

**Final evaluation report**  
**Enhanced Tuberculosis Adherence Programme**

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## EXECUTIVE SUMMARY

**Introduction:** To improve poor TB outcomes, the City of Cape Town Health Department piloted a new Enhanced TB Adherence (ETA) programme based on the model used successfully for antiretroviral treatment (ART) support.

**Intervention description and logistics:** The ETA model utilises intensive treatment adherence counselling for patients; assessment of patients' living conditions at home; a treatment buddy to support treatment taking; and lay health worker supported self-supervised TB treatment. It was implemented, following staff training, in 5 clinics delivering TB treatment. Implementing the programme required considerable human resources, training and management support.

**Evaluation aim:** To evaluate the design, implementation and outcomes of an intervention to improve adherence to TB treatment among patients attending five primary care clinics in Cape Town, South Africa.

**Evaluation methods:** A mixed methods approach was used, including an interrupted time series analysis of TB treatment outcomes and qualitative and quantitative assessment of intervention implementation.

### Key evaluation findings:

- Approximately 70% of new TB patients at the intervention clinics were placed on the ETA model from April 2007 to the end of March 2008. As planned, patients spent an average of two weeks on facility-based DOT before taking their treatment at home
- The ETA intervention was seen to have a number of advantages over the DOT model:
  - TB nurses felt it improved the clinic environment, by reducing the number of patients in the waiting area, and by releasing time for other activities
  - Adherence counsellors and treatment supporters felt that it benefited the community by providing communities with more information. Treatment supporters were also able to gain an in-depth view of patients' home environments, which they felt helped them assist patients.
  - Patients felt that the treatment counselling prepared them for their treatment. They also valued the support provided by buddies, adherence counsellors and treatment supporters
- Outcome data indicate that 2 month TB smear conversion rates improved significantly in intervention clinics, compared with comparison sites. TB cure and treatment success rates improved in both intervention and comparison clinics during the evaluation period but there were no significant differences between intervention and comparison clinics.
- The programme placed additional burdens on management regarding the recruitment and training of staff; logistics; day-to-day management; and monitoring. Some additional costs were incurred in the introduction of the intervention
- Recommendations for wider implementation of this programme include: providing ongoing supervision and training to staff; reducing lay staff attrition through increasing stipends; minimising the administrative work required; providing adequate space in the clinic for adherence counselling; and exploration of ways to integrate this programme with other ongoing initiatives, including support for patients on ART.

## INTRODUCTION

The City of Cape Town, working with the Provincial Government of the Western Cape and the TB/HIV Care Association<sup>1</sup>, has developed and implemented a pilot programme for TB treatment delivery and support, which is based on the ART community treatment support model (Bekker 2006). Reasons for development of the intervention included poor treatment outcomes for TB in many areas of Cape Town and high rates of TB-HIV co-infection among patients, as well as the perception that self supervision of TB treatment was already taking place in many areas. The MRC's Health Systems Research Unit was asked to evaluate this enhanced tuberculosis adherence (ETA) intervention. This report summarises the key evaluation findings.

## INTERVENTION DESCRIPTION AND IMPLEMENTATION

Intervention implementation began initially at two clinics in Cape Town in October (Quarter 4) 2006. The pilot was expanded in April (Quarter 2) 2007 to three additional clinics. These clinics were selected because of high caseloads, sharing similar patient demographics and reporting poor performance on TB treatment outcomes.

In this section we describe the aim and content of the intervention; and the management, clinic, community and training resources required to implement it.

### 1. Aim and description of the ETA intervention

The aim of the ETA intervention was to improve TB outcomes, by improving adherence to treatment and reducing defaulter rates.

The ETA model consists of the following:

- Initial TB treatment under supervision at a health facility until treatment counselling and other intervention components are completed (see below). TB patients spend approximately two weeks in clinic-based DOT while being prepared for ETA. This period allows time to detect any adverse effects to treatment, prepare the patient for self-administration of treatment, and evaluate the home circumstances of each patient.
- Assessment of the patient's home by a lay treatment supporter to check living conditions, verify the patient's address and identify TB contacts in the home.
- Identification by the patient of a buddy – usually a family member or friend – to support and motivate the patient's adherence in the home. Buddies were asked to report any problems that arose during treatment to the treatment supporter or clinic.
- Three to four intensive treatment counselling sessions on TB and its treatment for the patient and the buddy (more detail on counselling sessions is included in Appendix 1). Counselling was delivered by a dedicated lay adherence counsellor at the health facility during the first few days after the patient initiated treatment, using a flipchart developed for this purpose. Later in the project, an additional counselling session was added at the start of the continuation phase of treatment. The sessions focused on adherence planning, including possible reasons for defaulting and ways of countering them, and had an emphasis on patients taking responsibility for their treatment.
- A team meeting of the TB nurse, treatment supporter and adherence counsellor to assess and decide each patient's eligibility for community-based adherence support.

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<sup>1</sup> The TB/HIV Care Association is a non-governmental organisation (NGO) employing and managing lay health workers who provide support for people on TB treatment.

- If eligible for the model, the patient received a supply of pills, and returned monthly to the health facility for weighing, pill collection and monitoring by the nurse. The patient also returned to the clinic for their appointments with doctors and for 2 and 5 month sputum smear tests, if applicable. At home, patients marked a calendar each time they took their pills.
- If not eligible for the model, patients were retained on clinic DOT. This group included patients not within the catchment area of the clinic, and patients who were seen to be at risk of not adhering to treatment, such as patients who had substance use problems; patients who had a mental illness; patients who had no permanent place to live; and patients who could not find a buddy to support them in their treatment. Patients could also refuse to be part of the programme and opt for TB treatment at the clinic, or be placed on workplace supervised treatment.

In order to improve treatment adherence by all patients, staff were asked to ensure that treatment supporters conducted a home assessment for all TB patients, and that all TB patients received counselling from adherence counsellors, regardless of whether staff considered the patient to be eligible for the model.

A comparison of the ETA model and usual care (DOT) is presented in Table 1.

**Table 1: Comparison of directly observed therapy and the new treatment model**

<b>DOT</b>	<b>New treatment model (Enhanced Tuberculosis Treatment Adherence Model)</b>
Patient is initiated onto directly observed therapy in the clinic	Patient is placed on directly observed therapy in the clinic for a short period (approximately 2 weeks) while receiving adherence counselling
Mode of treatment delivery: directly observed therapy	Mode of treatment delivery: self supervision
Information about TB, treatment etc. given by nurse informally during contacts with patients	Dedicated lay adherence counsellor gives TB information to participant in 4 structured counselling sessions
Patient can receive DOT in the workplace, or 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
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-supervision, once per month until end of treatment
If the patient is placed on community based DOT, s/he visits a treatment supporter once a day to receive treatment	If the patient is placed on self supervision, a treatment supporter visits the patient once a week to monitor treatment taking
No formal integration of family or friends into the treatment plan	Treatment “buddy” attends counselling and acts as support and reminder to the patient. The buddy can be a friend, family member or neighbour of the patient

## **2. Management requirements for implementation of the ETA programme**

Additional dedicated human resources were needed to manage implementation of the intervention. At least one person day per month was required from City of Cape Town and TB/HIV Care managers in order to ensure smooth implementation. In addition, a full time senior nurse (previously a TB/HIV/STI Coordinator) was employed as a project manager. The project manager delivered some elements of the training and oversaw and provided daily support to intervention clinics, including on-site retraining where needed.

Additional materials developed included a flipchart to guide counselling; new forms to monitor intervention implementation; and an intervention patient register (which supplemented the existing TB register completed by each clinic).

Intervention implementation was guided by monthly meetings of the key stakeholders, including City of Cape Town Health Department staff; staff from the Provincial Health Department; TB/HIV Care Association staff; and clinic staff responsible for the implementation. These meetings focused on feedback on intervention processes, and on solving implementation problems.

## **3. Clinic and community human resource requirements for implementation of the ETA programme**

The model is delivered by four staff categories:

- Professional nurses – responsible for diagnosis, initiating treatment, clinic based DOT, and patient management throughout treatment
- TB/HIV Care Association supervisors – responsible for training and supervisory support of adherence counsellors and treatment supporters
- Adherence counsellors – based at the health facility and responsible for giving information to the patient and their buddy about TB treatment, with an emphasis on adherence planning and healthy living
- Treatment supporters – based in the community and responsible for home assessments, and visiting the patient three times a week in the first week of community treatment and once a week thereafter. They report any problems experienced by the patient to the clinic. They are usually retrained ‘DOT supporters’, and are supervised, supported and managed by the TB/HIV Care Association.

