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**IMPROVING ADHERENCE:  
AN EVALUATION OF THE  
ENHANCED TUBERCULOSIS  
ADHERENCE MODEL IN CAPE  
TOWN, SOUTH AFRICA**

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**Karolinska  
Institutet**

Stockholm 2011

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Published by Karolinska Institutet. Printed by US-AB

Layout Ringvor Hägglöf

The cover photo was taken by W.A. Odendaal

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ISBN: 978-91-7457-220-9

# ABSTRACT

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**BACKGROUND:** Patient adherence to tuberculosis (TB) treatment continues to be problematic despite the wide implementation of directly observed therapy (DOT). In many settings with high HIV and TB co-infection, the two diseases continue to be treated differently: antiretroviral (ARV) programmes often use a patient support and empowerment approach to treatment, while TB programmes use DOT.

**AIM:** To evaluate changing a TB treatment model from DOT to an approach based on the community antiretroviral therapy (ART) model in Cape Town, South Africa.

**METHODS:** Four studies were conducted as part of the evaluation of a new model called the Enhanced Tuberculosis Adherence (ETA) programme in primary health clinics. A mixed method approach was used. Study I: Seven key informants involved in the development or implementation of the ETA, or knowledgeable of TB treatment policies in South Africa, were interviewed. Data were analysed using thematic content analysis, and examined for their relation to the Kingdon framework of agenda setting to explore why the ETA was developed. Study II: Six nurses and five adherence counsellors were interviewed, and 64 treatment supporters were included in focus group discussions in order to explore their experiences of the ETA. Data were analysed using thematic content analysis and examined for their relation to the normalization process model. Study III: 28 patients on the ETA intervention and 31 patients in comparison clinics were included in focus group discussions in order to explore their experiences of TB treatment. Two non-adherent patients were interviewed. Data were analysed using thematic content analysis. Study IV: Using a time series design, TB treatment outcome data on 19 357 patients from five intervention and five comparison clinics were collected from the electronic TB register from 1 January 2005 to 31 March 2008. Outcomes were analysed using Poisson regression.

**FINDINGS:** Study I: The intervention was developed due to problems in TB management, the availability of an alternative model in the community ART treatment programme, political changes (including a focus on empowerment), and impending large-scale ART roll-out. The change was facilitated by key individuals. Study II: The main issues hindering the normalization of the programme within clinics related to hierarchical relationships, teamwork, training needs, insufficient internalisation of the empowerment approach by staff, and logistical and management issues. Study III: Intervention patients seemed to have more positive opinions of TB treatment than comparison clinic patients. There was some indication that ETA patients were more ready to take control over their health, although there was little evidence of patient empowerment. Study IV: There was a significant improvement in smear conversion rates at 2 and 3 months in intervention clinics relative to comparison clinics. There was no significant difference in TB cure or treatment success rates.

**CONCLUSION:** The ETA seems to be an approach that is feasible to implement in primary health clinics. It achieved results not significantly different from those of DOT, but was appreciated by patients. Further efforts are needed to empower TB patients. Overall, the ETA is a promising approach that now needs to be tested on a wider scale, and that could pave the way towards integrating TB treatment programmes with ART programmes in South Africa and other high-burden settings.

**Keywords:** Tuberculosis, directly observed therapy, patient empowerment, adherence, South Africa



# LIST OF PUBLICATIONS

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This thesis consists of the following four articles, which will be referred to by their Roman numerals (I-IV).

- I Atkins, S., Lewin, S., Ringsberg, K.C., Thorson, A.  
**Developing a new model of tuberculosis treatment support in Cape Town, South Africa: a qualitative process analysis.**  
*Submitted*
- II Atkins, S., Lewin, S., Ringsberg, K.C., Thorson, A.  
**Provider experiences of the implementation of a new tuberculosis treatment programme: A qualitative study using the normalisation process model.**  
*Submitted*
- III Atkins, S., Biles, D., Lewin, S., Ringsberg, K.C., Thorson, A. (2010).  
**Patients' experiences of tuberculosis treatment an intervention to support tuberculosis treatment adherence in South Africa.**  
*Journal of Health Services Research and Policy, 15(3), 163-170.*
- IV Atkins, S., Lewin, S., Jordaan, E., Thorson, A. (2010).  
**Lay health worker-supported tuberculosis treatment adherence in South Africa: an interrupted time-series study.** *International Journal of Tuberculosis and Lung Disease, 15(1), 84–89.*



# LIST OF ABBREVIATIONS

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ART	Antiretroviral therapy
ARV	Antiretroviral
DOT	Directly Observed Therapy
DOTS	Directly Observed Therapy, Short-Course
ETA	Enhanced Tuberculosis Adherence programme
FGD	Focus group discussion
GEE	Generalized estimating equations
HIV	Human immunodeficiency virus
NGO	Non-governmental organization
MDR	Multidrug-resistant
RCT	Randomised controlled trial
TB	Tuberculosis
US	United States
WHO	World Health Organization
XDR	Extremely drug-resistant





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# ABOUT THIS THESIS

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When I moved from Finland to South Africa at the age of 16, I thought tuberculosis (TB) was something landed gentry died from in the eighteenth century, gently coughing blood into their white lace handkerchiefs. I was perhaps less than well educated. I learned part of the truth a few years later when visiting a friend and being shouted at not to use a chipped cup, because it was the cup of someone who lived in the back yard – an alcoholic and a drug addict. I was told that I could get TB from that cup. TB was now slightly more real to me, and very disturbing.

Possibly under the influence of too many soap operas, at the end of my school training I chose psychology as my future profession. When faced with the choice of clinical or research psychology, I thought that in a multicultural, multilingual society someone who speaks English, but barely understands the English culture in South Africa, would not be appropriate as a clinical psychologist. I therefore chose to study research. Psychological research is not, however, one of South Africa's priority research fields, and I ended up as an intern in a research organisation which doubled as a non-governmental organisation (NGO) and focused on injury prevention. I was introduced to community based research there, coincidentally working in one community that was part of this thesis. I was then introduced to my first South African township.

I was later offered an opportunity to do a qualitative systematic review on adherence to tuberculosis treatment. Though I did not know that much about TB, I wanted the opportunity to use and develop my qualitative skills. I was introduced to the issue of directly observed therapy, and having observed the disempowerment of some South African communities and having also personally experienced some of the negative characteristics of the South African health system; it was an issue to which I could relate. The review took some time, and I heard of an opportunity to do work on evaluating a tuberculosis treatment programme while finishing the qualitative systematic review. As I had wanted to continue my studies, I felt this was an opportunity to work in an interesting area, and this work could also form my PhD. I would also have the opportunity to be supervised by my co-author from the systematic review, incidentally it would be my first long-term contract, and I could possibly register at Karolinska Institute. There was, therefore, no real choice.

Having completed the qualitative systematic review, I had formed a rather negative perception of DOT. For the duration of this work, I tried to keep these opinions explicit, and attempted to counter their influence on my analysis or interpretation of the results. This thesis brings together the results of four years' work on evaluating the Enhanced Tuberculosis Adherence (ETA) programme. This thesis will contribute to the discussion on the empowerment of TB patients and on the integration of TB and ART programmes through discussing the ETA programme that was modelled on the South African community antiretroviral treatment programme.



# INTRODUCTION

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Tuberculosis (TB) is one of the oldest and most feared diseases in the world [1]. It remains a major global health threat despite treatment having been available for over 50 years [2]. After the advent of anti-tuberculosis drugs, TB was considered virtually eradicated in high-income countries [3] and to be under control globally [4]. However, over a half a century later TB was declared a global emergency [3].

The need to curb the epidemic was followed by the development and global implementation by the World Health Organisation (WHO) of a TB control programme – Directly Observed Therapy (Short Course) (DOTS) – now referred to as the internationally recommended strategy for the control of TB [3]. When DOTS was first implemented, in 1994, it was estimated that 1.9 million people had died from TB in 1990, and increasing numbers of people were dying annually [3].

TB was again declared an emergency in Africa in 2005 [5]. In 2009, over a decade after implementing the DOTS strategy and some years after the transition to the Stop TB strategy, there were an estimated 9.4 million incident cases of TB, most of which were in Asia and Africa [6]. Especially in sub-Saharan Africa, the TB epidemic has been driven by the HIV epidemic [7]. Internationally approximately 1.6 million people in total, including 1.3 million HIV-negative people and 0.38 million HIV-positive people, died from TB in 2008 [6]. Incidence rates of all forms of TB in some countries, such as South Africa, are over 900 cases per 100 000 residents [6].

The contribution of TB to morbidity and mortality is therefore large; TB was estimated to be the seventh leading cause of death and the 11th leading cause of disability worldwide in 2004 [8]. The global burden of TB is still considerable today, even if the global incidence of the disease has been decreasing slightly since 2004 [9].

The treatment and control of TB is made more difficult by the magnitude of the problem and the complexity of the forces driving the epidemic. Globally, TB control has been approached from a public health perspective, which is discussed briefly below.

## **THE PUBLIC HEALTH FRAMEWORK**

Public health is traditionally concerned with the health of populations, and aims to improve health, prolong life and improve quality of life [10]. Programmes within this framework have taken both a population and an individual approach to improving the health of populations [11].

Although public health is used widely, the definition of public health may change between applications; therefore, the term may be seen as being contested [12]. One perspective on public health adopted a narrow biomedical definition that concentrates on ill health, whereas the other perspective adopted a more broad definition which includes the social and economic causes of ill health [13]. The main characteristics of the latter definition of public health include an emphasis on a collective responsibility for health and the role of the State in protecting the public's health;

a focus on whole populations; an emphasis on prevention; concern for underlying socio-economic determinants of health and disease and more distal risk factors; a multi-disciplinary basis that includes quantitative and qualitative methods; and partnership with the populations served [14].

TB control could be seen as originating from the sphere of the biomedical definition of public health. The assumptions underlying the DOTS policy (discussed in more detail later) are that smear-positive patients are most infectious, and treating smear-positive patients prevents the spread of TB [15]. The policy therefore focuses on ill health, rather than on the larger social determinants of health. However, it is increasingly being recognised that TB control cannot succeed without attention to the numerous factors that both influence the high incidence of the disease and affect patients' ability to adhere to treatment. These factors include broader social and cultural issues [16, 17] which are key to managing TB. It has also been suggested that approaches that do not include these aspects should be questioned [18]. Possibly due to this recognition, the Stop TB policy has begun shifting the focus to the wider definition of public health, and has attempted to take into account the broader socio-economic determinants of the disease, including empowerment and community participation [9]. However, DOTS, and therefore DOT, remains at the core of the new Stop TB policy.

DOTS, and one of its components, directly observed therapy (DOT), could be seen as particularly contrasting with the wider definition of public health, since it could be seen as focusing on controlling patients. In contrast, the central concept within the wider definition of public health, which seeks to redress inequalities and change the determinants of health through community-based and collective action, is power and empowerment [12]. The inclusion of empowerment within TB management has become more poignant since the emergence of extremely drug-resistant TB, which has led to considerable discussion about confinement and patient rights [19]. In addition, the HIV epidemic combined with the human rights focus of the HIV programmes [20] and support of people on antiretroviral therapy (ART), may also have influenced incorporation of empowerment issues into discussions about TB management. This shift within debates on the management of TB and the inclusion of empowerment within the Stop TB policy could suggest that there is also a greater focus on health promotion activities in TB control.

Health promotion is a key element of public health practice. Health promotion approaches see health as a positive concept, not only as an absence of disease [21]. Actions within the health promotion approach focus on individuals, but also on the social, environmental and economic conditions in order to alleviate their impact on public and individual health [10]. Empowerment is one of the central characteristics of health promotion programmes [22]. Health promotion therefore aims to increase individuals' control over the determinants of health, and to improve their health through these [10]. The Enhanced Tuberculosis Adherence programme (ETA), the programme which is the focus of this thesis, could be seen as being part of a health promotion approach to TB treatment.

This thesis presents parts of an evaluation of the ETA programme, which is modelled on the ART community support programme. The following sections will provide background to this programme through introducing the goals and targets of TB management efforts, the policies designed to reach these targets, and the challenges facing TB management.

## GOALS AND POLICIES FOR MANAGEMENT OF THE TB EPIDEMIC

### Goals and targets for halting the spread of TB

The Millennium Development Goals (MDGs) are goals which are designed to meet the needs of the poorest in the world. These goals focus on, among others, ending hunger, reducing poverty and promoting education and gender equality [23]. MDG 6.c includes a focus on TB: it sets as a target halting and beginning to reverse the incidence of malaria and other major diseases [23], including TB. The specific TB-related indicators are incidence, prevalence and death rates associated with TB, and proportion of cases detected and cured under DOTS [24].

The Stop TB goals have been aligned with the MDGs. They were initially launched in 2006 and revised in 2010 in order to take into account progress made and more recent estimates [9]. The Stop TB targets in the revised document from 2010 [9] are outlined in Table 1 below.

**Table 1: Focus areas and goals of the Stop TB partnership**

Focus area	Stop TB Goals, 2011-2015
Global burden of TB	Halved by 2015 compared to levels in 1990
Incidence of active TB	Reduce to less than 1 case per million population by 2050
Treatment success	Successful treatment of 90% of smear-positive cases by 2015
HIV testing	100% of TB cases tested for HIV
Cotrimoxazole preventive therapy	Enrol 100% of HIV+ TB cases
ART	Enrol 100% of HIV+ TB patients by 2010
Multidrug-resistant (MDR) TB	Treat 100% of confirmed cases of MDR by 2015
Funding	Mobilise 46.7 billion US dollars for the 5-year strategy, of which 79% is dedicated to implementation and 21% to research and development

The original targets of the Stop TB programme published in 2006 were ambitious, and these were increased after revision for the 2011-2015 strategy. Despite these goals, recent reports indicate that the world is not progressing fast enough to halve TB mortality by 2015 [25], and with present strategies and instruments the goal of eliminating TB by 2050 will not be met [26]. In addition, according to the MDG report of 2010 [22], TB management only inches forward. The report indicates that the global incidence is falling slowly, and prevalence is falling everywhere except in the Commonwealth Independent States (CIS) of Asia<sup>1</sup> and sub-Saharan Africa [23]; and mortality is falling everywhere except in the CIS of Asia. Though mortality rates are falling in sub-Saharan Africa, they are not returning to the levels of prior to 1990 because of the HIV epidemic [23]. The 2010 MDG report therefore estimates that while the world may halve TB mortality by 2015 if control efforts and funding are sustained, this goal will not be attained in sub-Saharan Africa [23].

<sup>1</sup> The CIS Asia include 8 countries: Armenia, Azerbaijan, Georgia, Kazakhstan, Kyrgyzstan, Tajikistan, Turkmenistan and Uzbekistan ([www.http://mdgs.un.org/unsd/mdg/Host.aspx?Content=Data/Regional/cis.htm](http://mdgs.un.org/unsd/mdg/Host.aspx?Content=Data/Regional/cis.htm))

The Stop TB partnership, however, has more optimistic indicators, suggesting that the global incidence of TB has been falling slowly but steadily since 2004, and they suggest that it is possible to reduce TB to less than 1 case per million residents - if there are radical transformations in diagnosis, treatment and prevention of TB [9]. However, in terms of progress in South Africa, a recent analysis suggests that the only goal that might be attained is detection and cure of TB cases under DOTS – the rest of the indicators are unlikely to be attained according to present trends [27]. Considerable investments are therefore likely to have to be made in diagnosis, prevention and treatment of TB globally, but in particular in sub-Saharan Africa.

Global progress towards the Stop TB goals has also been relatively slow. While 100% of TB patients are to be tested for HIV in 2015, only 26% were tested in 2009, and only 1.9 million TB patients globally knew their HIV status [6]. However, estimates that 80% of HIV- positive patients were enrolled on cotrimoxazole and 40% on ART in 2008 [6], does represent some progress in managing the global TB epidemic. However, particularly poor indicators were given for the diagnosis and treatment of MDR TB. Despite these mixed results, mobilization of funding seemed to have succeeded, although much was invested in MDR TB treatment [24].

The MDGs and the Stop TB partnership goals are important in working towards containing TB, since they can increase political attention on the TB epidemic. However, TB treatment programmes continue to face challenges - such as the growing problem of drug resistance - which is likely to be the result of poor adherence to treatment and wider health-system related problems [28]. In addition to political commitment, then, new innovations and general improvements in health systems [29, 30] are needed to reach the goals. The section below reviews the policies designed for curbing the TB epidemic.

### **Policies for management of TB**

The DOTS policy, a key policy in TB management, has been highly successful in terms of national alignment: in 2008, 202 countries reported implementing the strategy [26]. The approach has strengthened TB control at many levels, including increasing governments' attention to TB control; channelling new resources to TB treatment programmes; strengthening drug supplies and information systems; health education; continuity of care; and good follow-up and information systems [31]. There is also some evidence that the strategy as a whole has improved treatment success rates, although it is unclear which component of the strategy is responsible for this increase [32]. Despite these successes it has not yet halted the global spread of TB.

The DOTS policy has five key elements [33]:

1. Political commitment to TB control;
2. Case detection by sputum smear microscopy;
3. Standardized treatment regimen of 6 to 8 months of DOT;
4. Regular, uninterrupted supply of TB medications; and
5. A standardized recording and reporting system.

