

Khayelitsha

2001-2011



ACTIVITY REPORT 10 YEARS OF HIV/ TB CARE AT PRIMARY HEALTH CARE LEVEL.



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10 YEARS OF HIV/TB CARE AT PRIMARY HEALTH CARE LEVEL

Médecins Sans Frontières

Western Cape Province Department of Health

City of Cape Town Department of Health

University of Cape Town, Centre for Infectious Disease Epidemiology and Research

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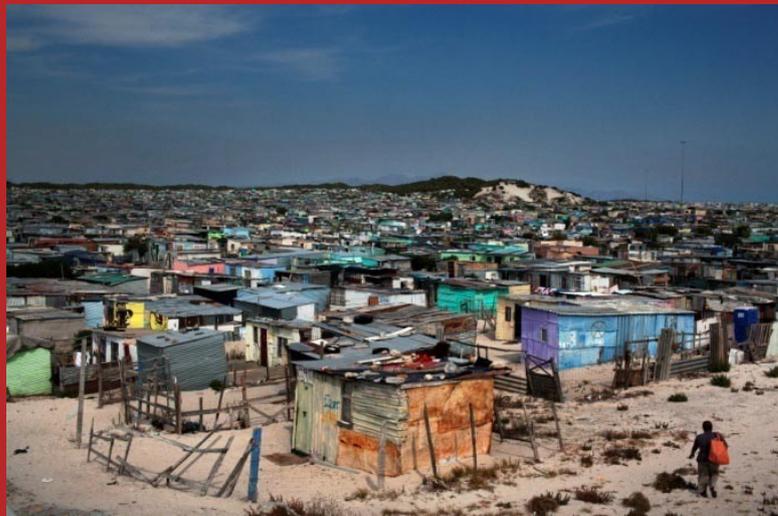
Most importantly, thanks are due to the many people with TB and living with HIV who have motivated their friends and family members to seek care and treatment early, and who continue to provide a positive role model for thousands of South Africans.

Special thanks to TAC for the use of their photos.

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INTRODUCTION



The Khayelitsha programme was the first in South Africa to provide antiretroviral therapy (ART) at primary care level in the public sector. It is also one of two pilot projects in the country to provide decentralized care for drug-resistant tuberculosis (DR-TB). This report highlights what has been achieved collectively by several service providers (Province of Western Cape, City of Cape Town, NGO and Community Based organizations) and describes the key clinical programme and policy changes that have supported universal coverage for HIV and TB care over the last 10 years. The report demonstrates that it is possible to achieve most targets set forth in the National Strategic Plan (NSP) for HIV/Aids and Sexually Transmitted Infections (STIs); including achieving “universal coverage” of ART needs, by 2011. Funding for ARV’s helped to strengthen the overall health system, and the implementation of a large-scale TB/HIV programme resulted in decreased illness and death among people living with HIV as well as a likely reduction in the number of new HIV infections. Although much remains to be done, this report shows that is possible to turn back the tide of HIV and TB.

EXECUTIVE SUMMARY

PREVENTING NEW INFECTIONS

Decreasing rates of HIV among pregnant women

Antenatal prevalence in Khayelitsha increased from 15% in 1999 to 31% in 2006. It then stabilized before decreasing to 26% in 2010. With more pregnant women receiving ART, one would expect an increase in prevalence if new HIV infections remained stable. It is likely that the rate of new HIV infections has started to decline in Khayelitsha although alternative explanations, such as migration, cannot be ruled out. A number of interventions have been implemented to achieve this aim, including: community-wide condom distribution, large-scale HCT, ongoing awareness campaigns, and high coverage of ART which reduces transmission by decreasing viral load in individuals and in the community.

Massive increase in HIV testing and counselling (HCT)

The number of people tested for HIV every year in Khayelitsha increased from 16 000 in 2003 to more than 55 000 in 2010. During the same period, positive rates among people tested decreased from 32% to 20%, indicating that HIV testing has become more acceptable and that more people test before they become unwell.