The number of staff varied across clinics depending on patient loads. A table detailing the responsibilities of these staff is included in Appendix 2. These staff categories were overseen by the project manager.

Turnover was high for treatment supporters and professional nurses during the evaluation period. Clinic 1 was the only clinic where the same cohort of professional staff was retained throughout the implementation. Staff rotation contributed towards staff turnover at some clinics.

## **4. Training requirements for the ETA programme**

The following initial training was given to staff responsible for implementing the programme:

- Treatment supporters: standard training for DOT supporters followed by ETA training for five days

- Adherence counsellors: Treatment supporter training; five additional days on counselling and use of the ETA flipchart from City Health, Cape Town; and a week of counselling training from a NGO (FAMSA - the Family and Marriage Association of South Africa)
- Nursing staff: One day of training on the intervention. All nursing staff at each facility participated in this training
- A session on teambuilding, comprising practical and theoretical exercises in teams for all staff involved in the project. This session aimed to improve working relations and to clarify roles for staff members implementing the intervention.

Due to staff attrition, three additional training sessions for lay workers were delivered, and on-site mentoring on implementation processes and on using forms was given to nursing staff, adherence counsellors and treatment supporters by the project manager.

Training was conducted mainly by the project manager, assisted by other professional nurses and TB/HIV Care Association staff.

### **EVALUATION AIM**

To evaluate the design, implementation and outcomes of an intervention to improve adherence to TB treatment among patients attending five primary care clinics in Cape Town, South Africa.

### **EVALUATION METHODS**

The evaluation used a mixed method approach, as described below.

#### *Process evaluation*

Quantitative process data on programme implementation were obtained from a specially developed patient register. This register captured patients' treatment start date; when they had completed counselling; the data on which their home assessment was done; and the meeting date at which their eligibility for the intervention was decided. These data were captured on paper by nurses, adherence counsellors or clerks at the clinics, and entered into an intervention database by the City of Cape Town. Data on implementation indicators were then extracted from this database. The indicators included time spent receiving treatment at the clinic (from treatment initiation to being placed on the ETA); time from home assessment to being placed on the ETA; and percentage of new TB patients placed on the new model. Descriptive analysis of this data was undertaken.

Additional quantitative process data was obtained from a review of patient folders. The aim of this folder review was to examine the quality of TB treatment data recording for the ETA intervention; and to collect process information for the intervention, including number of patient referrals by treatment supporters and numbers of patients referred for VCT (voluntary counselling and testing for HIV/AIDS) by project staff. Sixty folders per intervention clinic were examined. To obtain these, a retrospective sample of 60 consecutive TB register entries of new TB patients at each ETA intervention clinic was identified in November 2007 from the electronic TB register. Re-treatment TB cases were not included in the review. Patients starting treatment from 6 months after the implementation of the intervention in each clinic (April 2007 for two clinics and October 2007 for three clinics) were sampled. The total number of register entries sampled was 300. The specified folders were then located and accessed in each clinic's filing system, with the assistance of the clinic staff. Information on persons referred to the clinic by lay workers was captured from the forms completed by them, while information on transfers out and other clinical information were extracted from the clinic held patient folder.

Qualitative process data was obtained from interviews with the project manager; TB nurses and adherence counsellors; focus groups with treatment supporters and patients; interviews with two patients recalled from community treatment to clinic; and from observations of training sessions. This ensured triangulation of data, which enhances validity. Table 2 details the interviews and focus groups conducted. Two TB nurses and three adherence counsellors were interviewed at both 4 months and 9 months into the programme, as were one group of treatment supporters. Patients from the intervention clinics (n=28) and from a comparison clinic implementing DOT (n=31) were included in separate focus groups, which were conducted after they had spent an average of 4 months on treatment. Male and female patients were also included in separate groups. Data were analysed by first reading and re-reading transcripts, followed by open coding. We then generated categories and themes, referring continuously back to the transcripts. This report includes information specifically relevant to implementation of the new intervention. Additional analysis on qualitative data is presented elsewhere (see e.g. Atkins et al. (submitted)).

**Table 2: Interviews and focus groups conducted, by clinic**

Clinic	Nurse interviews	Adherence counsellor interviews	Treatment supporter FGDs	Patient FGDs	Interviews with recalled patients
1	4	4	3	4	1
2	1	2	1	2	1
3	2	0	1	0	0
4	0	1	1	0	0
5	1	1	1	0	0

We also conducted a focus group with patients at a clinic implementing standard DOT, in order to compare responses with patients from intervention clinics.

#### *Outcome evaluation*

The overall study design for the outcome evaluation is an interrupted time series with non-equivalent comparison groups. Alongside the five clinics selected purposively by City Health to receive the new TB treatment intervention, five comparison clinics were also identified by City Health and the research team in order to allow statistical comparison between intervention and ‘usual care’. These were matched as closely as possible for caseloads and treatment outcomes (although no exact matches were available).

For this evaluation, treatment outcome data were extracted from the routine electronic TB register (ETR) for TB patients aged 18 years or older and who were registered between 1 April 2007 to end March 2008 in the study and comparison clinics (post-intervention period). Data from January 2005 to March 2007 (pre-intervention period) were also included in the analysis to show time trends. January 2005 was chosen as the start point as a change in the standard TB outcome definitions had taken place in 2004, making earlier outcome data not comparable. The start point was selected prior to data analysis. Clinic 2 had treatment outcomes from October 2005.

A data manager cleaned and prepared the data. The data were used to generate weighted averages (and 95% confidence limits) for each outcome indicator, rounded to the nearest full percentage, across intervention and comparison sites. The weighted observed rates of the outcomes were initially smoothed using LOESS regression. The graphs presented include the LOESS regression. Following

this, data points were used in a Poisson regression analysis, which gives the overall results of the evaluation.

Smear positive patients, for which smear conversion and cure rates are presented, include patients with pulmonary TB or with both pulmonary and extra pulmonary TB. The successful treatment rate is calculated for both smear positive pulmonary TB and smear negative patients, who may have either pulmonary or extra pulmonary TB, or who may have both extra pulmonary and pulmonary TB. We have adhered in this analysis to the WHO TB treatment outcome definitions (WHO 2008).

We have also included graphs based on facility report data (i.e. data routinely produced by the electronic database held by the City Health Department on outcomes for each clinic) in order to show outcomes that match standard reporting in the city. The definitions used in facility reports differ from those used in the outcome evaluation described above. For example, facility reports include data for all patients, regardless of age. Cure and smear conversion definitions also differ, as ETR.net only accepts 2 month smears done within a given time period. For logistical reasons, detailed analysis was not conducted on these data. In this report, these data are summarized in a number of graphs. Data points in the graph represent average rates. Blue lines are moving average trend lines for control clinics, and red lines are moving average trend lines for intervention clinics. These graphs can be found in Appendix 3.

## **PROCESS EVALUATION RESULTS**

### **1. Case study: Implementing the intervention at one clinic**

A short case study has been included in the process evaluation in order to contextualise starting the project in clinics.

Clinic 2 was selected to be included the project as the site had just begun providing TB treatment for patients. The intervention was implemented at the clinic from October 2006. Initially the intervention encountered considerable resistance from clinic staff. After negotiations, the sister in charge of the clinic agreed to take on the project, if she was remunerated for the additional responsibility. However, implementation of the intervention remained the responsibility of one professional nurse, with other nurses not wanting to participate.

Implementation was constrained by the shortage of space in the clinic. The adherence counsellor had to counsel in a filing room with open access to the nurse's station. Achieving privacy was therefore near impossible. Retention of treatment supporters was also a problem: from the initial group of 12 treatment supporters, only one remained by February 2007.

Two months after intervention implementation had started, records showed that the intervention was not being implemented as planned. Problems included the placement of only a minority of TB patients on the ETA and that there was only one lay health worker left of those trained originally. At this stage, it seemed to management that implementing the intervention at the clinic would not be possible.

In light of these difficulties, the health services called a meeting with the facility staff and proposed withdrawing the intervention from the clinic. With strong motivation from the TB doctor it was agreed that the clinic would continue implementation. More lay health workers were trained and a new nurse took on the task of running the intervention. The adherence counsellor began using free rooms for her counselling, which helped her work, though she did not have a permanent office. Staff

reported that it took approximately 6 months to achieve smooth running of the intervention at this clinic. However, the clinic was one of the better performers by the end of the evaluation period.

## 2. Indicators of intervention implementation – intervention register

Table 3 below details the intervention implementation indicators obtained from the intervention register.