This policy evolved into the STOP TB policy in 2006, in response to indications that the DOTS strategy alone was not sufficient to achieve the 2015 TB-related MDGs [34]. However, the Stop TB policy re-emphasises the importance and central position of DOTS [28].



The general aim of the Stop TB strategy is to dramatically reduce the global burden of TB [35] which, it suggests, can be achieved through the following six initiatives [36]:

1. Pursue high-quality DOTS expansion and enhancement;
2. Address TB/HIV, MDR TB, and the needs of poor and vulnerable populations;
3. Contribute to health system strengthening based on primary health care;
4. Engage all care providers;
5. Empower people with TB, and communities through partnership; and
6. Enable and promote research.

As can be seen from the above, the Stop TB policy has expanded its focus from the DOTS policy by including the wider drivers of the TB epidemic. However, the Stop TB policy retains DOTS expansion as one of its goals. DOTS includes a focus on directly observed treatment (DOT), a method that is contested widely. The following section highlights some of the key debates involving DOT.

### *Debates around DOT*

For patients, and possibly also for health care providers providing treatment, the key part of the DOTS and Stop TB policies is DOT. DOT implies that treatment is taken by a patient under supervision by another person, often a professional or lay health provider [36]. Although DOTS is a global policy and the intention is that it facilitates a uniform approach across settings, the implementation of DOT varies considerably across contexts [37], as does its quality [28]. Both providers and places of treatment provision may differ [37], which makes it difficult to assess the impact that DOT has on treatment outcomes. In South Africa, DOT is usually provided at a clinic by a professional nurse; at a lay or community health worker's<sup>2</sup> [38] home in the community; or at the patient's workplace by their supervisor [39].

Although the DOTS strategy in general has been found to be useful in managing the TB epidemic, the debates and research surrounding the DOT component (e.g. Noyes & Popay (2007) [40] and Volmink & Garner (2007) [40, 41]) have resulted in a modification of some of its aspects. For example, the observer responsible for a patient taking their treatment has changed from having to be a health professional to the possibility of a lay health worker observer, and more recently to a family member [42]. Despite these modifications, observation has remained as a key part of the DOTS strategy, at least in the South African setting. This is despite a systematic review suggesting that DOT may be no more effective than self-administration of treatment by patients [41]. Although it is difficult to make firm conclusions about the effectiveness of DOT, given the differences in the ways that DOT is implemented in different settings [41], there remains strong evidence that DOT may not be necessary to contain the TB epidemic.

Despite this evidence suggesting that DOT may not be a useful approach, it is still part of DOTS and the Stop TB strategy [9], although now presented together with patient support. Authors have noted, however, that there remains little guidance on how this component of patient support is to be

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<sup>2</sup> A lay health worker can be defined as any health worker delivering health care; trained in the context of the intervention; and having no formal health professional or paraprofessional tertiary certificate or degree [38]

implemented in practice [43]. Using DOT to provide treatment for patients is not without problems. The nature of the intervention seems to reinforce imbalances of power and capacity between the public health profession and the infected person [44], since the person with TB is required to have each dose of treatment observed and needs to comply with appointments, on terms which are often not negotiable and are decided by the health care system. In addition, requiring patients to be observed by another person often requires that patients travel to a clinic or another site in the community, which results in transport costs and lost opportunities to earn a living while travelling and waiting for treatment [16]. Partly due to these issues, DOT has been criticized as being negative and dehumanising, and as one of reasons that patients disengage from services [40].

There have been more recent attempts at making DOT easier for patients. Having family members observing treatment has been suggested as a viable alternative to having the patient receive their treatment at a clinic or in the community [42]. However, this has been criticised for being a risky, feel-good strategy [45]. The authors, who support observation by health care workers, also assert that family members might not understand treatment, and that in places where there are existing power differentials within the home, supervision by another family member might not be possible. However, treatment supervised by a health care worker is not as cost-effective as other options [46], and family member-observed treatment for TB has been found to be effective in at least certain settings [42]. In addition, TB interventions could be expected to include information for patients and possibly also for their families on treatment requirements and the treatment course.

Little is also known of the processes that take place while a family member is asked to observe a TB patient's treatment. Asking a family member to observe treatment may result in an imbalance of power in the home, regardless of whether the family member required to observe treatment is below the patient in the family hierarchy or not. It is also possible that instead of directly observing the patient taking their treatment, family members remind and motivate the patient to take their tablets. Reframing 'family-observed' as 'family-supported' treatment is therefore not difficult. DOT then becomes a matter of discourse, and any effects of family member-observed treatment may not be due to the act of observing treatment; rather, the treatment could be self-administered with family member support.

Whatever mode of treatment is used, adherence to treatment is a key issue, and one of the major challenges to managing TB. Adherence and other challenges to managing TB are discussed below.

## **CHALLENGES TO MANAGING TB**

As indicated earlier, the management of TB faces a number of problems. Although a global, structured plan to manage TB epidemics has been constructed, TB treatment programmes need to be tailored to local settings, and implementers need to pay attention to key epidemiological characteristics and resources available [47, 48], as well as to local values, beliefs and preferences regarding taking treatment. Active TB is not only the result of infection with the TB bacillus - the socio-economic characteristics of the setting influence whether a patient develops active TB or not [1]. TB epidemics have complex relationships to socioeconomic factors [18], and the disease continues to affect the poor and marginalised [18]. This, combined with challenges within health systems [25], such as poor access to treatment [26], make managing TB a complex and challenging task.

Although TB drugs have been available for decades [49] and most patients can be cured [36], it has been suggested that there are still a number of challenges to overcome in order to eradicate the disease [26]. Some of these include MDR TB and extremely drug-resistant (XDR) TB, lack of drug and vaccine development, patient adherence to TB treatment, and TB and HIV co-infection. In addition, there are a number of important health systems challenges; these are discussed later with specific reference to the South African context.

The emergence of MDR and XDR TB as a consequence of weak health systems, inadequate management and erratic treatment [28], possibly including irrational use of antibiotics [50, 51] or patient non-adherence [52], has meant that treatment takes longer and costs more, and mortality rates are increased [53]. All of this places strain on already burdened health care systems. While MDR TB has been recognised for over two decades [54], XDR TB arose more recently in South Africa [55], and has been since identified in many countries globally [56]. Reports have also surfaced of TB strains that are resistant to all available antibiotics [57], raising the possibility of *incurable* TB – an alarming prospect given the existing problems in treating a curable form of TB. While drug-resistant strains can be spread from person to person, they may also often develop in the contexts of HIV and of inappropriate treatment or poor adherence [56]. Drug resistance therefore makes adherence to treatment a priority.

The increasing problem of drug resistance also means new drugs to contain the epidemic have to be developed urgently [49]. There has been a lack of meaningful drug development over the past five decades [19]. There is also a need for an effective and affordable TB vaccine [58], the lack of which places increased emphasis on the need for effective treatment programmes. New drugs and vaccines could contribute towards curbing the disease. The unavailability of new drugs and vaccines necessitates effectively using those tools and resources available to treat TB. This includes exploring new ways of delivering care, in order to improve adherence to treatment and therefore improve treatment outcomes.

### **Adherence to TB treatment**

Adherence is a term that arose in response to the negative connotations associated with ‘compliance’ [17]. Compliance has been seen as incorporating a hierarchy and power differences between patients and medical professionals [59]. Adherence could be seen as incorporating the self-management of treatment and the importance of cooperation between the provider and the patient [17], and is a more neutral term than compliance. Adherence to long-term therapies is complicated, and notoriously difficult to achieve [60]. In TB treatment programmes adherence is a central issue, since non-adherence can result in prolonged infectiousness, drug resistance, relapse, or death [41]. Non-adherence can therefore have consequences for the individual, their family and the wider community, and can set back TB control efforts even where medication is widely available. Non-adherence will also result in increased health service costs, since retreatment and drug-resistant TB treatment costs more [61]. Reducing non-adherence to TB treatment is seen as key to reducing mortality and improving treatment success [62] - but it has long been known that up to half of all patients with TB do not complete their treatment [63].

The problem of non-adherence to TB treatment has been investigated for decades. The debate on compliance has shifted from blaming certain ethnic groups for non-compliance, to victim blaming [64]. More recently it has been suggested that attributing adherence to personal motivations may

not be helpful [16]. Adherence to TB treatment is a complex issue [60], and closely connected with larger societal and historical forces [65]. As could be deduced from the concentration of the epidemic in Asia and Africa, TB tends to affect the most vulnerable populations [66], and the most vulnerable and disadvantaged persons within those [67]. Treatment adherence is therefore closely related to social inequalities [65] and their impacts on health and health care [64].

A recent systematic review of qualitative studies indicated some of the factors that may influence TB treatment completion. It highlighted structural factors, patient-related factors, the social context and health service-related factors [16]. The results of the systematic review are expanded on below. In terms of structural factors, poverty and the financial impact of TB treatment have been found to be a major influence on adherence. Patients may hide their disease from employers for fear of dismissal, which may result in non-adherence. They may also have difficulty in obtaining sick leave to attend treatment. In addition, work may often take priority over taking treatment, since patients have a responsibility to provide for their families; attending treatment could conflict with their work seeking or work attendance. Hidden costs of treatment, such as costs for X-rays in some settings or travel costs, could also impact on adherence, especially in impoverished settings. Gender discrimination is another structural factor that may influence treatment adherence, especially in some Asian settings, where females' TB status is sometimes hidden since TB-related stigma may result in divorce or reduced prospects of marriage.

Patient-related factors include their motivation for staying on treatment, and the psychological and physiological impacts of the treatment. The knowledge of, attitudes towards and beliefs about TB and its treatment may affect adherence – for example, a patient who believes in a different aetiology of the disease, does not understand treatment requirements, and does not trust the health care system, may be non-adherent. Patients' interpretations of illness and wellness may also affect adherence in that they may consider themselves cured when they no longer have TB symptoms. The social context, then, includes the response of the family and community to TB and the patient. Patients encounter stigma in many settings, which may result in hiding the diagnosis and being non-adherent. Social support seems to be a key feature in promoting adherence. Lack of this support may contribute to a patient stopping their treatment [16].

All of these factors are interrelated, and also interact with health service-related factors [16]. Factors related to the health service include the relationship between the provider and the patient: a negative relationship and being scolded for non-adherence may result in the patient not returning to the health centre. Access to health services may also be a barrier to TB treatment adherence, since opening times of facilities may be inconvenient, or distances to travel can be far. Health services being inflexible and not including a choice for patients could also result in non-adherence [16].

Later studies have emphasised the role of unemployment and alcohol abuse [62] as factors influencing treatment non-adherence. Without question, however, all aspects of a TB patient's day-to-day life are affected by TB [43], and support is needed to increase adherence to treatment taking. Patients could also be seen as *choosing* to adhere [31], in that they have to make difficult choices between different priorities, of which TB treatment is only one. Based on this, health services would then need to make additional efforts in order to ensure that adhering to treatment is easier for patients.

These issues related to adherence become especially complex when the patient is also HIV positive. For example, a study conducted in Cape Town suggests that patients may become non-adherent to their antiretrovirals (ARVs) when they have completed their TB treatment [68]. This indicates further that HIV-TB co-infection is a major challenge to TB control, especially in settings where HIV is endemic. This issue is discussed in more detail below.

### **TB and HIV co-infection**

Globally, HIV-associated TB remains a major challenge [69], and it is possible that without HIV infection, global incidence of and mortality due to TB could be falling [30]. Approximately 11 million people are affected by this co-morbidity, and nearly 200 000 died from it in 2005 [70]. TB is the most significant cause of morbidity and mortality for HIV-infected people [71]. In comparing the 2008 and 2009 WHO reports, Hanekom et al. [69] noted an apparent two-fold increase in the estimated disease burden of HIV-associated TB. Although this increase is, according to the authors, mainly due to the increased availability of data, HIV-associated TB is a strain on health systems globally. In HIV endemic countries, the treatment of TB only has a limited impact on reducing TB incidence [28].

Despite the interactions between the two epidemics, HIV and TB programmes have traditionally been organized in separate, vertical programmes, with a duplication of resources and little communication between them [30, 72]. Almost all countries have a TB control programme, but HIV programmes are still in their infancy in some settings [30], and it has been suggested that the failure to respond in time to the HIV and TB epidemic has resulted in missed opportunities [73]. The global response to the challenge of co-infection has been described as “timid, slow and uncoordinated” (p. 1906) [74]. The reasons for a slow response to this epidemic include a lack of human, financial and institutional resources, and insufficient political will [30]. The co-epidemic is also worst in sub-Saharan Africa [69], where there are even fewer of these resources.

Enhanced coordination among HIV, TB and other major disease control efforts is seen as both logical and practical [28]. Collaboration has been made more urgent by the scale-up of ART together with the increase in MDR and XDR TB [74]. In addition, the roll-out of ART may take up some of the human resources previously allocated to TB and other services [75]. It is also suggested that the HIV-associated TB epidemic will not be halted without more imaginative use of available and potential strategies [74], which could include increased integration of treatment for the two diseases.

Better integration of TB and HIV treatment programmes has been recognized as key to improving treatment outcomes and quality of life of people living with both conditions [72, 76, 77]. The influences on the outcomes of the two diseases are the same - large-scale social forces, which are rooted in historical and economic processes [78]. HIV, like TB, has also affected the disadvantaged the most, as can be seen by the diseases' prominence in low- to middle-income countries. Because of the similarities of the populations affected by these diseases and the high rate of co-infection, there seems to be no logical barrier to attempting to have a more coordinated response to the two diseases, even if there are differences in treatment and disease progression.

Coordination of HIV and TB programmes could be achieved by integrating treatment at the community level, at the organisational level or at the policy level. At the international policy level integration

has been seen as an important goal [79], and national guidelines and programmes emphasize the importance of integrating TB and HIV programmes (e.g. [80]). However, the challenge is to implement this approach at both the organisational level and the community level [81].

To date, published examples of integrated treatment at community level are few, although there are some examples from Malawi and South Africa [76]. These programmes are integrated to different degrees. One of the South African examples is a prospective operational study in one sub-district using home-based, modified DOT [82]. A total of 119 patients had their daily doses of TB and ARV medication observed at their homes, either by a lay worker or a family member, after having completed an HIV/AIDS training curriculum [82]. After a median of 67 days into their TB treatment, patients were given HIV medication, the taking of which was observed once a day by their DOT supporter or family member. Patients on this programme achieved high adherence levels for their TB and HIV medication, with 83% of patients having an undetectable viral load at 6 months, and 84% being successfully treated for TB. However, this study included only 66% of all patients eligible, with the main reasons for exclusion being non-completion of a treatment literacy programme and unwillingness to disclose their status to the community. In addition, these patients were observed while taking their TB medication, and self-administered their HIV treatment after completing their TB medication, highlighting the contrasting approaches used in these two treatment programmes.

In addition to the challenges and the few examples of practical integration of the two programmes, particularly at scale, the differences in the history and culture of TB and HIV treatment, added to territorial protectiveness within vertical programmes, have slowed the development and implementation of policies in this area [30]. In most settings TB and HIV continue to be treated using contrasting approaches.

### **Treating TB and HIV/AIDS with contrasting approaches**

Both TB and ART programmes have the same goal – to keep patients taking their treatment as prescribed for as long as possible or, in the case of TB, for 6 months. Both are chronic infectious diseases that affect mainly the most disadvantaged populations, both are public health priorities, and both have complex drug regimens [60]. Despite these similarities and the fact that many TB patients are infected with HIV, the approaches to treatment could be said to conflict, with ART focusing more on empowerment [83] and TB focusing more on control and having an authoritarian approach towards patients [64]. Some of the reasons for the conflicting approaches may arise from the history of these two diseases, including patient involvement in care. The involvement in care of HIV-positive patients and the ways in which people's identities are shaped by living with HIV/AIDS are large areas of research, which will be touched on only briefly below.

AIDS has had a strong human rights movement, which has informed public policy [83]. HIV-positive people in high-income countries started to participate in AIDS-related policy making in the 1980s, and have made considerable contributions to many areas related to HIV and health, such as policies and law, research on HIV, and treatment access [84]. ART is also viewed by patients more as a set of rights and responsibilities rather than only treatment for a disease [85]. This movement has also been strong in South Africa, where community participation, involvement and activism in issues related to HIV have been considerable [86]. In South Africa one of the reasons for this activism has been the need for better access to treatment. In many settings, therefore, HIV-positive people have become “expert patients” - patients who are more closely involved with health services [87].

In contrast with the strong involvement of HIV patients in many aspects of treatment policy making, TB patients have been much less involved in the public domain. TB patients have not become activists despite calls for a human rights-based approach for TB treatment, especially from academic circles, for some time [44]. More recently, international health and human rights experts called for a human rights approach to health care in South Africa [20], and among other things demanded a human rights approach to TB treatment. Empowerment and community participation were also included in the Stop TB strategy of 2006 [34]. Despite these efforts, TB patients to date have generally not become activists for their illness, and little has changed in the way TB is treated in practice.

The contrasting approaches used in treating TB and HIV have also informed the way in which treatment programmes are organized. TB is treated through DOT, which can be very resource-intensive [46], since a patient needs to see a health professional or a lay health worker every day. In South Africa ART for HIV-positive patients is usually provided through self-supervised, supported, community-based treatment [88], where patients are required to see a professional nurse or doctor less often than in TB treatment. Patients on ART are also monitored less intensively than TB patients, but the ARV model is based on intensive treatment preparation, empowering patients to undertake self-administered therapy, and community-based lay treatment support [88]. In contrast, TB patients need to start their treatment immediately and do not have a treatment preparation programme, and the information they receive has traditionally focused on biomedical aspects of their disease rather than the psychosocial aspects [89].

