

Report on the Integration of TB and HIV services in Site B Khayelitsha



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Summary

This report presents the findings after one year of integration of TB and HIV services at Site B “Ubuntu” Clinic in Khayelitsha. The rationale for the project is explored, together with the progress that has been made to date.

The rapid increase in patient number for both TB and HIV services in Khayelitsha and Site B is presented with 1 in 4 sexually active adults assumed to be HIV-infected and a passive TB case-finding rate exceeding 1,000/100,000.

The case for integration rests on the potential for:

- improved clinical care including VCT-uptake, and improved care pathways for HIV-infected patients with smear-negative TB
- a friendlier service for patients through a “one-stop” serve
- improved efficiency through a uniform approach to staff management and patient administration and monitoring
- better coherency in a uniform patient-centred approach to adherence, hopefully leading to a more manageable service and improved patient outcomes

Significant progress has been made in unifying administrative and clinical systems, with the single approach to adherence promotion in its infancy. Baseline information on VCT uptake, and TB cure rates has been collected.

Important challenges relate to the urgent need for a larger, more streamlined clinic building, and improved management capacity. Most importantly however is the prospect of ever increasing patient numbers, and the need for district-level plans to cope with the anticipated increases in both HIV and TB patient numbers.



Above and on cover. Patients in Ubuntu waiting area
Picture by Mariella Furrer

Introduction

The World Health Organization (WHO) estimates that tuberculosis (TB) kills approximately 2 million people each year and that between 2002 and 2020, 1,000 million people will be newly infected; over 150 million people will get active TB, and 36 million will die of TB (1). In 2002, there were an estimated 8.8 million new TB cases, of which 3.9 million were sputum smear-positive. The incidence of TB infection is growing by 1.1 % per year, and TB disease by 2.4% per year (2). South Africa is ranked ninth among the 22 highest burden countries accounting for 80% of TB worldwide. Within South Africa, the Western Cape Province has the highest notification rate in the country; and Khayelitsha the highest notification rate in the Province

Table 1. Tuberculosis notification rates in 2002

South Africa	481/100,000
Western Province	917/100,000
Cape Metropole	638/100,000
Khayelitsha	1,283/100,000

TB has been endemic for many decades in South Africa, and particularly in the Western Cape. Little is known as to why the incidence of tuberculosis in the Western Cape is amongst the highest in the world.

Pilheu (3) has however previously identified a number of factors that have contributed to the large TB epidemic. These include:

- Population migration, including worker migration from the rural to the urban areas.
- Incorrect treatment and diagnosis by health workers.
- The HIV epidemic.

The TB/HIV co-epidemic

In areas of high HIV-prevalence, the HIV epidemic undoubtedly contributes to the increased TB burden. Untreated HIV infection leads to progressive immune deficiency and increased susceptibility to infections such as tuberculosis. Research has shown that even in areas where there is a good TB control programme, when the prevalence of HIV is greater than 20%, the annual percentage increase in TB will be high at over 10% (4).

HIV is the strongest factor capable of promoting progression of mycobacterium tuberculosis (MTB) infection to active tuberculosis (5;6) both in people with recently acquired (exogenous re-infection) and with latent MTB infections (endogenous reactivation) (7). The lifetime risk for active TB in an HIV-negative person is 5 to 10% while the *annual* risk in HIV-infected persons is 5 to 15% (8)

TB in HIV disease is associated with decreased survival. TB specific mortality is four-fold higher among HIV-infected patients than amongst the uninfected (17.8 and 4.4 deaths per 100 per year for HIV-infected and uninfected patients respectively) (9). In Southern Africa, tuberculosis is the leading cause of mortality in HIV infected persons.

TB control efforts

For many years there has been a strong vertical TB programme in South Africa. The government adopted the resolutions of the March 2000 Amsterdam "Stop TB" declaration and a strategic plan for 2001-2005 was put in place. This covered diagnosis and treatment, multi-drug resistance, sputum collection, prophylaxis, side effects of drugs, record keeping, notification and the protection of health workers. Despite strong investment from the government in ongoing-support and training, and DOTS implementation, the cure rate for detected smear positive cases had not exceeded 65% by 2002 in many parts of South Africa, including Khayelitsha.

