'You must tune your TB programme well...'

Integrating TB, HIV and ARV care in a Cape Town primary care setting

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Towards the partial fulfilment of a Masters in Public Health

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14 February 2007

Declaration

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Abstract

Background

This study occurred in the context of three problems that have arisen within the South African HIV/AIDS crisis: the prevalent HIV and tuberculosis (TB) co-epidemic, the concern that antiretroviral (ARV) provision might compromise the existing TB control programme, and that the Western Cape's current limited vertical model of ARV roll-out will soon reach capacity. This study evaluated whether and how TB control changed following ARV introduction in a Cape Town primary care TB clinic and explored the process of integration of the TB and ARV services in the clinic.

Design

This health systems research used a before-after study design. It involved the retrospective analysis of performance data from two years of a TB programme, followed by a qualitative validation of the quantitative results using focus group methodology.

Methods

Standard aggregated outcomes of all 353 TB cases for the two years were recorded along with a folder review examining 'time from presentation with TB symptoms till starting TB treatment'. The sampling for the focus group was purposive and involved those clinic staff members who were involved in the TB and ARV programmes in the clinic. The group explored their experience of the ARV/TB programme integration and reflections on the quantitative

outcomes. Data was analysed using both quantitative and qualitative methods.

Results

During the first year of the introduction of the ARV programme to the clinic, most routinely measured TB programme outcomes remained unchanged. A drop in cure rate with a concomitant rise in treatment completion rate was observed. There was less delay in diagnosing TB and commencing TB treatment. The TB cases' sample size was too small to detect a significant difference in the outcomes between the two years studied, which was borne out by statistical analysis.

The focus group described the gradual expansion of the TB nurse's role to include the HIV/ARV care of co-infected patients and identified staff ownership, doctors' mentoring role, comprehensive patient and integrated clinic care, ARVs' boost to staff morale, coordinated TB/ARV programme management and staff training as factors facilitating programme integration.

Conclusions

Overall the TB programme performance was not compromised following the introduction of the ARV programme. Providing integrated TB and ARV care is feasible in a primary care setting. Such a service creates a 'one-stop-shop' visit for the co-infected patient and is satisfying for the staff in the facility. Care should be taken to avoid neglecting the rigorous routine follow-up of the TB

patient. Using a mixed methodology for exploring this health systems issue provided the benefit of explaining some of the quantitative outcomes.

Contents

1. Acknowledgements

Thank you to the following who assisted me in the preparation of this thesis:

All staff of the Hout Bay Main Road Clinic

David Coetzee, my supervisor

Pat Mayers, qualitative research consultant

Gill Faris, facilitator of the focus group

Andrew Boulle for statistics advice

Christopher Colvin for advice on mixed methodology

Judy Caldwell and Jacqui Ross for Electronic TB Register data

And all those who debated and listened and encouraged

2. Abbreviations

AIDS – acquired immuno-deficiency syndrome

ARV – antiretroviral

CHC – community health centre

CNP – clinical nurse practitioner

DOTS – directly observed treatment short course

ETBR – Electronic TB Register

HAART – highly active antiretroviral therapy

HBM – Hout Bay Main road clinic

HIV – human immunodeficiency virus

IPT – isoniazid preventive therapy

MOU – midwife obstetric unit

MPH – Masters in Public Health

MTB – *Mycobacterium tuberculosis*

MTDP – Medium Term Development Plan

NGO – non-governmental organisation

NTCP – National TB Control Programme

OR – odds ratio

PMTCT – prevention of mother to child transmission of HIV

STI – sexually transmitted infection

TB – tuberculosis

VCT – voluntary counselling and testing for HIV

WHO – World Health Organisation

3. Introduction

South Africa's post-1994 restructuring of its public health services has been severely compromised by the unprecedented public health crisis of HIV/AIDS. This study occurred in the context of three problems that have arisen within this crisis:

- the prevalent HIV and tuberculosis (TB) co-epidemic,
- the concern that ARV provision might compromise the existing TB control programme,
- and that the Western Cape's current limited vertical model of ARV roll-out will soon reach capacity.

3.1 TB/HIV co-epidemic

The World Health Organization Global TB Report 2004 placed South Africa eighth in the world for TB incidence. The report states that South Africa has poor TB surveillance, TB cure rates are still too low and interruption rates too high. The estimated annual cost of TB control in South Africa is US$300 million.[1]

The country-wide incidence of all types of TB registered with South Africa's National TB Control Programme in 2005 was 645/100 000 population and in the Western Cape 1 037/ 100 000.[2] In Cape Town, a 66% increase in reported TB cases occurred over a five-year period from 1997 to 2003.[3] The

National Health Council declared TB a crisis in South Africa in November 2005.[4]

By the end of 2005, 5.54 million South Africans were estimated to be infected with HIV.[5] Antenatal prevalence rates nationally were 30.2% and in the Western Cape, 15.7% of pregnant women were HIV infected. [5] The National Department of Health's Operational Plan for Comprehensive HIV and AIDS Care Management and Treatment for South Africa was released in November 2003. The plan includes the provision of ARVs and estimated then that 500 000 people needed ARVs in South Africa.[6] Recent estimates for HIV prevalence in the Western Cape are 250 000 adults and that 20 000 HIV infected adults will develop AIDS during the year 2006/7.[7]

Tuberculosis is one of the commonest HIV related diseases in developing countries. In persons infected with *Mycobacterium tuberculosis*, the lifetime risk of developing TB disease is 10-20%. However in those dually infected with MTB and HIV, the risk of developing TB disease is 10% per year.[8] It can occur at any stage of HIV infection and in the early stages presents in a typical way with smear positive sputum.[9] As HIV infection progresses TB often manifests in an atypical way and these co-infected patients often have sputa that are smear-negative (making it more difficult to diagnose).[9] Tuberculosis is the commonest cause of death among HIV-infected patients. This is especially so for those who have smear negative pulmonary TB or extra-pulmonary TB.[9] Co-infected patients are also more likely to develop AIDS-defining illnesses than those with HIV alone.[10]

Over the past ten years, the HIV epidemic in sub-Saharan Africa has led to a four-fold increase in the number of TB cases registered.[1] The WHO Global TB Report 2004 regards TB and HIV co-infection as a 'significant health problem' and estimates that 61% of TB cases in South Africa are HIV infected.[1] The Western Cape TB incidence has been steadily increasing, but disproportionately so in sub-districts where HIV prevalence is higher.[4]

3.2 South African National TB Control Programme

The South African National TB Control Programme (NTCP) lays out the following objectives in its Medium Term Development Plan (MTDP):

- To reduce mortality, morbidity and transmission of TB;
- To reduce human suffering and the social and economic burden that families, communities and the country bear as a consequence of TB;
- To establish optimal coordination and coordinated action with HIV/AIDS and STI programmes; and
- To prevent the development of TB drug resistance.[11]

The NTCP adopts the WHO's DOTS (Directly Observed Treatment Short-course) strategy that aims to provide TB patients with standardised treatment under direct supervision. This approach has been shown to reduce TB morbidity and mortality, prevent TB drug resistance, and improve TB programme performance.[12]

Monitoring TB programme performance

TB programme performance is the extent to which the programme achieves the objectives, targets and goals of the NCTP. It is measured by the NTCP management performance indicators contained in the MTDP which comprise TB case finding, case holding and treatment outcomes of smear positive cases as well as community DOTS coverage and HIV testing rates. In the Western Cape these indicators are collected at clinic level and reported on at quarterly intervals in the Electronic TB Register (ETBR). This reporting system was introduced in the province in 2003 in order to standardise the outcomes of TB control programmes and to allow for the comparability of this data nationally and internationally.[3]

The reporting system includes:

Case finding

- Total number of TB cases registered
- Proportion of new smear positive TB cases - the DOTS strategy focuses on improving cure rates among new infectious TB patients (those who are sputa smear-positive). The ETBR does not specify the proportion of smear negative cases, nor the proportion of re-treatment cases (both are more likely to be HIV infected).
- Smear positive rate – the proportion of smears sent that are positive. The WHO target of one smear-positive in ten smears evaluated (10% smear positive rate) indicates efficient case-finding in a TB programme in an HIV negative population.[3] As HIV infected TB patients are more likely to be smear negative, this is expected to be even lower in an HIV prevalent population

(requiring more than ten sputa sent to find one positive). Data from the NHLS in the Western Cape revealed that in 2003, 218 088 sputum smears were examined, of which 38 705 were positive, giving a 17.7% smear positive rate or 5.6 smears sent to find one positive.[3] This suggests inadequate case finding in the province.

The above indicators are useful to reflect the efficiency of TB case finding in an HIV negative, smear-positive population. Persons with HIV are more likely to present with repeat episodes of TB and are more likely to be smear negative and thus less infectious. The process of diagnosing smear-negative TB can be more complicated and requires a higher index of suspicion for TB in HIV-infected patients and persistent work-up to exclude TB.[9] None of the above indicators adequately measure the altered approach to case finding required in a setting of high co-infection rates and growing concomitant smear-negative TB.

Case Holding

- Smear conversion rates – the proportion of negative smears at 3 months of all new smear positive cases. These are regarded as a fairly accurate predictor of cure rates.[3] As the ETBR provides a limited period of time for reporting conversion results, they also reflect the efficiency of assessing and reporting sputum conversion.[3] This indicator is of those new smear positive TB cases only.
- DOTS coverage: Proportion of total TB cases receiving community, clinic and workplace DOTS throughout their course of TB treatment.

HIV co-infection

- Proportion of all TB cases offered voluntary counselling and testing for HIV (VCT)
- Acceptance rate among those TB cases offered VCT
- HIV positivity rate – the proportion of TB cases accepting VCT that test HIV positive.

Treatment outcomes

As in the ETBR, these outcomes are specifically for new smear positive TB cases.

- Cure rates – the proportion of new smear positive cases that on two occasions have two negative smears prior to discharge. The smear-positive cure rate is considered the key indicator of TB programme performance in high burden countries. The WHO sets an 85% target for this indicator.[1] The cure rate in the Western Cape in 2004 was 70% and nationally was 50.8%.[2]
- Treatment completion rates – the proportion of new smear positive cases that complete the course of treatment but are not proven to be 'cured' (eg if sputa are not obtained at the end of treatment).
- Success rates – a combination of cure and treatment completion rates, representing the proportion of new smear positive cases that complete the course of treatment.
- Interruption rates – the proportion of new smear positive cases that do not complete the course of TB treatment. This indicator reflects the ability of the programme to ensure adherence of patients to TB regimens. This rate may

however include some patients who die during the course of treatment, but as their death is unknown to the TB programme, the patient's outcome is included in 'interrupted' rather than death rates.

- Death Rates – the proportion of new smear positive TB cases that die from any cause during the course of TB treatment.

The Western Cape Province comprises four regions each of which are divided into several sub-districts. In the Cape Town Metro region, the TB control programme is situated in Local Authority Clinics, which are usually the closest primary care facilities for patients. These clinics provide diagnosis and care for adults and children with TB, HIV and sexually transmitted infections (STIs), routine (immunizations, developmental assessments, nutritional support) and curative care for children younger than 7 years and family planning services.

Patients with TB either self-present to these clinics for TB testing and treatment or are referred from other primary and secondary health facilities, commonly the local Community Health Centre (CHC). Each sub-district has several CHCs which provide adult acute and chronic curative care and often contain casualty units for emergencies. HIV testing and care occurs at both Local Authority and CHC facilities, the organisation of which differs from sub-district to sub-district. It is not uncommon for co-infected patients to receive care for each disease at different sites.