Studies indicate that patients who self-administer their ART can achieve high adherence rates at 6 months [68, 90], and a high proportion of these are retained in care after 6 months [91], at least in selected settings in sub-Saharan Africa [92]. Although the adherence rates of ART and TB programmes are difficult to compare due to different methods of measuring adherence and treatment success, TB programmes do not seem to be able to achieve the same high rates of patient retention on treatment. TB treatment success rates remain relatively low, and below the international target of 85% [6]. The question remains, however, whether the high adherence rates achieved by the ART programmes are sustained when ARV medications become more widely available and enrolment into these programmes is less selective [52]. Some results from Kenya suggest that these high adherence rates may not be sustained in high-risk, highly mobile, resource-limited settings [93].

Despite the challenges in measuring success in these two programmes, and the conflicting approaches taken to treatment, the similarities between HIV and TB and the rates of co-infection suggest that an integrated approach is needed. As the approaches of the current treatment programmes contrast, at least at the patient level, changes would have to be made to programmes in order to integrate treatment. The alternatives are a new treatment delivery programme for both; DOT for ART and TB [94]; or self-administered treatment for ART and TB. There is, however, little evidence of the effectiveness of DOT for TB treatment [41], or for ART [95]. The good outcomes achieved by HIV programmes that provide community-based treatment through an empowerment approach [90], although in limited settings, suggest that the approach should be evaluated in TB care. Given the paternalistic approach of DOT [40], self-administration based on more empowerment-focused approaches may be the preferred option for patients.

The following section gives a brief overview empowerment, the central issue in this thesis.

## **PATIENT-CENTEREDNESS AND EMPOWERMENT**

In 1978 the Alma Ata declaration recognised that people have a right to participate, both individually and collectively, in their own health care [96]. The Ottawa Charter took this further in 1986, stating that power should be shared between health services and communities [21]. It is increasingly also recognized that inclusion, agency and control are important for people's health and well-being [29]. Authors have also suggested that patients are experts on their own bodies, and this knowledge is essential for successful treatment [97]. This move towards sharing power and recognising patient expertise suggests that approaches to care that incorporate the concepts of patient-centeredness and empowerment could be beneficial for TB patients and eventually for treatment outcomes.

Patient-centeredness is not synonymous with empowerment, but the concepts are complementary. Patient-centred care refers to the context of clinical health care settings and the relationship between caregiver and patient [97], while patient empowerment focuses on empowering individuals and sometimes groups of individuals, and is broader and more challenging for caregivers and healthcare organizations. Patient-centred care is not limited to communication, and often also focuses on other aspects of care such as accessibility of services [98].

Empowerment, on the other hand, can be seen as a process by which people can gain mastery over their own lives; it can lead either to a sense of control or practical power to effect change [99]. It could be seen as the process of "enabling people to choose to take control over and make decisions about their lives" (p. 309) [100]. The benefit of empowerment approaches is that they focus on capabilities and the environmental influences of social problems, rather than victim blaming and risk factors [101], and posit patients as responsible for their choices and the consequences of their choices [102].

There is a need for patient-centred services in TB care [40, 103], and a need for a shift from controlling patients to supporting them [17, 66]. However, patient-centeredness and empowerment are not new concepts within TB care [104]. There have been a number of attempts to introduce a patient-centred approach in TB care [105-107], and interventions to increase the patient-centeredness of care delivered by physicians have had positive results on patient satisfaction and on how care is delivered [108]. In TB care one of the challenges to providing patient-centred care has been identified as the rigid, task-orientated implementation of DOTS by nurses within TB clinics [109, 110].

Some authors have also criticised these approaches, stating that it has become part of the rhetoric of health professionals but has not translated into action [111]. However, the development and implementation of empowerment-focused programmes is difficult, since one cannot 'give' empowerment to someone - people must themselves want it and gain it [12]. There are also too few published examples of how patient-centred or empowerment-focused programmes are to be implemented within the context of TB [104], and the Stop TB policy gives little guidance on its implementation [43]. Developing programmes with an empowerment approach also requires community or target group participation from the beginning - from defining the problem to finding the solution and defining the ways in which the problem is addressed [12]. This method of developing programmes - especially those which are to deliver a public health intervention - may require considerable time and effort. Time is not always available, especially given the urgency of treating an infectious disease such as TB. TB treatment, then, may be an area in which it is



particularly challenging to develop an empowering programme, not least because TB treatment is traditionally focused on the control of patients [64].

Some of the ways in which communities can be part of TB treatment programmes is through employing community health workers or recruiting key members of communities to provide input or feedback to health care systems. For some time researchers and policy makers have called for the involvement of civil society, community representatives and patients as part of TB control [30, 112]. Within the empowerment approach communities can have a central role in the fight against TB [111]. Existing programmes that have included community participation in TB treatment have focused on, among others, increasing awareness of the disease; case detection and referral for diagnosis; increasing access to drugs; addressing stigma; and supporting and motivating patients [113]. The results of these studies suggest that community involvement in TB treatment may be beneficial.

The programme focused on in this thesis has been posited as taking an empowerment approach to treatment, by facilitating individual patients to take control over their treatment course and their health.

## **THE PROBLEM**

Despite the synergies between the HIV and TB epidemics in South Africa, the diseases continue to use contrasting approaches to treatment delivery and support. TB treatment is managed using DOT, while ART programmes are based on supported self-administration and come from the sphere of empowerment. There is an urgent need to integrate these two treatment programmes, which could be done through using the community ART programme for TB. This approach would respond to policy makers' and researchers' calls for including an empowerment approach in TB treatment programmes, and would be aligned with the Stop TB policy.

However, to date there is little published evidence of the effectiveness of empowerment-based TB programmes [104], and little guidance on how empowerment-focused programmes should be implemented in practice [43].

# AIM AND RESEARCH QUESTIONS

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The aim of this thesis is to examine changing a TB treatment model from DOT to an approach based on the community ART model.

*General research questions:*

1. Why was the ETA developed? (Study I)
2. What were the key issues that influenced the implementation of the ETA from staff perspective? (Study II)
3. How did the ETA affect patients' experiences of TB treatment? (Study III)
4. What impact did the ETA have on TB treatment outcomes? (Study IV)

*Specific aims of articles I-IV:*

- I. To examine the development of a new TB treatment support programme modelled on the community ART programme
- II. To explore staff perceptions of implementing the ETA
- III. To explore patient experiences of a TB treatment programme modelled on the community ART programme
- IV. To determine the impact of the ETA compared to DOT in Cape Town, South Africa

The structure of this thesis is guided by the research questions.

# METHODS

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## OVERVIEW OF STUDY DESIGN

Table 2 presents an overview of the thesis and the studies within it.

**Table 2: Overview of studies in the thesis**

Study	Research question	Design and method	Subjects and sample	Setting	Data collection
I	Why was the ETA developed?	Qualitative explorative study	5 managers and developers of the new intervention and 2 academics involved with TB policy	Cape Town	Semi-structured interviews with all participants
II	What were the key issues that influenced the implementation of the ETA from staff perspective?	Qualitative exploratory study	5 adherence counsellors; 6 TB nurses and 64 treatment supporters	5 clinics providing new intervention within City of Cape Town health district	Semi-structured interviews with adherence counsellors and nurses. Focus group discussions (FGDs) with treatment supporters
III	How did the ETA affect patients' experiences of TB treatment?	Qualitative exploratory study	61 TB patients: 28 intervention, 31 comparison, two recalled patients	One clinic providing usual care to TB patients, two clinics providing the new intervention	FGDs with adherent patients; semi-structured interviews with non-adherent patients
IV	What impact did the ETA have on TB treatment outcomes?	Time series design with comparisons	19 357 TB patients (over 18 years of age) registered between January 2005 and end March 2008	10 primary health care clinics within the City of Cape Town health district	Data collected from routine TB register

The thesis combines the use of qualitative and quantitative methods, which complement each other: quantitative methods can determine the effects of the programme, while qualitative methods

can highlight the processes and mechanisms that result in these effects and produce in-depth knowledge of the phenomenon [114]. The qualitative studies were done from a participatory evaluation perspective [115], in that the health services had an opportunity to contribute to research questions and comment on findings.

Using Kingdon's [114] model of agenda setting, Study I aimed to examine the reasons behind the decision to pilot a new programme, given the history and tenacity of the DOT approach. Study II examines the implementation of the programme according to staff, and presents results contextualised within the normalisation process model [116] (please see the later and articles I and II for a more detailed description of these theoretical models). Study III examined the qualitative effects of the programme on patients' experiences of TB treatment, based on FGDs at intervention and comparison clinics, and interviews with 2 patients who had been recalled to clinic treatment after having been non-adherent while on the ETA model.

Using a time series design, Study IV compared the TB treatment outcomes of clinics implementing the ETA with clinics implementing DOT to establish the outcomes of the ETA [117].

## STUDY SETTING

### South Africa

South Africa is a middle-income country on the southern most tip of Africa, populated by approximately 50 million people [118]. South Africa is divided into nine provinces and 52 health districts [119]. The country is strongly affected by HIV – the prevalence of HIV was estimated at 29,4% in women attending public sector antenatal clinics in 2009 [120]. The overall HIV prevalence in the country was estimated at 16.9% in 2008, and approximately 5,6 million South Africans are living with HIV [121]. The HIV epidemic in South Africa is embedded in the social inequality coming from a history of oppression and exploitation [122], and is one of the major contributors to problems in the health care system. Key demographic data on South Africa are presented in Table 3.

**Table 3: South Africa's key indicators**

Population	49,99 million (estimate 2010)
Languages [123]	11 official languages, with the largest language groups being IsiZulu and IsiXhosa
Population below poverty line (\$2 per day, 2000-2007) [124]	42,9%
Unemployment (April-June 2010) [125]	25,3%
Life expectancy at birth [118]	53,3 (male), 55,2 (female)
Literacy rate in those aged 15 and above (1999-2007) [124]	88,0%
Sex [118]	49% female, 51% male
Infant mortality per 1000 live births [118]	46,9
Fertility rate (children per woman in 2010) [118]	2,38

South Africa is also one of the most unequal countries in the world. The Gini coefficient, which measures income inequality within populations, was 0.72 in 2006 [126], which is extremely high. Statistics South Africa also reported in 2008 that the richest 10% of the country were earning more than 50% of household income in the country, while the poorest 40% received only 7% of the total household income [126].

### **Health care systems in South Africa**

South Africa utilises the district health care system to organize and provide treatment, which means that one health authority is responsible for primary health care and makes decisions on the health care for a particular district [127]. In theory, the district health system allows communities the opportunity to contribute to health care decisions for improved access for all and for the decentralization of care [127]. However, it has been suggested that the problems within South Africa's health care system are substantial and generally underestimated [128].

The proportion of the global burden of disease borne by South Africa is disproportionately high [50], and despite global support, leadership has faltered at national level [19, 50]. One of the indications of the problems within the South African health care system is the emergence of XDR TB in South African communities [55].

There are also early indications that South Africa will not reach the MDGs in many areas, including reducing the prevalence of underweight children, reducing the under-five and infant mortality rate, increasing life expectancy and decreasing maternal mortality [27]. However, some goals - such as improving drinking water, sanitation facilities and malaria incidence and deaths, antenatal care coverage and a reduction of HIV prevalence - are likely to be reached [27].

In addition to a high disease burden, which results in challenges to service delivery, South Africa is also one of the countries affected by the human resources for health crisis [129], and has experienced a 'brain drain' of health personnel, both to overseas [130] and within the country into the better managed and funded ARV programmes [75], and into the better-paid private sector.

The combination of high burden of disease and limited resources when compared with high-income countries has necessitated searching for different approaches to health care services. The WHO has recommended task shifting as one of the approaches that could rapidly increase access to HIV and other health care services [131]. Task shifting means that another, lower, cadre takes on some of the tasks of a higher cadre of health worker [132], for example lay health workers taking on some of the tasks of nurses.

Task shifting has been used as one way to supplement the human resource supply in South Africa, and TB treatment programmes in South Africa have depended on lay health workers for years. Global research indicates that having lay health workers supervise TB treatment taking does not have negative impacts on treatment outcomes [38, 41]. Other findings of the benefits of task shifting include increasing access, and there is some weak evidence that it does not harm quality of care [133]. However, there is a need for ongoing training and supervision, and tension between lay health workers and nurses is possible [133]. Therefore, while perhaps more cost-effective, having lay health workers taking on some of nurses' responsibilities remains challenging.

## **TB in South Africa**

South Africa has the third highest burden of TB in the world. The incidence rate of all forms of TB in South Africa was estimated at approximately 971 per 100 000 residents in 2009 [134]. Although the HIV epidemic in the country seems to be stabilizing [121], approximately 58% of South African TB patients are estimated to be co-infected with HIV [134]. The TB epidemic is interacting with the HIV epidemic [120], and this, combined with growing drug resistance, means that South Africa faces one of the worst TB epidemics in the world [128]. The toll of TB on HIV-positive people in South Africa can be illustrated by a small-scale post-mortem study conducted on 240 cases between 20 and 40 years of age in KwaZulu-Natal in South Africa. Patients were selected if they had died in inpatient treatment at the medical or surgical ward of the hospital, were between 20 and 40 years of age, and consent was given by a family member for the study. Patients who died from trauma or obstetric complications were excluded. Of the total 240 cases, 226 were HIV-positive; half of the patients were being treated for TB at the time of their death, while of the other half not on treatment, 42% were culture-positive for TB [135].

TB programmes in South Africa follow the approach recommended in the international DOTS policy. As most TB patients take treatment for 6 months, this is placing strain on an already overburdened public health system. Treatment is observed at primary health care clinics [110], by lay health workers in the community, or by a work supervisor at the patient's workplace [33]. However, the clinics at which treatment is provided are often overcrowded and have scarce resources [136]. In addition, the health care professionals responsible for running the clinics and providing TB treatment have been described as overworked and stressed [136]. Despite implementing DOTS, national TB treatment success rates were 76% in 2008 [134]. While this represents an increase in treatment outcomes over time, it does not reach the internationally recommended target of 85% [6].

### **Specific setting for this study**

The study took place in the Cape Town Metropole health district in the Western Cape Province of South Africa (see Figure 1), which could be considered relatively well resourced when compared with the rest of South Africa.

Cape Town has approximately 3,4 million inhabitants [137] and eight health sub-districts [138]. As in South Africa in general, the burden of HIV and TB in Cape Town is high: antenatal surveys suggested an HIV prevalence of 16.1% in 2008 [120], and the incidence of smear-positive TB in the district was approximately the national average of 283.4 cases per 100 000 residents in 2007 [139]. In 2006 77.3% of smear-positive TB cases in Cape Town were cured [140], which is higher than in most settings in South Africa, but remains lower than international targets. HIV was first and TB was third in the top causes of death in Cape Town in 2006 [141].

The five clinics in which the programme was implemented are located within three of the eight health sub-districts within the City of Cape Town. They are located on the outskirts of Cape Town, in areas populated by mainly Xhosa-speaking Africans. The clinics involved in the study all had high TB caseloads (500-1000 patients per year), with an average treatment success rate of 78%, and similar HIV incidence, where approximately 68% to 73% of TB patients tested in 2007 had a positive HIV test result [142].

The next section describes the programme being focused on in this thesis.

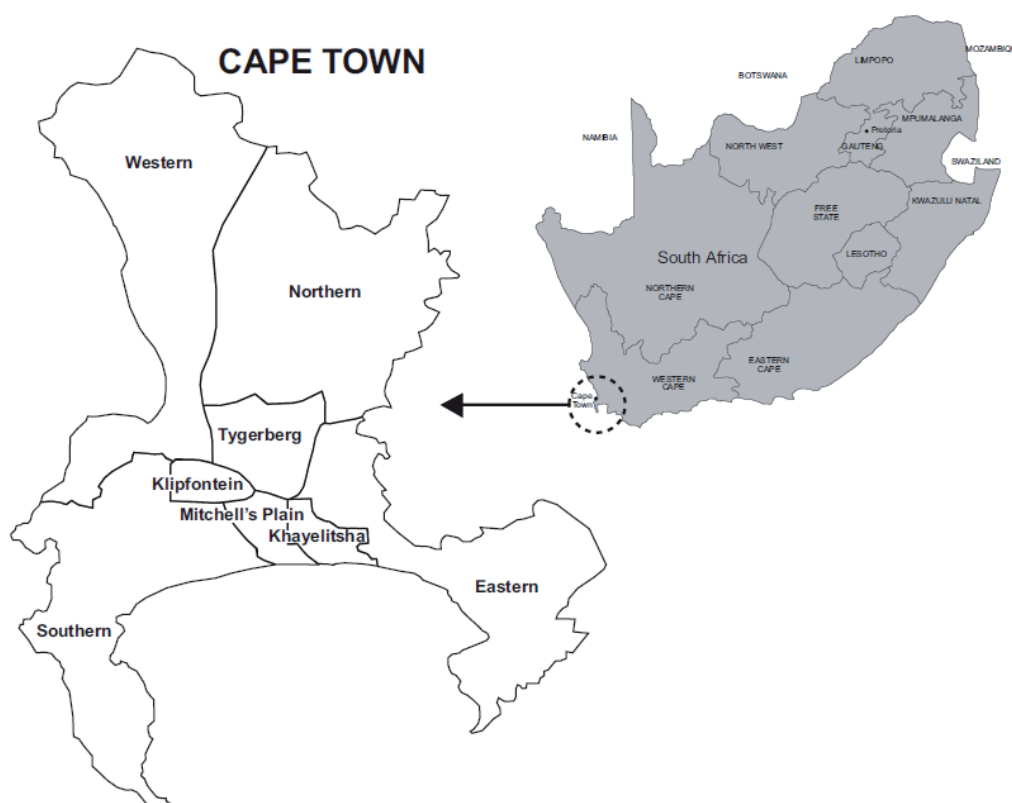


Figure 1: Map of South Africa with an enlargement of Cape Town health sub-districts

## THE ETA PROGRAMME

### Background

City Health, Cape Town developed a new programme to increase adherence to TB treatment in collaboration with Provincial Health, Western Cape, and TB/HIV Care (a non-governmental organization (NGO) involved in the support of people on TB and HIV treatment). They began developing the programme in 2005. The programme is modelled on the ART programme [88]. Table 4 provides a description of differences between the usual DOT approach and the new programme. The programme is in line with the key elements of the WHO 2006-2015 Stop TB strategy [34], one element of which includes increased participation in treatment and monitoring by communities affected by the TB epidemic [143].