There is increasing discussion on the merits of explicitly linking control efforts directed at both epidemics. The WHO has produced guidelines for collaboration between TB and HIV services or activities, stating that: (7)

“Tackling tuberculosis should include tackling HIV as the most potent force driving the tuberculosis epidemic; tackling HIV should include tackling tuberculosis as a leading killer of PLWH”.

Clinical issues specific to TB diagnosis and management in HIV-infected individuals

The South African guidelines on TB management emphasise the importance of direct microscopy of sputum smears for the diagnosis of TB. Sputum culture is not recommended as an initial investigation tool, but is reserved for people who have previously been treated for TB for more than four weeks, for patients with abnormal chest X-ray and negative sputum smears, or for those who continue to have positive sputum smears despite adequate treatment (10).

The sensitivity and specificity of sputum microscopy compared to culture in the context of HIV has been explored in a number of studies. Some have concluded that there is no difference in the sputum smear sensitivity among HIV positive and negative patients(11), while others have noted that sensitivities are lower in the HIV positive group (5;12)

Setting the stage for exploring the integration of TB and HIV services

With the extremely high co-infection rates, the progressive failure of traditional tuberculosis control efforts in the era of HIV, and the emerging clinical challenges as a result of co-infection with TB and HIV, there is a strong rationale for viewing the control efforts directed at both epidemics through a single lens.

The context – TB and HIV in Khayelitsha

Khayelitsha sub-district is one of the eleven sub-districts comprising the Metropole District of the Western Cape. It is a poor peri-urban area with a population estimated at 400 000. There is high unemployment rate (greater than 40%) in the sub-district with the associated social problems this brings.



In February 2000, Médecins Sans Frontières (MSF) and the Health Department of the Provincial Government of the Western Cape initiated a comprehensive service for persons infected with HIV in Khayelitsha. In May 2001, this site became the first public sector service to provide antiretroviral therapy (ART) in South Africa. It was soon realised that a comprehensive TB/HIV service was required due to the large numbers of co-infected patients. This led to the establishment of an integrated TB/HIV service at one of the three clinics, *Ubuntu clinic*.

Prior to the integration, the two services functioned independently of each other, apart from the referral of persons between the services.

TB and HIV as two concomitant epidemics in Khayelitsha

The TB epidemic

Khayelitsha had the highest TB incidence (1,122/100,000) and the second highest HIV prevalence (25%) in the Metropole District in 2003 (13). Khayelitsha accounted for 20% of the new TB cases in the Metropole in 2003. Table 2 and Figure 1 present TB case-finding for Khayelitsha from 2001 to 2003.

	2001	2002	2003
Total Cases	3,559	3,925	4,566
Incidence Total TB per 100,000	1,031	1,283	1,122
Pulmonary TB (including primary)	2,812 (79.0%)	2,999 (76.4%)	3,407 (74.6%)
Extra-pulmonary TB	747 (21.0%)	926 (23.6%)	1,159 (25.4%)

* Source: Cape Town TB Control Report 1997 – 2003 (13)

Extra-pulmonary TB has increased in Khayelitsha from 490 cases in 2000 to over 1,100 cases in 2003, with much of this increase being attributed to the HIV epidemic (13).

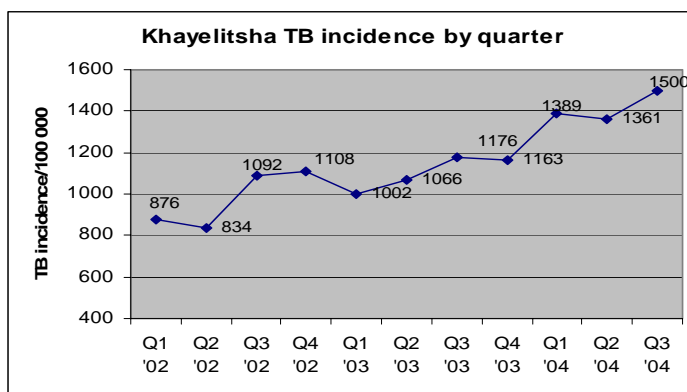


Figure 1. TB Caseload in Khayelitsha 2000 - 2004

Cure rates have remained between 65 and 70 % over the last 7 years despite the yearly increase in registered TB cases (Table 3), and the increase in extra-pulmonary TB (Figure 2).