3.3 Antiretroviral (ARV) Rollout

The public sector roll-out of ARV programmes is occurring at primary care level in the Western Cape, either in conjunction with TB programmes sited in Local Authority clinics, or largely within CHCs that receive referrals for ARVs from Local Authority clinics. ARV sites are currently doctor-led and with the exception of three Local Authority sites, require the co-infected patient to receive care and medication at both the clinic (for TB) and the CHC (for ARVs and HIV-related care).

Over 20 000 patients have commenced ARVs in the province at 43 ARV sites[13], more than 60% of them in primary care.[7] It is estimated that in the 2005/2006 financial year, 57% of those HIV infected persons progressing to AIDS accessed ARVs.[7] Given that 20 000 HIV-infected patients are likely to develop AIDS during 2006/7 and that currently around 1 000 patients start ARVs every month in the province, the programme will need to rapidly scale up its delivery of ARVs in order to treat these patients.[7]

It is also estimated that between 7 000 and 10 000 people died of HIV-related disease before accessing ARVs during 2005/6.[7] In order to at least keep constant or reduce this number of deaths the number of patients starting ARVs every month needs to double.[7] Thus the current model of ARV delivery is likely to reach its limit soon. The Provincial Department of Health's plan is to create capacity in Local Authority clinics for the on-going care of ARV patients down-

referred from ARV sites, and ultimately for selected Local Authority facilities to comprehensively manage HIV-infected patients including initiating ARVs and diagnosing and managing patients co-infected with TB.

3.4 Context and background

Hout Bay Main Road clinic

At the beginning of 2004, a programme to treat HIV infected patients with ARVs was introduced to a primary care Local Authority clinic in the Western Cape, the Hout Bay Main Road clinic (HBM).

During the year 2003, prior to the introduction of the ARV programme into the clinic, the clinic offered the usual clinic services (see above) as well as a weekly antenatal clinic run by MOU (midwife obstetric unit) staff. An integrated approach to HIV care had evolved, which included offering VCT to all TB patients and those presenting with STIs, screening for TB in all HIV infected patients, the provision of co-trimoxazole prophylaxis to all HIV infected TB patients, and the management of HIV-related opportunistic infections.

The staff complement comprised:

- a clinic manager who also performed clinical duties when needed;
- three clinical nurse practitioners, one with a special interest in HIV,
- a registered nurse who ran the TB control programme;
- an enrolled nurse who screened the patients on arrival,
- two HIV VCT counsellors,
- an administrative clerk

- caretaker of the facility
- a 'TB' doctor who visited for two sessions a week to see all TB patients, HIV patients with problems, and any other patients the staff required advice about.
- community DOTS (directly observed treatment short course) supporters

All staff with the exception of the counsellors and DOTS supporters were employed by the Local Authority. The counsellors were employed by a lay counselling non-governmental organization (NGO); the DOTS supporters by a TB NGO.

On arrival at the clinic, the patients were initially screened by the receptionist to ascertain whether the nature of their problem was appropriate for the services offered by the clinic. Those with TB symptoms (chronic cough, sweats, weight loss) would be admitted to the clinic for TB investigations. Any other unwell patient, for example with a rash, would be promptly referred to the clinical nurse practitioner to triage. If the patient's problem was deemed by the CNP to suggest TB, HIV or STI, s/he was admitted for assessment; if not, referred to attend the CHC (10-minute taxi-ride from HBM) for adult curative care. Those severely ill patients who required urgent attention would be prioritized, and referred if necessary on the same day to the local secondary hospital.

For most of 2003, TB suspects did not receive a clinic folder, but were processed through TB investigations using a 'suspect envelope'. Usually if their sputa were negative, the clients were discharged as 'no TB', and no further workup was done. Sub-district resource constraints resulted in the active discouragement of

sending sputa for TB culture, unless the patient was a re-treatment TB case as per TB protocol.

Several initiatives to integrate HIV, TB and STI care occurred on sub-district, clinic and clinician level:

All staff received training in an integrated clinical approach to the ill patient which prioritized excluding TB, screening for STIs, and offering HIV testing to all TB suspects and cases, and those with STIs. This was reinforced with a wall-chart graphic representation of this approach and the monitoring of VCT offering and uptake for TB cases as part of the routinely collected quarterly statistics.

Towards the end of 2003, a clinic folder was created for all TB suspects, in order to incorporate their TB workup with their HIV and STI care. Once TB was diagnosed, the TB folder was linked with the clinic folder.

All those considering an HIV test received standard VCT pre-test counselling. An HIV peer educator NGO conducted HIV education sessions in the waiting room of the clinic and some outreach HIV education in the community.

The TB programme had prior to 2003 expanded into providing care to HIV clients as many TB patients were co-infected, and on discharge from their TB treatment continued to receive ongoing HIV care at the clinic. Thus the clinic became identified by the community health centre and general practitioners in the area as a referral site for HIV testing and care.

As she was the only doctor in the clinic, all HIV clients with problems were referred to the 'TB' doctor. This was encouraged by the fact that the 'TB' doctor had an enthusiasm for and a confidence about HIV care, and was willing to give advice about and see HIV patients even when they did not have TB. A 'staging clinic' was established for routine HIV care but as it relied on an appointment system was not reliably attended by clients, especially if they were well.

A few adult clients clinically identified by nursing staff and doctor to have advanced HIV disease (CD4+ cell counts were not done routinely) were chosen for antiretroviral treatment. They accessed this either privately (often financed by disability grants or the community health forum) or through secondary or tertiary hospital ARV treatment or clinical trial sites. All HIV infected children were referred to one of the secondary or tertiary level paediatric HIV clinics, either for care or to participate in a trial. They were often able to access ARVs via this route.

The introduction of the ARV programme to the clinic at the beginning of 2004 saw the arrival of the 'ARV' doctor and programme manager (the researcher) and visiting ARV pharmacist; and three months later a registered nurse to staff the ARV programme, and community worker 'patient advocates' to provide support to patients commencing ARVs. All the additional staff were employed by an NGO (an NGO supporting the ARV roll-out in the province) working with the provincial Department of Health to support the ARV roll-out in the province. A social worker and nutritionist visited the clinic on a weekly basis to assess patients due to

commence ARVs. None of the existing clinic staff changed, but the Local Authority provided a clinical psychologist who visited the clinic on a monthly basis to provide mentorship and emotional support to the staff as a group.

The two lay VCT counsellors received ARV adherence counselling training, and *all* staff (including the clerk) attended ARV training sessions. Staff members fell under different managerial authorities:

- the Local Authority sub-district TB coordinator continued to supervise the clinic's TB programme,
- the Local Authority ARV programme manager visited occasionally to provide mentorship for the ARV programme,
- the ARV NGO managed the patient advocates,
- another HIV NGO managed the social worker and nutritionist,
- the TB NGO managed the DOTS supporters,
- the lay counselling organization continued to mentor and manage the counsellors,
- the HIV peer educator NGO continued to run HIV education in the clinic and community.

The Local Authority nursing staff each took a turn to work as the ARV nurse in order to familiarize themselves with the process of the programme, the ARVs and the patients themselves.

A weekly ARV clinical meeting was held to discuss all those patients due to commence ARVs and was attended by the ARV doctor and nurse, pharmacist,

social worker and nutritionist as well as the patient advocates. Apart from the Local Authority nurse attached to the ARV programme, the rest of the Local Authority staff rarely attended these meetings.

In May 2004 the 'TB' doctor left the clinic and was not replaced for six months. The TB nurse took on much of the routine diagnosis, commencing treatment, monitoring and discharging of those uncomplicated smear positive TB patients with the guidance and support of the 'ARV' doctor. TB patients were referred to the 'ARV' doctor if they had smear-negative pulmonary, extra-pulmonary or complicated TB, for X-Ray reading or if unwell. The TB nurse also administered co-trimoxazole prophylaxis and pyridoxine to co-infected patients, and identified and managed or referred patients with HIV-associated symptoms.

Six new DOTS supporters and a DOTS coordinator were employed in 2004. Their role included assisting with clinic DOTS, patient education (one-on-one and in the waiting room), tracing defaulting patients and ensuring that community DOTS patients adhere to their treatment plan.

The patient advocates educated and provided support to patients needing ARVs. Their time was split between accompanying the patients through their ARV work-up process in the clinic and conducting home visits. They also assisted in the TB room with clinic DOTS and TB, HIV and ARV education. Some TB patients selected their DOTS supporters to be their patient advocate for ARVs, and at the beginning of 2005, two DOTS supporters were trained up to be patient advocates.

Summary of staff roles in HBM clinic

Staff member	**Role in HBM clinic**
Clinic manager	Overall manager of facility; some clinical duties
Clinical nurse practitioner	Clinical assessment and treatment of all patients Pre-ARV care of HIV patients
TB nurse	Runs the TB control programme Pre-ARV care of co-infected patients
Enrolled nurse	Initial screening of patients
VCT counsellor ARV counsellor	Pre and post HIV test counselling; education of all TB suspects around TB, HIV and co-infection Education of ARV patients about ARVs
Administrative clerk	Administrative duties; gate-keeper to clinic
Caretaker	General maintenance of facility
'TB' doctor	Twice weekly visits to see TB and HIV patients
DOTS coordinator	Co-ordinates DOTS activity within clinic and community
Community DOTS supporter	Support and educate TB patients
ARV nurse	Day-to-day running of ARV clinic, routine follow-up care of ARV patients
ARV doctor	Pre-ARV assessment of ARV patients; routine review of patients on ARVs; receives referrals from staff Manager of ARV service
Patient advocate	Support ARV patient work-up and adherence
Pharmacist	Dispensing of all ARVs for patients on a named-patient basis
Social worker	Routine assessment of all ARV patients
Nutritionist	Routine assessment of all ARV patients
Clinical psychologist	Mentorship to Local Authority clinic staff

The researcher

The researcher was from January 2004 until October 2005 the 'ARV' doctor and ARV programme manager in HBM clinic. Prior to this time she had worked on a part-time, locum basis at HBM clinic and was familiar with the clinic set-up and staff when starting fulltime in 2004. Much of the descriptive data given above of the HBM clinic and its organisation was gathered as a result of her familiarity with the clinic as a clinician there.

4. Literature Review

While there is extensive debate around the importance of and possible approaches to integrating TB and HIV (particularly ARV) care, the literature contains little of this experience in primary care in the context of a co-epidemic of HIV and TB.