**Table 4: Differences between the DOT and ETA approaches to treatment delivery and support**

<b>DOT</b>	<b>ETA</b>
Training: Standard nurse training for nurses; 5-day training for lay DOT supporters	Training: Additional 1 day induction to the ETA for nurses; additional 3-day induction to the programme for DOT supporters (now called treatment supporters); adherence counsellor training for ex-DOT supporters, including five days of programme training and five days of counselling training
Patient is initiated onto DOT in the clinic (takes treatment once a day under supervision of the TB nurse)	Before initiating self-administered treatment, the patient is placed on DOT in the clinic for a short period (takes treatment once a day under the supervision of the TB nurse for approximately 2 weeks) to identify problems that might preclude self-administration of treatment
Mode of treatment delivery: DOT	Mode of treatment delivery: self-administration at home with pill counts by treatment supporter
Short information session about TB and its treatment given by the TB nurse	Trained lay adherence counsellor gives TB information to the participant in 3 - 4 counselling sessions of half an hour each, focusing on treatment education, side-effects, healthy living and adherence planning and TB and HIV
No visits are made routinely to patients' homes	A treatment supporter conducts a home visit to document the patient's home circumstances and verify their address. TB contacts, immunocompromised persons and children under 5 years in the household are also referred to the clinic for testing and vaccinations
No meeting of different role-players to discuss treatment support	Nurse, adherence counsellor and treatment supporter meet to discuss each patient's eligibility for self-administration
Patient can receive DOT in the workplace, at the clinic, or by visiting a DOT supporter in the community	Patient can take treatment in the workplace, or at a clinic, but can also obtain a one-month supply of tablets from the clinic and self-supervise their treatment
If patient is not on clinic DOT, nurse sees patient at diagnosis, for DOT, for 2/3 month sputum and at the end of treatment	Nurse sees patient at diagnosis, DOT for two weeks and, if the patient is eligible for self-administration, once per month until the end of treatment and for 2/3 month sputum and end of treatment sputum
If the patient is placed on community-based DOT, s/he visits a treatment supporter once a day to receive treatment. Maximum DOT supporter caseload is 30 patients per month	If the patient is placed on the ETA model, a treatment supporter visits the patient three times in the first week and once a week thereafter to monitor treatment taking. Maximum treatment supporter caseload is 60 patients per month
No formal integration of family or friends into the treatment plan	Treatment "buddy" has an important role – s/he attends counselling and acts as a support and reminder to the patient. The buddy can be a friend, family member or neighbour of the patient



## **Implementation of the programme**

The programme was implemented in two primary health care clinics from October 2006, and in three additional primary health care clinics providing treatment for TB from 1 April 2007 to 31 March 2008.

Once diagnosed, a TB patient would attend four adherence counselling sessions with the adherence counsellor – a trained lay health worker. These sessions were guided by a flipchart specifically developed for this purpose, which gives information on: (a) TB; (b) TB treatment and HIV; (c) adherence planning; and (d) general health issues. All counselling sessions were intended to be attended by patients and a “treatment buddy” (a close friend, neighbour or family member who lives in close proximity to the patient) who was asked to support adherence in the patient’s home during treatment.

A TB treatment supporter – also a lay health worker – would conduct a home assessment to establish whether the home environment was conducive to adherence. Following the four counselling sessions, an evaluation meeting was held between the TB nurses; TB treatment supporter and adherence counsellor to decide whether the patient would be offered self-administered treatment. Those patients deemed suitable for the programme received one month’s treatment supply. The exclusion criteria were:

- Patients with substance abuse problems
- Patients without a permanent place to live
- Patients who were mentally incapacitated
- Patients who had drug resistant TB
- Patients who were on retreatment for TB
- Patients who could take TB treatment at their workplace
- Patients who were transferred to another clinic within the first two weeks of treatment
- Patients who preferred clinic-based treatment

Patients were asked to use a calendar to keep track of their adherence at home. The envisaged role of the treatment buddy was to give general support to the patients throughout the treatment, such as reminding about medication, attempting to solve difficulties in taking treatment, and reporting these to the clinic. The TB treatment supporter would visit the home three times in the first week and once a week thereafter to discuss any issues that may have emerged and to monitor adherence. The patient also visited the clinic TB nurse monthly to be weighed and to collect medication. At 2 and 5 months into the treatment smear-positive patients would visit the nurse to provide sputum samples.

In order to implement the programme, a trained lay adherence counsellor was employed at each clinic, while two were employed at a clinic with caseloads over 1800 patients per year. These adherence counsellors were drawn from a pool of existing lay health workers working for the TB/HIV Care NGO. In addition, lay treatment supporters were employed at each clinic to conduct the community-based arm of the programme. They were also employed by TB/HIV Care.

The programme initiators proposed that increased support, not having to spend time and money in visiting a clinic daily, and a structured plan for adherence would increase patients' adherence to TB medication. In addition, taking patients out of the clinic setting and delivering treatment in the community would allow more time for TB nurses to attend to those cases that required more attention.

## **METHODS OF THIS THESIS**

### **Participants and data collection**

Qualitative data collection was conducted in English and in IsiXhosa. The interviews conducted in English were performed by SA, and FGDs and interviews with treatment supporters and patients were conducted by experienced Xhosa-speaking assistants with university level training in social science. The interviews and FGDs were also translated by these assistants, and further checked by another Xhosa speaker. Although invited, the assistants declined to be part of the analysis due to other study commitments. Debriefing was conducted after each group, about the assistants' opinions and feelings regarding the group and any issues that should be resolved. Most interviews and all FGDs were digitally recorded and transcribed verbatim. Two interviews with one nurse were not recorded at her request.

In addition to the interviews and FGDs, participant observation was conducted at steering group meetings in which the implementation and planning of the ETA was discussed. These meetings were attended by the NGO responsible for managing the lay health workers part of the programme; the managers from City Health, Cape Town; and staff representatives from each clinic implementing the programme. In addition, facility managers and representatives from the Provincial Department of Health were invited to the meetings. Notes were taken during these meetings that were referred to in analysis for Studies I and II. In addition to participating in the steering group meetings, SA also attended a number of the clinic meetings between nurses, adherence counsellors and staff. The clinic environment was observed during these visits and informal conversations were had with staff about the programme. This provided insights into the implementation of the programme at the participating clinics. The detailed methods of each study are described below and in each included article.

#### *Study I: Interviews with programme managers, policy makers and academics*

Five programme managers were invited to interviews via telephonic and email contact. All programme managers involved in the programme from the start of implementation were asked to participate, as they were best placed to discuss why the programme was developed. In addition to these interviews, two academics that had over 20 years of experience in TB research were approached purposively for interviews. They were best placed to comment on recent developments in the field of TB treatment and how these related to past policies.

All interviews were in English and took place in the participants' offices, beginning approximately 2 months after implementation. A semi-structured guide was used to conduct the interviews (Appendix 1), which was modified during data collection to explore issues that emerged as important in influencing implementation of the programme. Data collection continued until data were saturated.

*Study II: Interviews with TB nurses and adherence counsellors and FGDs with treatment supporters*

This study focused on professional TB nurses', adherence counsellors' and treatment supporters' experiences of implementing the ETA. All TB nurses, adherence counsellors and treatment supporters involved in the ETA were asked to attend interviews or FGDs through a personal invitation by SA. A suitable time and place was agreed upon. Treatment supporter FGDs for two clinics were held at a nearby meeting hall due to space restrictions within the clinics. At three other clinics the FGDs were held in a free space at the clinic or in the clinic grounds. All interviewees and FGD participants were offered refreshments. In addition, treatment supporters were reimbursed for their travel costs. The final number of participants in interviews and FGDs is described in Table 5 below.

**Table 5: Participants and FGDs within each participating clinic**

<b>Staff category</b>	<b>Participants male/female</b>	<b>No. of interviews (Int.) or FGDs</b>
Professional nurses	1/5	7 Int.
Adherence counsellors	0/5	8 Int.
Treatment supporters	1/63	8 FGDs

In total, 64 treatment supporters attended the FGDs. All adherence counsellors, all but one of the treatment supporters and all but one of the nurses were female. The interview and FGD guides were similar (Appendix 2), and touched on issues relating to experience of implementing the intervention, relationships with other staff, relationships with patients, and any challenges or positive issues that may have emerged during the programme.

*Study III: FGDs with adherent patients and interviews with non-adherent patients*

This study, which focused on patients' views and experiences of TB treatment, was based on ukz FGDs with patients from two intervention clinics and two FGDs with patients from a comparison clinic. In addition, two interviews were conducted with patients who were part of the ETA but who had not completed their treatment. All patients were sampled using convenience sampling.

At intervention clinics, treatment supporters were asked to contact all of their patients and to invite them to attend an FGD at time and place away from the clinic itself. On the day, patients were received by the focus group moderator.

Non-adherent patients were contacted by adherence counsellors in collaboration with nurses. Nurses were asked to inform adherence counsellors when non-adherent patients attended their treatment, and adherence counsellors then asked them to participate in an interview. These patients were interviewed on the clinic grounds.

At comparison clinics, a nurse was asked to contact all of their patients to invite them to attend an FGD, which was held in a central place outside the clinic.

The FGDs and interviews followed a similar semi-structured guide (see example in Appendix 3). Men and women were included in separate groups. This choice was made due to the recognition that women might allow men to dominate the conversation, and because women and men have

been reported to have different adherence patterns and health-seeking behaviour when infected with TB [144]. In addition, due to TB’s close link with HIV, participants may have wanted to raise issues that would not have been discussed in a mixed group. All participating patients were given refreshments during the focus group and were reimbursed for travel costs (approximately R6/US\$1 per person).

Characteristics of patients who participated in the FGDs are outlined in Table 6.

**Table 6: Characteristics of patients participating in FGDs**

	Intervention	Control	Patients who were not adherent on the ETA (intervention clinics)
No. of FGDs/ interviews	1G	1G	1G
No. of participants	11	3F	1G
Men	11	1H	1F
Women	1H	1F	1F
Age (median)	3H (18-19)	1B (18-78)	1G (21-27)
Employed	3	10	0
Married	1	1	0
On other chronic medications	1	1G	1
Median time on treatment	4 months	4 months	4 months

*Study IV: Time series study*

This study aimed to determine the impact of the ETA intervention on treatment outcomes when compared with clinics providing DOT. This study is based on the electronic TB register (Etr.net) of the five intervention clinics and their five comparison clinics. The five intervention clinics were chosen by the City of Cape Town, based on their need for intervention. In order to choose comparison clinics, the clinics within the City of Cape Town which were not part of another research project were listed. From these, the clinics most suitable and similar to the intervention clinics in terms of TB patient loads and treatment outcomes were chosen.

All data on TB patients newly registered at the 10 clinics were extracted electronically from etr.net from 1 January 2005 to 31 March 2008. The electronic TB register has rigorous quality controls implemented by the City of Cape Town. The start period was chosen as 2005 since there was a change in TB definitions used in the services at the end of 2004. Information on patients receiving the ETA programme was collected with a separate clinic-based register. This information was merged with the intervention database.

Following extraction, data were cleaned and children under 18 years of age, MDR cases and transfers into the facility were removed. The dataset was examined carefully for errors, and a quality check was performed based on clinic registers and folders where available. Missing data were sought in the first instance from the paper-based TB register of each clinic, then from clinic patient folders.

In total, 192 missing outcomes, representing 1% of the total sample, were identified in the dataset between January 2005 to end March 2008. Of these, 109 were in intervention sites and 83 in comparison clinics. From intervention clinics, 91,7% of these were found and entered, and in comparison clinics 75,9% were found and entered. The remainder entered the analysis as missing data.

For quality control purposes an initial sample of five random register entries from each quarter for the period April-September 2006 and April 2007-March 2008 were extracted. The total number of register entries checked was 200, which represented 2.7% of entries for intervention clinics and 4.8% for comparison clinics. These register entries were checked either in the register or folder at the clinic, and corrected in the dataset. The quality assurance process revealed 13 discrepancies between the electronic register and paper-based register or folder, representing 0.065% of the checked entries.

After removing duplicates, the final dataset included 19 357 patients.

Figure 2 details the cleaning process and the final number of patients included in the study. A total of 24 447 patients were registered into the electronic TB treatment register from 1 January 2005 to end March 2008. After excluding patients who had started treatment elsewhere, MDR patients, those under 18 years and double entries, 19 357 patients were eligible for this study. Of these 19 357 patients, 2519 were eligible for the intervention between 1 April 2007 and 31 March 2008.

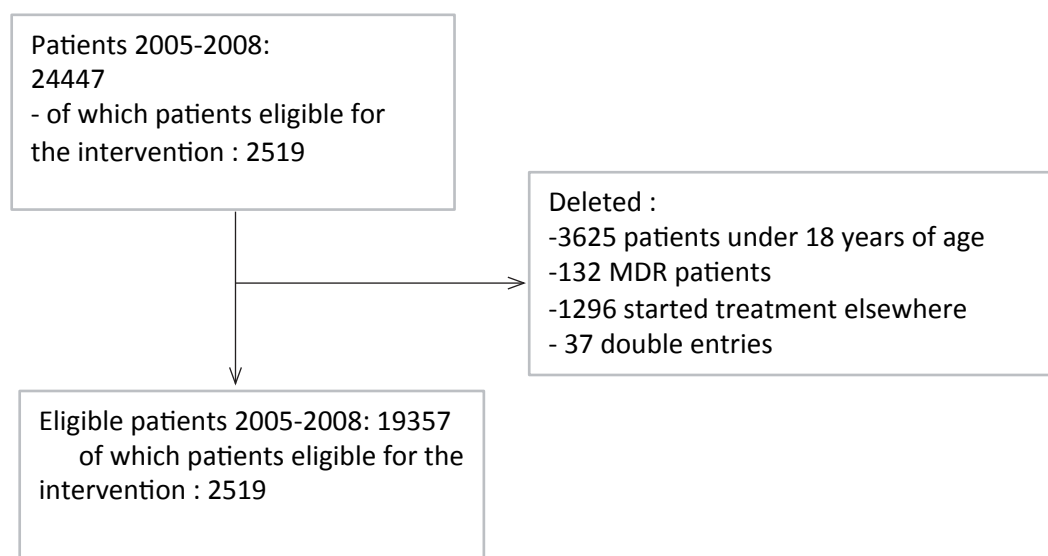


Figure 2: Patient inclusion into the study

Table 7 presents the characteristics of the patients included in the study before and after the intervention at intervention and comparison sites.

**Table 7: Study participant characteristics**

		Pre-intervention period (Q1 2005-Q1 2007) (n=13 524 patients)		Intervention period (Q2 2007-Q1 2008) (n=5833 patients)	
		Intervention clinics* (n=8627)	Comparison clinics (n=4897)	Intervention clinics* (n=3668)	Comparison clinics (n=2165)
		n (%)	n (%)	n (%)	n (%)
<b>Sex</b>	<i>Males</i>	4792 (55.5)	2741 (56.0)	1923 (52.4)	1211 (55.9)
	<i>Females</i>	3835 (44.5)	2156 (44.0)	1745 (47.6)	954 (44.1)
<b>Age</b>	<i>Mean age (yrs)</i>	35.2 (SD 11.43)	34.9 (SD 11.3)	35.6 (SD 11.6)	35.5 (SD 10.9)
<b>Patient category</b>	<i>New</i>	6068 (70.3)	3397 (69.4)	2518 (68.6)	1457 (67.3)
	<i>Retreatment</i>	2559 (29.7)	1500 (30.6)	1150 (31.4)	708 (32.7)
	<i>New smear positive</i>	3214 (37.3)	2066 (42.2)	1141 (31.1)	771 (35.6)
<b>Site</b>	<i>Pulmonary</i>	6275 (72.7)	3870 (79.0)	2579 (70.3)	1715 (79.2)
	<i>Extra-pulmonary</i>	1900 (22)	822 (16.8)	838 (22.8)	318 (14.7)
	<i>Both</i>	452 (5.2)	205 (4.2)	251 (6.8)	132 (6.1)
<b>Smear result for pulmonary TB or both pulmonary and extra- pulmonary TB</b>	<i>Smear positive</i>	4577 (68.0)	2985 (73.3)	1723 (60.9)	1132 (61.3)
	<i>Smear negative</i>	1688 (25.1)	924 (22.7)	975 (34.5)	605 (32.8)
	<i>No smear</i>	462 (6.9)	166 (4.1)	132 (4.7)	110 (6.0)

## Data analysis

### *Qualitative content analysis (Studies I-III)*

Qualitative content analysis can identify either latent or manifest content in text [145]. Manifest content refers to that content that is visible and obvious, whereas latent content refers to that content that is the issue that the text talks about, the underlying meaning of the text [145]. While both the manifest and latent level of analysis requires interpretation, it could be said that the latent level of analysis would require further abstraction, as being more in-depth and requiring more interpretation than the manifest level of analysis [145].