Table 3. Treatment outcomes for new smear positive cases 2001 to 2003)*

Year	2001		2002		2003**	
	District	Site B Clinic	District	Site B Clinic	District	Site B Clinic
Case load	2750	N/A	3800	1278	4550	1643
Cure rate	66.6%	68.4%	67.8%	73.6%	65.4%	65.0%
Completion Rate	79.7%	80%	85.2%	85.2%	75.8%	76.0%
Interrupter Rate	15.0%	16.0%	11.0%	11.6%	9.8%	15.0%
Death rate	4.3%	3.3%	3.4%	1.6%	3.7%	3.0%

* Source: Cape Town TB Control Report (13)

** Outcomes only concern patients registered in the first two quarters of 2003

Multi-drug resistant (MDR) TB rates remain low at 1% of new cases and 4% of re-treatment cases. The proportion of total cases that are re-treatment cases has remained stable since 1997, at about one third of all reported TB cases.

Due to the high workload many two-month or end of treatment sputa are not sent to the laboratory for smear diagnosis. There is limited defaulter or contact tracing. Adult isoniazid (INH) prophylaxis is rarely given in the Khayelitsha district.

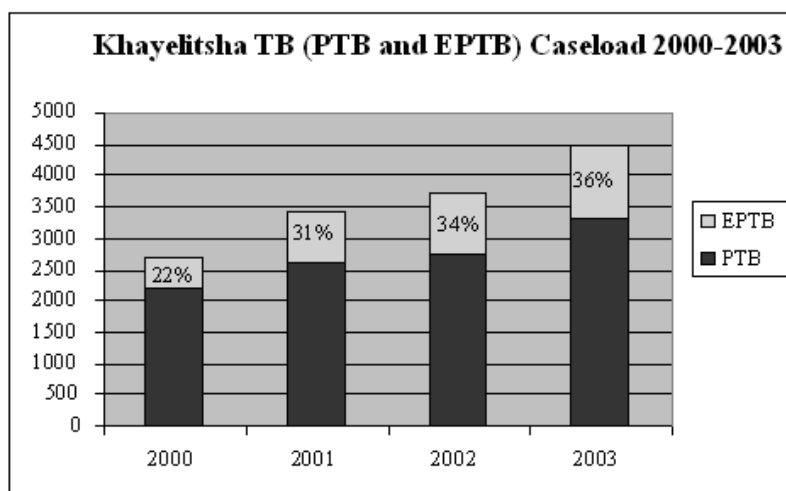


Figure 2. TB caseload from 2000 to 2003

The HIV epidemic

It is estimated that approximately 52,000 adults in Khayelitsha are infected with HIV (14), with higher rates amongst younger age groups and women. As of 2001, one fourth of all women presenting for antenatal care in Khayelitsha are HIV-infected (Table 4 and Figure 3), with an acceptance rate for HIV testing greater than 95% (15).

Table 4. HIV prevalence in South Africa, the Western Cape Province and Khayelitsha

Year	National	Western Cape	Khayelitsha
2000	24.5% (23.4-25.6%)	8.7% (6.0-11.4%)	19.3% (18.0-20.6%)
2001	24.8% (23.6-26.1%)	8.6% (5.6-11.6%)	23.2% (21.1-25.3%)
2002	26.5% (25.5-27.6%)	12.4% (8.8-15.9)	24.7% (22.6-26.8%)

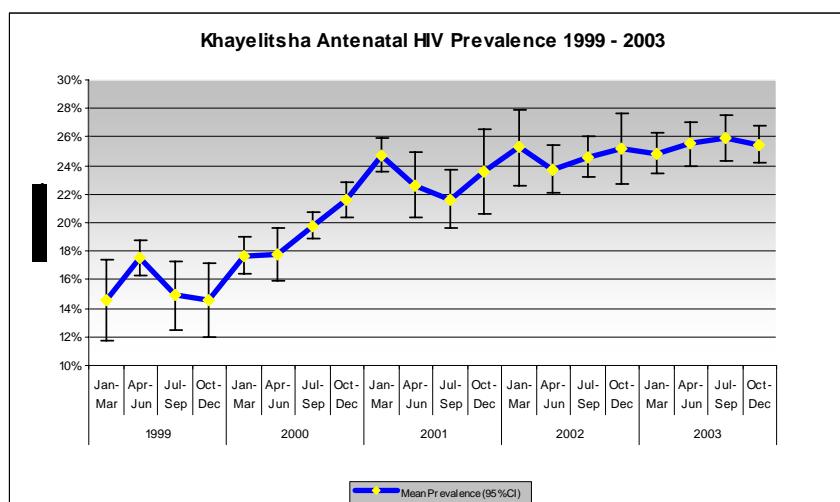


Figure 3. Antenatal HIV prevalence in the two Khayelitsha antenatal care centres 1999-2003

By the end of 2003, each of the three HIV clinics in Khayelitsha had between 1,500 and 2,000 regular patients and between 250 and 500 people on ART (Table 5).