**Table 3: Intervention processes between April 2007 and March 2008**

Clinic	1	2	3	4	5	All Sites
Number of new TB patients in register	1195	398	632	420	722	3367
Proportion of patients who were counseled, of all new patients	77.5%	87.9%	88.3%	80.7%	78.3%	81.3%
Proportion of patients who had a home assessment, of all new patients	67.4%	82.2%	78.2%	68.8%	63.9%	70.6%
Number (%) of new TB patients in the register for which the register contained intervention information	1004 (84%)	352 (88.4%)	575 (91%)	354 (84.3%)	618 (96.3%)	2903 (86.2%)
Number (%) of patients who were placed on the intervention, of all new patients	820 (68.6%)	319 (80.2%)	477 (75.5%)	272 (64.8%)	439 (60%)	2327 (69.1%)
Days spent on average at clinic from treatment initiation to placement on ETA, of patients who had satisfied all intervention criteria	19.4	19.3	14.1	21	24	19.6
Days spent on average at clinic from home assessment to placement on ETA, of patients who had satisfied all intervention criteria	5.8	3.1	4.9	6.9	6.8	5.5

On average, 81.3% (range 77.5%-88.3%) of new TB patients were counselled in the clinics and 70.6% (range 63.9%-82.2%) of new patients had a home assessment. The intervention register contained information on the treatment support option on which patients were placed for an average of 86.2% (range 84% and 96.3%) of new patients. According to these data, the proportion of patients placed on the ETA ranged from 60%, to 80.2% across the intervention clinics (average = 69.1%). Patients spent between 14 and 24 calendar days in the clinic before being placed onto the ETA. These indicators fluctuated considerable throughout the year for home assessments, placements and counselling rates.

The main reasons for not being placed on the ETA were that the patient was from outside of the clinic catchment area; defaulting clinic DOT during the first two weeks while counselling was being conducted; being transferred out; and poor social circumstances. Many patients were also placed on the workplace DOT programme. Some patients also had no buddy and therefore did not qualify for the intervention. The main reasons for not being placed on the programme varied between clinics. However, transfers out and residing outside of the catchment area were the most important reasons for exclusion. For a number of patients, register discrepancies or missing folders meant that it was not possible to ascertain which intervention option they received.

### **3. Indicators of intervention implementation - Folder review**

In total, we located 249 folders across the five clinics, constituting 83% of the sample. There were a number of challenges to locating folders in clinics using register numbers. In most clinics the register number was used as a folder identifier. However, at clinic 1, at least three different folder numbering systems had been used during the study period, resulting in folders needing to be first identified by register number in the register, and then tracked by the names of patients. In clinics 3 and 4 the filing system and some folder numbers had changed, and not all folders could therefore be found.

In total, 91 persons were referred by treatment supporters from patients' homes to the clinics. This included individuals with TB symptoms; immunocompromised persons, such as those with cancer, or HIV; and children under five years old who needed vaccinations.

### **4. Qualitative process evaluation findings**

#### ***4.1. Results of training observations***

Most participants participated actively in the training sessions, and seemed to have good interaction with the trainers. Some comments received by trainers during the training suggested that some staff and treatment supporters had reservations regarding the intervention. These staff felt that they were already achieving good TB treatment outcomes using DOT, and did not believe patients would adhere without daily DOT. In addition, treatment supporters appeared to have difficulty in mastering how to conduct pill counts and use the ETA forms.

#### ***4.1. Programme managers and other stakeholders' views***

Health managers responsible for overseeing the delivery of the intervention identified a number of challenges to successful delivery. These included human resources challenges, such as staff attrition at all levels of the programme; selecting sufficiently skilled and appropriate staff, especially in terms of treatment supporters and adherence counsellors; and needing to identify a champion at each clinic in order to ensure the intervention proceeded as planned.

Implementation challenges included resistance from staff to what was perceived as additional work; ensuring that staff attended the required weekly team meetings; and changes in staff and lay worker roles. There were challenges also in treatment supporters' understanding of forms, as they had never previously only been required to complete the adherence section of patients' treatment cards. Confusion surrounding line management and reporting was mentioned, as lay health workers were not sure whether to report to the City Health Department, to TB/HIV Care or to both; and a considerable training and supervision burden was noted by managers. The programme also needed constant modification as new issues arose.

Challenges surrounding monitoring included determining whether the intervention was implemented as planned in patients' homes and the need for management to attend weekly meetings at each clinic to monitor progress. Budgetary challenges identified included payment of treatment supporters.

A number of successes were also identified by managers: the intervention was seen to have encouraged teamwork among clinic staff; treatment supporters had learned new skills and had been empowered to, for example, report back on their work and speak English; patients' knowledge regarding their disease was perceived to have increased; and communities also appeared to be more informed about TB and its treatment. Managers also noted that clinic staff were experiencing lower workloads and shorter patient queues and that clinic crowding had reduced. They felt that the intervention was appreciated by patients.

#### **4.2 Providers' views – TB nurses**

Some nurses were initially not convinced of the programme, and some initial resistance was experienced in implementing the model in some clinics. Nurses had agreed with the concept underlying the programme, but not with additional work, which involved referring patients to counselling, keeping an intervention register, and maintaining a list of treatment supporters allocated to patients. In addition, due to referrals coming in from the community, it initially seemed that caseloads and workloads were increasing. However this was quickly overcome as nurses became used to the tasks or as additional tasks were given to other cadres. Nurses then began seeing the benefits of the programme: *"...at least the workload is a little bit down but now.. the stationery is more at times."* It seemed however that the project was seen as one TB nurse's responsibility and not as the responsibility of the entire TB room. When the nurse responsible for the programme changed at two of the included clinics, the new nurses often consulted the adherence counsellors when unsure about an aspect of the programme.

In general, nurses viewed the new treatment model positively: *"...I'm very happy about it because really, the load of the clients that you have.. you know, we don't have a lot of staff.."* Nurses also mentioned that the approach improved their working conditions by reducing crowding and patient numbers within clinics. As mentioned above, lists of treatment supporters and patients needed to be updated frequently due to treatment supporter attrition. However, later in the programme, at most clinics this responsibility was given to area treatment supporters and the responsibility for maintaining the register was given to clerks or adherence counsellors. Nurses interviewed at both 3 and 9 months were more emphatic about the reduction in their workload: *".. we now have fewer numbers on the benches waiting to be seen... We now finish earlier at something to four [in the afternoon], and by four we are just doing our records and folders"*. They also reported that patients appreciated the programme, but that they sometimes defaulted when feeling better. The main challenge was the difficulties experienced by treatment supporters in finding patient homes in the community. This, it was suggested, contributed to slowing intervention implementation.

#### **4.3 Providers' views – adherence counsellors**

Initially, most counsellors felt unsure about counselling, and were sceptical of the likely impact of the ETA programme. However, after the programme had been running for some time, adherence counsellors reported enjoying their work, noting that: *"The adherence [ETA] programme is very helpful to the people."*, and *"So it's helping the clinic a lot you know"*. They believed counselling was a "mind opener" for patients, and felt that the patients appreciated the educational flipchart used as they could see the pictures even if they could not read the text.

Adherence counsellors added information, for example on proper nutrition, to the standard counselling sessions when they thought it necessary. They did, however, seem frustrated when there were not sufficient treatment supporters available or when these supporters performed poorly. They also reported that they were frequently asked questions related to HIV/AIDS and therefore needed more knowledge and training about HIV and ART, as one counsellor noted: *“Like they ask how can they start their ARVs? But simple questions I can reply to. But the other questions, like the ARVs, I don’t know”*.

Space in the clinic was also an important issue: *“I’m in the space with the clerk. It’s not good at all. Some other patient sometimes wants to talk, and sometimes it’s confidential, and he can’t”*. Other challenges included dealing with patients with extra pulmonary TB: *“[she said] you must not tell me about their lungs because my child is sick from TB meningitis... the TB medication is for the lungs”*. Most adherence counsellors felt the new intervention was better than DOT as they were now able to impart information to the whole community: *“It’s a programme that needs to be in all clinics... I am here to make [the patients] community health workers”*.

#### **4.4 Providers’ views – treatment supporters**

Treatment supporters saw several benefits to the new programme. They noted that the programme provided more support to patients than the DOT approach: *“now we are three against one; it’s me the treatment supporter, buddy and the clinic... the patient sees s/he has a stronger support system”*. Supporters appreciated being able to see the patient’s living conditions, and having a closer relationship with patients: *“Now we do not just give our patients the pills, we get to meet their families, we get to hear about their problems, and we get to make sure their families are not infected with TB”*. According to them, patients would now not have to spend money to come to the clinic or need to travel to the clinic in bad weather. One treatment supporter also pointed out it was easier to find defaulters in the ETA system, when compared to the community-based DOT approach, where they did not always know where the patient lived. Supporters also noted that their families would now be less likely to contract TB: *“we were at risk with DOTS”*.