Qualitative content analysis was conducted using the principles of Graneheim and Lundman [145]. The transcripts of each FGD or interview were considered the unit of analysis. First the transcripts were read and reread to gain familiarity with the data and a sense of the whole. Following this, each transcript was coded openly, identifying phrases, words and sentences that formed meaning units. These were then condensed into condensed meaning units. These condensed meaning units were then abstracted further, and labelled with a code. In Study I codes were further arranged according to sub-themes and major themes, as the level of abstraction was increased and the analysis examined the latent content of the interviews rather than staying at the manifest level of

analysis [145]. In studies II and III, codes were assigned to sub-categories, following which the sub-categories were classified into categories [145].

In Study III, the initial coding was done independently by a co-researcher (DB), a student in public health, and SA. SA, DB, and SL then met to discuss these codes. After this, sub-categories and major categories were generated. These were then presented to the full study team and discussed.

In studies I and II, the initial codes were read by the whole study team. After this, SA generated sub-categories and categories, or sub-themes and major themes. These were discussed among the study team. In order to organize and make sense of the results, as well as to make recommendations for further action, the major categories in Study II and major themes in Study I were organized according to existing theoretical models.

Study I utilized Kingdon's model of agenda setting [146]; this model is useful for identifying those factors that lead to an issue being placed on policy makers' agendas. The model suggests that three different streams need to come together at a certain point to enable an issue to reach the policy agenda: the problems stream - perceptions of problems as public matters requiring attention; the policies stream (or solutions to the problem) - ongoing analysis of problems and their solutions and the debates and discussions surrounding them; and the politics stream - which includes the local and national mood, elections, or pressure from interest groups. The three streams are independent of one another, and flow in parallel. The coming together of these streams can lead to the opening and closing of policy windows, or opportunities for shifting an issue onto an agenda. Further detail on this model can be found in article I.

Study II used the normalisation process model [116], which was designed for understanding the processes of implementing a complex intervention, and understanding how interventions become workable and integrated into everyday work. The model has four main constructs and eight categories. The constructs are as follows: interactional workability, examining how the programme affects interactions between people and practices; relational integration, which examines how the programme relates to existing concepts and relationships; skill set workability, which examines how the division of labour is affected by the intervention; and contextual integration, which concerns how the intervention relates to the existing organization and practices. Further detail on this model can be found in article II.

#### *Statistical analysis (Study IV)*

Outcome variables for TB treatment were defined using the WHO standard outcomes (see Table 8). For smear-positive patients, analysis was conducted on smear conversion at 2 months; smear conversion at 3 months; and cure and treatment success. Smear conversion at 3 months was included in the analysis because this would include patients who smear converted, but who had their smear test later than 70 days into their treatment. For all patients analysis was conducted on treatment success at the end of treatment.

Descriptive statistics were generated for all the outcomes, and for patient characteristics. Aggregated data for each clinic and quarter were analysed, resulting in counts for each response variable. This was transformed into a ratio from total patient numbers at a clinic in a given quarter. A Poisson regression model was used to analyse the data. Variables indicating whether the observation was pre- or post-intervention, and another indicating whether the clinic belonged to the comparison or intervention group, were created. A significant interaction between these two variables indicated a change in the rates, i.e. the relative change in rate between intervention

and comparison sites. We used a generalized estimating equations (GEE) model to account for the correlation between the responses from the same facility, using the first-order autoregressive (AR(1)) structure. Results were reported as incidence rate ratios, with 95% confidence intervals.

**Table 8: Terms used in the study and their definitions (adapted from [36])**

<b>Term</b>	<b>Definition</b>
Case of TB	A patient in whom TB has been confirmed by bacteriology or diagnosed by a clinician
Definite case	A patient with positive culture for the <i>Mycobacterium tuberculosis</i> complex. In countries where culture is not routinely available, a patient with one sputum smear positive for acid-fast bacilli (AFB+) is also considered a definite case
Pulmonary case	A patient with tuberculosis disease involving the lung parenchyma
Smear-positive pulmonary case	A patient with one or more initial sputum smear examination/s (direct smear microscopy) AFB+
Smear-negative pulmonary case	A patient with pulmonary TB not meeting the above criteria for smear-positive disease. Diagnostic criteria should include: at least two sputum smear examinations negative for AFB; and radiographic abnormalities consistent with active pulmonary TB; and no response to a course of broad spectrum antibiotics (except in a patient for whom there is laboratory confirmation or strong clinical evidence of HIV infection); and a decision by a clinician to treat with a full course of antituberculosis chemotherapy; or positive culture but negative AFB sputum examinations
Extrapulmonary case	A patient with TB of organs other than the lungs (e.g. pleura, lymph nodes, abdomen, genito-urinary tract, skin, joints and bones, meninges). Diagnosis should be based on one culture-positive specimen, or histological or strong clinical evidence consistent with active extra pulmonary disease, followed by a decision by a clinician to treat with a full course of antituberculosis chemotherapy. A patient in whom both pulmonary and extra pulmonary TB has been diagnosed should be classified as a pulmonary case
New case	A patient who has never had treatment for TB or who has taken antituberculosis drugs for less than one month
Retreatment case	A patient previously treated for TB, who is started on a re-treatment regimen after previous treatment has failed (treatment after failure), who returns to treatment having previously defaulted (see below; treatment after default), or who was previously declared cured or treatment completed and is diagnosed with bacteriologically positive (sputum smear or culture) TB (relapse)
Cured	A patient who was initially smear-positive and who was smear negative in the last month of treatment and on at least one previous occasion
Completed treatment	A patient who completed treatment but did not meet the criteria for cure or failure. This definition applies to pulmonary smear-positive and smear-negative patients and to patients with extra pulmonary disease
Died	A patient who died from any cause during treatment
Failed	A patient who was initially smear-positive and who remained smear-positive at month 5 or later during treatment
Defaulted	A patient whose treatment was interrupted for 2 consecutive months or more
Transferred out	A patient who transferred to another reporting unit and for whom the treatment outcome is not known
Successfully treated	A patient who was cured or who completed treatment



## **ETHICAL CONSIDERATIONS**

Ethical approval for all studies was obtained from the Medical Research Council of South Africa, and the Centers for Disease Control, Atlanta, United States. Approval for the study was obtained from City Health, Cape Town, and facility managers at each clinic. A challenge to obtaining ethical permission to conduct the study was the use of age groups in TB reporting. Standard TB reports in Cape Town include children over the age of 15 in the adult cohort, since their treatment is the same as that for adults. However, this was not acceptable to the Ethical Committee, and the age limit had to be raised to 18 years.

All participants in qualitative interviews or FGDs were given an explanation of the study in a language with which they were comfortable. Written informed consent was received from each participant. Participants were not paid, but were given refreshments and their travel costs were reimbursed. Participants were also told they were free to stop the interview at any time, and were free not to participate at all.

At FGDs participants were asked to maintain confidentiality and not reveal topics of discussion outside the group. Patients were reassured that participating in the FGD would not affect their treatment in any way. At the start of one FGD two men who had arrived for the discussion departed without participating. This suggested to the research team that there was at least some awareness of their rights, and ability to act on these, among participants.

At the comparison clinic nurses invited patients who attended the clinic for treatment to join the FGD. This was initially a concern, because the research team considered that patients may have interpreted the FGD as part of their treatment. However, the purpose of the FGD was clearly explained to each participant. The criticisms of the clinics that emerged in these groups suggested that participants did not perceive the FGD moderator as part of clinic staff.

Nurses and lay health workers were assured that participation or non-participation would not affect their employment or working conditions. Individual informed consent was not required for the quantitative component, since individual patient data were made anonymous and the study did not interfere with the usual treatment provided by the health services.

Several ethical challenges arose during the process of conducting the study. Firstly, conducting it required a fine balance between being useful for programme managers and maintaining the confidentiality of interviewees. The managers would at times ask questions about programme progress at clinics, and while general indications of process issues could be given – for example, that there was a need for a particular resource, such as a treatment calendar, at a particular clinic, care was taken not to reveal the particular opinions of any of the participants to management. Secondly, issues discussed in FGDs could not be maintained as confidential, although emphasis was placed on the need for confidentiality and keeping issues discussed within the group, since FGD participants could recognise each other in the clinic or in the community.

However, the range of personal experiences reported in the patient FGDs suggested that participants were comfortable sharing their experiences with each other. When asked how they experienced the FGD, most participants reported that they appreciated having a forum in which to share their experiences.



# RESULTS

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This section provides a summary of results from the study. The focus is on the development of the programme, its implementation, effects on patients' experience of TB treatment, and impacts of the programme on treatment outcomes.

## **WHY WAS THE ETA DEVELOPED? (STUDY I)**

Study I indicated that although there have been considerable challenges to TB control over the years, the approach to treating TB through supervision has remained more or less unchanged. Since 1996, South African policy has demanded that all patients undergo treatment under DOT, for the full 6-month duration. There were a number of problems within the TB treatment programme in the study setting – patient loads were high, HIV co-infection was high, treatment outcomes were poor, and, unofficially, patients were given tablets to take home. However, these problems had been present in the TB control system for a long time.

In Study I the key issues influencing the development and implementation of the ETA were identified. These included considerable problems within the TB control system; an available model to use in the form of the ART programme; and the political climate being ready for a change. These, in combination with the presence of key individuals, made the programme possible. Further detail on these key issues is presented below.

### **Problems that influenced development of the ETA**

The problem driving the development of the ETA was that the existing model of TB control was not working. This was seen to be closely related to large case loads, overcrowding in clinics, and the overloading of staff. According to participants, the DOT component was designed for small caseloads and was no longer appropriate due to the HIV epidemic:

*“But I am 100% convinced that we can't carry on using the same old model in these new days” (programme manager 2)*

In addition, there was a perceived need to improve management of the programme. Respondents in the health services noted that there was a large number of DOT supporters (a form of lay health worker), and that they viewed the DOT supporters' management system as 'loose' in that DOT supporters reported to the participating NGO supervisors, but were not accountable to the clinic. Another perceived problem was that the current programme had insufficient focus on people, and instead was rather mechanical and focused on treatment outcomes. Participants also contested the benefit of all patients attending the clinic or visiting a lay health worker for treatment observation:

*“And what is the real benefit of watching people? The real benefit of watching people, in my view, is not at all confirmed because I remember in some clinics where we saw the patients, passing by the clinic, waving us goodbye, and they were supposed to come to be watched swallow the medication! But they didn’t come. What do you do? You go running after them? You open their mouths and stuff the tablets down their throat?”*  
(programme manager 2)

One of the largest issues driving change, however, was the co-epidemic of TB and HIV. HIV was increasing patient numbers, and a large percentage of patients were co-infected. At the same time, treatment outcomes were perceived as being better in the ART programme than in the TB control programme.

### **The proposed solution**

The aim of the ETA programme, as outlined by respondents, was to improve treatment outcomes through implementing a patient-centred or empowering approach, and through better teamwork between nurses, adherence counsellors and treatment supporters at the clinic. Modifying the ART programme for use in TB treatment was seen as a way to provide solutions for problems surrounding human resources in the TB programme, and to give patients treatment in a manner more suited to them. However, participants recognized that it was not a ‘cure-all’ for the problems outlined above.

The ART model also provided a different way of managing lay health workers:

*“Because I think in the past, what we’ve done is we’ve come to devolve all responsibility to [the relevant NGO] – and you can’t really do that. You know, the line management still kind of has to be ... accountability has to lead back to the clinic”* (policy maker 1)

Management and accountability could be improved through increasing teamwork between facility staff and lay health workers, and by asking lay health workers to document their work. Including more skilled lay health workers that were managed more strictly, and an additional cadre (adherence counsellors) that helped to ensure that patients understood the treatment requirements of the TB treatment programme, was seen as allowing professional staff to concentrate on problem cases and on their administrative work. However, participants lamented that this often meant losing the more dedicated, older cadre of lay health workers. They were also concerned about how the system would allow for monitoring of lay health workers’ work in the community:

*“..who exactly is going to manage the performance of the treatment supporter to make sure that they provide the support to the patient, if it’s needed for them to adhere to their treatment?”* (programme manager 4)

Participants also saw encouraging teamwork between the different cadres and clarifying roles as potentially reducing the distrust between lay and professional health workers.

Some respondents also discussed the potential of using this model to better integrate TB treatment with other treatment programmes, through the use of one lay health worker to provide comprehensive services for one household.

### The political backdrop

The Western Cape's history of academic research on the effectiveness of the TB control programme and of contesting policies developed at national level was a political backdrop perceived by participants as facilitating piloting of the programme. The wider political movements within South Africa also seemed to influence the development of the programme. Empowerment of communities was on the government agenda, and TB control was seen as particularly disempowering by some participants:

*“[the] whole move has been towards empowering people on the ground, and the TB system in particular was a very disempowering one. It was kind of based on the mentality that we as health professionals know best. We will tell you what to do and when to do it – and you just follow directions. And there wasn't really very much accommodation made for what patients' needs ... or people talked about a client-centred approach, but a client-centred approach that suited the health system”* (policy maker 3)

A national community or lay health worker policy was also being developed, that would call for community or lay health workers to do more than one task in the community, instead of focusing only on one disease. There was a:

*“...call from the national health department that people in organisations with vertical programmes would not be funded... had to start working as an integrated model of care where one carer would address all the problems of a particular person”* (programme manager 4)

Another influence was the growing ART programme. There was a need to rapidly expand ART, which had further implications for human resources for health, and therefore for the TB programme. Respondents highlighted problems of sustainability and affordability with regard to disease-specific interventions, suggesting that more integrated approaches were more sustainable:

*“..but I can't see with six million people needing ARVs in the next three to four years, how else we're going to do it ... before we can even afford the ARVs.”* (policy maker 2)

The political influences seemed to impact on participants' examination of the problems within the TB treatment programme and search for solutions. All these three factors were, however, brought together by “champions”, who also had access to programme information from other disease programmes.

More detailed information on these issues can be found in article I. The next section describes staff perspectives of implementing the ETA.

## WHAT WERE THE KEY ISSUES THAT INFLUENCED THE IMPLEMENTATION OF THE ETA FROM STAFF PERSPECTIVE? (STUDY II)

Influences on the implementation of the ETA were obtained from interviews with nurses and adherence counsellors and FGDs with treatment supporters. The results were categorized according to elements of the normalization process model [116]. In terms of interactional workability, which refers to the programme's effect on interactions between programmes and practices, the main issues to emerge as impacting on implementation were the content of work and staff roles within the ETA (congruence) and perception of goals and effects of the ETA (disposal).

In terms of relational integration, which refers to existing knowledge and relationships, the main influences were the additional knowledge required by the programme (accountability) and the general credibility of the programme (confidence).

In terms of skill-set workability, which refers to the effects of the programme on division of labour, the main issues were task allocation and skills (allocation), and staff capacity to implement the ETA (performance).

Finally, in terms of contextual integration, which refers to the programme's relation to the organization in which it is set, the main issues related to resource requirements (execution) and modifications to practices and resources (realization). Each of these issues is discussed briefly below.

### **Interactional workability: Content of work, staff roles and perception of goals and effects**

Staff had been assigned clear roles at the start of the programme. Despite this, adherence counsellors reported performing duties outside their set tasks, such as directing patients in the waiting area to correct treatment rooms. The main change in content of work was that a more empowering approach needed to be taken – however, nurses and adherence counsellors did not feel that a major change had been made, and continued to express patronising attitudes towards patients:

*“[The patient is] Like a child, you tell him you are going to buy sweets, but you don't buy it. Then they cry because they lose faith” (nurse)*

Nurses also described patients as unreliable and untrustworthy. It also seemed that adherence counsellors and treatment supporters wanted to maintain a higher status for themselves in comparison to the patients, and made a number of remarks that suggested that they were not equals with patients.

In terms of the goals and effects of the programme, not all staff were convinced that the programme would be beneficial. Although they could identify a number of benefits of the programme, such as reduced queues and easier follow-up, they continued to question patients' adherence and suggested that the DOTS approach helped in patient monitoring:

*“To add on DOTS was [better] than [the ETA] because you as a health worker knew for sure that the patient is taking the pills – now, even though there is someone responsible for the patient, there is no way of knowing” (clinic 4)*

### **Relational integration: Credibility of the programme and the need for additional knowledge**

Staff needed to learn the processes of the programme and new administrative procedures. Training sessions were conducted for all, but some nurses had not attended them and some felt they had not paid as much attention as they might have if they had been directly involved with the ETA at the time of training. This created some apprehensions regarding the programme and being responsible for implementing it:

*“... I think for the [lay health workers] they are doing the training, but for us nurses, I haven't been trained and I'm supposed to supervise. What am I supervising if I don't know anything about the [ETA]?” (clinic 4)*

The gaps in training and perception among some nurses that lay health workers knew more about the programme than they did, also created some strain in working relationships. While some nurses felt that lay workers were trained adequately for the programme, others doubted whether the training had been sufficient.