The expanded scope of the WHO's strategy for TB control in high HIV prevalence populations comprises intensified tuberculosis case-finding and cure; tuberculosis preventive treatment; and interventions against HIV (and therefore indirectly against tuberculosis).[14]

The WHO 'ProTEST initiative' which was established in the late 1990s is a comprehensive range of interventions aimed at decreasing the burden of HIV-related TB and providing a package of TB prevention, care and support to the HIV positive patient. It aims to integrate TB, HIV and STI care and uses VCT as the introduction to HIV for the newly diagnosed TB patient.[15] The Central District of the Western Cape was a Protest pilot site for this initiative in 1999, and this integrated approach is now the model of care adopted in many Local Authority facilities in the province.[3]

The WHO's draft TB diagnostic algorithm for use in an HIV prevalent setting has been adapted for the South African context and was endorsed for use in the Western Cape and Free State provinces by the National Department of Health's TB Directorate in April 2006 (see appendix 1). It addresses the HIV context in which TB now presents and prioritizes diagnosing TB within four visits, thus

encouraging persistence with TB investigations in co-infected patients who are often smear negative.[16]

A small cross-sectional study conducted among TB patients in a primary care facility in Cape Town explored their perceptions of an integrated TB/HIV service. The study found that the vast majority of patients (92%, n=78) were willing to attend an integrated service for the sake of convenience and to achieve good health. The minority who were reluctant to attend an integrated service were concerned about the negative stigma of HIV.[17]

The overall objective of ARV programmes is to decrease HIV-associated morbidity and mortality, as well as the transmission of HIV. The provision of ARVs has been shown in a secondary level hospital trial setting to decrease the incidence of TB by more than 80% in an area endemic with TB and HIV, like Cape Town, especially amongst symptomatic patients and those with advanced immune suppression.[18] A primary care clinic-based study in Khayelitsha, which has a TB incidence greater than 1000 per 100 000 population per year, showed a two thirds reduction in TB incidence in those a year on ART compared to the TB incidence over a year prior to ART. However, as the authors note, 'the tuberculosis incidence in patients both on ART and awaiting ART is extremely high, suggesting the urgent need for control efforts for the combined epidemic that extend beyond the provision of ART.'[19]

A review of TB epidemiology in Africa in the context of the HIV treatment scale-up declared that 'Tuberculosis control in Africa has yet to adapt to the new climate of antiretroviral availability'. Coordination of TB and ARV services remains limited, and often manifests as cross-referral between the two services rather than full integration. Cross-referral of patients between services often leads to logistic difficulties for the patient who has to access two services instead of one.[20] The review stresses the importance of decentralizing and integrating ARV services as far as possible into the local health system, and reports good uptakes rates of ARVs in programmes that offer TB treatment and ARVs from the same clinic.[21]

Anthony Harries et al in the WHO bulletin of 2002 argue that 'ARVs must be provided in a structured framework' – they suggest that the national TB control programme could be a good example of such a model.[22] They later suggest using the DOTS strategy for TB control as a model to deliver HAART. The DOTS strategy has 'principles of standardized case finding, standardised treatment regimens, regular monitoring and evaluation, and uninterrupted supplies of drugs (that) can be used to deliver HAART.'[23] No literature was found of an example of DOTS as a national model for ARV roll-out.

A pilot study was performed in an urban clinic in Kwa-Zulu Natal to determine the feasibility and effectiveness of integrating an ARV programme into an existing TB programme. Twenty co-infected patients needing ARVs were given a once-daily dose of ARVs (comprising didanosine, lamivudine and efavirenz) along with their TB DOTS, Monday to Friday and their adherence to

ARVs checked over the weekend (as TB DOTS is taken for five days in the week). Once the course of TB treatment was completed, the patient was referred to the local HIV clinic for ongoing care. While the researchers concluded that such an approach could be feasible and effective for the introduction and monitoring of ARVs in a resource limited setting, the suggested once-daily ARV regimen is not in line with the South African national guideline's twice daily regimens, nor does it leave a feasible second-line option should the patient fail first-line ARV therapy (the remaining ARVs currently available in South Africa are zidovudine, stavudine and lopinavir/ritonavir which should not be prescribed in combination).[24] Another concern is that providing TB treatment at one site and then referring for ongoing HIV care at another does not provide an integrated service or the continuum of care that would be ideal for the co-infected patient.[25]

At the clinic level, Coetzee et al compare the separate TB and HIV services in Khayelitsha, Cape Town and explore the potential for integration. Their experience (like elsewhere in the Western Cape, including Hout Bay) is of a high number of dually infected patients. They identified an overlap of tasks between the two services, and that opportunities were missed for both TB and HIV care and prevention. Integration of the two services would thus be a more efficient response to the epidemics of TB and HIV. 'An integrated programme (also) has the greater chance of affecting the TB burden than any course of action undertaken by TB control programmes alone'.[26] Concerns raised about such integration include possible nosocomial spread of TB amongst an HIV

population within a combined facility, and that the TB control programme could be compromised.[26; 22]

A surveillance study of drug-resistant TB in Kwa-Zulu Natal demonstrated high rates of multi-drug resistant (MDR) and extremely drug resistant (XDR) TB. Those with XDR TB were all found to be co-infected with HIV and most (85%) had never been treated for TB before. One plausible explanation given for this was nosocomial infection as two thirds of the patients had been recently hospitalised, supported by genotyping results of the XDR TB strain. The authors highlighted the extremely limited infection control procedures found in the facilities studied.[27]

The Khayelitsha experience of integrated TB and HIV/ARV care shows both clinical and administrative benefits, but also ongoing challenges. The aims of integrating the two services are to improve clinical care with increased VCT uptake for TB patients and better management of smear negative TB; to provide a one stop service for TB/HIV patients; to streamline staff and programme management; and to develop a uniform approach to adherence for both TB and HIV medication. After one year of such integration, achievements included all staff in both services trained and involved in the clinical management of co-infected patients and a single manager for the whole site. Challenges identified were the many missed opportunities for VCT for TB cases and the difficulties with integrating the monitoring systems and flow processes of the two programmes. Between 2001 and 2003, the TB caseload continued to increase (1 283/100 000 population in 2002); cure rates

remained at 65% and interrupter rates at 15%. No conclusions could be drawn as to the influence of integration on TB control outcomes.[28]

The experience of Khayelitsha is most similar to that of Hout Bay in that both are Local Authority clinics and are part of the government ARV roll-out. However, Khayelitsha is a much larger clinic, with lower cure rates. It describes combining existing parallel provincial ARV services and Local Authority TB services, while the experience of Hout Bay is the introduction of an ARV programme into an existing TB service, which could well be the model for ARV roll-out in future in the Western Cape.

5. Justification for the study

The rollout of ARV programmes should aim to strengthen the existing public health system in order to provide a high quality, sustainable and equitable health delivery system. However, a huge injection of resources (of time, money, space and skilled staff) into the ARV rollout, has led to the concern that this programme will compromise the rest of health service provision.[29]

An assessment of the national ARV rollout until November 2004 found that in the majority of ARV sites, the drug supply and management systems were strengthened rather than weakened. Staff morale had improved and the ARV programme had brought with it an overall more positive approach to health service delivery. However, the report states that 'successful integration of ART with other essential programmes like TB and PMTCT (prevention of mother to child transmission) services remains limited, resulting in resource inefficiencies and lost opportunities to improve treatment outcomes.[30]

In the foreword to the Cape Town TB Control 1997 – 2003 Progress report, ARV provision is described as 'an exciting opportunity to further strengthen TB control'.[3] This could be achieved in the context of the ARV programme with active TB case finding, voluntary counselling and testing for HIV of all TB cases, and the provision of isoniazid prophylaxis to prevent the reactivation of TB in HIV positive individuals.[3] As HIV significantly increases the risk of

developing TB disease, 'HIV prevention and integrating HIV and AIDS care are key to controlling the TB epidemic'.[26]

An evaluation of the performance of a TB control programme following the introduction of an ARV programme in a primary care facility as part of the government ARV roll-out, and of the process of integrating the TB and ARV programmes in a Local Authority clinic, could help to identify some of the benefits and problems arising from the integration of these programmes in HBM. This could be useful in improving the TB/ARV service in the clinic and in guiding the integration of ARV programmes with TB programmes at primary clinic level in the province in line with the Department of Health's plan to decant the ARV service to nurse-based primary care level when feasible and required.

6. Methods

6.1 Study Aim

The aim of this study was to evaluate how the performance and operation of the TB programme in the clinic changed following the introduction of the ARV programme.

6.2 Objectives

- To assess and compare the TB programme performance over two one-year periods:
    - The year prior to the introduction of the ARV programme into the clinic (2003)
    - And the first year of the ARV programme in the clinic (2004).
- To describe and explain the clinic staffs' understanding of the change in HBM clinic's TB programme performance and operation since the introduction of the ARV programme.

6.3 Research questions

- Did TB programme performance in HBM clinic change in the year following the introduction of the ARV programme to the clinic?

- How do staff explain any deterioration or improvement in TB programme performance following the introduction of the ARV programme?

- What factors might have influenced (facilitated or hindered) the integration of the ARV programme with the TB programme in the clinic?

6.4 Study Design

This health systems research study used a mixed methods study design that combined a before-after study, involving the retrospective analysis of performance data from two years of a TB programme, with a qualitative validation of the quantitative results using focus group methodology.

6.5 Study Area

The clinic is situated in the suburb of Hout Bay, Cape Town, on the edge of the informal settlement, Imizamo Yethu or Mandela Park. The population of Hout Bay is 20 000, 15 000 of whom live in Mandela Park, most in crowded shacks. Water and sanitation services are poor. The Mandela Park informal settlement has existed for more than twenty years and continues to grow. Its inhabitants arrive largely from the Eastern Cape and there is a growing population of immigrants from Namibia and Angola (predominantly men) many of whom join the fishing trade in Hout Bay harbour.[31]

6.6 Sampling

Study population

The study population comprised *all* TB cases registered in HBM clinic for the years 2003 and 2004, and the staff of HBM clinic.

Sample size calculation

As the research question examining whether any change occurred in TB programme performance arose from a concern that integrating ARV care into a TB programme could compromise TB programme performance, a 5% change in cure rates (either improvement or deterioration) was considered acceptable following the introduction of the ARV clinic. The cure rate in 2003 was 87%. In order to detect a 5% difference in cure rates, with the study power set at 80% and significance level at 95%, 945 TB cases per group would be required for this purpose.

6.7 Indicators

All but two of the indicators (the 'time from presenting with TB symptoms to starting TB treatment' and the isoniazid preventive therapy screening indicators) were selected as they are already routinely collected to assess and reflect the quality of the TB control programme in HBM clinic and throughout the province, and were readily available on the ETBR.

Case finding

1. Total number of TB cases registered
2. Proportion of all TB cases that were new smear positive cases
3. Smear positive rate
4. Time in days from first presenting with TB symptoms in the clinic to starting TB treatment.

This indicator was added to try to reflect the degree of active TB case-finding and the efficiency of TB diagnosis in a clinic population with high HIV prevalence. For those patients who present with TB symptoms to the clinic, several factors might determine the speed with which their TB is diagnosed and they are started on TB treatment:

- Nursing staffs' clinical suspicion of TB and commencement of TB investigations
- Efficiency of the clinic's TB programme to process the TB investigations and commence treatment if smear positive
- Index of suspicion for TB to persist with the TB workup when smear negative (which includes further collection of sputum specimens for direct microscopy, cultures, chest X-Rays and referral to the doctor)
- Patient factors – missing follow-up appointments, not returning sputum jars
- Patient education by clinic staff around the nature of the TB workup

Symptoms and signs recorded in the folder suggestive of TB included a history of any one or several of cough, sweats, fever, weight loss, malaise, or on clinical

assessment a temperature greater than 37.5°C, or a recorded weight loss of more than 2kg in 4 weeks (the patients' weights are noted at every visit).

Case Holding

5. Smear conversion rates
6. DOTS coverage

HIV co-infection

7. Proportion of all TB cases offered VCT
8. Acceptance rate among those TB cases offered VCT
9. HIV positivity rate
10. Proportion of all HIV patients with CD4 cell count of more than 200 cells/µl screened for isoniazid preventive therapy (IPT). A six-month course of IPT has been shown to decrease the risk of TB disease in HIV infected persons with a positive mantoux (which indicates that they have TB infection).[32]

Treatment outcomes

The outcomes examined were specifically for new smear positive TB cases. The ETBR provides the treatment outcomes for the re-treatment smear-positive cases, however, as the register does not specify the proportion of total TB cases registered that are re-treatment smear-positive cases, these rates were not

examined. Nor were the treatment outcomes of those smear-negative cases examined as this group was not specified in the register.

11. Cure rates
12. Treatment completion rates
13. Success rates
14. Interruption rates
15. Death Rates

6.8 Data Collection

Tools used for Quantitative data collection phase

A retrospective review of all TB cases for the years 2003 and 2004 was conducted. Most of the outcome indicators including those reflecting TB case detection and holding, treatment outcomes, and VCT and DOTS provision were accessed directly from the Electronic TB Register (ETBR) for the years 2003 and 2004.