There were also a number of challenges. Some treatment supporters felt that the delivery of DOT from their homes was easier for them: *“DOTS was very easy than adherence [the ETA] because the patients came to your house instead of you going to them... we were working like volunteers but... adherence[ETA] is a full time job...”*. Finding a private space to talk with the patient in the patient’s home was sometimes difficult: *“when you get there the patient is not alone and maybe her boyfriend is there and he starts asking questions.. and such questions become very difficult for us to answer...”*. Some also had concerns about patients’ adherence to treatment, noting that: *“...there is no way to know for sure the patient is taking the pills..”*. Treatment supporters reported that they were called on to deal with issues outside of TB treatment, including poverty and HIV related issues in the community: *“...he heard that he was also HIV positive and that got too much for him to handle.. I had to sit and listen to him...”*. They also were concerned about being able to fill in forms correctly, and reporting back in English at the clinic. Some were also not happy with their salaries and delayed payments, though they were initially excited that the programme provided fixed stipends rather than payment per patient supervised.

#### **4.5 Patients’ views**

Participants from the intervention areas expressed far more positive sentiments than their counterparts from the DOT sites. Patients from the ETA sites appreciated the flipchart used during adherence counselling: *“The chart really helped me understand how TB can be managed and how one can be cured”* (clinic 1 female). They also found the counselling useful: *“...I would say after the session I was able to tell or rather educate others about TB and to tell them to go to the clinic should*

*there be any problems*” (clinic 1 male). Intervention site patients seemed to have better relationships with community-based treatment supporters and nurses, and also did not cite any of the typical barriers to maintaining treatment adherence (e.g. money and transport to health facilities). Overall, the intervention site patients felt well prepared for their treatment: *“That really helped because they prepared us for the road ahead”* (clinic 2 male), though some misconceptions still remained, for example about the relationship between HIV and TB. A patient recalled to clinic treatment also pointed out that he had not taken in everything that he heard in the counselling sessions: *“I was grateful [when the treatment supporter visited] because I was sick and my mother did not understand everything, she came to explain how everything works and that was very good.”* Patients in intervention clinics also seemed to have taken onboard the message of personal responsibility for treatment, and many had incorporated treatment taking into their daily routines: *“I wake up and take my pills then clean and then eat...”*.

In the DOT group, patients wanted to take their tablets at home and not to have to visit DOT supporters’ houses daily: *“If we were to get our treatment supporters to visit us instead of us visiting them”* (comparison male). The visits were perceived as too public suggesting that, if given the opportunity, these patients may have appreciated the ETA. Two patients who had been recalled to clinic treatment from the ETA programme felt that their non-adherence had been due to problems with their treatment buddy, and due to peer pressure to use substances. In both intervention and comparison clinics patients felt that people would default from treatment when they felt better.

## **OUTCOME EVALUATION RESULTS**

The characteristics of new and retreatment patients are presented in table 4. The overall treatment outcomes for new and retreatment patients (both smear positive and negative) for the pre-intervention and post intervention periods in intervention and comparison clinics are presented in table 5 below. The tables show that treatment completion was consistently slightly higher in intervention clinics than comparison clinics (although this difference was not statistically significant), and that intervention clinics had more smear negative and extrapulmonary cases than comparison clinics.

**Table 4: Characteristics of TB patients (new and retreatment) included in the study**

		<i>Pre-intervention period (Q1 2005-Q1 2007) (n=13524 patients)</i>		<i>Intervention period (Q2 2007-Q1 2008) (n=5732 patients)</i>	
		<b>Intervention clinics (n=8627)</b>	<b>Comparison clinics (n=4897)</b>	<b>Intervention clinics (n=3668)</b>	<b>Comparison clinics (n=2165)</b>
		<b>n (%)</b>	<b>n (%)</b>	<b>n (%)</b>	<b>n (%)</b>
<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 in years</i>	35.2 (SD 11.43)	34.9 (SD 11.3)	35.6 (SD 11.6)	35.5 (SD10.9)
<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)
<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</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)

**Table 5: Treatment outcomes for patients attending all study clinics in the pre- and post-intervention periods**

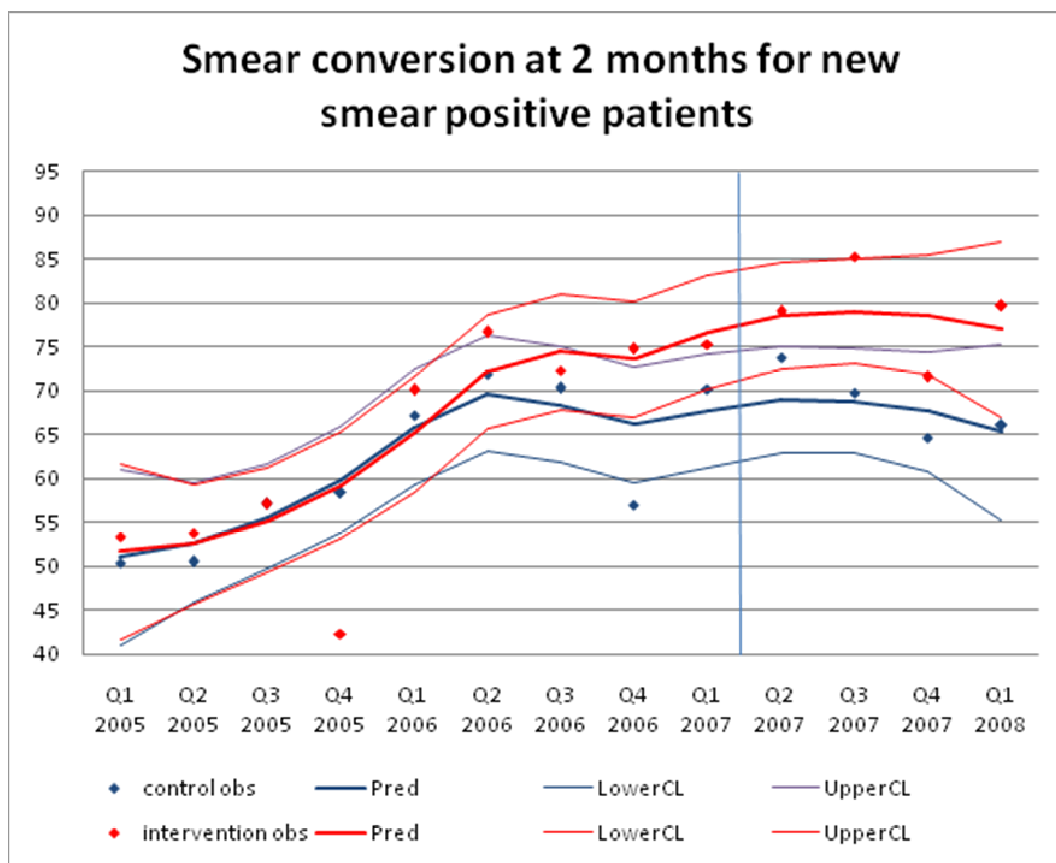
	<i>Pre intervention period (Q1 2005-Q1 2007)</i>		<i>Post intervention period (Q2 2007-Q1 2008)</i>	
	<b>Intervention</b>	<b>Comparison</b>	<b>Intervention</b>	<b>Comparison</b>
<b>Cured</b>	2774 (32.15%)	1808 (36.92%)	1144 (31.19%)	754 (34.83%)
<b>Completed</b>	3331(38.61%)	1720 (35.12%)	1536 (41.88%)	860 (39.72%)
<b>Failed</b>	85 (0.99%)	48 (0.98%)	32 (0.87%)	27 (1.25%)
<b>Defaulted</b>	1582 (18.34%)	661 (13.50%)	588 (16.03%)	240 (11.09%)
<b>Transferred</b>	345 (4%)	236 (4.82%)	122 (3.33%)	98 (4.53%)
<b>Moved</b>	19 (0.22%)	24 (0.49%)	14 (0.38%)	16 (0.74%)
<b>Died</b>	482 (5.59%)	380 (7.76%)	224 (6.11%)	165 (7.62%)
<b>Not evaluated</b>	9 (0.1%)	20 (0.41%)	8 (0.22%)	5 (0.23%)
<b>Total</b>	8627 (100%)	4897 (100%)	3668 (100%)	2165 (100%)

The graphs illustrating treatment outcomes over time are shown below (Figures 1 to 5). In all the graphs, blue dots are observed actual rates at comparison clinics, while red dots are observed actual rates at intervention clinics. “Pred” implies a predicted rate, calculated by LOESS smoothing. Lower CL and upper CL refer to lower and upper 95% confidence limits, that is, the points between which the true value may lie. The vertical blue line indicates the time when all five intervention clinics were implementing the intervention (April 2007). Two of the facilities had started the intervention from October 2006.