Large-scale community condom distribution led to a drastic decrease in sexually transmitted infections

Between 2004 and 2009, condom distribution increased from less than

200 000 to more than one million a month. During the same period, the number of adults treated for sexually transmitted infections (STI) decreased from 2 000 to 500 per month.

Male walk-in clinic successfully testing and treating men

Since the opening of the male walk-in clinic in 2007, the number of men treated for STIs increased from 843 to 3 547 in 2010. In the same year, 27% of all men tested for HIV in Khayelitsha were tested in one single clinic located next to a taxi rank and dedicated to males.

Improved diagnosis and treatment of tuberculosis (TB)

TB case-finding increased from 900/100 000 in the first quarter of 2002 to 1 500/100 000 in 2008 and then remained stable until 2010, with an increase in smear-negative and decrease in smear-positive TB cases. During the same period, cure rates initially decreased to 44% by mid 2005 and then increased to 81% in the second quarter of 2010. Decentralization of integrated TB/HIV services to every clinic along with increased diagnosis of smear-negative TB with improved TB diagnostic methods (smear-negative algorithms, systematic TB culture, line-probe assay, and piloting of the GeneXpert in Ubuntu Clinic) as well as systematic screening of all HIV patients for TB, has led to an increase in TB diagnosis. Despite the increased case load, improved case detection has resulted in better treatment outcomes, such a higher cure rates for TB.

DECREASING DEATH RATES

Reduction in mortality of adults on ART

The death rate of adults at three months on ART decreased from 10% in 2002 to 2.2% in 2010. This is the consequence of earlier initiation of ART. It is possible that improved detection of TB pre-ART has also contributed to this reduction.

The number of patients started on ART increased from 100 at the end of 2001 to 20 000 in May 2011. Enrolment onto treatment went up from less than 10 a month in 2001 to 465 a month in 2010. Active decentralization of nurse based treatment initiation in every single clinic in Khayelitsha was the main factor for this achievement.

Reduction in infant deaths

Infant mortality has decreased from 42/1 000 live births in 2003 to 35/1 000 in 2009 following the introduction of a prevention of mother to child HIV transmission programme by the Provincial Government of the Western Cape in 1999, demonstrating a clear impact of this intervention at the population level. HIV testing of pregnant woman is above 99% and most of these women choose the option of free exclusive formula feeding. In a pilot project in Site B, ART has been integrated into the midwife obstetric unit in order to improve access for pregnant women. As a consequence of all these strategies, **transmission of HIV from mother to child decreased from 12% in 2002 to 2.5% in 2010.**

Fewer children need to start ART

The number of children started on ART each year increased from 4 in 2001 to 145 in 2008, then decreased to 115 in 2010. This decrease is most likely due to the success of the PMTCT programme.

Improved survival in DR-TB patients

Mortality related to drug-resistant TB has decreased since the programme started in

2007. Of those diagnosed with DR-TB in 2008, 62% were still alive 18 months after diagnosis. This compares favourably with reports from elsewhere in South Africa given that 76% of DR-TB patients are co-infected with HIV.

DECREASING ILLNESS

Patients start ART earlier every year.

The median CD4 count at initiation of ART rose from 43 cells/ μ l in 2001 to 162 cells/ μ l in 2010. In parallel, 50% of patients starting ART in 2001 were classified as WHO stage 4 and only 16% as stage 1 or 2. In 2010, almost 50% were WHO stage 1 or 2, and only 20% were stage 4. This is the result of increasing access to ART over time, which has been achieved by decentralizing ART to every health facility in Khayelitsha, integrating TB and HIV care, nurse-based care and large scale HIV counselling and testing. In addition, ongoing information campaigns by the Treatment Action Campaign, these interventions have led to a reduction of stigma as well as patients seeking better treatment. Despite significant policy change, South Africa still has to adopt full WHO guidelines which recommend earlier ART initiation for all PLWHIV with a CD4 count of ≤ 350 cells/ μ L, regardless of the clinical stage.