The ETBR provides TB programme performance indicators in absolute numbers and as rates, but does not provide individual patient details. The Western Cape Tuberculosis programme list is a collation of each clinic's TB register and contains age and gender details of all TB patients who were registered and started treatment during the years 2003 and 2004. The number of adult and child TB cases and the gender ratio per year were recorded to assess the comparability of the TB case population over the two years.

Smear positive rates are not routinely recorded with the ETBR and those for the two years under study were accessed from the National Health Laboratory Service.

IPT screening was not recorded routinely in the clinic or in the ETBR and as, according to clinic staff, this aspect of HIV care was limited to a few patients (less than ten per year), a folder review examining IPT screening in HIV patients with CD4 cell count of more than 200 cells/µl was not performed.

A folder review was prompted by the fact that the 'time from first presenting sick to the clinic and starting TB treatment' is not routinely recorded in the clinic. TB cases for the years 2003 and 2004 were identified from the Western Cape Tuberculosis Programme List of all TB patients who were registered and started treatment during the years 2003 and 2004. This list was accessed from the City of Cape Town's TB programme.[33]

The TB cases' folders were extracted from the clinic filing system.

Those patients who had been referred to the clinic with a TB diagnosis or specifically for TB investigations were not included in this indicator as TB itself (rather than the symptoms and signs thereof) was their presenting issue. They were acknowledged instead as 'referred in' and the source of referral specified. The folders of those patients who presented with TB symptoms without referral were reviewed to identify the date of their first presentation with TB symptoms

and the date of commencing TB treatment. The findings of the folder review were recorded on a spreadsheet for each year. The number of days between presentation and starting treatment was calculated for each patient.

The tools used to access each indicator are represented in table 1.

Table 1. Tools used to access indicators

Tool	**Indicator**
Electronic TB Register	TB case detection Case holding Treatment outcomes HIV co-infection DOTS
Western Cape TB programme List	TB case gender ratio TB case age
National Health Laboratory Service Review	Smear positive rate
TB case folder review	Time from presenting till treatment

The researcher collated all the quantitative data and performed the folder review.

Qualitative data collection phase

Complementing the quantitative outcomes with a qualitative analysis should help to deepen the researcher's understanding of the process of integrating the TB and ARV programmes and the likely reasons underlying the quantitative results.[34]

One focus group was conducted following the collection and statistical analysis of the quantitative outcomes.

The purpose of the focus group was twofold: first to present the quantitative outcomes for comment and explanation and second to explore the process of integration of the ARV and TB programmes. It was not to identify slight differences of opinion or explore new issues, but rather to summarise and consolidate the ongoing informal, ad-hoc discussions the group had had as a team during 2004 as the process of integration evolved and thereby improve the reliability of the researcher's understanding of this process and the quantitative outcomes.

The sampling for the focus group was purposive.[35] The researcher selected those clinic staff members who worked at HBM and had been involved with the provision of TB and HIV care in 2003 and with the introduction of the ARV programme during 2004. They were selected as they had been most closely and consistently involved with the ARV and TB programmes in the clinic over the two years of the study. The group comprised the clinic manager who was also a clinical nurse practitioner (CNP); the CNP with an interest in HIV care; the registered nurse who managed the TB programme in the clinic and the

doctor/manager of the ARV programme. The nurses were all employed full-time at the clinic during these two years; the doctor intermittently on a locum, sessional basis in 2003 and then every morning for 2004.

The focus group occurred at a venue outside the clinic to ensure that the group was uninterrupted by clinic activities. As the researcher was also a staff member, a neutral, outside group-facilitator ran the focus group. The facilitator's role was to ensure that the purpose of the focus group was fulfilled and that the researcher as doctor and manager of the programme did not dominate the discussion.

To set the scene for a discussion of TB programme performance following the integration of the ARV programme with the TB programme, the group was first asked to explore their experience of this process. This was done by eliciting from the group a description of the clinic function, the TB programme and HIV care in 2003 and identifying what changed in 2004 with the arrival of the ARV programme and ARV staff.

The quantitative findings of the study were presented in table form to the group and discussed one outcome at a time. The participants were requested to reflect on each outcome, and to attempt to explain any significant difference recorded between the two years. They were asked, 'How does the group explain the differences in TB programme performance between 2003 and 2004?'

The group was asked to describe what changes occurred in the TB programme to accommodate the introduction of the ARV programme, and to identify what factors might have influenced the integration of the ARV programme with the TB programme. The group was asked a broad question to prompt this discussion: 'What would the group recommend similar primary care facilities do to integrate their TB and ARV services?'

The focus group was audio-taped.

6.9 Data analysis

Quantitative data analysis

Apart from the 'time to diagnosis' indicator, the data was taken manually from the ETBR and displayed in a table (see table 2 below). The indicator 'time to diagnosis' was collated onto an Excel spreadsheet during the folder review, and then analysed manually. The researcher performed the statistical analysis of the quantitative data.

All quantitative data represented as proportions were analysed using a Chi-squared test for statistically significant difference between the two years, and the p values, odds ratios and 95% confidence intervals recorded. The statistical package used was STATA S/E 9.0.

The change in the number of TB cases registered in the clinic over the two years was compared statistically with that of the province for the same period.

For the purpose of analysis the indicator 'number of days till TB treatment' was categorised into the following ranges: 0 to 7 days, 8 to 30 days and more than 30 days. Weekends and public holidays were not excluded. The rationale for the ranges was as follows:

- 0 - 7 days: a two-smear positive patient with typical TB symptoms (cough, sweats, weight loss) should ideally hand in sputa on day 1 and day 2 and return on day 4 for results and to commence treatment. The range extends to up to 7 days to allow for weekends.
- 8 - 30 days: a patient who is smear negative or with an atypical clinical picture will require a higher index of suspicion for TB, the exclusion of HIV and a more extensive TB workup. The WHO recommends that one should aim to diagnose TB within 4 visits, which if occurring at weekly intervals will take up to one month.[36]
- > 30 days: patients who wait this long to commence TB treatment might do so for several possible reasons: diagnostic delay, irregular attendance at the clinic, poor patient insight/ understanding of the workup process, TB diagnosed on culture (which can take up to 60 days to prove positive), or a combination of factors. A wait lasting more than a month is obviously undesirable for the patient's health (particularly in HIV where the progression to AIDS is accelerated), and for the risk of transmission to his/her contacts.

The proportion of TB cases that fell into each of the time ranges was compared over the two years, using the Chi-squared test for proportion.

Qualitative data analysis

The data emanating from the focus group were analysed by the researcher.[35] The tape recording was listened to repeatedly, initially to get a sense of the whole discussion and then in relation to the questions posed. An outline of the discussion and essential points were transcribed. The transcriptions were checked for accuracy by re-listening to the recordings.

One part of the focus group dealt directly with the question 'What might explain the changes in quantitative outcomes?' and is represented in the qualitative results section as such.

The following sub-questions informed the approach to analysis of the rest of the discussion:

- What about the existing set-up in the clinic facilitated the introduction of the ARV programme?
- What changed or needs to change in the clinic and TB programme in order to accommodate the integration of the two programmes?

The transcriptions dealing with this part of the discussion were coded and these arranged into several themes that contributed to an understanding of the factors that influenced the integration of the TB and ARV programmes and the process

of change in the TB programme. Linked to the themes are verbatim transcriptions. Where there was consensus about a particular theme, one or two comments were ascribed to the whole group; if any member of the group had an opinion that differed from the rest this was included separately and the participant acknowledged. The themes are presented in response to the sub-questions posed.

6.10 Ethical considerations

Written permission was obtained to conduct the study from the Local Authority administration and the clinic manager and staff.

TB cases for the two years were identified by patient name from the Western Cape TB Programme List by the researcher (also the programme doctor) and the clinic clerk who were both familiar with the patients and their clinical records. These were recorded for this study according to folder number. No patient names were recorded on the spread sheet, thus assuring confidentiality within this study.

Informed written consent was elicited from the participants in the focus group. The participants' anonymity was assured, and that they could withdraw or refuse to participate during the focus group was made explicit. Plans for disseminating the findings of the study were shared with participants. Appendix 2 contains the signed consent forms.

Ethical approval for the study was obtained from the University of Cape Town, Faculty of Health Sciences Research Ethics Committee. (Appendix 3)

6.11 Conflict of interest

As they might have influenced both the method and the analysis of this study, the researcher's own assumptions and potential biases were acknowledged prior to commencing data collection, and the analysis thereof:

- The researcher was also the clinic doctor and manager of the ARV programme, and hence has a personal investment in the TB/ARV programme outcomes.
- The rest of the clinic staff were also committed to the success of the TB and ARV programmes.
- The researcher holds the belief that TB and HIV/ARV care should be integrated, this belief was especially strong in the context of the provincial political will to place TB and ARV programmes in different sites (most ARV sites are located separate from the local TB clinic; this is however due to change with the introduction of ARV programmes into Local Authority clinics).

6.12 Dissemination of findings

A report of the study findings will be prepared and disseminated to the National Department of Health TB/HIV directorate, as well as those at provincial level in the Western Cape and Free State provinces where ARV programmes are being expanded in the primary care setting with a view to increasing nursing staff

responsibility for both pre-ARV and ARV care and improving access to ARV services. The findings will also be fed back to the staff of the participating clinic and to similar facilities with ARV/TB programmes.

7. Results

7.1 Quantitative Findings

The ETBR reported a total of 392 cases registered for the two years. The register had an incomplete record of the type of TB (eg. pulmonary TB, extra-pulmonary TB) at the time of data collection and did not distinguish gender and age distribution of cases. The Western Cape TB Programme List had recorded a total of 362 cases, 30 fewer than that recorded in the ETBR. Gender and age of TB cases for the two years was obtained from this list. See table 2 below.

Table 2: Ratios of gender and adult to child for TB cases at HBM in 2003 and 2004 (Figures in bold are significant)

	2003	2004	Chi^2 test p value	Odds Ratio	95% CI
Male: Female	89:58	127:88	0.7788	0.941	0.599 – 1.475
Adult: Child	140:7	195:20	0.1063	0.488	0.170 – 1.243

CI – confidence interval

The indicators derived from the ETBR for 2003 and 2004 are displayed in Table 3.