The interrupted time series analysis shows a significant improvement in smear conversion rates at 2 and 3 months<sup>2</sup> for smear positive TB patients in intervention clinics, relative to the comparison clinics (Incidence rate ratio (IRR) 1.1, 95%CI 1.00-1.2; p<0.05). However, there were no significant differences between intervention clinics and comparison clinics for treatment success for all patients (IRR 1.0, CI 0.92-1.15); treatment success for smear positive patients (IRR:1.01; 95%CI 0.94-1.09; or cure rates for smear positive patients (IRR1.03, 95%CI 0.92-1.15).

These findings suggest that the intervention effects may not be carried from the intensive phase of treatment to the continuation phase. Possible reasons for this include a general attenuation of intervention effects; or a reduction over time in the level of support provided by the lay health worker and/or buddy. Further investigation of the reasons for this finding, and ways of improving ongoing treatment adherence, is needed.

Figure 1: Two month smear conversion for new smear positive TB patients (weighted)



<sup>2</sup> Both 2 and 3 month smear conversion rates were used, as patients may sometimes arrive for smear testing later than the 2 month mark accepted by ETR.net (70 days). The South African TB control programme uses 2 months as standard.

Figure 2: Three month smear conversion for new smear positive TB patients (weighted)

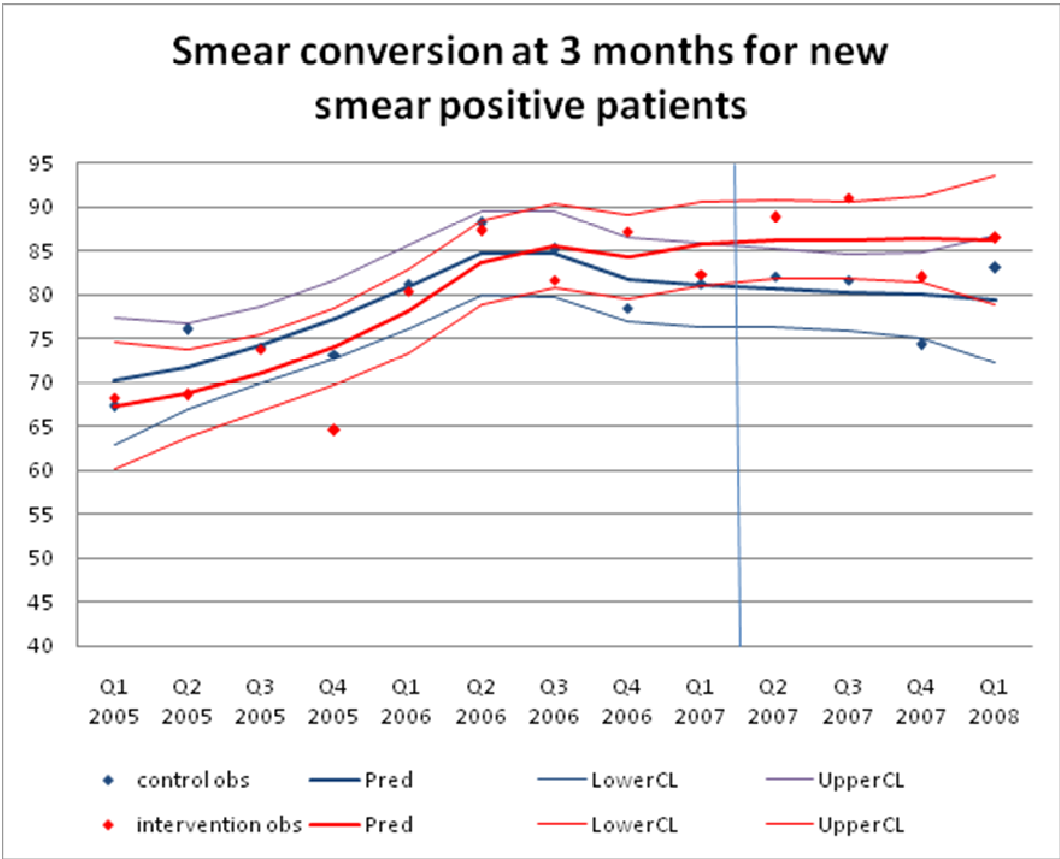


Figure 3: Cure rates for new smear TB positive patients (weighted)

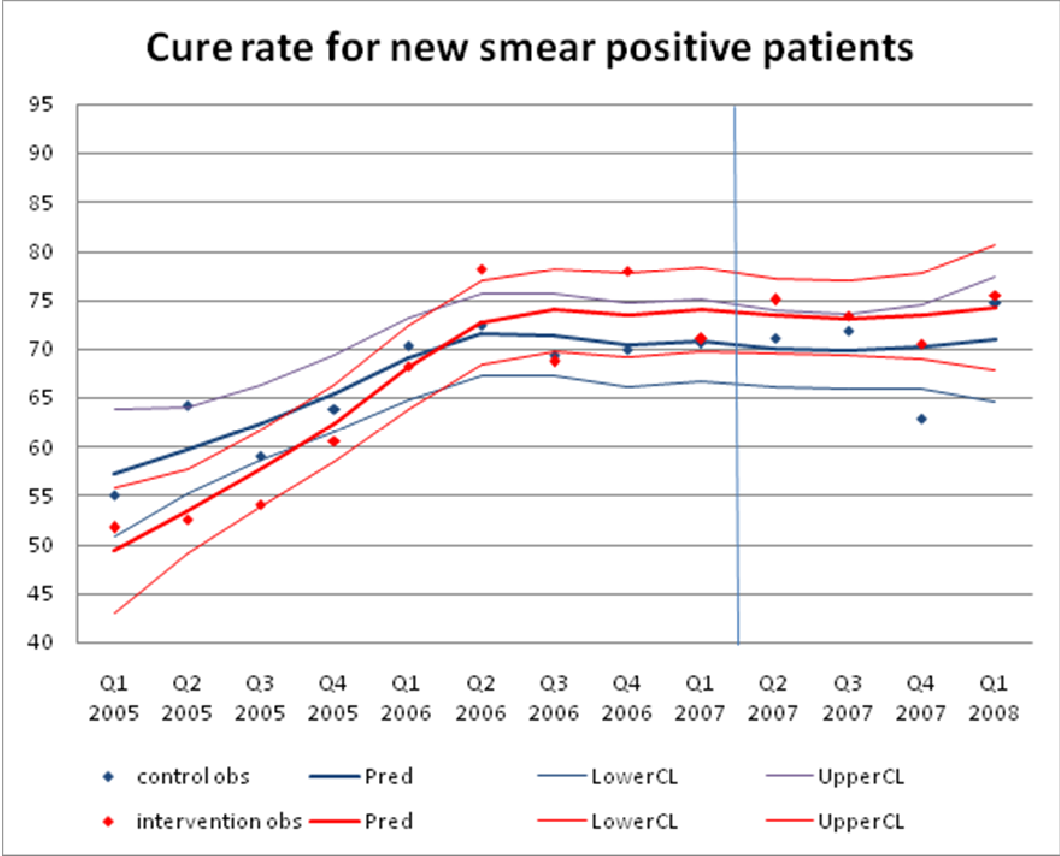


Figure 4: Treatment success for new smear positive TB patients (weighted)