Decreasing TB rates in patients on ART and shorter time to ART for TB patients with 'one-stop shop' TB/HIV integration

Fifty per cent of patients starting ART at Ubuntu Clinic have TB and 70% of TB patients have HIV. To respond to this dual epidemic, integration of TB and HIV services was first piloted in Ubuntu and Town 2 clinics, and later rolled out to all clinics in Khayelitsha. In a 'one-stop shop' fully TB/HIV integrated clinic, co-infected patients have one folder and see the same health staff in the same clinic for both diseases. **TB/HIV integration has resulted in dramatic reductions in the time to start ART in TB patients (from 42 to 26 days in one clinic).** In 2008, 99% of TB patients in

integrated clinics were offered HIV counselling and 95% were tested for HIV. In addition, 99% of patients tested HIV positive had a CD4 count result recorded and > 95% were started on cotrimoxazole preventive therapy.

Earlier initiation and decentralization of treatment for patients with drug-resistant tuberculosis

Diagnosis and treatment of drug-resistant tuberculosis at primary care level has resulted in a **decrease of the median time to initiation of treatment from 71 days in 2007 to 33 days in 2010**. Prior to 2007, all patients had to be admitted to a TB hospital to receive their treatment. In **2010, 71% of patients were managed at their local clinic and only 14% were admitted to hospital to initiate treatment**.

Gradual evolution towards improved first line regimen

Documentation of high rates of adverse events with D4T in Khayelitsha contributed to the evidence base that led to the WHO recommendations to reduce the dosage and later to replace D4T with a less toxic alternative. Tenofovir was introduced initially in 2005 for patients with D4T toxicity and then in 2010 was incorporated as part of the new national first line regimen.

CHALLENGES

Retention in care

While mortality decreased steadily from 2001 to 2010, losses to follow-up initially increased when the numbers of patients on treatment increased and services were showing signs of saturation. In Ubuntu Clinic, loss to follow-up rates started to decrease again after 2008, suggesting successful adaptation of the clinic in managing high numbers of patients on treatment. This adaptation included the introduction of adherence clubs and nurse-led management of the majority of patients. At five years on treatment, 65% of patients were still in care, highlighting the need for innovative strategies to improve retention in care.

Pre-ART loss to follow-up remains a major challenge.

Youth

Pre-ART loss to follow-up is especially high among the youth. In 2010, up to 70% of eligible young people in the Youth Clinics defaulted care before starting ART; 60% of those defaulted immediately after HIV testing. This trend improved during 2010, possibly as a result of increased support interventions.

Treatment failure

At five years on ART, an estimated 14% of patients had virological failure and 12% were on 2nd line ART. Mortality and treatment failure is high in patients on 2nd line. Out of 32 patients failing 2nd line ART, 60% had chronic poor adherence, 30% returned to undetectable viral loads after enhanced adherence support and four had to be switched to a 3rd line regimen. Third line drugs such as darunavir, raltegravir and tipranavir are currently not available in the public sector due to their high cost (up to 15 times the price of first line drugs).

CHALLENGES AND INNOVATION

A way to keep patients in care: the Adherence Clubs

Adherence Clubs, in which groups of up to 30 stable patients are seen every two months by a lay health worker, have been piloted in Ubuntu Clinic since 2007 to alleviate pressure on health care staff and to adapt care to the needs of chronic stable patients. **An interim evaluation of the clubs revealed that of 755 patients enrolled into clubs only five (0.7%) patients died and eight (1.1%) became LTFU, with 99.2 % of the patients alive at one year and 97.5% alive at two years of club care.**

Preliminary analysis of the clubs data strongly suggest that patients in the clubs are less likely to be lost to follow-up compared to similar patients attending normal care. In 2010,

the first community clubs were started, where patients are able to receive their ARVs in the community.

Reducing HIV and TB incidence further

Despite the early signs indicating reduced incidence of HIV infection in Khayelitsha, the initial target of 50 % reduction in incidence, which was the aim of the current NSP in adults, has not been achieved. A noticeable exception is PMTCT where transmission has been reduced by 250 % making the objective of 'an HIV-free new generation' with vertical transmission <1 % achievable within the next 5 years.