Table 3: TB control programme performance indicators for HBM 2003 and 2004

(Figures in bold are significant)

Indicator	2003 Absolute proportion; (%); (95% CI)	2004 Absolute proportion; (%); (95% CI)	Chi^2 test p-value	Odds Ratio	95% CI
TB cases registered at HBM as a proportion of the total in the Western Cape	164/44 161 (0.371%) (0.00-0.00)	228/45 165 (0.50%) (0.00-0.01)	**0.0027**	**1.361**	**1.108 – 1.675**
New Smear pos cases (% of total cases)	60/164 (36.59%) (0.29-0.44)	96/228 (42.11%) (0.36-0.49)	(0.2707)	0.793	0.514 – 1.223
Smear positive rate	108/936 (11.5%) (0.10-0.14)	200/1355 (14.8%) (0.08-0.11)	**0.0263**	**1.328**	**1.027 – 1.722**
Smear conversion rate*	52/60 (87%) (0.75-0.94)	78/96 (81.25%) (0.72-0.88)	0.3771	1.5	0.568 – 4.284
Conversion results not available at 3 months*	6/60 (10%) (0.04-0.12)	10/96 (10.4%) (0.05-0.18)	0.9335	0.956	0.269 – 3.100
Interruption rate*	4/60 (6.67%) (0.02-0.16)	7/97 (7.2%) (0.03-0.14)	0.8957	0.918	0.188 – 3.809
Success Rate*	54/60 (90%) (0.79-0.96)	80/97 (82.47%) (0.73-0.89)	0.1950	1.9	0.663 – 6.288
Cure rate*	52/60 (87%) (0.75-0.94)	69/97 (71.1%) (0.61-0.80)	**0.0245**	**2.638**	**1.055 – 7.221**
Treatment completion rate*	2/60 (3.3%) (0.00-0.12)	11/97 (11.3%) (0.06-0.19)	0.0769	0.270	0.282 – 1.312
Transferred out rate*	1/60 (1.67%) (0.00-0.89)	4/97 (4.12%) (0.11-0.10)	0.3942	0.394	0.008 – 4.129
Treatment failure rate*	0/60 (0%) (0-0.60)	3/97 (3.1%) (0.01-0.88)	0.1690	0	0 – 2.058
Death Rate*	0/60 (0%) (0-0.60)	3/97 (3.1%) (0.01-0.88)	0.1690	0	0 – 2.058
Proportion of adult TB cases offered HIV testing	156/160 (97.5%) (0.94-0.99)	208/210 (99%) (0.96-1.00)	0.2430	0.375	0.336 – 2.661
HIV testing uptake among adult TB cases offered testing	126/156 (80.77%) (0.74-0.87)	184/208 (88.5%) (0.83-0.92)	**0.0410**	0.548	0.292 – 1.021
HIV positivity rate	98/126 (77.78%) (0.70-0.85)	138/184 (75%) (0.68-0.81)	0.5731	1.167	0.661 – 2.080
Community DOTS coverage Number TB cases registered Community DOTS	262 93/262 (35.5%) (0.30-0.42)	301 143/301 (47.5%) (0.42-0.53)	**0.0040**	**1.645**	**1.155 – 2.344**
Clinic DOTS	144/262 (55.0%) (0.49-0.61)	140/301 (46.8%) (0.41-0.52)	0.0546	1.385	0.980 – 1.958
Workplace DOTS	7/262 (2.7%) (0.01-0.05)	10/301 (3.3%) (0.02-0.06)	0.6528	0.799	0.254 – 2.365

CI -Confidence Interval

*Case holding and treatment outcome rates are for new smear positive cases only.

Folder Review

Of the 362 TB cases registered on the Western Cape TB Programme List for 2003 and 2004, 353 folders were reviewed. The remaining 4 (for 2003) and 5 (for 2004) folders could not be found in the clinic's filing system. One possible reason for this was that the patient's name in the WC TB Programme List did not correspond with that on the clinic's electronic database of all patients seen at the facility. Statistical analysis revealed no significant difference in the response rates for the two years (97.28% vs 97.67%, p = 0.9788).

Reviewing the folders for the 'time from presenting with TB symptoms at the clinic to starting TB treatment' indicator revealed that of all 353 TB cases, 172 (76 folders in 2003 and 96 in 2004) were referred in either specifically for TB investigations or with a TB diagnosis confirmed. While the proportion of cases referred in to the clinic dropped between the two years, this was not significant. During both years, of those referred in, a similar proportion was from the local secondary hospital. The remaining 163 patients presented to the clinic without referral, and it was from their folders that the indicator 'time from presenting sick to starting TB treatment' was measured.

The results of the folder review are displayed in Table 4.

Table 4: Folder review of TB cases in HBM 2003 and 2004

(Figures in bold are significant)

Indicator	2003 Number/total (%)	2004 Number/total (%)	Chi^2 test p-value	Odds Ratio	95% CI
Records Reviewed	143	210			
Response Rate	143/147 (97.28%) (0.93-0.99)	210/215 (97.67%) (0.95-0.99)	0.9788	0.851	0.180 – 4.368
Days from presentation to starting TB treatment					
0-7	21/58 (36%) (0.24-0.50)	56/105 (53%) (0.43-0.63)	**0.0360**	0.4979	0.243 – 1.007
8-30	18/58 (31%) (0.20-0.45)	36/105 (34%) (0.25-0.44)	0.6729	0.863	0.406 – 1.802
> 30	19/58 (32%) (0.21-0.46)	13/105 (12%) (0.06-0.19)	**0.0017**	**3.073**	**1.281 – 7.473**
Referred in with a TB diagnosis or for TB investigation	76/143 (53.1%) (0.45-0.62)	96/210 (46.0%) (0.39-0.52)	0.1326	1.347	0.860 – 2.110
Proportion of referrals from secondary hospital	42/76 (55.3%) (0.43-0.67)	55/96 (57.3%) (0.47-0.67)	0.7899	0.921	0.480 – 1.768

CI – confidence interval

Case finding

During the first year of the ARV programme, significant increases in TB case finding were observed. The number of TB cases registered grew by 39% from 164 in 2003 to 228 in 2004. This is significantly greater than the provincial case detection increase of 2.27% over the same period (0.37% vs 0.50%, p-value 0.0027, OR 1.361, 95% CI 1.108 – 1.675).[2] The proportion of new smear positive cases grew in 2004, but not significantly.

There was an improvement in the rate at which TB cases were commenced on TB treatment: those started within 7 days grew by 17% and those who waited

more than 30 days dropped by 20% - the latter a statistically significant decrease (32% vs 12%, p-value 0.0017, OR 3.073, 95% CI 1.281-7.473). In spite of the improvement in case detection, and that the number of smears sent increased by 419 from 936 in 2003 to 1355 in 2004, the smear positive rate dropped significantly (11.5% vs 14.8%, p-value 0.0263, OR 1.328, 95% CI 1.027 – 1.722) As the confidence interval is close to 1 the significance of this drop is marginal.

Case holding

Smear conversion rates dropped though not significantly. During both years, a similar proportion was unavailable at three months.

Treatment outcomes

All treatment outcomes except for the cure rate showed no significant change over the two years. The cure rate dropped significantly in 2004, by 16% (87% vs 71.1%, p-value 0.245, OR 2.638, 95% CI 1.055-7.221) However, as the confidence interval is both wide and very close to 1, this drop is of marginal significance.

In 2003, the two-month conversion rate accurately predicted the cure rate: they are both 87%. This is not true for 2004. However, a sensitivity analysis of this indicator showed that had ten of those patients who were discharged 'treatment completed' actually been 'cured' the cure rate would have matched that year's conversion rate of 81%, and there would have been no significant difference between the cure rates of the two years (87% vs 81.4%; p= 0.3923).

HIV testing

While the proportion of adult TB cases offered VCT remained unchanged over the two years, the proportion of those cases who accepted testing increased in 2004, though not significantly. The HIV positivity rate remained constant.

DOTS coverage

The proportion of TB cases managed with community DOTS increased significantly (35.5% vs 47.5%, p-value 0.004, OR 1.645, 95% CI 1.155 – 2.344), and clinic-based DOTS dropped, though not significantly.

7.2 Qualitative findings

The discussion in the focus group occurred in two parts. The focus group reflected on those TB programme performance indicators that changed in 2004 try to explain the differences between the two years and then explored the process of integration of the TB and ARV programmes in the clinic.

Focus group discussion of the TB programme performance indicators

Case finding

The group explained the increase in TB case detection as follows: 'we were screening more aggressively for TB than we had been in 2003'. 'We screened more people more for TB…we were more aware…' The ARV programme encouraged screening for TB symptoms and excluding TB prior to commencing ARVs. The nurse participants also referred to their increased awareness of

TB/HIV co-infection. 'If you have HIV I'm going to look for TB, it's somewhere there'.

The group considered that the frequent smear-negative presentation of a co-infected patient made the increase in the smear positive rate difficult to interpret. The clinic manager stated, 'HIV makes this rate difficult to interpret.... but smear positives show we've waited a long time to diagnose TB.'

The group suggested that the decrease in waiting time for patients with TB to start TB treatment could have in part been due to the fact that the staff considered TB sooner and persisted more with the TB workup than they had in the previous year. 'If a patient (with TB symptoms) returns smear negative - I don't stop there - there must be a reason why you're coughing.' The group expressed that they were 'more intent on getting a diagnosis. You don't sit there like an idiot... we go to X-Rays, culture and we refer to the doctor more.'

Treatment outcomes

The TB nurse and clinic manager stated that ten 2004 new smear-positive TB patients had been discharged as 'treatment completed' instead of 'cured'. They had completed their course of TB treatment but either their discharge sputa were not tested or the results were not recorded. A number of possible reasons were discussed by the group for the missed 'opportunity to close the gap between treatment completion and cure'[3] after the introduction of the ARV programme.

'We didn't manage to get all the discharge sputa done properly or the patients were unable to produce – it can be sometimes difficult to get sputum off a patient.' The group did not see the ARV programme as adding to the TB nurse's responsibilities (there was one nursing staff member other than the TB nurse assigned to the ARV programme as detailed above), but the clinic manager suggested, 'maybe we got distracted in the beginning of the ARV programme by patients on ARVs and forgot to do their sputa'. Along with patient education and monitoring adherence, the role of the DOTS supporter is to ensure the patient is not lost to the TB programme and at the appropriate times hands in sputa. The TB nurse was reluctant to 'scapegoat' the DOTS supporters for the drop in cure rate, as they were new and that the ultimate responsibility for discharge sputa lay with the clinic staff. As patients who started ARVs after discharge from TB treatment were found to re-present with TB, TB treatment was sometimes prolonged until the patient was settled on ARVs. This practice was not thought to have interfered with TB outcomes as in these cases discharge sputa were sent and recorded on time (either five or seven months) even if TB treatment continued.

HIV testing

The routine offering of HIV testing to all TB suspects and cases was introduced prior to 2003 throughout the sub-district which explained that the proportion of adult TB cases offered HIV testing was in both years studied close to 100%. The group reflected however that their attitude to testing had changed following the introduction of the ARV programme, which in turn had helped improve the uptake of HIV testing in 2004. Prior to the ARV programme, they were not as confident

to offer HIV testing and felt that the patient had the 'right to refuse' – 'we didn't make the effort to get people to diagnose', as access to ARVs was limited and complicated. Once ARVs became available in the clinic, the benefit of testing for the patients became clearer to staff. 'Now we have an incentive to test... if you don't know your status, then you can't get treatment'. 'We were pushing HIV testing... I tell the patients, 'You can forget about dying now if you have HIV''.

DOTS coverage

The introduction of the ARV programme to the clinic prompted the addition of 6 DOTS supporters and a coordinator. This led to the increase in community DOTS coverage and corresponding decrease in clinic-based DOTS. The nurse participants considered that moving TB patients into the community might protect those attending the ARV clinic from TB: 'if you're well on TB treatment, you don't want to mix with sick ones'. They noticed that following the introduction of the ARV programme, co-infected patients on ARVs improved more quickly and coped better on TB treatment (compared to co-infected patients not on ARVs the year before) and thus were discharged sooner from clinic-based DOTS into the community. 'We could manage them in the community once they were on ARVs, because they were not so sick any more.'

IPT provision

The nurse participants estimated that fewer than ten HIV infected adults were screened for and commenced on IPT per year. The group discussed possible reasons for this.

They expressed the belief that IPT was ineffective at preventing TB, and that there was 'no proof that it works'. They suggested that IPT would only tentatively guarantee the patient to be TB-free for a limited period of time, which cast doubt on whether it was worthwhile –'what is the point?' The group recalled an HIV infected child who after six months of IPT, had contracted TB anyway. They were also uncertain about the duration of effectiveness of IPT in preventing TB disease.

The group voiced concern about isoniazid resistance, as they had observed this among TB-culture sensitivity results. 'I worry about resistance – it sticks in the back of my mind'. Ensuring patient adherence to IPT was difficult, with only one of those adults given prophylaxis completing the course. The CNP suggested that patient commitment and adherence were poorer with a course of isoniazid than with ARVs or co-trimoxazole as these are life-long, the isoniazid only for 6 months. 'It's work to keep track of them, encourage them.'

The TB sister thus considered IPT as a low priority in HIV care. The CNP with the HIV interest offered IPT to patients she considered at risk, for example patient advocates who were HIV-infected and working daily in the clinic. Of expanding IPT more generally she stated, 'I'm prepared to do it, but I'm not convinced.'