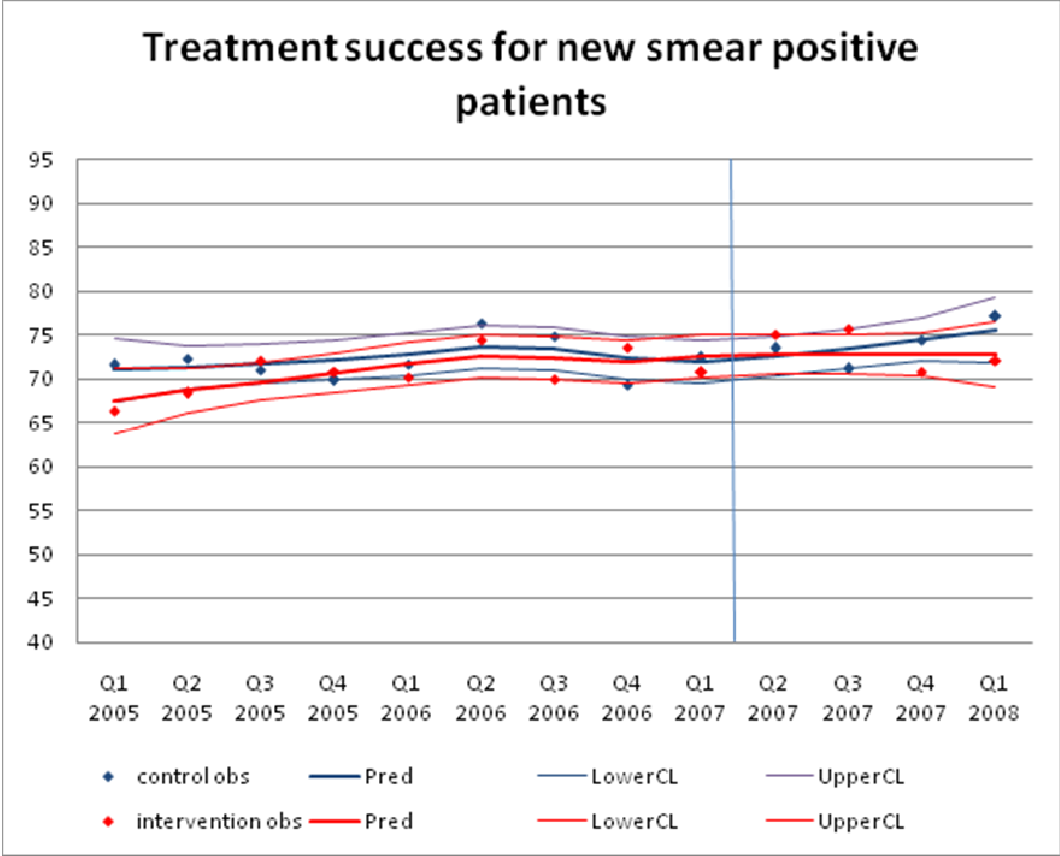
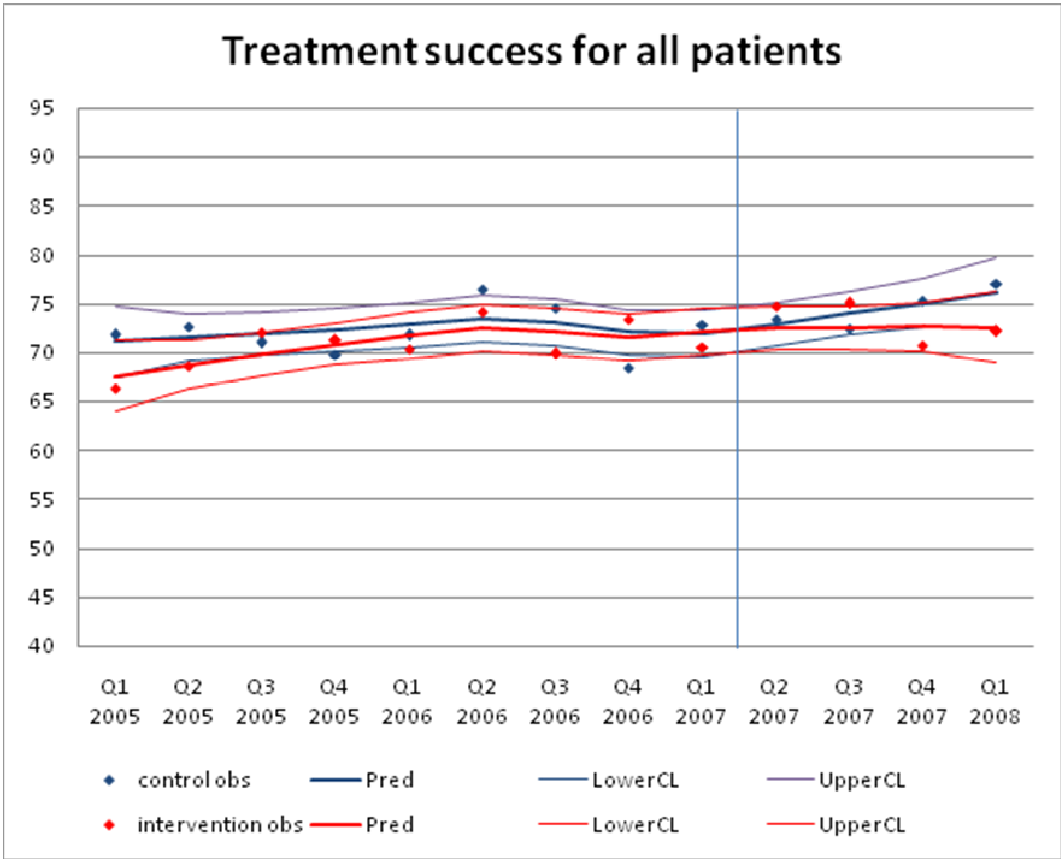
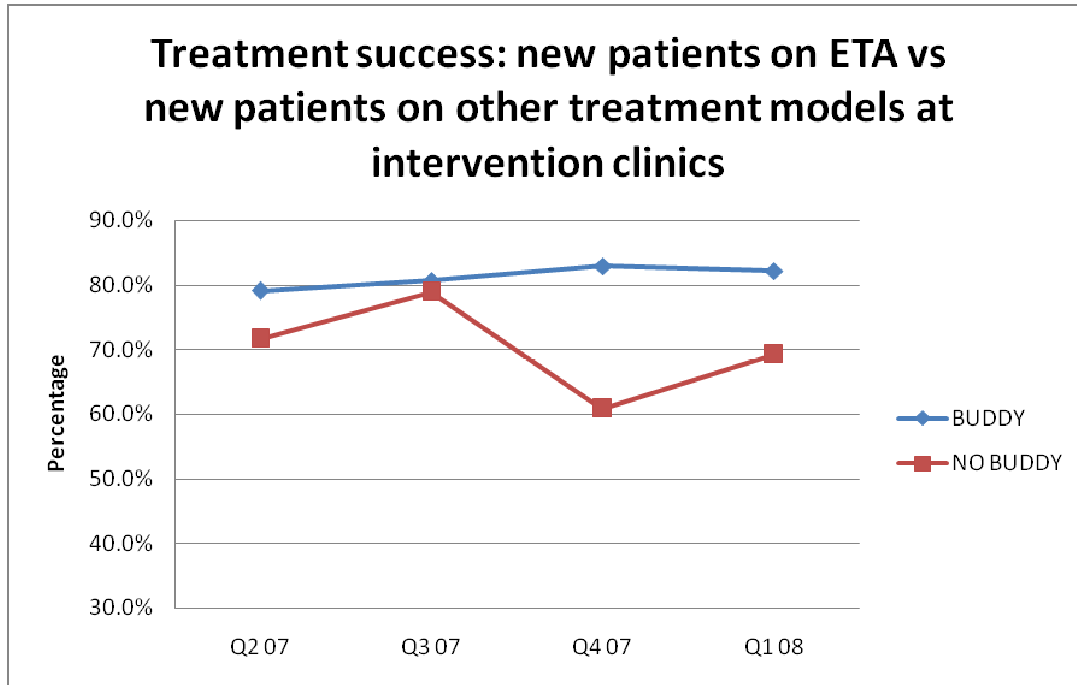


Figure 5: Treatment success rates for all TB patients (new and retreatment) (weighted)



The graph below (figure 6) is not part of the interrupted time series analysis, but is included in order to show treatment success rates for new patients on the intervention and patients not on the intervention during the intervention period at intervention clinics. As can be seen, the rates for patients on the intervention remain higher than patients not on the intervention. This is partly due to the intervention patients being a highly selected group of patients, likely to have better rates than those who remained on clinic treatment.

Figure 6: Treatment success for new TB patients on ETA vs. patients not on ETA at intervention clinics



### STUDY LIMITATIONS

There are a number of limitations to the study. Firstly, the lack of randomisation of clinics and the difficulties of matching clinics more closely limit our ability to determine conclusively whether the intervention was the reason for the differences found between comparison and intervention clinics outcomes. The special nature of the intervention clinics, in that they were among poorly performing clinics and larger than most other clinics in the City, limits to some extent the generalisability of the study to other clinics within the City. All the clinics in this study were urban, therefore caution should also be exercised when generalising results to rural settings. The City of Cape Town is also better resourced and organised than many other urban settings within South Africa; therefore further research needs to be conducted to establish whether an intervention such as this one can succeed within settings in which resources are more limited. In addition, the intervention clinics received considerably more management and supervision compared to usual practice in TB clinics, through the employment of a particular project manager who conducted mentoring on many areas of TB management.