Behavioral interventions along with the current medical intervention should be enhanced.

Innovative preventive biomedical interventions and intensification of the current strategies must be prioritized in order to succeed and move toward prevention of new HIV infections in adults.

Improve TB/DR-TB case detection (ICF)

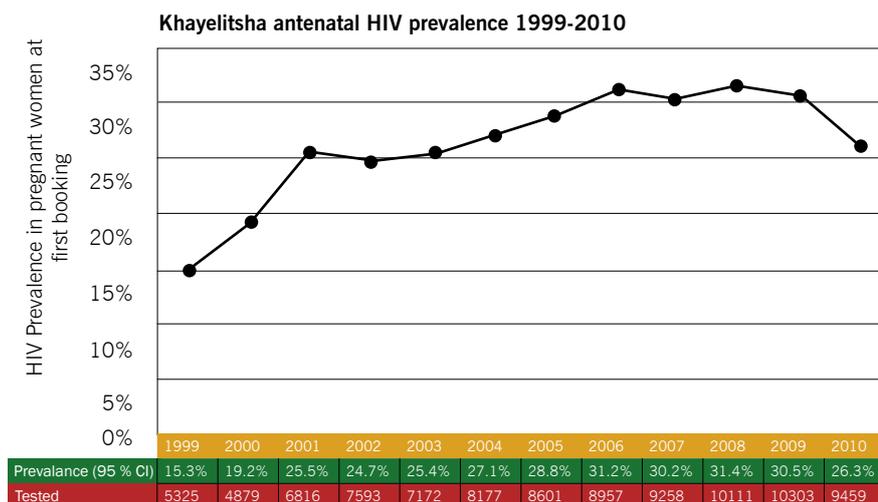
For both TB and DR-TB, the paradigm of treatment as prevention has already been established. Early diagnosis and treatment initiation reduces the risk of ongoing transmission, as treatment for both TB and DR-TB dramatically reduces patients' infectiousness. Access to molecular diagnostic tools (LPA/Xpert MTB/Rif) should be improved to include screening for all TB suspects in Khayelitsha. This would greatly increase TB and DR-TB case detection which, combined with early treatment initiation and wider use of INH prophylaxis, will improve treatment outcomes and reduce transmission of TB in Khayelitsha.



IMPACT OF LARGE-SCALE HIV/TB PROGRAMME

PREVENTING NEW INFECTIONS

Decreasing rates of HIV among pregnant women



HIV prevalence among women presenting for antenatal care (ANC) has been routinely measured since 1999 and since 2003 the testing acceptance rate has been close to 100%. The stabilization since 2006 and the decrease in antenatal HIV prevalence during the last year in the context of increasing proportions of pregnant women on ART, could be the first sign of reduced new infections. Alternative explanations include migration and increased mortality (although the latter is unlikely). Innovative tools to measure HIV incidence are needed to measure progress towards the NSP's target of reducing the rate of new infections by 50% by 2011.

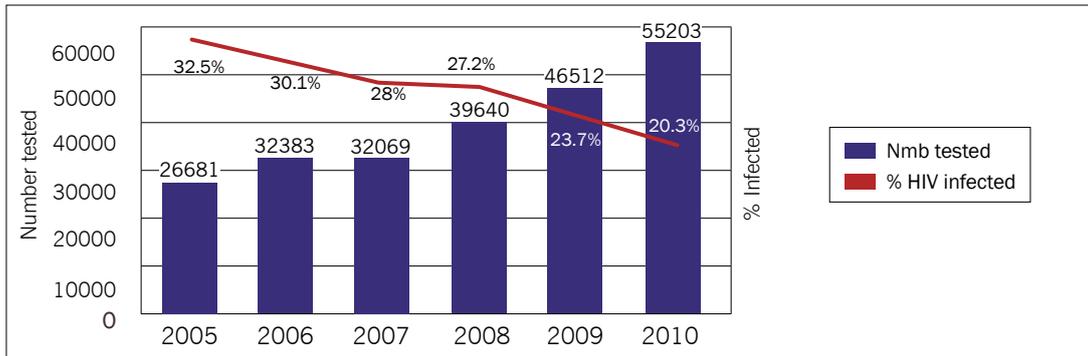
Strenuous efforts have been made to scale up best practice prevention interventions, with substantial improvements over the last decade. In particular:

Substantial improvements in PMTCT coverage, with a paramount reduction in the mother to child transmission rate, have consequently increased the number of **HIV-free newborns** over the decade.