Another hindrance to implementation of the ETA may have been staff attitudes towards it, and their perceptions of its credibility. Not all nurses felt that an HIV model would be appropriate for TB, and some felt that patients could be confused if they went through two separate education sessions. They did feel, however, that patients liked the ETA better than the previous DOT model, and most perceived the ETA as a good programme for patients.

### **Skill-set workability: Task allocation and capacity to implement the programme**

Tasks were allocated to staff by management. There remained, however, a hierarchical working relationship between different cadres of staff. This affected treatment supporters the most, and they seemed to resent their treatment by other staff and their status at the clinic. Nurses and adherence counsellors also seemed to have little faith in treatment supporters' abilities, although they held them responsible for the success or failure of the programme:

*“... So if it didn't work then they [the treatment supporters] must know it's their baby – it's their fault that it didn't work. Yes, it is their fault because they are the ones who go to the clients. They are the ones who bring back the feedback to the clinic. Is the client taking treatment every day? What did they see? So they come back and report to us.”*  
(adherence counsellor)

Initially all staff also expressed uncertainty regarding implementation of the programme, and whether they would be able to carry it out. Initially staff also complained regarding the administration they had to do. Later some staff appreciated the time for administration they now had because patients were not at the clinic but out in the community. However, treatment supporters also encountered a number of challenges when visiting patients, such as gaining entry into the home, crime and patients' or their families' substance abuse.

One of the largest challenges to staff capacity to implement the programme was HIV. Adherence counsellors and treatment supporters especially reported having to answer questions about HIV when dealing with patients. This also created complications when treatment supporters visited families in the community:

*“...at times it is your patient who is HIV [positive] and now it feels like you asking him/her to tell the whole family.”* (treatment supporter)

Most staff expressed further training needs. Nurses expressed training needs in terms of programme implementation, while adherence counsellors wished for training on HIV and its treatment. Treatment supporters wished for more training on the administration of the programme and HIV-related issues.

### **Contextual integration: Resource requirements and modifying practices and resources**

The issues related to resources and practices centred mainly on funding for lay health worker stipends and lack of space at the clinic. Funding needed to be arranged for stipends, and the flow of resources from the City to the participating NGO meant that payments were sometimes late. This created considerable frustration among treatment supporters:

*“They are robbing us, they take their time to give us our money, they make promises they can't keep, and they hardly support us with our needs. We know we are regarded as volunteers but they promised to give us little something to motivate us but ... we are struggling. We always keep up with our work because should we not they shout at us.”*  
(clinic 3)

Lack of space for counselling was another issue that complicated implementation. Adherence counsellors had to counsel in storage and filing rooms, which may have impacted on the confidentiality and privacy of counselling.

Other modifications to resources included a dedicated project manager, who gave hands-on help to all the participants in the programme. Her participation was seen as a positive influence on implementation, and staff reported turning to her with their problems regarding day-to-day running of the programme. One of the main challenges, however, was lay health worker attrition, as both some adherence counsellors and many treatment supporters left the programme. New treatment supporters could not be trained, so as not to create an expectation of employment.

Staff identified a number of constraints to implementing the programme, but appeared to view it positively and felt that patients appreciated it. Resource constraints impacted on the implementation of the programme.

The next section examines the effect that the ETA had on patients' experiences of TB treatment.

### **HOW DID THE ETA AFFECT PATIENTS' EXPERIENCES OF TB TREATMENT? (STUDY III)**

Overall, findings from Study III suggested that patients from intervention clinics were more positive towards TB treatment than patients from comparison clinics. Intervention clinic patients also reported having constructed routines around their treatment taking:

*“I wake up and take my pills, then clean and then eat ...”* (male participant, intervention)



Intervention clinic patients also spoke of the treatment necessitating lifestyle changes, and that they had embraced a healthier lifestyle:

*“... you should not smoke, you should not drink and you should not default your treatment”* (male, intervention)

Some said that initially they had not succeeded in making these changes, but had been ‘caught up on’ by treatment supporters. Issues related to lifestyle changes were reported less in comparison clinic focus groups, with some male patients reporting that some of the group had surely been out drinking, the night before, and emphasising that people needed to be educated on their treatment. The male interviewee who had been recalled to clinic treatment due to poor adherence reported that one of the influences on his non-adherence was taking up drinking and smoking again, and therefore becoming ‘lazy’ to go to the clinic for check-ups.

Patient empowerment was used as a central concept in the programme. It seemed that intervention patients had heard these issues during the counselling and, following from this, expressed their reasons for remaining on treatment as ‘taking responsibility for their health’, ‘loving themselves’ and ‘taking care of themselves’:

*“I think people should learn to value themselves and their lives and then they will not stop taking their treatment. People have to love themselves so much that they do not need [a] caregiver to run after them to take their treatment”* (female, intervention)

Although intervention patients emphasised the need to take responsibility and control over their treatment when speaking about themselves, their suggestions to encourage other non-adherent patients to take their treatment were at times extremely coercive. Among others, these included hospitalization and DOT by a treatment supporter.

A prerequisite for being on the ETA was to have a treatment supporter visiting, and assigning a treatment buddy from the home or neighbourhood to support the patient in taking treatment. In comparison clinics, most patients visited a local treatment supporter for their daily treatment. Participants receiving the ETA intervention expressed a range of responses to their treatment supporters. Initially, most patients were suspicious of their treatment supporters’ motives, but later appreciated this relationship and even reported that treatment supporters were people who took care of them. However, comparison clinic patients, especially men, reported more distrust and suspicion toward their treatment supporters, while women seemed resigned that having a treatment supporter was part of TB treatment. The relationship between treatment supporters and patients did not seem to develop into friendship – interactions between patients and their treatment supporters were limited to discussing treatment.

Patients from intervention groups mostly appreciated the support they got from their buddies. The two patients who had been recalled to clinic treatment from the programme reported problems with their buddies as one of the reasons they had not remained adherent. However, the buddies also seemed to have a limited role to play, since some intervention participants reported that buddies did not care whether treatment was taken or not. Some also felt that their family relationships had become strained after selecting a person as their buddy.

Some intervention clinic patients also reported that their buddies had taken on a supervisory role in treatment:

“... she does not only remind me to take my treatment she makes me take it right in front of her”

This seemed to conflict with the intention of the new programme.

Overall, the intervention seemed to be received positively by patients, and patients from intervention clinics expressed positive opinions of TB treatment. The responses to and activities of buddies and treatment supporters were mixed.

The next section examines the impact of the ETA on treatment outcomes.

## WHAT IMPACT DID THE ETA HAVE ON TB TREATMENT OUTCOMES? (STUDY IV)

In Study IV, a total of 19 357 patients met the inclusion criteria for the time series analysis. Table 9 presents treatment outcomes for intervention and comparison clinics before and after the implementation of the programme.

**Table 9: Treatment outcomes for intervention and comparison clinics**

	Pre-intervention period (Q1 2005-Q1 2007)		Post-intervention period (Q2 2007-Q1 2008)	
	Intervention n (%)	Comparison n (%)	Intervention n (%)	Comparison n (%)
Cured	2774 (32.2%)	1808 (36.9%)	1144 (31.2%)	754 (34.8%)
Completed	3331 (38.6%)	1720 (35.1%)	1536 (41.9%)	860 (39.7%)
Failed	85 (1%)	48 (1%)	32 (0.9%)	27 (1.3%)
Defaulted	1582 (18.3%)	661 (13.5%)	588 (16%)	240 (11.1%)
Transferred	364 (4.2%)	258 (5.3%)	136 (3.7%)	114 (5.3%)
Died	482 (5.6%)	380 (7.8%)	224 (6.1%)	165 (7.6%)
Not evaluated	9 (0.1%)	20 (0.4%)	8 (0.2%)	5 (0.2%)
Total	8627 (100%)	4897 (100%)	3668 (100%)	2165 (100%)

The regression analysis showed that there was a significant difference in smear conversion rates at 2 and 3 months, between intervention and comparison sites (IRR: 1.08, CI:1.00-1.17 for 2-month smear conversion and IRR: 1.08, CI: 1.02-1.14 for 3-month smear conversion).

There was no significant difference in the cure (IRR: 1.03, CI 0.92-1.15) and treatment success (IRR: 1.01, CI 0.94-1.09) rates for smear-positive patients in the intervention and comparison clinics. There was also no significant difference in treatment success rates for all patients, including retreatment and smear-negative patients (IRR: 1.01, CI: 0.94-1.09).

# DISCUSSION

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## METHODOLOGICAL CONSIDERATIONS

### Evaluation research

Programme evaluations can provide useful feedback for management and administrative purposes; can support the oversight activities of funders, sponsors and authorities to which the programme is accountable; and can accurately depict programme activities and accomplishments to advocates, adversaries, clients and other stakeholders. They may also contribute information for planning and policy purposes by indicating whether the approach is worth pursuing or by demonstrating the usefulness of a professional practice [147].

The framework for evaluating complex interventions to improve health suggests that evaluating the effectiveness is a four-stage process, the last one of which is a definitive randomized controlled trial (RCT) [148]. The evaluation that frames this thesis could be seen to fit within phase two of this process, in which the acceptability and feasibility of the intervention under study are evaluated. Evidence-based approaches suggest that RCTs are the best way to establish effectiveness [149]. However, RCTs or other methods of establishing effectiveness, such as the time series study discussed in this thesis, do not always highlight those areas of the strategy that have made the desired impact [150], or those parts that failed or prevented the intervention from making an impact.

In contrast, process evaluations provide insight into the processes and mechanisms through which an intervention achieves its effects [150]. Using qualitative methods, such as those used in this thesis, can produce valuable information on how things worked in the programme, which then enables making recommendations on how parts of the programme can be altered [115]. The process evaluation which frames this thesis assists in gaining insight into how this model could be implemented in other settings, a key issue in intervention research [151]. It includes and examines the perspectives of staff and patients, which are integral to assessing the overall intervention since an intervention that is not acceptable to the end user or the implementers may be unsuccessful [152].

SA was part of early meetings discussing the possible implementation of this study. Therefore, the evaluation questions and broad methods were decided in collaboration with City Health, Cape Town, in accordance with utilisation-focused evaluation [153], and the resulting articles were used in this thesis. However, conducting research on a programme implemented by others at their request places limitations on the time and methods available [115]. For example, in study IV randomisation was precluded because the authorities selected the clinics to receive the new programme.

The evaluation that frames this thesis was conducted from a participatory framework [115], which both strengthened the understanding of the intervention and its processes, and presented challenges in performing the evaluation. Members of City Health had the opportunity to comment on the findings of the research, but did not take part in the analysis of results. In addition, SA took

part in steering group meetings that discussed planning and implementation of the intervention. Although an attempt was made to take a less active and more observational role in the meetings, participatory evaluation can result in complications due to issues similar to those facing action researchers doing research in their own organization (for example, political relationships within the organization, role conflict and role duality [154]). Role duality can affect the data, in that relationships with some members of the organization would affect relationships with others, and thus alter the data [154]; for example, the interviews at clinics may have been affected by the interviewer's relationship with programme management. In addition, role duality resulted in being part of both evaluating and implementing the programme, through needing to be useful to the implementers and, for example, delivering resources during clinic visits or designing forms used in the intervention.

### **Study designs**

This thesis utilised mixed methods in establishing both what is happening and why it is happening in the way that it is [155]. The strength of using mixed methods is that the results from qualitative and quantitative studies complement each other [155]. The disadvantage, however, is that at times treatment of the results of one or the other may be superficial and results may not be completely integrated [156]. In this thesis, qualitative and quantitative results complemented each other, although it was difficult to link them explicitly to each other. While quantitative results provided information on the effects of the programme, qualitative results highlighted issues related to implementation and the experiences of both staff and patients. Studies I to III explored the human and social experience related to the ETA, especially related to interaction, relations, development, interpretation and activity [157, 158].

Study IV used an interrupted time series design to estimate the effectiveness of the new intervention. The inclusion of comparison clinics added to the strength of the design [117], since these could control for the effects of policy changes or other improvements occurring at the same time as the intervention. Interrupted time series designs are the strongest quasi-experimental designs, and a good alternative when randomisation is precluded [117]. In this study, the time series design allowed for estimating the effect of the intervention, taking into account the continuing trend of improvement over time.

### **Qualitative methods**

#### *Benefits and limitations of interviews and FGDs*

There were a number of key issues that related to the use of interviews and FGDs in Studies I-III. Some of these are outlined below.

Interviews were used in Studies I-III since they are useful when wanting to elicit individual experiences and opinions on sensitive topics [159]. In this thesis interviews allowed the participants to express their opinions in their own terms. Therefore, issues such as rank between nurses could not impact on how participants told of their experience of implementing the programme in Study II. However, some nurses experienced the interview as stressful, and felt they were being tested, despite assurances to the contrary. This could have resulted in these nurses holding back some of their experiences or more forceful negative opinions of the programme.

The interviews were also conducted in English, and though all participants were fluent in it this was not all of their first language, and therefore may have prevented a more nuanced description of their experience. Interviews functioned well when dealing with the development of the programme (Study I) and the opinions of management, who were more comfortable in a one-to-one setting. Interviews were also conducted with two patients who had been non-adherent in the programme; this was most appropriate since locating a number of recalled patients to a FGD would have been difficult.

FGDs were conducted with patients (Study III) and treatment supporters (Study II). The advantage of FGDs is that a range of responses can be captured at the same time, persons who may not feel comfortable in a one-to-one setting may be included and participants can share experiences [160]. However, group dynamics and relations between different people can influence the results. In patient FGDs it seemed from reports of the focus group moderator that everyone could contribute to the discussion, and a range of opinions - even conflicting - were expressed. However, this issue was more complicated in treatment supporter FGDs, where group dynamics resulted in older females dominating the conversation, and discussions were steered towards extensive discussion about payment problems, despite the FGD moderator's attempts to counter this.

#### *Participants and sampling: Studies I-III*

The participants in Study I were those programme planners and implementers that were involved in the programme from the start. In addition, academics and policy makers involved in TB control for some decades were included purposively. Purposive sampling, in this case purposive stakeholder sampling, implies selecting those participants that are best able to answer the question at hand [161]. Although all but one of the participants were female, this was not a conscious choice; rather, those participants who were available and had suitable experience were selected for interviews.

Sampling for Study I followed the data saturation principle in grounded theory [162], which meant that more data were collected as analysis progressed, and when no new themes seemed to emerge from interviews, data collection was stopped. This approach, although beneficial in limiting the number of interviews, could mean that some individuals who may have had a different view of the development of the intervention were not included in interviews. Individuals who could inform this study were limited in number, but a substantial proportion were included in the analysis.

In Study II all nurses, treatment supporters and adherence counsellors were asked to participate. While none explicitly declined, two nurses would not keep their appointments or made it difficult to make an appointment. After at least two attempts, this was considered declining to participate. Although nurses, adherence counsellors and treatment supporters were invited personally to interviews and FGDs, and it was assured that non-participation would not translate into sanctions at their workplace, they may have attended because they thought it part of their jobs. However, the range of negative opinions expressed at these FGDs and interviews suggested that they were comfortable in expressing their opinions.

Participants for FGDs in Study III were invited through treatment supporters in intervention clinics, and clinic staff in comparison clinics. Although all patients were invited, there is a possibility that treatment supporters encouraged those with whom they had better relationships to attend FGDs. This may have resulted in a more positive impression of the programme.

*Using theoretical models within qualitative research*

One of the strengths of the evaluation discussed in this thesis was the use of additional theory to disentangle the programme effects. The normalisation process model [116] used in Study II assisted in establishing those areas of the intervention that were beneficial, and those that hampered the implementation of the intervention, and can inform judgements about the probability that a complex intervention will become routinely incorporated in practice.

Studies I and II used theoretical models to organise the results of qualitative content analysis. This type of organization is unusual in qualitative research and could be seen as a combination of inductive and deductive analysis.

The analysis in Studies I and II progressed in stages. Initially, main categories were created through qualitative content analysis, after which these were examined for how they fit within the constructs of the model. In Study I, which utilized Kingdon's model of agenda setting [146], the approach was more inductive. When the results were examined in relation to this model, it was realized that some key aspects that may have resulted in policy change, in particular information on the political context, was missing, and further interviews were conducted in order to inform this gap. The model was therefore of benefit in examining the way in which policy change came about, and allowed for a more comprehensive picture of the phenomenon than would have emerged through the use of qualitative content analysis alone.

Study II used the normalisation process model to contextualize results. A similar approach was undertaken for analysis, in that initially qualitative content analysis was performed, and the major categories that emerged were examined for their relation with the normalization process model [116]. In this case, some issues that would have had a more strong representation in the results, such as teamwork and hierarchy, were emphasised less in the model, while issues that did not initially emerge as key to implementation were given attention. Having the model part of the analysis enabled making suggestions on key issues that should have been paid attention in order for the programme to become part of clinic routine. These suggestions would have been more difficult to make based on thematic content analysis alone.

This aspect, while perhaps unconventional in qualitative research, was of benefit in examining the intervention and having the results present more practical suggestions for improvement in order to implement this programme on a wider scale.

