000-2003.

Communicable Diseases Programme Manager: Mrs. Ncandana **(041-5087414)**
T.B. Co-Coordinator: Ms N.Matutu **(041-5087412).**
Information Manager: Mrs. L. Erasmus **(041-5087415)**

You are wished every success in your research and studies

Thanking You

BUSINESS UNIT HEALTH
DR EBRAHIM HOOSAIN
5/4/4/5/1

Annexure 11: Approval by O.R Tambo District municipality, Eastern Cape Department of Health

PGDP EASTERN CAPE 2004 - 2014
PROVINCIAL GROWTH AND DEVELOPMENT PLAN
Ikamva eliqaqambileyo!

Province of the Eastern Cape. Iphondo leMpuma-Koloni
Department of Health. Isebe LezeMpilo
DEPARTMENT VAN GESONDHEID
OR TAMBO DISTRICT

Private Bag / Ingxowa Eyodwa X5005, MTHATHA, 5099
Batho Pele / People First / Abantu KuQala

Enquries : Mrs. Thiphanyane
Ref : 0001
Date : 16 January 2007

Telephone : 047-5310797
Fax : 047-5323995

TO : LSA MANAGERS
Clinic Supervisor
Health Facility Managers
Professional Nurses in Charge

Cc : Mr. Eric Maimela

RE: DISTRIBUTION OF TUBERCULOSIS QUESTIONNAIRES TO HEALTH FACILITIES IN THE O.R. TAMBO DISTRICT

Kindly allow Mr. Maimela to distribute Tuberculosis (TB) Questionnaires to al the Health Facilities in O.R. Tambo District, and to interview the people coordinating the TB Programme in the Facilities.

The distribution of these questionnaires is part of data collection for his research, and the title of his research study is: **EVALUATION OF TUBERCULOSIS TREATMENT OUTCOMES AND THE DETERMINANTS OF TREATMENT FAILURES IN THE EASTERN CAPE PROVINCE 2000 – 2003.**

Mr. Maimela's application to conduct the research has been approved by the office of the Superintendent General and the Epidemiological Research and Surveillance Management Unit in the Province (See attached copies).

Hoping that the findings and the recommendations of the research would be utilised in the manner that could improve the TB situation in the Eastern Cape Province.

Yours in Health Service Delivery

.....
District Manager: O.R. Tambo

Annexure 12: Approval by Ukhahlamba District municipality, Eastern Cape Department of Health

UKHAHLAMBA DISTRICT HEALTH OFFICE
P.O. BOX 210
ALIWAL NORTH
9750
debbie.mzinyati@impilo.ecprov.gov.za
051-6342661

Tuesday, January 16, 2007

From: Mrs. D.Mzinyati
Ukhahlamba District Manager
P.O. Box 210
Aliwal North
9750

To: Mr. Eric Maimela

RE: PERMISSION GRANTED TO CONDUCT TB RESEARCH IN UKHAHLAMBA HEALTH DISTRICT

Permission is hereby granted to Mr. Eric Maimela of the Department of Health (Eastern Cape) to conduct his research within clinics of the Ukhahlamba District, subject to the approved, written terms and conditions provided to him from our Provincial Office . He will be distributing TB questionnaires to all health facilities in our district. Your co-operation will be appreciated.

Yours Sincerely

Mr. K.G. Moss
Acting Ukhahlamba District Manager

DEPT. OF HEALTH
UKHAHLAMBA DISTRICT
2007 -01- 16
DISTRICT OFFICE