A successful progression of **HIV testing, condom distribution** and reduction in sexually transmitted infections along with a large scaling-up in **ART coverage** with more than 85% of the patients with an undetectable viral load at 12 months, is supporting an expected dramatic **reduction in the community viral load** and consequently, an expected reduction in HIV transmission and the number of new adult infections.

HIV testing and counselling (HCT)

HCT in Khayelitsha 2005-2010: number of tested and % HIV+



EVOLUTION OF HIV TESTING IN KHAYELITSHA 1998-2010

- In 1998, with ELISA testing, about 500 HIV tests were performed
- In 1999 HIV counselling and testing (HCT) started using rapid HIV test kits, employing lay counsellors and providing of treatment to HIV+ “mothers- to-be”
- In 2003, all TB patients were offered testing, progressing to TB-suspected, STI cases and family planning
- In 2003, PCR testing for diagnosis of HIV in infants was piloted and rolled out soon afterwards. 100% of babies have been tested and almost 2 400 PCR tests were performed in 2010
- In 2006, accelerated counselling & testing with routine “opt” testing for youth was implemented
- In 2007, HCT for men was implemented with the opening of the Male Clinic
- Community-based testing sites and HCT campaigns started by TAC, promote broad access to HCT
- TB and STI screening is included in the HIV testing process
- Twenty-two centres were providing counselling and testing at the end of 2010.



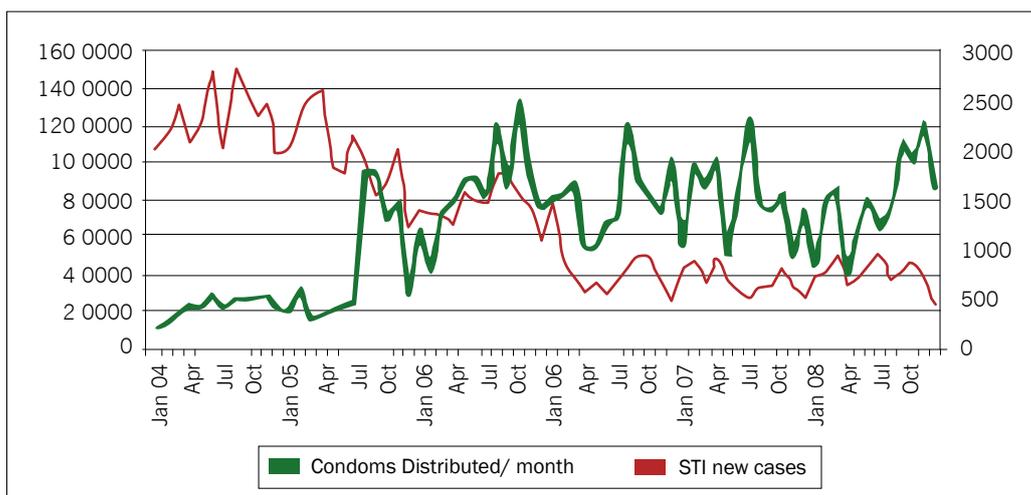
TAC-HTC CAMPAIGN

Following the announcement of the HCT campaign in April 2010, the Treatment Action Campaign (TAC) committed itself to supporting the campaign within the districts it actively works in, including Khayelitsha, through its prevention and treatment literacy (PTL) and community health advocacy (CHA) programmes. This included efforts to train its prevention and treatment literacy practitioners (PTLPs) and community health advocates (CHAs) on the updated treatment guidelines, as well as training and disseminating information to healthcare workers within health facilities. Other activities include TAC's door-to-door campaign which encourages people to get tested and access earlier treatment, as well as informing people of their health rights under the new guidelines. Other widespread educational efforts include the publication and distribution of print materials, including its Equal Treatment magazine, pamphlets and posters, in addition to the promotion of HCT within media and radio interviews. Condoms, supplied by the Department of health are being distributed in taxi ranks, hair salons, schools, along with many other locations, including homes.