*Validity*

Triangulation implies comparing the results of two or more methods or two or more data sources to corroborate an overall interpretation [163]. In addition to qualitative and quantitative methods complementing each other, triangulating through involving researchers from different backgrounds in analysis was particularly useful in this thesis [164]. It enabled discussions that strengthened the analysis of particularly qualitative data in Studies I-III, and countered the influence of preconceptions. Quotes included were also intended to increase the validity of the findings, by allowing the reader to estimate the validity of the interpretation.

Main threats to validity were the impact of the interviewer or focus group moderator being part of the health services, and using translated material in analysis. Although the perception of being

part of the health services or of reporting back to others more senior in the health services did not impact in Study I, it could have impacted on the data in Studies II and III. As suggested earlier, patients may have thought that the FGD moderator was part of the health services and that the FGDs were compulsory. However, the range of negative opinions expressed suggested that this was not the case.

In Study II, nurses and adherence counsellors more than treatment supporters may have been influenced by the perception that the interviewer was part of the health services, since their responses to the programme seemed more positive and SA conducted the interviews. However, it is unlikely that this influence impacted on the data to a great degree.

One of the main threats to validity is using translated material in analysis, and not including a Xhosa speaker in analysis. The FGDs were translated by the FGD moderator, who was considered competent as a bilingual social science university graduate [165]. The translations were later checked for accuracy by another bilingual community member. However, having a person who would be able to join in the analysis and use the original Xhosa-language transcripts would be the ideal situation, since then the idiom and nuances in the conversation could be included in analysis in more detail.

## Quantitative methods

### *Participants, sampling and statistical inference: Study IV*

There were four main issues impacting on the quantitative study. Firstly, the lack of randomisation limits the causal inferences that may be made. The advantage of using an interrupted time series study, however, is that it is the most robust quasi-experimental design available [108], since it counters secular trends and is strengthened by the inclusion of comparison clinics [166]. Poisson regression, which is suggested as an appropriate method of analysis [167], was used in this study.

In time series studies such as this one, data collected were from different time periods from the same sources, and therefore can be correlated. We controlled for this correlation in the analysis by using the GEE approach. However, the causal inferences made from this study are also limited by the short time period after intervention, which prevents conclusions being drawn about the long-term effects.

Secondly, data quality and the way that it is entered could sometimes introduce information bias into the study. However, in Study IV including patients from routine quality controlled registers that were collected and entered at a central point meant that the recording systems for patients at the different clinics were similar. Therefore this would not have impacted on the results of the study. The checking of register data against clinic-held registers and folders also enhanced validity in this study, as the number of errors found was small. However, using register-based data meant that some useful variables were not captured, such as patients' HIV status and whether they were taking ARVs concurrently with their TB medication.

Thirdly, the outcome measurements for the time series study were based on the TB definitions used by the WHO. Patients were diagnosed as TB-positive either with Ziehl-Nielsen sputum microscopy, cultures, or clinically. Since diagnosing TB is more difficult in HIV-positive than in HIV-negative patients [7], not all TB patients in our study may have had TB. However, as our outcome for smear-negative patients was treatment completion, and the same approach was

applied across intervention and comparison sites, this did not affect the findings. The Cape Town central laboratory analysed all sputa from all clinics, and they have rigorous quality controls. Therefore sputum results were not verified at the laboratory.

Fourthly, not knowing the HIV status of the patients may have impacted on outcome measurements. HIV-positive patients may be on concurrent ART, and they may have more complicated treatment regimens and side-effects than patients with only TB. Patients on ART may also have attended treatment information sessions already, and may have to take more tablets daily. However, the HIV prevalence at intervention and comparison clinics did not differ considerably (between 68% and 73%).

One of the differences between intervention and comparison sites was that four of the intervention sites and one of the comparison sites were co-located with clinics providing ARVs. However, HIV-positive people at the clinics not co-located with ART sites would have been referred to another site if eligible for ART.

### **Generalisability**

The conceptual generalisability of Studies I and II is increased by the use of theoretical frameworks. Conceptual generalisability implies generating an understanding of issues in a certain setting, and applying the concept rather than the specific issue more generally [168]. For example, in Study II, although the specifics of the hierarchical relationship between nurses and lay health workers might not be applicable to all clinics, the idea that there might be a hierarchical relationship when engaging in a programme such as the ETA could be extrapolated from this study.

A similar application could be done for Study I, where the Kingdon framework [146] was used. In Study III, the concepts of change in lifestyles and challenges in terms of empowerment could be applied. However, as in qualitative research in general, these results are not intended to be generalized as being representative of all patients, lay health workers or nurses in South Africa.

Study IV was an interrupted time-series study with comparison clinics. Randomization would have allowed for greater generalisability of results, since the specific characteristics of each clinic could not have impacted on the study results. Since the clinics part of this study was pre-selected by the City of Cape Town, they may not have been representative of the clinics within the Cape Town area. Therefore, the results of Study IV should be interpreted with caution. However, the results could be applied to similar clinics with high HIV and TB co-infection within similar urban settings in South Africa.

## **FINDINGS**

This thesis focused on the development, implementation, and outcomes of a TB treatment intervention, the ETA programme. The intervention was developed because key individuals in the health services were aware of the problems within the TB programme and of possible solutions, and because the political situation was amenable to change (Study I).

Study II examined implementation of the programme from the perspective of the normalization process model. The findings indicate that implementation of the ETA was influenced mainly



by human resource issues, including, among others, perceptions of the programme, attrition of health workers and training issues. Study III indicated that patients may have experienced their TB treatment more positively, were more inclined to take responsibility towards their treatment taking, and incorporated treatment taking into their daily routines, although there was little evidence of empowerment.

Resource issues in terms of facilities and financial inputs also influenced implementation of the programme to a great degree. The time series study (Study IV) indicated small but significant improvements in smear conversion rates in intervention clinics after the intervention, relative to the comparison clinics. These findings are elaborated on in the section below.

### **Influences on the decision to introduce a change to the TB programme**

Researchers have long searched for avenues through which research can influence policy [169, 170], but empirical examples of this process - especially in low- to middle-income contexts, remain few [171]. Some of the empirical investigations available indicate that research influences policy in a diffuse manner [169]. There were also indications of this in Study I, which indicated that key individuals had a considerable contribution in bringing about the ETA, as also noted in another study from sub-Saharan Africa [172] and in other contexts [173]. The key individuals who were part of the programme change were also aware of the research conducted on TB DOT, and had interacted with researchers and activists who were trying to promote a change. However, this interaction did not seem to directly influence the change from DOT to the ETA. Although interaction between researchers and policy makers is considered an important consideration in using evidence [173], this did not emerge as an important consideration in Study I.

Instead of research directly influencing the change from DOT to the ETA, the interaction of problems, solutions and the political environment together with key individuals, as postulated by Kingdon [146], seemed to influence the programme change to a greater degree. Although the study included few participants, the role of these well-placed individuals came through clearly from interviews. These individuals were also members of a committee that dealt simultaneously with HIV- related issues, TB-related issues and those related to managing sexually transmitted diseases. They were therefore aware of the need for a change, and potential strategies that could be effective.

In the case of this study, then, it seems that integration initiatives at policy or managerial level might have translated into changes at community level after some time. This change seems to have necessitated the presence of “champions” to drive the change. Further investigation is needed to establish whether this also happens in other settings.

Although it is likely that there was a multitude of factors influencing the change from DOT to the ETA in TB management in Cape Town, the impact of the impending ART roll-out is difficult to ignore here. South Africa is planning to have 80% ART coverage for those who need it by 2011 [174]. Early estimates based on the number of people living with HIV/AIDS in South Africa in 2005 suggest that over 2,6 million people would require ART by 2015 [175]. Most of these will come to the already overburdened primary health care system. Therefore, there is a need to ensure that the primary health care system is strengthened, and that ART provision will be integrated into the existing primary health care system [176, 177], along with other treatment programmes such as that for TB.

There have already been indications that health professionals may move to the better resourced ART programme from other primary health care departments [75]. There is therefore an urgency to ensure that programmes remain functional, and wider use of community health workers [178] and task shifting in general [133] has been posited as one way of dealing with human resource problems in the context of ART. This situation therefore could have created additional pressure to try alternative approaches to the human resource-intensive DOT programme, especially in terms of professional staff, and may have motivated trying approaches that would enable integration with existing programmes.

In the context of the human resource crisis and the ART roll-out, and the high rates of TB and HIV co-infection, integrating TB treatment and ART makes logical sense. However, DOT once a day for all those patients taking TB treatment and eventually for all those patients taking ARVs seems a large burden on health services.

Transferring the role of observation from health services to a family member seems like an option to reduce some of the burden. However, it is possible that family members could in some cases not provide support at all, as found in Study III, or in some cases not observe treatment but support and motivate the patient, as is the intention in the ETA. Therefore, this would not constitute DOT but a supportive approach such as that intended in the ETA. In addition, having families support the patient during treatment should also not absolve the health care system from responsibility for the patient's treatment course [43], and health care systems would be expected to continue providing support and education to patients.

### **Influences on implementing the ETA**

Study II suggested that the dedicated project manager employed with the assistance of additional financial resources assisted staff in implementing the programme, and it is possible that she enabled the programme to maintain outcomes. This corresponds with the recognized importance of mentoring and supervision for health care staff [179]. It would be interesting to discover whether providing similar close supervision to the control sites would also result in improvements in treatment outcomes.

When nurses and treatment supporters were being supported in their work, and they knew their outcomes were closely monitored, they could have been more motivated and could have put more effort into their work. In addition, it seemed that there was a real drive and a wish for the programme to work, and for it to be rolled out elsewhere, especially on the part of treatment supporters and adherence counsellors.

A number of issues also hampered implementation. The programme experienced high levels of treatment supporter attrition. Attrition of lay health workers is a common problem in community-based programmes [180], and was therefore to be expected. A number of disincentives for community health workers have been suggested, such as inconsistent payment, inequitable distribution of incentives between different community health workers, inadequate supervision and lack of respect from health facility staff [180].

We discovered in the data analysed for Study II that there seemed to be two main contributors to attrition in the ETA: a hierarchical working relationship where treatment supporters were lowest in the pecking order and were perceived to have low status, and delayed and low stipends.

Problems in teamwork [136] and tensions between lay health workers and professional nurses [133] are well documented elsewhere. In addition, all lay health workers also encountered issues unrelated to TB in their work, in particular issues related to HIV, although there was no direct evidence that this contributed to attrition. Treatment supporters also faced challenges, such as drug and alcohol abuse, when working in the community. These may have made their work more demanding than envisaged by programme managers, and could also have contributed to attrition.

The solution to lay health worker attrition is not simple, and would require more detailed investigation, especially if lay health workers are to be depended on to provide a wider range of health tasks in the community. It did appear that in some of the participating clinics, treatment supporters were more likely to stay in the programme despite a number of complaints and problems with payment. Some of the reasons for this could include that the treatment supporters in this clinic had been part of TB treatment there for a long time, whereas the other clinics had more new members, and that the clinic was known in the area for having a good team spirit, had had considerable investments in infrastructure, and was frequently referred to as a model site.

One of the likely causes of attrition - problems in teamwork and hierarchical working relationships - is difficult to correct. Staff were offered teambuilding for one day which, while perhaps contributing positively to teamwork, may be too little to prevent teamwork problems in day-to-day work. However, additional training might contribute towards improving working relationships at the clinic. In this study training seemed to influence both relationships between staff and attitudes towards the programme. However, the duration of training was very short, especially for nursing staff, who only received one day of training in addition to clinic-based support.

Another aspect of training was that staff at times doubted lay health workers' skills, which may have in turn contributed to difficulties in relationships between staff members, and thus possibly to lay health worker attrition. However, staff had been given clear roles and tasks, which may have facilitated implementation and prevented major territorial conflicts.

Attitude changes, which would be necessary when shifting the approach from DOT to a more empowering approach, are unlikely to be achieved in one day, and support at the clinic centred mainly on administrative forms and implementing the programme. Changes in the behaviour of health care professionals do not always happen automatically [152]. These may also be hampered by nurses being rushed and overloaded with work in overcrowded and chaotic clinics [136].

Making a change in working patterns is therefore likely to take time and effort, which may be in short supply at the clinic, but also in the management level of South African health care systems, which would be expected to facilitate this change.

Another major stumbling block to the new programme was the available facilities. Similarly to findings in a study focusing on prevention of mother to child transmission services in South Africa [181], lack of infrastructure in terms of counselling rooms was a major challenge in the programme. When adherence counsellors had to counsel in shared rooms, confidentiality could be breached, or this could make patients uncomfortable, which could in turn lessen intervention effects. In addition, treatment supporters interpreted the lack of space allocated to them as an indication that they were not officially part of the clinic.

Implementing new programmes would therefore require arranging dedicated space for new members of the team, even if this were a structure in the clinic grounds. Rolling out this programme on a wider scale would also necessitate taking care of other logistical challenges, such as ensuring a steady stipend for lay health workers.

### **Impacts of the ETA on patients' experiences of TB treatment**

The study findings suggest that the ETA may have had a positive impact on some patients' experiences of TB treatment. Whether the ETA was empowering, however, is an interesting issue, which is discussed in more detail below.

Empowerment of patients is part of the Stop TB strategy [34], and was presented as a central concept to staff implementing the programme. However, empowerment is a broad concept that encompasses more than just the provider-patient relationship or treatment taking [12]. Empowerment also needs to be sought by people and not given to them by others [182]. In addition, empowering programmes need to be so from the beginning [12]; and while the approach used in the ETA was intended to be empowering, the methods and problems were implemented 'top-down', and according to data not included in the articles, little consultation was undertaken prior to implementation at community or clinic level.

The change to the ETA from DOT therefore could be seen as a more semantic change than a practical change, at least for adherence counsellors and professional nurses. Some of the study sites had already implemented unofficial self-supervision due to human resource constraints, by providing patients with weekly supplies of tablets. For lay health workers, the ETA required more administration and walking in the community, which was a large change in practice. However, it is possible that they perceived their relationship with the patient as not having changed at all. It is possible that this is one of the reasons why (as found in Study II) staff did not change their approach considerably, since the ETA did not represent a large change in their day-to-day work.

It is possible that although the ETA was presented in terms of empowerment, it was not truly an empowering programme. There may be many reasons for this, and one of these may include that the programme was envisaged and implemented from the health services' perspective rather than from the community perspective. It is also possible that the DOT ethos of supervision was transferred to patients and their treatment buddies in counselling sessions, or in discussions with the treatment supporters. There is limited information on what adherence counsellors told patients and their buddies in counselling sessions.

However, reports in steering groups suggested that each counselling session was approximately 20 minutes in duration. It is likely that this time did not allow for an in-depth discussion of the information presented, or much time for patients to present their views on treatment and thus may not have been empowering. In addition, some patients in Study III indicated that buddies had begun supervising the patients' treatment taking. This issue would need further investigation.

Although questions can be raised about the content of the counselling sessions in this study, TB nurses also have to undertake many tasks in a short period of time when receiving a TB patient, and this may result in pressure and little time for interaction or for sharing information. Having separate adherence counsellors may therefore be helpful. Sharing information could be seen as part of the process of empowerment [102]. In addition to empowering patients,

sharing information could result in better provider-patient interaction, which has been found to influence patients' treatment adherence [16]. The involvement of a separate counsellor to provide information and knowledge about TB and its treatment therefore gives the patient the knowledge about treatment and its effects that they have asked for [43]. Adding this counselling element to TB treatment may help patients to understand the treatment requirements and contribute to empowering patients to take greater control over their own health.

Despite the above questions about the empowerment approach used in the programme, and empowerment being a long-term process [12] and requiring a longer time period and measurement, there were some indications that patients may be more ready to take control over their own treatment taking. Some patients had also incorporated treatment into their daily routines. It is possible that they were repeating information they had heard in counselling sessions. However, in contrast to patients in clinics implementing the ETA, patients from comparison groups spoke of taking control over their treatment from treatment supporters. This suggested that they were not only feeling inconvenienced by having to visit treatment supporters [16], but also felt disempowered by this requirement.

#### *Taking TB treatment into the community*

The inconvenience of attending daily DOT is also cited as one of the reasons for poor adherence [16]. This requirement was removed in the ETA, and therefore patients had to take fewer trips to the clinic. In return for this reprieve from frequent clinic and community visits, however, they had to receive treatment supporters at their homes. Not all patients had trusted the treatment supporters' intentions initially, similarly to findings in similar contexts that indicate that treatment supporters had to negotiate their entry into the home [183]. This may be related to stigma about TB and HIV, which is very prevalent in these communities and in other settings with high HIV and TB prevalence [184].

Treatment supporters had a key role in the programme, and it is unlikely that their work would be lessened in future TB programmes. However, keeping this aspect of TB treatment would require investigating how treatment supporters could be better received by patients. Facilitating treatment supporter entry into the home is not a simple process; although name badges including the clinic name might allow for entry, at the same time it risks stigmatising the patient and identifying them as a TB patient, which may in turn result in the patient being labelled as HIV positive.

Although treatment supporters visiting the home could be seen as continued monitoring of the patient, and extending surveillance from the clinic to the community [185], it can also have benefits. Having treatment supporters visit the home allowed for identifying HIV-positive contacts, children and those who exhibited TB symptoms, although this aspect could not be investigated in this study. In contrast the DOTS system depends on passive case finding – on patients coming to the clinic presenting with symptoms. Active case finding has been suggested as an effective method for identifying TB cases and reducing mortality, for example in India [186]. The form of active case finding used in the ETA, by having treatment supporters visit the home and identifying TB contacts, may assist in reducing the burden of TB in the community, and further attention should be paid to its processes and impacts.