There was a considerable amount of missing information which created difficulties in determining on which intervention patients were placed. This allocation depends on accurate data capturing at clinic level. Appointing a dedicated data capturer and collector could have improved the accuracy of these data. Lastly, this report does not include an economic evaluation of the intervention, which would assist managers in deciding whether this intervention is worth replicating. A costing of the intervention is in progress and the findings will be reported in due course.

## CONCLUSIONS AND RECOMMENDATIONS

### *What worked well:*

- The ETA intervention improves TB smear conversion rates significantly at both two and three months, when compared to comparison sites. End of treatment outcomes for sites implementing the ETA remains similar to those achieved by sites using directly observed therapy (DOT).
- The intervention is viewed positively by both patients and the staff implementing it. Patients appreciated the counselling and the information provided. Given that patients reportedly default after two months of treatment, when their symptoms have abated, a refresher session at the end of the intensive phase (and before the start of the continuation phase) might be helpful in improving treatment outcomes.

### *Where further work is needed:*

As with DOT, the ETA requires extensive and ongoing training and supervision of professional staff, and lay health workers. Some training gaps were identified: for example, lay staff in the programme felt that they could not adequately answer patients' questions about extra-pulmonary TB, HIV and ART.

- *Recommendation 1:* Lay staff who provide counseling and support for TB patients should receive additional training on extra-pulmonary TB and training on HIV and ART

Professional and lay health worker attrition present challenges to the implementation of both DOT and the ETA programme. An important reason for lay health worker attrition was the low level of stipends and opportunities for better paid employment elsewhere.

- *Recommendation 2:* Increasing stipends, instituting protocols for handover from departing to new staff, as well as retraining and mentoring, could offset some of the challenges in staff retention. It should be noted that lay health worker retention and payment issues are not unique to this project.

Process data shows fluctuating rates between clinics and over time in the proportion of patients who received a home assessment, received counselling and were placed on community treatment.

- *Recommendation 3:* There may be a need for closer supervision of these processes to ensure that all eligible patients are placed out after a short period of clinic-based DOT.

Outcome data indicates that the positive effects on two and three month smear conversion outcomes are not carried through to the end of treatment.

- *Recommendation 4:* Ways of improving support to patients in the continuation phase of treatment need to be explored. Further investigation of patient-buddy and patient-treatment supporter relationships; patient support needs; as well as the content and frequency of treatment supporter visits in the continuation phase, might be helpful.

Data collection added to the considerable administrative duties of nurses. Some lay health workers also struggled to complete the data collection expected of them.

- *Recommendation 5:* The range of data to be captured by nurses needs to be minimised and duplication avoided. Lay health worker administrative duties should be lessened, and forms simplified, as some lay workers do not have the capacity or training to perform these tasks effectively. However, given the importance of monitoring, consideration should be given to lay health worker selection to ensure they are able to complete the forms required.

Adequate space for counselling remains a challenge in some clinics.

- *Recommendation 6:* Additional space will be needed in some clinics in order to ensure that counsellors are able to counsel patients confidentially in a private space.

The ETA model, with its focus on community-based treatment support, has potential for integration with other programmes, particularly the ART support programme.

- *Recommendation 7:* Given the high prevalence of HIV in TB patients, integration of the ETA approach with the ART support programme should be piloted and evaluated rigorously.

The ETA model appears to be as effective as DOT but is preferred as a model of support by staff and patients. The model is patient centred and empowering.

- *Recommendation 8:* The ETA programme should be rolled out more widely in the context of rigorous evaluation. An assessment should be made of whether the programme achieves similar outcomes outside of a pilot setting.

Changing procedures for treatment provision can be complicated and health service managers noted a number of challenges in implementing the intervention. The first two clinics to implement the programme took approximately six months to achieve smooth implementation, as staff and management dealt with emerging issues and developed systems. Staff in some clinics were also resistant to change. The three clinics that started thereafter were able to implement the programme more quickly. Following implementation, there was consensus among providers that the ETA approach was preferable to DOT and staff requested that the new approach be maintained at the intervention sites.

### **Acknowledgements**

Our thanks to all patients participating in this study; all providers and lay health workers and managers who worked on this intervention, and consented to interviews and focus groups. Thanks especially to Deanna Carter for her work in supervising the implementation of the programme and her cooperation and data collection during the implementation; Judy Caldwell, Pren Naidoo and Karen Jennings for their management of the intervention; TB/HIV Care managers (Ria Grant, Harry Hausler, Mavis Nonkunzi and Belinda Fortuin) and lay health workers. Jerusha Soomar from TB/HIV Care for her assistance in the folder review; Ryan Fester for developing the intervention database; Arrie Odendaal for assisting in data cleaning and Hennie Schoeman for preparing the extensive dataset for analysis.

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## **Appendix 1: Content of counselling sessions**

### **Session 1:**

- What is TB?
- How is TB spread?
- Who is at risk of developing TB?
- How to identify the signs and symptoms of TB
- Know the length of treatment and the importance of compliance
- Know who is in the TB team
- Know where to go for help

### **Session 2:**

- The length of TB treatment
- What the treatment journey is
- The side effects of TB treatment
- The link between TB and HIV
- Why it is necessary to have an HIV test

### **Session 3:**

- When will you take your TB tablets?
- How will you keep track whether you have taken your tablets?
- What will your treatment buddy do?
- Where will you store your TB tablets?
- What could get in the way of the client staying on treatment?
- What will you do if you visit a friend and decide to spend the night?
- What will you do if you get a job?
- What will you do if you get called away to an emergency?
- What will you do if you move away to another area?

### **Session 4:**

- How to reduce the chance of spreading TB to those around you
- What healthy nutrition is
- What health living is