Examining the integration of the ARV programme with the TB programme

When asked the question, 'What would the group recommend similar primary care facilities do to integrate their TB and ARV services?' one participant commented, 'We're learning all the time, it's a dynamic process'.

On analysis of the focus group transcript, four themes emerged in answer to the question: What about the existing set-up in the clinic facilitated the introduction of the ARV programme?

- **'You must see the patient as a whole.' -** comprehensive patient care
- **'It's your setup' -** integrated clinic care
- **'Doctors must teach and support' -** doctors as leaders and teachers
- **'The staff need to know' -** training

'You must see the patient as a whole.' - comprehensive patient care

The approach to the patient in the clinical context was a comprehensive, holistic one. 'I've always been a comprehensive person,' stated the CNP with the HIV interest. She felt that nurses cannot be '...tunnel-visioned, they've got to see the patient as a whole.' The focus group participants derived a 'sense of satisfaction' from treating the patient comprehensively.

'Seeing the patient as a whole' also extended to regarding the patient as a person: the clinic staff usually knew their patients' names, families and medical stories. 'If you live in the area you belong to us'. Participants were aware of their relationship with their patients and sense of responsibility for them.

'It's your setup' - integrated clinic care

Prior to 2004, each staff member was 'multi-skilled' and familiar with all clinic tasks. 'We've always integrated the care of our patients anyway.' Examples that they gave to illustrate this included treating the mother and child together rather than placing them in separate queues, and screening for and treating the STI of a woman requiring family planning. The group felt that the integration of an ARV programme into a TB clinic was more likely to be successful if both the clinicians' and the clinic's approach to the patient was already an integrated, holistic and comprehensive one. 'So it was easy for us to integrate something extra into our programme.'

The nurse participants appeared unaware that in most other ARV programmes in the Western Cape, patients received their TB, HIV and ARV care separately, and that many TB programmes and TB nurses have little involvement with the ARV programmes to which they refer their patients. They described the 'functional approach' to running a clinic which is adopted by many similar Local Authority clinics – a task-oriented rather than patient-oriented approach. They saw no other option to integrating patient care and felt that 'those clinics who have not integrated they lose out'.

Referring to a hypothetical non-integrated clinic due to incorporate an ARV programme, the clinic manager stated, 'If they don't integrate now they'll never integrate that ARV programme – they'll see it as extra work.'

'Doctors must teach and support' - doctors as leaders and teachers

The nurse participants identified the doctors as having been key to leading, teaching and influencing the nursing staff.

The group acknowledged the 'TB' doctor's vision and preparation for HBM as an integrated TB/ARV site. She set the example in approaching the client in a holistic manner when she received HIV referrals from the staff and thus evolved into the 'TB/HIV/ARV' doctor as described above. Describing the care of a co-infected patient who commenced ARVs during 2003 – 'it was done at the same time … that was the precedent that was set – it was the same doctor.'

The 'ARV' doctor (also the researcher), was easily accepted as a member of the clinic team as she had worked in the clinic previously as a 'TB' doctor. The nurse participants appreciated the fact that she became involved in TB patient care as she had the clinical experience and familiarity with the TB programme. The TB nurse stated it was good that doctor had worked in the clinic, we were familiar with doc, we could understand and accept doc, and doc knew the TB programme and could influence us.'

The group related an anecdote of a visiting ARV doctor who refused to see the TB patients – they were surprised by his fragmented approach to the patients, but suggested that perhaps he had little training or experience in managing patients with TB.

The nurse participants felt the freedom to 'follow your patient' as there was ready communication about patients between nursing staff and the doctor. 'We could ask the doctor anything at anytime'. Thus they did not lose the patient to the doctor once s/he was referred, but instead felt involved in the patient's further management. Being involved in the ongoing care of the patient was an important learning experience. 'This doctor taught us stuff, pushed us to make decisions and take responsibility… 'I'm confident I'm doing the right thing'. The doctor's role as teacher also extended from a clinical one to a managerial one: 'The doctor taught us a lot of things' which helped to 'prepare us to take it (managing the ARV programme) on ourselves… We're ready for that now.'

'The staff need to know' – ARV training

All staff in the clinic had been trained about ARVs prior to the introduction of the ARV programme. This helped them to gain an understanding of 'what ARVs will do' and thus encouraged them to promote ARVs in the clinical context. 'We had to be trained before about ARVs even if we weren't going to be hands on.' ARV training also highlighted the link between HIV and TB.

Four themes emerged in answer to the question: What changed or needs to change in the clinic and TB programme in order to accommodate the integration of the two programmes?

- **'You must tune your TB programme' –** Reorganising and strengthening the TB programme
- **'I had to be involved'** – ownership of the ARV programme and its integration with the TB service
- **'They're alive, they're all alive'** – Boosting staff morale and motivation: the positive effect of ARVs
- **'One hell of a headache'** – disparate management of TB and ARV programmes

'You must tune your TB programme' – Reorganising and strengthening the TB programme

The TB nurse stressed the importance of ensuring that the TB programme was efficiently managed and adapted to the needs of the ARV programme. 'If you manage your TB programme well then… you must tune your TB programme in such a way ...because a lot of clients are coming from the TB programme – then if you've got a proper effective programme then you'll be able to identify easily the people that need ARVs'.

One of the first steps towards integrating TB and ARV care was to combine the TB and HIV folders. 'TB was always integrated into the clinic, but in 2003 TB suspects had a separate folder, or a little envelope only'. During 2003 the TB suspect workup began to be recorded in the general clinic folder. Thus with the introduction of the ARV programme, the ARV notes were included in the already

combined TB/HIV folder, so that the patient received TB, HIV and ARV care all at one visit.

The TB nurse was mainly concerned in 2003 with the compliance of his patients to their TB treatment: 'The only thing that I was supposed to be doing was to manage them and to make sure that they finished the course (of TB treatment)'. In 2004, he took on more responsibility for the TB programme when the 'TB' doctor left: 'I can now take some of the work away from the doctors and I can prepare better for the TB clinic.' His responsibility also expanded to identifying which TB patients required ARVs: either on routine CD4 check (taken at two months' TB treatment) or earlier if his clinical assessment indicated that the patient might require ARVs urgently.

The TB nurse also became familiar with and involved in the co-infected patient's ongoing ARV care which involved coinciding TB and ARV appointments, dealing with adherence issues (including tracking down TB and ARV defaulters), liaising with patient advocates about co-infected patients, ensuring reliable contraception for women on efavirenz (one ARV of choice when on TB treatment), and encouraging support group attendance.

The TB nurse emphasized that the staff (doctor, nurse and patient advocates) who joined the clinic assigned to the ARV programme consider themselves part of the clinic and participate in general clinic activities (not only ARVs), especially the TB programme. 'If you come here and then you influence me to do something else (helping with ARV care) without contributing to my (TB) programme, then that becomes a problem.'

'I had to be involved' – Creating ownership of the ARV programme and integration with TB service

'You need input from the staff' was the opinion of the clinic manager in order to create ownership of the ARV programme and the process of integrating it with the rest of the clinic. On introducing the plan for an ARV programme to the staff, she proposed that they introduce the ARV programme subject to review by the staff themselves. The staff initially felt it would be extra work, but could see the obvious need for it.

This sense of ownership grew as the staff recognised the need for ARVs and the high TB/HIV co-infection rates. The TB nurse saw several of his patients die: 'You start the person on TB treatment, then later you realize they're dead'; 'A patient died trying to access ARVs – woke me up that we need ARVs in the clinic. I had to be involved'. Staff involvement in and ownership of the ARV programme made them feel 'good' about themselves and the service they provided.

Ownership of the ARV programme required that the clinic staff believed that the programme belonged to them and that they were accountable for its success even though it was officially funded by an NGO. During 2004, the first year of the ARV programme in HBM, the clinic was still largely regarded as belonging to the ARV doctor and the ARV NGO. The suggestion in 2005 that the ARV programme

would move to fall under provincial management prompted the staff to consider their involvement with the programme and its integration with the rest of the services provided (particularly TB). The clinic manager commented, 'We must make the (ARV) programme work for us. We now talk about problems and roles of staff. The clinic should take ownership of the (ARV) programme, for example, J___ is the TB programme manager and he's accountable for it, but we own the TB programme.'

'They're alive, they're all alive!' – Boosting staff morale and motivation: the positive effect of ARVs

The nurse participants described feeling overwhelmed in 2003 by the emotional demand placed upon them by their sick patients, their 'unnecessary deaths', and the limited clinical support they received (the doctor visited only twice a week and the referral hospital often sent back their patients). However as the introduction of the ARV programme approached towards the end of 2003, 'we could give the patients hope that ARVs were coming, which helped to feel good about yourself (sic) and about the service.'

Staff saw that patients who started ARVs were usually restored to physical and psychological health. This impressed on the staff the effectiveness and benefit of ARVs. 'Those in trouble we sought ARVs for and they're alive, they're all alive!' exclaimed the CNP with the HIV interest.

The positive effect of ARVs on patient well-being helped to motivate staff to integrate the new programme into their clinic: 'we saw it (ARVs) as beneficial to the client, therefore we needed it; we were going to try to make it work (even though) it wasn't going to be easy.'

'One hell of a headache' – disparate management of TB and ARV programmes

The group were concerned that the ARV programme had several coordinating managers who were not involved with the TB programme. The ARV programme was assessed without reference to the TB programme, and required separate reports and statistics for each managerial authority (on any of a weekly, monthly or quarterly basis). The repetitive and redundant effort of collating and reporting the ARV statistics was described by the clinical nurse practitioner who had taken on this responsibility as 'unnecessary red tape' and 'one hell of a headache'.

The group also suggested that TB programme performance was inadequately assessed in the HIV prevalent context of the clinic with its high co-infection rates and thus growing proportion of smear-negative TB cases. Referring to the provincial TB Control Programme: 'They should really look at the TB programme objectively; it's not meeting the needs: they want cure rates and other things…we are unable to fulfil what they want from us.'

8. Discussion

8.1 Study limitations

Co-interventions

The researcher assumed that little else changed in HBM clinic from 2003 and 2004, apart from the introduction of the ARV programme, but acknowledges that along with the ARV programme came more doctor and nurse time (a doctor and a nurse post were created for the ARV programme). All nursing staff had completed ARV training prior to the introduction of the ARV programme in the

clinic. During 2004, they continued to receive critical input from their TB district coordinator about the TB control in the clinic, which might have influenced nursing staff practices with regard to diagnosing and managing TB. As this study was not aiming to ascribe improvements in TB programme performance to the introduction of the ARV programme, this ongoing routine supervision did not compromise the study outcomes in any way.

Clinician as researcher

The conflict of interest for the researcher as the clinician and manager of the ARV programme in the clinic studied was described above. Inevitably, the researcher's opinion and bias as staff member were expressed in the focus group, but she tried to encourage and follow-up on the opinions of other participants in the focus group. She was assisted in this by the facilitator of the group. Attempts were also made when analysing the qualitative data and writing the study up, to remain aware of her bias as a member of staff.[35] The opinions of the researcher were checked within the focus group itself, with colleagues with similar ARV experience, within the context of MPH supervision and an MPH thesis workshop. So while the outcomes of the study were inevitably influenced by the conflicting role of the researcher as clinician, peer review will have tempered this and improved the validity of the findings.

Small sample size

A sample size calculation suggested that 945 TB cases in each year would be required to demonstrate at most a 5% statistically significant difference in TB cure rate. Thus a total sample size of 362 TB cases was too small to detect a

significant difference between the two years studied. Confidence intervals around the odds ratios were reported to give some estimate of the effectiveness of the sample size to demonstrate a difference. They confirmed that there was no statistically significant difference between most outcomes for the two years, and those that did demonstrate a significant difference had confidence intervals that were wide and close to one. The sample size was determined by the number of TB cases seen by the clinic in the two years and the study period was limited by time constraints.