Table 5. HIV and ARV consultations 2001 – 2003

	2001		2002		2003	
	All	Site B	All	Site B	All	Site B
Total New Cases	1,616	578	1698	531	1802	743
Total Follow-up visits	9,877	3499	16858	5200	21194	7754
Number started on ART	94	33	243	67	433	184

When the HIV clinics were opened, the largest proportion of clients was referred from the Prevention of Mother-to-child transmission (PMTCT) programme. Very quickly, referrals from other sources became more important, particularly the TB clinics and the community health centres (CHC's) (Figure 4). In addition it was seen that those referred from TB clinics or CHC's were the sickest with the lowest CD4 cell counts.

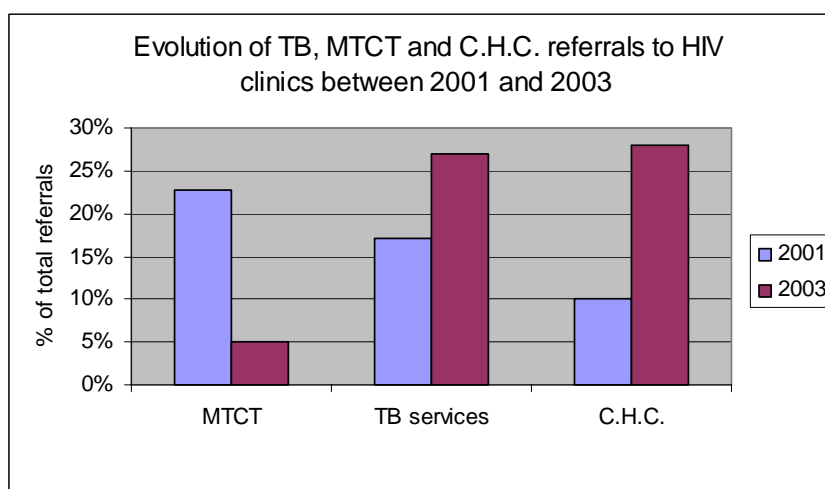


Figure 4. Origin of referral to HIV clinics 2001 and 2003

TB is one of the most frequent opportunistic infections and the leading cause of death amongst HIV patients. In the cohort followed in the Khayelitsha HIV clinics, stage III and IV patients were shown to have an annual risk of developing TB disease of 36% (36,000 per 100,000) (16).

The above overview of TB and HIV in Khayelitsha demonstrates a setting of extremely high co-morbidity, with HIV contributing to a dramatic increase in TB case-finding. There is strong evidence of increased case-finding amongst individuals known to be HIV-positive. The clinical spectrum of TB is changing as a result, with increased extra-pulmonary TB, and sputum-negative pulmonary presentations. The patient load on the TB clinics as evidenced in Site B (Ubuntu clinic) has risen dramatically in the past few years, as has the patient load in the HIV clinics. This provides an ideal context in which to explore the framing of the services as an integrated service-delivery platform.

Objectives of the integration at Ubuntu clinic

At Ubuntu clinic, the HIV and TB services have been integrated with the overall aim of improving efficiency of service delivery. The services were integrated with the following specific objectives are to:

- 1) Increase VCT amongst TB clients as an entry point to HIV care
- 2) Diagnose TB disease earlier in HIV-infected persons
- 3) Facilitate an integrated approach to the management of co-infected persons, creating a “one stop” service
- 4) Increase service efficiency through more rational staff deployment and increased competence in the management of co-infected patients
- 5) Improve cure rates for both co-infected and TB patients through a more patient-centred approach to adherence
- 6) Benefit from the experience of the TB programme to standardise the approach and the monitoring of ARV patients

Progress in pursuit of the integration objectives

1) Increase VCT amongst TB clients as an entry point to HIV care

The HIV status of 984 TB patients was assessed by reviewing patient folders from January to 30 September 2003. This accounted for 85% of all patients in the TB register over this period. At entry to the clinic, 214 (22%) patients knew their HIV status, of which 91% were HIV-infected. Forty seven percent of those not knowing their status were counselled and 87% accepted testing. By the end of their TB treatment, 54% of patients knew their status of which 64% were HIV-infected.