#### *Empowerment in the ETA in relation to wider society*

One of the more general issues related to the lack of evidence of empowerment is that patients were not part of any wider social movement or support group, as is the case for ART patients. These groups have been found a key component of empowerment [12]. ART patients have peer

support groups, which may assist in them becoming more empowered; and are supported by the larger movement to find their own voices in the struggle to gain access to treatment [77].

Although to date TB patients have had no need to demand treatment, peer support groups could be considered as an addendum to the ETA approach and one way to increase empowerment. These groups have been found to be beneficial for adherence in Ethiopia [187], and patients' responses in FGDs suggested that they might appreciate an opportunity to share their treatment experiences. Despite the limitations in empowering patients, the programme was well received by patients and thus may present a less paternalistic alternative to TB treatment than DOT.

Empowering patients would necessitate taking into account the wider community and wider society. The TB patients in this study were mainly from the most disadvantaged part of South African society, and may also not be empowered in other spheres of their life. Therefore, efforts of empowerment in a TB programme may not translate into effects in the patients' lives in general, and the attempts within TB programmes may also be countered by the disempowerment faced by patients in their daily lives.

In addition, changes in the TB treatment programme may not be able to counter the nature of the public health system in general. Both the public health care system and the TB care system [136] could be structured in such a manner that they may not facilitate an empowering approach to patients. The public health care system in general could be considered as technocratic and 'top-down' [188] and as containing inherent power differentials. The working relationships within public health nursing have been found to be hierarchical, and containing differences in power within the hierarchy [189]. Similarly, there remain power differences between nurses and lay health workers, and nurses find it difficult to accept lay health workers as partners in care [190]. It therefore could be expected that the relationships between health care professionals and patients also contain a dimension of power and inequality.

### **Treatment outcomes of the ETA**

The significant difference in improvement of smear conversion rates at 2 months between the intervention and comparison clinics is, however, promising. This suggests that at least initially, patients were arriving for their sputum tests, and had taken their treatment. Despite this, there was no significant difference in treatment success and cure rates between the clinics implementing the ETA and comparison clinics. Rates of default also remained higher than the international average [36].

Improved sputum conversion rates are a positive impact of this intervention. It suggests that patients may have been more adherent, and could suggest that more patients are now less infectious - and therefore less likely to spread infection in the community [191]. It is possible that the lack of impact at the end of treatment is due to the diminished support during the last 4 months of treatment. It is not clear which processes of the intervention resulted in improved sputum conversion rates. It is also possible that treatment supporters reminded the patients to come for their sputum tests while visiting; but it is also possible that patients were now more aware of the importance of keeping appointments due to the counselling, or that they had truly been adhering better and therefore felt more confident in coming for testing.

Patient education and counselling is a key step in ensuring that patients understand treatment requirements [192], and may also contribute to adherence to treatment. Therefore the impact of counselling is an area that needs further investigation.

The settings in which this study was conducted are also highly mobile. The pattern of labour migration is well established in South Africa, with rural dwellers travelling between the city and their home to make their living in cities. This pattern has also been found to result in a high burden of disease in rural areas from where people originate, and the cities in which they work [193]. It is likely that many of the patients in this study travelled home to rural South Africa to attend funerals or other important family events. They may also have taken up residence with their family close to the study clinics when ill, and returned to their own homes when they felt better. The advantage of the ETA in this situation is that patients can have their monthly treatment supply with them and do not need to attend a clinic in the rural areas, to which there may be a considerable distance to travel.

The mobility of these settings is also a challenge to adherence rates, as found also in ART treatment [93], since many patients may not be able to take their treatment as they have travelled away and sometimes may not have sufficient money to return to Cape Town for treatment, even if they wanted to do so.

Although not all results in this study were significant, it seems that treatment outcomes in ETA clinics maintained their pre-intervention levels or continued to increase. This suggests, as in other studies before this [41], that providing TB treatment can be done in other ways besides through daily DOT. While DOT has been found to be beneficial for certain groups of patients who may already lack agency, such as prison inmates [64], it is not necessarily an approach that should be implemented for all TB patients. It is likely that some patients are motivated by their family or other reasons to complete treatment [194], and may not need to be observed taking their treatment every day. One of the reasons for the staying power of DOT could be the lack of a reliable, established alternative.

Although this research cannot conclusively suggest that the ETA is equivalent to or better than DOT, it is a promising approach that should be evaluated further.

Given that the results are promising, the potential of rolling out the programme should be discussed. Considerable management and logistical challenges that fall outside the aims of this thesis remain, and are reported in more detail elsewhere [195]. Despite these, the programme does hold promise in the development of an integrated approach where patients infected with both HIV and TB could receive treatment.

This study also offers support for the calls for integrated TB and HIV treatment. The challenges to treatment supporters and adherence counsellors in encountering issues beyond TB while counselling, as found in Study II, suggest that patients indeed do not compartmentalise their diseases [73], but would prefer to receive information and treatment for both diseases (TB and HIV) at the same time. Having one community health worker responsible for both treatments would be more efficient in terms of human resource allocation, and might also place less pressure on the patient in terms of welcoming a number of different people into their homes or having to travel to different locations in the community. Having one community health worker might also be beneficial to the patient-treatment supporter relationship, if the treatment supporter could respond to the patient's concerns regarding more than one medical issue.

Further research should focus on whether an approach such as this would be sustainable, and whether treatment supporters would have the capacity to deliver combined ART and TB services.





# CONCLUSIONS

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This thesis aimed to examine the ETA programme, which was implemented in five primary health care TB clinics in Cape Town, South Africa. This thesis explored the development of the ETA programme in order to generate information for those seeking to influence agenda setting for policy making. In addition, the implementation of the programme from a staff perspective and the impact of the ETA on patients' experiences of TB treatment were explored. The ETA's impact on TB treatment outcomes was also measured.

The results suggest that the ETA is a feasible approach, although challenges remain in implementation, and that it is an approach that is acceptable to patients. The main conclusions that can be drawn from this study are the following:

- Programme changes, such as the ETA programme, come about through the interaction of a number of factors, but are driven by key individuals with access to information and resources (Study I).
- The ETA was developed partly in order to address human resource issues, but its implementation was also constrained by these, in particular problems with teamwork, staff attrition and lack of training. Having a dedicated project manager was integral to programme implementation (Study II).
- Patients who were enrolled in the ETA seemed to have incorporated treatment into their daily routines, and seemed to have embraced the idea of taking control over their own treatment taking (Study III). However, empowerment did not seem evident in patient reports or in staff attitudes towards patients (Studies II and III).
- Patients had varying responses to treatment supporters visiting their home, and more attention should be paid to how treatment supporters gain access to patient homes, especially in the context of HIV (Studies II and III).
- Buddies had a range of roles in supporting their patient in treatment, from providing valued support to observing each treatment dose taken (Study III).
- The ETA had modest positive effects on smear conversion, but there was no significant difference in treatment outcomes (Study IV).
- The ETA holds promise for TB and HIV treatment integration, and staff experiences support the need for this integration (Studies II and IV).

## **POLICY IMPLICATIONS AND RECOMMENDATIONS**

This study has shown that an approach that differs from DOT can be acceptable to patients, and can be implemented by clinic staff. Treatment outcomes in both intervention and comparison clinics continued to increase, and there was no significant difference in outcomes between the two. Therefore, wider implementation and testing of this approach in different settings in South Africa, and possibly in similar settings outside South Africa, could be encouraged.

If treatment outcomes are maintained in participating clinics, policy makers could consider incorporating ART with the ETA. This more integrated approach might reduce duplication of human resources. Rolling out the programme on a larger scale should be carefully evaluated. Implementing this programme at other clinics would also require solving some of the logistical issues that emerged during this evaluation, which include, among others:

- ensuring a private, confidential place for adherence counsellors to counsel patients;
- ensuring a steady payment schedule of stipends for lay health workers;
- addressing other issues related to lay health worker attrition and focusing on retaining those already part of the system;
- investing in training and on-site supervision of staff implementing the programme; and
- paying attention to issues of teamwork, hierarchy, and teambuilding among staff involved in the programme.

Further studies should be conducted on how programmes such as these could be embedded into routine practice, and how the dedicated staff for these programmes could be retained, without their time being pulled into other crises that need handling at primary health care clinics. This study also offers support to the need for mentoring and supervision in primary health care clinics in South Africa.

Further investigations could also be made of how treatment supporters and adherence counsellors implement this programme, and of how TB patients could become more empowered and have more equal interactions with the health care system in South Africa. Community-based support groups could be one avenue through which this could be explored.

# ACKNOWLEDGEMENTS

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Most importantly, I would like to thank all the patients, nurses and lay health workers who allowed me to interview them, include them in focus group discussions, and use their data for this thesis.

I would also like to acknowledge the funders of the larger study on which this thesis is based: Centers for Disease Control, Atlanta, US, National Research Foundation of South Africa. The South African Medical Research Council and the Swedish International Cooperation Agency and the Swedish Research Council, Sweden, provided salary and other support during my study.

Thank you to City Health, Cape Town, in particular Pren Naidoo, Karen Jennings, Judy Caldwell and Virginia de Azevedo for allowing me base my thesis on the ETA. Thank you also to members of Provincial Department of Health, Western Cape, particularly Marlene Poolman and Brenda Smuts. The work of TB/HIV Care, in particular Ria Grant, Harry Hausler, Mavis Nonkunzi, Belinda Fortuin and Jerusha Soomar has also been important in this thesis.

A warm thank you to Deanna Carter, who with her friendliness and love, not forgetting endless chats and precise maps, enabled me to navigate the communities and primary health care clinics part of this study.

A large, large thank you to my supervisory team who stood by me during this work:

Simon Lewin, for his support, sense of humour and patience, and expertise in the South African health system.

Anna Thorson, for her excellent guidance and her positive and cheerful attitude despite being so busy.

Karin Ringsberg, for her always timely advice.

Judy Dick, my mentor, for the many cups of tea and listening to my anxieties – your lesson on time management may have been learned late, but will not be forgotten!

I am also grateful to my colleagues and supervisors at the Health Systems Research Unit and the Medical Research Council in general, but in particular:

Mickey Chopra, for giving me the opportunity to do this PhD; Sylvia Louw for administrative support; Karen Daniels for friendship, skill and advice, Lungiswa Nkonki for sharing the good and the bad, Marian Loveday for the long chats about TB and everything else, Sarah Dewing, Wesley Solomon, Loraine Townsend, Cathy Mathews, Sandra Marais, Clive Glass and Joy Oliver, for making the MRC my academic home and a wonderful place to work.

Thank you to Jimmy Volmink for setting me on this path.

*Salla Atkins*

I am most grateful to those who collaborated in parts of this study: David Biles, Arrie Odendaal, Hennie Schoeman, Esme Jordaan, Babalwa Sifuba, Yolisa Mtshizana, Xoliswa Njokweni , Nosethu Dingwayo, Leon van Wyk, and Leverne Gething.

Many people at IHCAR assisted me and gave me their friendship, but I would particularly like to thank Anders Ragnarsson, Ziad El-Khatib, Elin Larsson, Anastasia Pharris, Klara Johansson, Yanga Zembe, Vinod Diwan, Asli Kulane, Ashley van Niekerk, Gaetano Marrone, Paul Bangirana and Anna-Berit Ransjö-Arvidson.

Thank you to Kersti Rådmark and Gun-Britt Eriksson for their administrative assistance.

Thank you to my colleagues at the Finnish Institute of Occupational Health for their support.

Finally, a huge thank you and apology to my friends and family:  
Mom and Dad, for taking me to South Africa.

My sisters and their families: Emma, Hanna, Janne, Joel, Milo, Linda, Emil, Lari and Meri, for understanding my absent-mindedness.

My new family, Irmeli, Mikko, Miska, Marja, Petja, Heidi, Lilja, Matja and Kriska for your good humour and bringing content - other than the PhD! - into my life – sorry about the continuous writing.

And Dimitri, for holding my hand, at all the right times.

The very last mention should go to Musta and Vaalee, who, though periodically destroying my work and my computer, provided much needed comic interludes, warmed me and kept me company during the later and most difficult parts of my work. Every PhD student should have a cat or two.

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# APPENDIX 1:

## Interview guide for programme planners, Study I

**Why did the intervention start?** (Or: What were the main reasons for initiating the intervention?)

In your opinion, what motivated the need for a new TB adherence intervention?

How did this intervention begin? What was the original idea? What did you see as the key objectives?

**What and who drove the intervention towards implementation?**

To what extent was the community or other stakeholders (health providers etc) consulted in the process? Were their views taken into account in some way?

Who were the main actors who drove the project to implementation? Were there particular “champions” for the project? How did they succeed in driving the project?

What drives the project/ what motivates people to try out this project?

**How does the programme work?**

What, in your view, are the key elements of the programme? How will it effect change?

Do you believe that this programme will make a change to tuberculosis treatment outcomes? If yes, how? If no, why not?

What are the particular aspects of the programme that will improve outcomes and how?

If you were to explain to someone how this programme works, what would you say?

On what aspects of the TB treatment does this programme focus on (most/least)?

**What are the successes and challenges thus far?**

What, in your view, are the successes of this programme to date? What do you think has helped implementation?

What, in your view, are the challenges of this programme? What do you think has hindered implementation?

In your view, how has the programme impacted on relations between nurses and patients? How has it impacted on relations between treatment supporters and patients?

If you were to design the programme again, is there anything you would do differently?

When implementing the programme on a wider scale, is there anything you would change?

Is there anything else you would like to add that we have not covered in this interview?

## APPENDIX 2:

### Adherence counsellor interview guide example

#### **Please tell me about the working environment in the clinic:**

Do you have good relationships with staff?

Prompt: 1. programme managers, 2. treatment supporters, 3. TB nurses, 4. other adherence counselors?

Have you experienced any problems with staff?

How were these resolved? By whom?

Do you find your work environment helpful to your work?

Prompt: supplies, space, confidentiality

Are you concerned about MDR or XDR TB?

If yes, how do you deal with this?

Do you have any other duties at the clinic besides your counselling work?

#### **Please tell me about your counselling**

Do you think the way you counsel patients has changed since you started counselling?

If yes, how?

How do you go about a counselling session?

Do you patients ask questions that you were not taught in training? What are these?

Have you become more familiar with issues related to disseminated TB?

Have you become more familiar with issues related to HIV/AIDS?

Would you change anything about the counselling?

#### **Please tell me about patient response.**

How do patients respond to counselling?

Are there differences in response between people (e.g. do some people respond better than others)?

Prompt: gender, age, etc.

#### **Now I would like to talk about the programme in general**

Now that you have been part of the programme for a long time, would you change anything about it?

What do you like the least about the programme?

What do you like the most?

Is there anything else we have not talked about that would be important for others to know about your work?

If someone was considering doing this programme at another clinic, what would you tell them about it?

## APPENDIX 3:

### Patient focus group guide example

**All of you have been on TB treatment. We are now trying to find out what you think of the treatment, and how it could be improved.**

**Start each group by asking each person to share with the group their response to the following question:**

- what was the most important event during your TB treatment?

#### **Clinic experience:**

When you first arrive in the clinic and you are told that you have TB, how do you feel?

How are you treated by clinic staff

- Prompt: TB nurse, adherence counselor, treatment supporter, others

Do you have any problems when you arrive at the clinic?

- Prompt: what are these?

#### **General experience:**

Could you tell me, what was it like to be on TB treatment first?

What was it like after a couple of months?

What is it like now?

How does being on TB treatment affect your daily life?

What kind of problems have you experienced with taking treatment?

What has helped you in taking your treatment?

- Who supported you in your treatment?

Why do you think people don't complete their TB treatment?

What did you think is needed to support people to complete their treatment?

#### **Experience of counseling**

Before you took your treatment at home, you attended some counseling sessions.

What did you think of these?

- How did it change the way you thought about TB?

What was the counselor like?

Do you think it prepared you for taking your TB treatment?

- Prompt: why?

What did you think of the flipchart that was used?

- Prompt: information, pictures

#### **Experience of treatment supporter**

Each of you were assigned with a treatment supporter, who did a home assessment and then visited you.

*Salla Atkins*

How did you feel when the treatment supporter visited you for the first time?

How was your relationship with the treatment supporter in the beginning?

What was it like in the middle of the treatment?

What is it like now?

How often did they come to see you?

What kind of issues do you discuss with your treatment supporter?

What kind of issues do you not discuss with him or her?

What do you like most about the treatment supporter?

What do you like the least about him or her?

If a friend of yours had HIV and TB, do you think they would like to have a treatment supporter visiting their home?

If yes, why? If no, why?

### **Buddies**

You also were asked to have a buddy to support you in treatment.

What did the buddy do to support you?

Was having a buddy helpful to you?

- prompt: if yes, how? if no, why not?

Did your buddy know about TB? If yes, how? (Prompt: Had they had TB before?)

### **General experience**

If you could change anything about TB treatment, what would you change?

If a patient had TB, would you tell them to come to this clinic?

If yes, why?

If no, why not?

Is there anything else you would like to mention about TB treatment that we have not mentioned before?

How have you found talking about these issues in a group?

**Thank you!**