Discrepancies between quantitative tools

The ETBR, Western Cape TB programme list and the TB case folders all reflected different numbers of TB cases over the two year study period. This suggests some discrepancy and inaccuracy in data collation among the tools. The data for this study made use of the register and list as these are commonly used to reflect TB programme performance, and while not the purpose of this study, does highlight that these sources are not entirely reliable.

Focus group questions and discussion

Other than criticising the management of the two programmes (which was external to the clinic), the group identified factors that had a positive effect on the process, and did not discuss any other factors that might have complicated or hindered the process of introducing the ARV programme into the clinic. This might have been the case for several reasons:

- They did not in fact experience any other barriers or frustrations in the process of integration.

- They were intimidated by the presence of the researcher in the focus group who had also been the manager of the ARV programme.
- There might have been the concern that identifying failures or problems could be insulting or upsetting to those in the focus group.
- The focus group questions did not explore deeply enough the problems faced but rather focussed on 'how did we do it?' and 'what made it work?'

Credibility of focus group analysis

Due to time constraints, no member checking of the focus group findings was performed with participants. Only the researcher read the transcripts. This limitation can be mitigated somewhat by the fact that the focus group was designed to be a validation of the researcher's understanding of the quantitative results and process of integration, and a confirmation of the frequent ad hoc discussion the clinic staff had had about the integration of the two programmes.

8.2 Study strength

Use of mixed methodology

Combining quantitative and qualitative research approaches requires a pragmatic perspective that aims to build on both their strengths. Outcomes from research integrating both methods appear to be more 'convincing' than those of either method alone.[34]

Using a mixed methodology for exploring this health systems issue has provided the benefit of explaining some of the quantitative outcomes. The justification for using a quantitative approach is that comparing quantifiable

outcomes over the two years clearly identifies whether there is a change in TB control according to commonly accepted measures like TB Control Programme outcomes. Complementing these outcomes with a qualitative analysis helped to deepen the researcher's understanding of the process of integrating the TB and ARV programmes and the likely reasons underlying the quantitative results.

One good example of this is that the folder review revealed improved efficiency in diagnosing TB following the introduction of the ARV programme, but from this result one can only speculate that this was due to the ARV programme itself. The findings of the focus group discussion make explicit how this might be explained (staff ARV training, increased awareness of active TB screening, renewed enthusiasm to diagnose HIV and TB, etc), and strengthen the case for saying that introducing the ARV programme might have led to staff more efficiently diagnosing TB.

8.3 TB programme performance indicators

Case finding

Possible reasons for the significant increase in number of TB cases registered include improved awareness amongst staff about the increased likelihood and nature of TB disease in those HIV positive and more active TB case finding as part of the workup of HIV patients for ARVs. Of the fifty-one TB patients started on ARVs in 2004, nine developed TB *after* starting ARVs. These patients might otherwise have died had they not been on ARVs, which might have added only

slightly to the 2004 TB case load. Other possible causes could be nosocomial spread of TB to HIV patients attending the ARV programme in the clinic, and poor infection control procedures in the TB room. The latter aspect was not examined in this study.

The increase in sputa sent may reflect both the increased burden of disease and the increased active case finding activity in the clinic, some of which was related to the ARV programme. The WHO target of a 10% smear-positive rate indicates a well functioning TB programme in an HIV negative population; as HIV patients with TB are more likely to be smear-negative or have indeterminate sputa (where a patient's smear results are one positive and two negative), this target is expected to be even lower in the context of a co-epidemic. The significant increase in the smear positive rate may reflect the impact of HIV on the TB epidemic with a greater percentage of smear-negative TB.

The increase (though not significant) in the number of patients commencing TB treatment within seven days might indicate that the routine admission, workup, diagnosis and commencement on TB treatment was not compromised during the year of the ARV programme's introduction. Calculating the 'time from presenting sick to starting treatment' is an effective way to measure the efficiency of TB work-up and diagnosis, and could be a useful adjunct to monitoring TB control, especially in the HIV context.

Nursing staff appear to have a greater index of suspicion for TB and were more diligent about excluding TB as reflected by the drop in the number of patients

who were delayed starting treatment for more than 30 days in 2004. Several factors could have contributed to this improvement:

- Growing experience and familiarity amongst all staff with the clinical presentation and diagnosis of TB in the co-infected patient.
- ARV training for all staff (including clerks and counsellors) emphasizing the link between HIV and TB, resulting in greater staff awareness of TB.
- Routine active screening for TB within the ARV programme.
- More doctor-time available for referral and advice in 2004.
- From 2004, every TB suspect required a folder, formalizing the process of the patient workup, including HIV testing, follow-up and a sense of continuity of care.
- Patient education improved in 2004 in the waiting room, the consulting room and in the counselling session. This may have improved patients' understanding of the TB workup and the importance of HIV testing which in turn made them more likely to return for follow-up appointments or if unwell.

Case Holding

Smear conversion rates reflect the adequacy of case holding and are said to predict the cure rate. That there was no significant difference between these rates in 2003 and 2004, (nor between the proportion of conversion results that were unavailable), indicates that despite the added burden of the ARV programme and the extra responsibility for TB patients, adherence levels were maintained.

Treatment outcomes

One possible reason for an increase in a TB programme death rate could be the neglect of TB defaulters due to an overburdened TB programme. Those patients who defaulted TB treatment and subsequently died would be reflected in either the treatment interruption or death rates. However there was no significant change in either of these indicators, once again showing the ability of the TB staff to maintain patients within the TB programme, despite the added burden of the ARV programme.

Although the success rate did not differ significantly between the two years, the cure rate dropped with an increase in the treatment completion rate. This drop in cure rate could be related to both patient and staff factors. The patient at discharge was either unable to produce sputum, or reluctant to do so, or the staff omitted to either request, follow-up or record the discharge sputa. For six months of 2004, there was no 'TB' doctor, which placed a greater burden on the staff to manage the TB patients. It is possible that this added burden led to inefficiencies in discharging TB patients. The validity of the suggestion that the commencement of co-infected patients on ARVs distracted the staff from the patients' TB care was not examined in the folder review. In spite of the TB nurse's reluctance to blame the DOTS supporters for the diligent follow-up of some TB patients it is possible that some patients omitted to hand in discharge sputa as they were not reminded to do so in time by their new DOTS supporter.

The drop in cure rate is likely to be due to a combination of the factors above. Of note is that the HBM cure rate for new smear positive cases in the first quarter of

2005 was 83.3% (20/24). This recovery could be due to greater integration of the ARV programme with the TB programme, it becoming more stream-lined, the staff became more accustomed to the ARV programme, and as a result of the increase in doctor sessions following the return of the 'TB' doctor.

HIV testing

HIV testing uptake among TB patients increased significantly even though offering HIV testing remained close to 100% during both years. It appears that staff attitudes towards HIV testing changed with the introduction of the ARV programme in the clinic, they became more persuasive offering HIV testing as the benefits of ARVs became tangible to staff. Other factors that could have influenced the increase in uptake of HIV testing were the change in workup strategy for TB suspects (who were in 2004 routinely sent to the counsellor for education about TB, STIs, HIV/ARVs and the TB/HIV link), the growing experience of counselling staff with patients on ARVs, expanded efforts by TB and HIV NGOs at patient education around HIV and ARVs in the clinic waiting room and within the community of Imizamo Yethu, and the obvious improvement in HIV patients who had recovered, often remarkably, on ARVs.

Had the HIV positivity rate changed over the two years, this might have explained some changes in TB outcome indicators. (For example time from presentation to commencing TB treatment might have improved if the co-infection rate had decreased, making recognising and diagnosing TB more straightforward.) However this indicator remained unchanged.

DOTS coverage

The introduction of the ARV programme seems to have prompted the need for additional DOTS support staff to provide care to TB patients in the community. Reasons for this were that the TB nurse required more assistance as the TB case load grew and co-infected patients required more attention, and staff beliefs that TB patients should be managed in the community where possible to diminish the risk of TB infection by patients attending the ARV clinic, and also that co-infected patients on ARVs improved quickly and could cope earlier with community DOTS.

IPT provision

The reluctance to implement IPT to prevent TB disease in those HIV patients who qualified for it was multi-factorial and seemed to be influenced by doubts about its effectiveness and concerns regarding the risk of the development of isoniazid resistance. These concerns in turn probably influenced the low priority the intervention received in HIV care in the clinic and hence resulted in poor patient adherence to the treatment course.

Health seeking behaviour of TB cases

Despite the fact that the clinic is the geographically closest health facility for the residents of Imizamo Yethu, almost half of all TB cases (49.4%) were not initially identified as suspects by the clinic, but were referred in for TB workup by other clinics, the local community health centre, general practitioners and the local secondary hospital. This proportion did not change significantly over the two years of the study.

The stigma associated with HIV may have prevented people from attending the clinic, as they might have been concerned about the possibility of being forced to test for HIV. There might also have been the concern that attendance at the clinic implied one's HIV positive status. Another reason for the high proportion of referrals in might be poor awareness in the community of TB. Patients with TB symptoms might not consider them to be due to TB, and hence do not attend the 'TB clinic' and instead seek help for 'flu' or 'bronchitis' elsewhere. A third consideration is that patients ignored their TB symptoms until they were incapacitated by them and required hospitalization.

8.4 TB and ARV programme integration

The staff identified those factors that they felt influenced the integration of ARV and TB programmes.

Adopting a comprehensive approach to the patient addresses all factors that influence the patient's health, rather than focusing on one disease. It encompasses regarding the patient in the context of a family or community, manifest for example in the STI treatment of sexual partners, concomitant care of patients' children, or the screening for TB in susceptible household TB contacts. The staff often knew their patient's names, families and social circumstances. It was this personalizing of the patients' illness experience that may have contributed to their commitment to providing a good quality service.

It is likely that this comprehensive approach to the patient both grew from and led to an integrated clinic approach to organising patient care. That the clinic already organised patient care in an integrated way made incorporating the new task of screening and working patients up for ARVs less complicated than it might have been in a task-oriented system. One of the first steps in integrating HIV and TB care in the clinic, combining the TB and HIV folders, must have helped to make patient care more comprehensive, streamlined and thorough by making explicit the workup for TB, and for co-infected patients, allowing continuity of care for their often considerable HIV-related issues.

The 'TB' doctor's enthusiasm about HIV helped to expand the nursing staff's approach to the continuum of HIV client care in the clinic even before the ARV programme was introduced. Those patients in 2003 who needed ARVs were assessed and managed for TB, HIV and ARVs by the same doctor and nurse, leading the 'TB' doctor to become the 'TB/HIV/ARV' doctor, and the patients' clinic visit thus could become a 'one-stop shop' of managing their TB, family planning requirements, STIs, HIV symptoms and ARVs.

Even though the ARV programme was introduced into a somewhat integrated setting, aspects of the clinic's TB programme did change in 2004 in order to accommodate it.

The principle change in the TB programme seemed to be the expansion of the TB nurse's role for the care of his co-infected patients. This occurred partly from necessity (more than 70% co-infection rate and the absence for six months of a

'TB' doctor) and partly out of his growing clinical confidence and sense of ownership of the integration of the TB programme with the ARV programme. His extra tasks included HIV and ARV education, assessment for ARVs and involvement in HIV and ongoing ARV care.

As the 'ARV' doctor helped with the TB clinic, this is likely to have made the TB nurse feel supported by the doctor and more willing to take expanded responsibility for his TB patients and become involved in his co-infected patients' ARV workup and adherence issues.

Thus with the growing patient load and especially once the 'TB' doctor left, the TB nurse taking on more of the routine TB caseload, referring to the doctor only those patients with complicated or smear negative TB (who were highly likely to be HIV infected and requiring ARVs, anyway), resulted in a more efficient division of labour than previously where the doctor saw most TB patients and almost all co-infected cases.