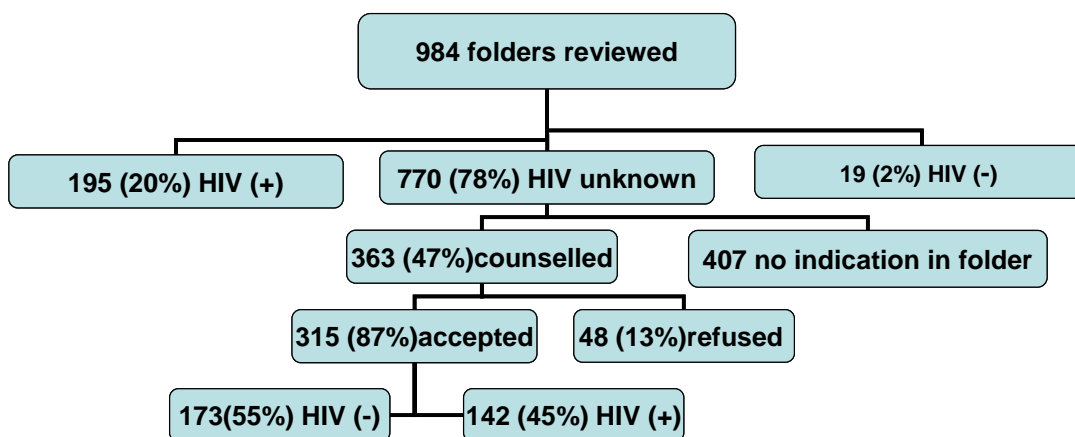


Figure 5. VCT status at initiation of TB treatment (folder review)

There are still many missed opportunities for VCT even within this integrated clinic.

2) Diagnose TB earlier in co-infected persons:

Prior to the integration, the emphasis was on diagnosing and treating smear-positive pulmonary TB. Patients with negative smears were repeatedly referred between the HIV and TB services, resulting in delay in treatment, loss to the services and even death. There was little attempt to identify extra-pulmonary TB in the TB service. A large proportion of the extra-pulmonary TB was diagnosed in the HIV service, rather than in the TB service. An analysis of new or recurring TB episodes of patients followed regularly in the three HIV clinics revealed that of 109 consecutive patients with TB, 53 (49%) had negative sputum

smears and positive sputum cultures for TB (smear-negative culture-positive TB). Only 18 of the TB episodes were identified by smears. This gives a smear sensitivity of 16% and a culture sensitivity of 63%.

Table 6. TB diagnosis of HIV patients (folder review)

	Smear (-ve)	Smear (+ve)	Total
Culture (+ve)	53	16	69
Culture (-ve)	38	2	40
	91	18	109

The poor sensitivity of smears is due to the advanced stages of HIV disease amongst people attending the HIV clinics. As HIV disease progresses the types of TB diversify (17), and diagnosis by microscopy becomes progressively less sensitive.

A new algorithm has been developed for the diagnosis of smear negative TB and has been implemented following discussion with specialists from the referral hospital (GF Jooste) (see annex 1). Operational research to validate the algorithm has almost been completed.

3) Facilitate an integrated approach to the management of co-infected persons, creating a “one stop” service

Prior to the integration co-infected patients attended two separate services with little or no exchange of information between caregivers. The clinic now has a common reception area and folders have both the TB and HIV records. Dually infected patients are now treated for both conditions simultaneously. By providing a “one stop” service patients attend one rather than two consultations, which reduces travelling and waiting time.