## Appendix 2: Staff responsibilities within the ETA intervention

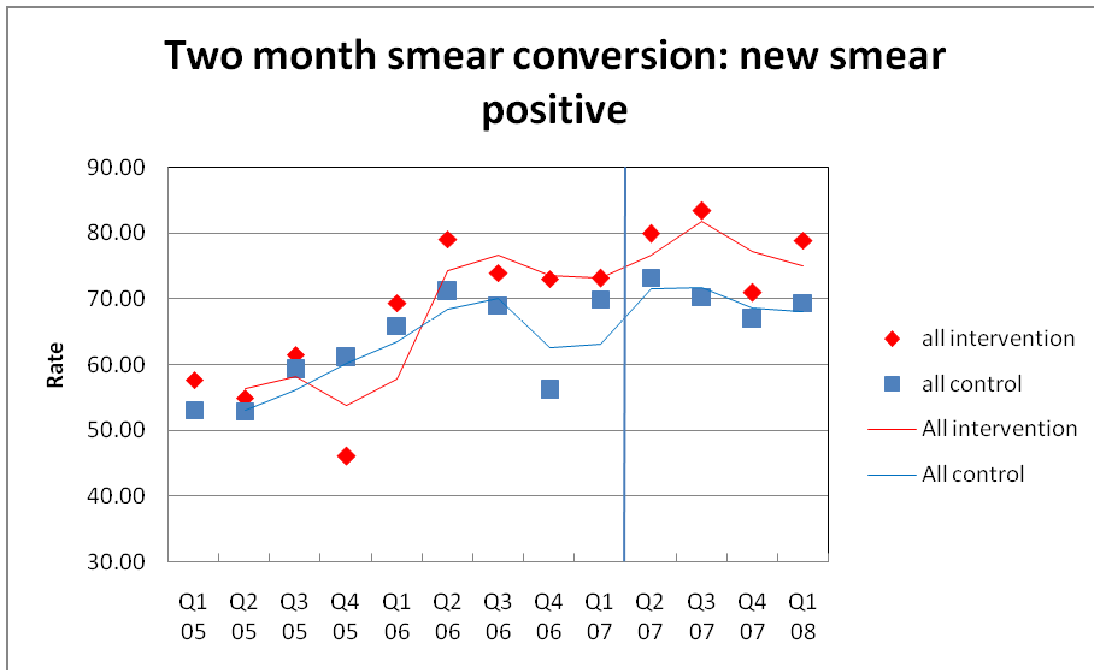
Staff category	Tasks within the programme	Administrative responsibilities
Professional nurses	<ul style="list-style-type: none"> <li>• Diagnosing smear-positive pulmonary TB</li> <li>• Initiating patients on treatment</li> <li>• Providing initial directly observed therapy at clinic</li> <li>• Monitoring patient adherence</li> <li>• Monthly weighing, taking sputum samples, assessing problems.</li> <li>• Sending patients to adherence counsellors for counselling.</li> <li>• Dealing with referrals to the clinic.</li> </ul>	<ul style="list-style-type: none"> <li>• Filling in patient-held records (white cards) with calendar to indicate sputum dates, and other clinic appointments.</li> <li>• Keeping track of which treatment supporter is responsible for which patient.</li> <li>• Checking home assessment and counselling sheets; signing patient off for treatment self administration</li> </ul>
Adherence counsellors	<ul style="list-style-type: none"> <li>• Informing patients of the programme.</li> <li>• Counselling the patient and their buddy about TB, TB treatment, side effects of TB treatment, the importance of good adherence and promoting HIV counselling and testing</li> <li>• Reporting back to the team about patient's eligibility for the programme</li> </ul>	<ul style="list-style-type: none"> <li>• Filling in intervention register.</li> <li>• Filling in counselling sheet.</li> <li>• Filling in patient name, address and contact number for treatment supporters</li> <li>• Assigning treatment supporters to patients</li> <li>• Giving out home assessment forms.</li> </ul>
Treatment supporters	<ul style="list-style-type: none"> <li>• Conducting home assessments, identifying TB contacts and individuals at risk of contracting TB in the home and referring children under 5 years of age to the clinic to be assessed for TB treatment or TB preventive therapy</li> <li>• Reporting back to clinic team meetings on home assessments</li> <li>• Visiting patients and conducting pill counts after patient placed out: three times in the first week and once a week thereafter until the patient completes treatment</li> <li>• Reporting back to team meetings on patients that experience problems with taking treatment</li> </ul>	<ul style="list-style-type: none"> <li>• Filling in home assessment forms</li> <li>• Filling in referral forms</li> <li>• Filling in forms when patients are not available or have problems with their treatment</li> <li>• Filling in monitoring forms, including when patient was visited and dates for sputum smear testing</li> </ul>
Treatment buddy*	<ul style="list-style-type: none"> <li>• Attending 4 counselling sessions with patient</li> <li>• Supporting, motivating and reminding patient in the home</li> </ul>	<ul style="list-style-type: none"> <li>• Reporting problems that patients experience to treatment supporter or clinic</li> </ul>

**Appendix 3: Descriptive graphs based on facility report data**

**Descriptive graphs based on facility reports**

In all figures below, the square point indicates an unweighted average of comparison clinic results, while the diamond shape indicates an unweighted average of intervention clinic results. Weighted average are not presented as they do not differ considerably from actual averages. The red line is a moving average trend line generated from intervention clinic results, and the blue line a moving average trend line generated from comparison clinic results. The vertical blue line indicates the time at which all five intervention clinics were implementing the ETA intervention (April 07 – Q2 07). Two of the intervention clinics were implementing the intervention from October 2006 (Q4 06).

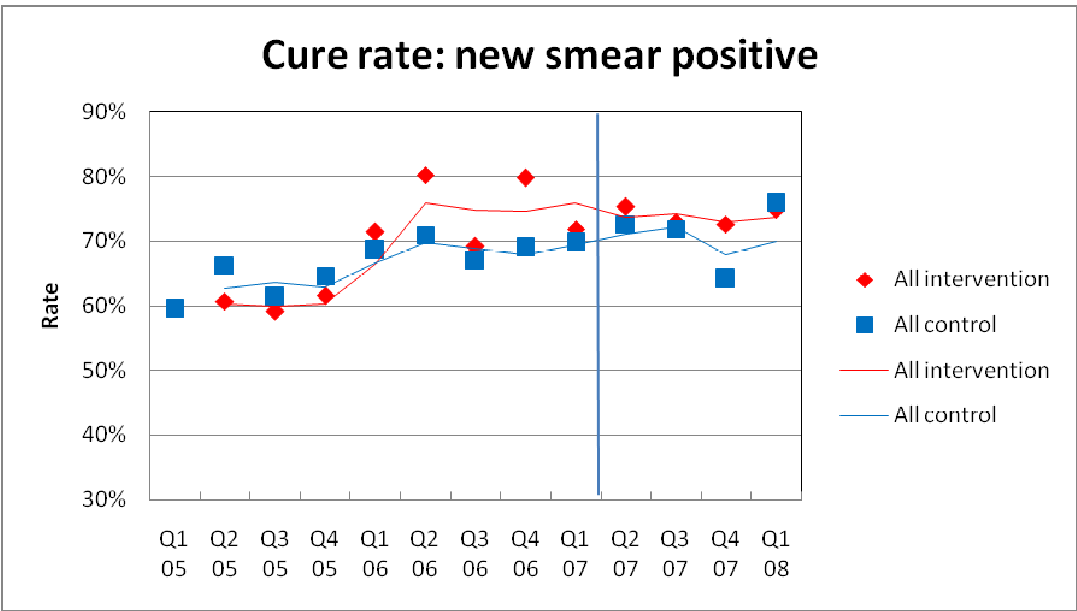
**Figure 7: Smear conversion at two months for new smear positive TB cases, based on facility reports**



Red= moving average trend line for intervention clinics  
 Blue= moving average trend line for control clinics

The above figure indicates that smear conversion rates have improved in intervention clinics, and smear conversion rates in comparison clinics have been consistently slightly lower than intervention clinics since the beginning of 2006.

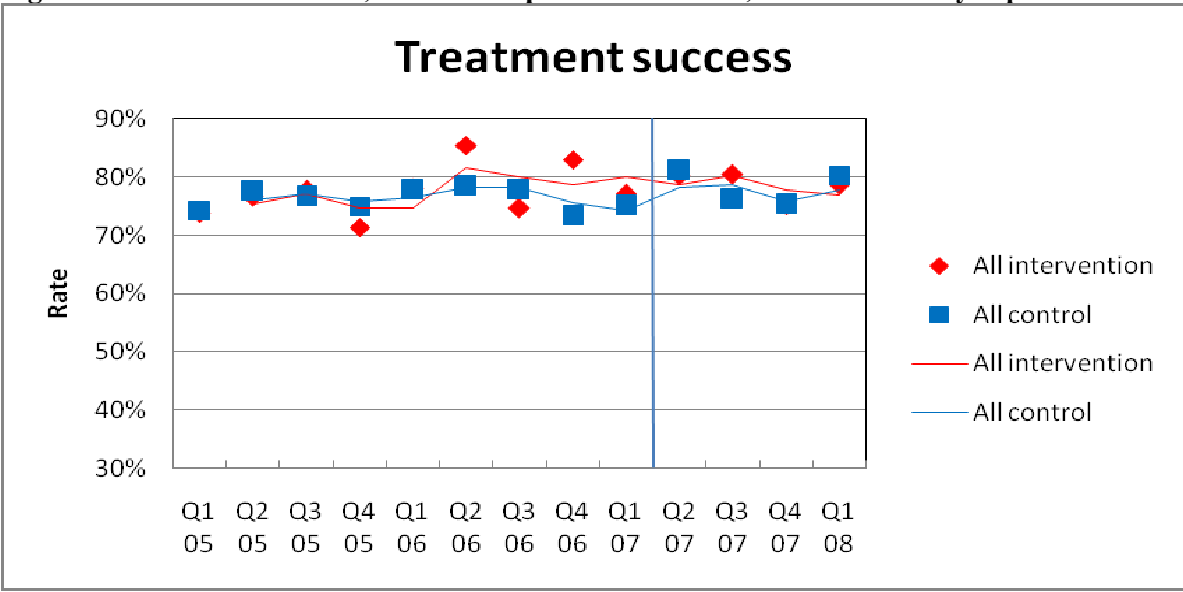
**Figure 8: Cure rates for new smear positive TB patients, based on facility reports**



Red= moving average trend line for intervention clinics  
 Blue= moving average trend line for control clinics

Figure 8 indicates that cure rates for new smear positive TB patients were generally higher in the intervention clinics than in comparison clinics, both before and after the intervention. However, the differences are small.

**Figure 9: Treatment success, new smear positive TB cases, based on facility reports**



Red= moving average trend line for intervention clinics  
 Blue= moving average trend line for control clinics

Figure 9 indicates that treatment success rates for new smear positive TB patients were similar across intervention and comparison sites prior to the intervention and remained similar following the intervention.