The TB nurse also encouraged 'ARV' staff to be involved in general clinic activities especially the TB programme. The benefits of this could have been to create an awareness among ARV staff about the logistics of TB workup and treatment (for example, sputum collection, the TB regimens and their differences in treatment, completing the TB card), to share the workload and to familiarize TB patients with ARV staff in preparation for commencing ARVs.

That active TB screening formed part of the ARV workup meant that TB programme staff (TB nurse and DOTS supporters) became accustomed to this new approach to the patient (as opposed to the passive approach of screening for TB only in patients who present with symptoms), and to further investigating the smear-negative patient. This principle of HIV care (that TB should be diagnosed or excluded prior to starting ARVs) reinforced the ARV training that all staff had received.

Doctors might take on or even be given the role of leaders and teachers often because nurses lack the clinical confidence and sense of trust from their managers and doctor colleagues to make clinical decisions and work independently. These nurses responded positively to being involved in clinical and managerial decisions by taking decisions that were traditionally made by a doctor. This led them to work independently with confidence and to take on a greater share of the clinical workload while feeling 'safe', trusted and supported in their clinical and managerial judgement.

The success of integrating ARV and TB care in the clinic relied in part on the passion and commitment of the staff to their patients and to making a success of the initiative. The staff felt that the clinical effect of ARVs and the hope they offered to patients helped to improve markedly the value of the service the clinic offered. Providing a good service to their patients helped to boost staff morale and motivated them to feel proud of themselves and the service they provided. This enthusiasm and commitment was fostered by the effective leadership of the

clinic manager who attempted to consult with staff in the decision making process of transforming the clinic.

It was unfortunate that the initiative to integrate TB and ARV care in the clinic was not reinforced by the middle management of the TB and ARV programmes (described above), which was largely vertical and did not prioritize or support integration of the two programmes.

9. Conclusions

During the first year of the introduction of the ARV programme to the clinic, most routinely measured TB programme outcomes remained unchanged. The drop in cure rate and concomitant rise in treatment rate may reflect inefficiencies in patient discharge due to the increase in patient load. Care should be taken to avoid neglecting the rigorous routine follow-up of the TB patient. Following the introduction of the ARV programme, there was less delay in identifying TB and placing patients on TB treatment. Thus it can be concluded that overall the TB programme performance was not compromised by the introduction of the ARV programme. Providing integrated TB and ARV care is feasible in a primary care

setting with a high HIV and TB prevalence. Such a service creates a 'one-stop-shop' visit for the co-infected patient and is satisfying for the staff in the facility.

Doctors can play an important role in integrating TB and ARV care by establishing a safe and supportive environment for independent clinical practice by nurse clinicians. This was most evident in the gradual expansion of the TB nurse's role to include the HIV and ARV care of his co-infected patients.

Coordinated middle management of the ARV and TB programmes might have strengthened and reinforced the integration process and would have streamlined the administrative responsibilities for the two programmes.

10. Recommendations

The principle recommendation arising from the findings in this study is to integrate TB and ARV services in primary care. This can be achieved in the following ways:

Train all clinic staff

All clinic staff will benefit from training in ARVs, HIV care and TB. For nurses, appropriate training should increase their confidence in managing the routine care and drug side-effects of the patient on ARVs. The training should also emphasize the TB/HIV link, and the priority of TB screening prior to commencing

ARVs. Doctors should be trained to integrate TB, HIV and ARV care, and to adopt the role of example and support to nurses. Community-based health-workers like DOTS supporters and ARV patient advocates should all receive ARV and TB training. This could result in heightened awareness amongst these workers of TB symptoms, the indications for starting ARVs, ARV side-effects and adherence issues among the co-infected patient, as well as tackling the stigma associated with both diseases and their treatment.

Encourage comprehensive patient care and an integrated clinic system

An ethos of a client-centred service and holistic patient care should be encouraged among staff. This will be encouraged within a clinic system that integrates patient care rather than adopting the functional approach to care which is task- rather than patient-oriented. Combining the patient's general or HIV folder with the TB folder will make feasible the 'one-stop shop' visit for the co-infected patient and also streamline their ARV and TB work-ups.

Integrate ARV and TB programme management

The management of the ARV and TB programme needs to have an integrated approach at clinic, district and programmatic levels. The ARV programme in the clinic should be managed by one of the clinic staff (rather than an NGO-employed 'ARV' doctor) in order to encourage ownership of the programme within the clinic. This ownership needs to be reinforced by the area TB/ HIV coordinator who should help supervise the management of the ARV programme in order to monitor and maintain the rigorous routine follow-up of TB cases to avoid a fall-off in cure rates.

'You must tune your TB programme well'

Adapting the TB programme to incorporate the ARV programme entails improving the education of both TB suspects and cases around TB, HIV and their treatment, expanding the TB nurse's role for HIV and ARV care in the co-infected patient, combining TB and HIV/ ARV folders, adopting an aggressive approach to TB screening, and involving ARV staff in the TB programme.

Use 'time from presentation to treatment' as an indicator of TB programme performance

TB programme performance indicators act to reflect TB control in a TB programme and to motivate staff to prioritize the standard of care delivered by the programme. Given that the revised version of the TB diagnostic algorithm for the province prioritizes diagnosing TB within four visits, 'time from presentation to treatment' could be a useful addition to the TB programme performance case findings indicators to highlight the imperative to diagnose TB promptly. Such an indicator could be calculated easily on commencing TB treatment if the TB folder and the general clinic folder recording all previous consultations in the clinic are combined.

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DIAGNOSING TUBERCULOSIS (TB)[1]

Initial visit

SUSPECTED NEW CASE (No previous TB or < 4 weeks previous treatment)

Sputum testing

Day 1: Spot specimen for AFBs
- Offer HIV testing if status is unknown.
- **If ill (temperature ≥ 38 °C, bedridden < 50% of the day in the last month) *or* HIV client:**
  Prescribe amoxicillin[3] 500mg three times a day for 5 days.

Day 2: One early morning sputum (at home) for AFBs and drop off at clinic.

Ask client to return to the clinic for results within 2 working days after day 2.

SUSPECTED RETREATMENT CASE (Previous TB treated for ≥ 4 weeks) *or* KNOWN MDR[2] CONTACT

Sputum testing

Day 1: Spot specimen for AFBs
- Offer HIV testing if status is unknown.
- **If ill (temperature ≥ 38 °C bedridden < 50% of the day in the last month) *or* HIV client:**
  Prescribe amoxicillin[3] 500mg three times a day for 5 days.

Day 2: One early morning sputum (at home) for AFBs and sputum **culture and sensitivity** and drop off at clinic.

Ask client to return to the clinic for results within 2 working days after day 2.

1st follow-up visit

SPUTUM 1: + SPUTUM 2: +

→ **Treat as TB**

- If a retreatment case or MDR contact, ensure culture and sensitivity have been requested. Review results at subsequent visits.
- Screen household contacts who are:
  - < 5 years
  - HIV infected

HIV TB client: see below

SPUTUM 1: + SPUTUM 2: -

- **HIV +** → **Treat as TB** (as above)
- **HIV -** or unknown → **WORKUP OF CLIENT**

SPUTUM 1: - SPUTUM 2: -

- **HIV +** or unknown → **WORKUP OF CLIENT**
- **HIV -** → Amoxicillin[3] 500mg three times a day for 5 days (if not yet given).
  - No or partial response → **WORKUP OF CLIENT**
  - Resolved → **Advise to return if symptoms recur.**

WORKUP OF CLIENT

- Send 3rd sputum for AFBs and culture.
- Client to return for smear result within 2 working days.
- Arrange CXR.
- Make a doctor appointment for exclusion of TB or other conditions.
- Re-assess markers of severe disease. (Go to page 13)
- If a retreatment case or MDR contact, ensure culture and sensitivity have been requested. Review results at subsequent visits.
- Prescribe amoxicillin[3] 500mg three times a day for 5 days if not yet given.
- If status not known, offer HIV test.

2nd follow-up visit

SPUTUM 3: + or culture positive

→ **Treat as TB**

- If a retreatment case or MDR contact, ensure culture and sensitivity testing have been requested at the first visit. Review results at subsequent visits.
- Cancel doctor follow-up visit and x-ray.
- Screen household contacts who are:
  - < 5 years
  - HIV infected

HIV TB client: see below

SPUTUM 3: -

3rd follow-up visit: Doctor

AND
- CXR evidence of pulmonary TB *and/or*
- Culture positive

→ **Treat as TB**

- Ensure culture and sensitivity testing have been requested at the first visit. Review results at subsequent visits.
- Screen household contacts who are:
  - < 5 years
  - HIV infected

HIV TB client: see below

AND
- No CXR evidence of pulmonary TB *and/or*
- Culture negative or pending

→ **Consider differential diagnosis:**

- Smear-negative TB
- Extra-pulmonary TB
- PCP
- Other respiratory causes such as asthma or COPD.

Reassess markers of severe disease.

Treatment of HIV TB client:

Routine Care
Weight
Exclude TB
Review CD4
Update Stage
STI screen
Condoms
Pap

- Review CD4 count or draw bloods if not already done. If:
  - < 50: refer urgently for ARV workup (same week).
  - 50-200: refer for ARV workup (next available appointment).
  - > 200: repeat and evaluate at end of TB treatment.
- Initiate co-trimoxazole 960 mg (2 single strength tablets) daily if not yet started.
- Commence pyridoxine 25mg daily.
- Reassess for markers of severe disease at each visit.

[1] National TB control programme guidelines are under review. The Western Cape Department of Health endorses this PALSA Plus TB algorithm. Revised guidelines are anticipated late 2006.
[2] MDR – multi-drug resistant TB. [3] *If penicillin allergic:* erythromycin 500mg orally four times a day for 5 days.

APPENDIX 1

Informed consent from to be completed prior to participation in Focus Group

I, Ruth Cornick, am currently studying a Masters in Public Health at University of Cape Town (UCT) and for my thesis I am examining the integration of the Antiretroviral programme into Hout Bay Main Road clinic, particularly the effect this has had on the outcomes and process of the TB Control Programme.

As a staff member at this clinic, you have been involved in this process. I would like to explore your views on the integration of the ARV programme into the clinic in a focus group of several of the other members of staff, including myself, for the purposes of this study. The group will be facilitated by an independent researcher and will be taped and later transcribed electronically. It will take approximately an hour and a half.

It is important that you know that your participation is voluntary and that you may refuse to participate or may choose to not answer questions or withdraw from the group at any time. I shall share the findings of the study with Local Authority and Provincial health departments, as well as UCT. The study may be published in the academic literature. However, your participation will be anonymous and I shall not reveal what any particular individual said.

Please take your time to read the above and consider your reply. If you are happy with the above, please sign below:
I understand the content of the above.

Sign: _____

I agree to what is written above and to participate in the focus group.

Sign: _____

Date: 09/03/06

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Date: 9/3/06

UNIVERSITY OF CAPE TOWN

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Research Ethics Committee
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21 November 2005

REC REF: 439/2005

Dr R Cornick
Public Health & Family Medicine
Infectious Disease Epidemiology

Dear Dr Cornick

PROJECT TITLE: EXAMINING TUBERCULOSIS CONTROL AFTER THE INTRODUCTION OF THE ANTIRETROVIRAL PROGRAMME

Thank you for submitting your study to the Research Ethics Committee for review.

It is a pleasure to inform you that the Ethics Committee has **formally approved** the above-mentioned study on the 11 November 2005.

Please quote the REC. REF in all your correspondence.

Yours sincerely

PROFESSOR T ZABOW
CHAIRPERSON, HSF HUMAN ETHICS

lemjedi