One of the difficulties has been the integration of the two monitoring systems, which were initially based on different philosophies. As of April 2004, a data capturer enters all HIV visits into a database on the day of the consultation. The information entered includes the date of next visit, allowing daily tracking of patients who default their scheduled visits. This system was extended to include all TB patients starting TB treatment. The clinician (nurse or doctor) who initiates the TB treatment schedules dates for consultation at the end of the initiation phase and prior to discharge. The dates for these visits are entered into the database at the first visit, allowing tracking of people who default either of these appointments. The electronic TB register is being linked to the HIV database, which will allow identification of patients who do not come for their scheduled appointments or to collect their medication. For daily or weekly DOTS, a bar code scanner is being installed which will allow for rapid and easy tracking of patients coming for their medication.

4) Increase service efficiency through more rational staff deployment and increased competence in the management of co-infected patients

The TB staff were trained in HIV care including the staging of patients and the screening for and management of opportunistic infections. Some of the TB staff has also had training on antiretroviral treatment. Many of the HIV staff have had training on TB management. Some had worked in TB services and therefore only required in-service training. All staff can now attend to TB or HIV or dually infected patients according to their level of training. Weekly clinic management meetings are attended by all staff.

The nurses see the majority of patients, and only complicated cases are referred to the doctor. This allows time for better care for those who are sick and allows the doctors to spend time with the nurses for on-site training.

The integration process has brought together staff from five different organisations: The Cape Town City Health Services, the provincial Department of Health, MSF, and non-governmental organisation (Lifeline and Famsa). This initially caused problems in overall clinic and staff

management with regard to leave co-ordination, ordering of supplies and budgeting. In December 2003, the staff decided to elect one person on a 3-month rotational basis to be the clinic manager. This person becomes responsible for all staff management issues, as well as any other problems pertaining to management of the clinic. This system is working well and has resulted in cohesiveness and team building. Some of the nurses have rotated in the different posts of the clinic (DOTS, clinical consultations) gaining experience, varying their job and creating cohesion in the clinic.

5) Improved cure rates for both co-infected and TB patients through a more patient-centred approach to adherence

Although the workload has increased substantially at the TB service (as evidenced by the increasing caseload) there has not been a similar increase in the staff complement. It is not possible to directly observe TB therapy as at any one time there are over 1,000 persons on treatment, who would need to be seen daily if therapy was to be observed in all cases. Directly observed therapy for all patients means that there is no time for other activities such as identifying defaulters, ensuring two-month and end of treatment sputa are not missed, examining patients who are sick and offering VCT for HIV at every opportunity.

Approaches to adherence to TB medication have been studied extensively. In a South African randomized controlled trial of self-supervised and directly observed treatment of tuberculosis, self-supervision achieved equivalent outcomes to direct observation at lower cost (18). In addition, self-supervision achieved better outcomes for re-treatment patients. The importance of a good patient/provider relationship that emphasises patients understanding and responsibility rather than authoritarian surveillance should not be underestimated. A randomized trial in Pakistan (19) comparing outcomes between patients followed by health-workers, family-members and self-administered treatment found no difference in outcomes. None of the 3 strategies was superior to the other and DOTS did not give any additional improvement to treatment outcomes.

Experience with adherence in HIV treatment is beginning to suggest advantages to patient-centred approaches, notwithstanding that HIV cohorts are to date generally smaller than TB cohorts. Between May 2001 and December 2002, 287 treatment-naïve patients began ART in Khayelitsha. At the end of July 2003, only one patient from the cohort was lost to follow-up, 3 patients had moved to a different province, 6 patients were still attending the service but had stopped ART while 3 patients had stopped attending the services altogether but were known to be in good health. The probability of achieving viral load suppression increased rapidly in the first year on ART, with cumulatively 93.0% [95% CI 88.9 – 95.9] of patients achieving this in the first year(20) .

The experience from the promotion of ARV adherence and support is being adapted for TB adherence and support. TB support groups will be made mandatory at treatment initiation, and educational materials will be provided to patients starting treatment. Patients will be asked to identify drugs they are taking as well as to know the duration of treatment and when sputa should be obtained. New patients who have not previously defaulted or interrupted treatment and who do not have the options of workplace DOTS will be offered the possibility of weekly or monthly supplies of drugs once they have understood the principles of their treatment. They will be asked to pack their pills into pillboxes in order to ascertain their understanding of their dosing and provide an additional adherence aid.

6) Benefit from the experience of the TB programme to standardise the approach and the monitoring of ARV patients

The TB programme has accumulated experience in dealing with large patient numbers, and has standardised monitoring and reporting. There are potentially many lessons to be learned from the experience of the TB programme with respect to monitoring. A rational and universal monitoring system could assist scaling up of ART in South Africa. This could comprise structured clinical records, patient-retained cards with selected clinical and administrative information, and facility-based tools such as registers and standard reports. ART delivery in the public sector is new and needs to define best practices. TB registers and quarterly reporting have been adapted to the ART programme in Khayelitsha and in the Western Cape province (21), and can either be paper-based or electronic.

The TB programme has started to rely on the laboratory system as a secondary source of management information through the capturing of limited clinical information in the laboratory database. The same approach is being explored for HIV laboratory specimens, and attempts are being made to increase efficiency through electronic access to all results.



Structured clinical records for both TB and HIV

Progress to date

The present HIV and TB services in Khayelitsha are currently struggling to respond to the needs of the dual HIV and TB epidemics. As presented above, there is a powerful rationale for the integration of these services with potential efficiency and quality-of-care gains.

The integration project at Ubuntu clinic is at an early stage, but has nevertheless demonstrated the potential for the functional integration of many systems, both administrative and clinical. Quantifying benefits from this functional integration is extremely difficult in the context of a rapidly changing environment and increasing patient numbers (the TB patient-load has increased by 50% year-on-year each year over the last three years at Ubuntu clinic without concomitant staff increases). Clerks and clinicians are however reflecting positively on many areas including:

- greatly simplified care pathways and algorithms for HIV-infected patients with smear-negative TB episodes
- a single and unified filing and patient-administration system
- coherency in the approach to monitoring interventions for both conditions
- the prospect of a single approach to treatment readiness, adherence support and medicines dispensing for both conditions

The last area, of unifying adherence support and dispensing approaches and practices, is the newest and least developed area at present, whilst possibly being the most dramatic shift from the current service delivery paradigm in the TB program.

The Ubuntu integrated clinic is possibly a victim of its own success. At present there are more than 300 new TB patients and 100 new HIV patients presenting per month, case loads much higher than in any other of the HIV or TB clinics in the province. The patient-numbers at this clinic are out of proportion to the drainage area the clinic serves, with the one-stop service resulting in patients from other parts of Khayelitsha seeking care at the clinic.

Not surprisingly, ergonomic and space issues have plagued the combined clinic, with physical structural issues the most common impediment or frustration cited by staff.

Remaining challenges

Adaptations to the model of service delivery are insufficient to cope with the rapidly increasing numbers of patients, both HIV-infected and with active TB. For Ubuntu clinic to succeed in improving outcomes, some of the anticipated increased service load in Khayelitsha will need to be absorbed by new facilities, or by increased capacity at other existing facilities. The changes at Ubuntu require parallel district-level planning to cope with the evolving epidemics.

Approaches to TB and HIV management are steeped in different service philosophies; nurse-based, directly-observed therapy and sputum-result driven clinical protocols in the TB programme, while the current HIV programme has a greater reliance on doctors, and has a patient-centred approach to adherence promotion and clinical care. Integrating disparate service approaches requires strong service management and supervision, functions that have been under-capacitated in primary care settings. This management has to be common across the entire integrated service if true integration is to be achieved.

A new clinic building for Ubuntu, adapted both in size and lay-out to the integrated service, is an absolute priority. In addition, the goodwill demonstrated by staff from various organisations in working together should ideally be followed by management structures that underpin and support the revised staffing arrangements and systems.

The new smear-negative algorithm needs broader endorsement in order for it to gain wider acceptance. This endorsement is necessary to ensure that nurse-clinicians are fully empowered to take advantage of the algorithm, as a nurse-predominant service remains the reality for both HIV and TB service delivery. New rapid diagnostic methods if validated could have a huge impact on both clinically and in terms of improving clinic efficiency and functioning, and should be closely watched.

The integration process at Ubuntu clinic is a response to a specific service challenge. One of the most important lessons from Khayelitsha however is the importance of context-specific flexibility – what has been appropriate for Ubuntu clinic might not be appropriate in other settings.

Translating the observed changes in the functioning of the facility into changes in or the maintenance of treatment outcomes remains a huge challenge for a variety of reasons alluded to above. Demonstrating this remains a key deliverable for future reporting on the integration process.



Tuberculosis consultation, Ubuntu clinic, 2003
Picture by Mariella Furrer

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