The empowerment of health care workers, health advocates and the community at large, through information dissemination, is integral to the success of the HCT campaign.

Fewer sexually transmitted infections

Khayelitsha number of adults treated for STIs vs. male condom distribution each month



After condom distribution was massively increased STI cases decreased four-fold between 2004 and 2009 in Khayelitsha.

Khayelitsha represents approximately 11% of the total population in the City of Cape Town but has the highest burden of STI disease. Male condom distribution has been a major priority for health providers and NGOs in Khayelitsha, particularly TAC, and their efforts have resulted in a massive increase in health facility and community-based (taxi ranks, public libraries, toilets and shebeens) condom distribution from 2.7 million in 2004 up to 10 to 12 million in 2010.

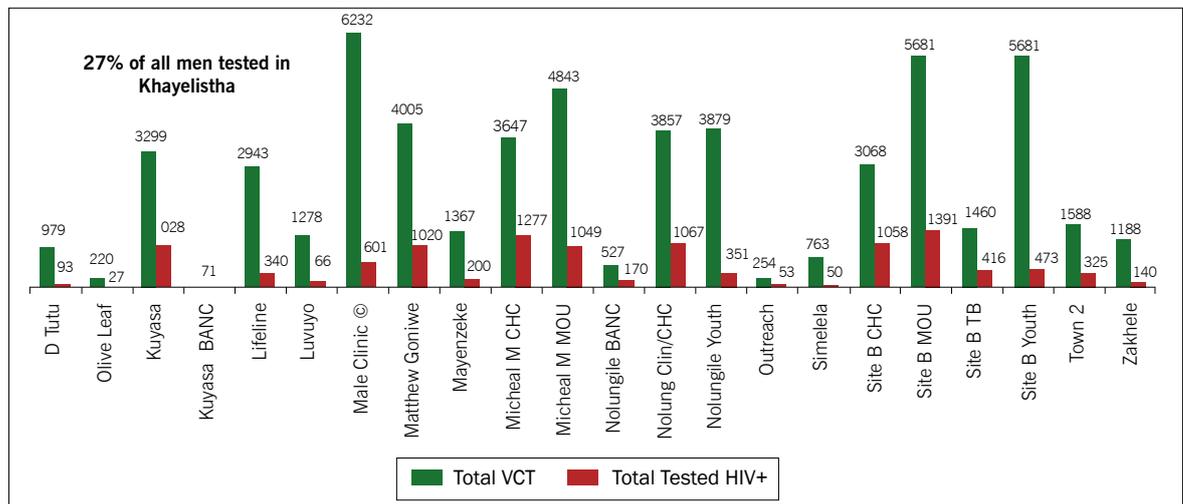


Male walk – in clinic

A service dedicated to reaching men and offering HCT and treatment of STIs was opened at the end of 2007 as a pilot project in Site C. The service, a friendly walk-in-clinic advertised through taxi ranks at Site C and on local radio, aimed to test the impact of a dedicated clinic for men to increase acceptance of HIV testing among men. Since it was started, the clinic has become the largest STI treatment site in the Cape Metro. The number of STIs treated at the male clinic increased from 843 in 2007 to 3 547 in 2010.

The clinic is the entry point for men’s reproductive health and health education, promoting and empowering men to take responsibility for their sexual life and safety and for the health of their partners. The clinic also provides services to partners. HIV positive clients are referred to the nearest clinic for continuation of care. The majority of the clients are self-referred and two new male clinics are planned for 2011. In the first half of 2011, the male clinic reached the HCT target achieved for 2010 and represented 27% of all men tested in Khayelitsha during 2010.

Khayelitsha 2010: Total HIV Testing (56,811) and number HIV positive (11,296)



Khayelitsha sub-district, HIV testing 2010

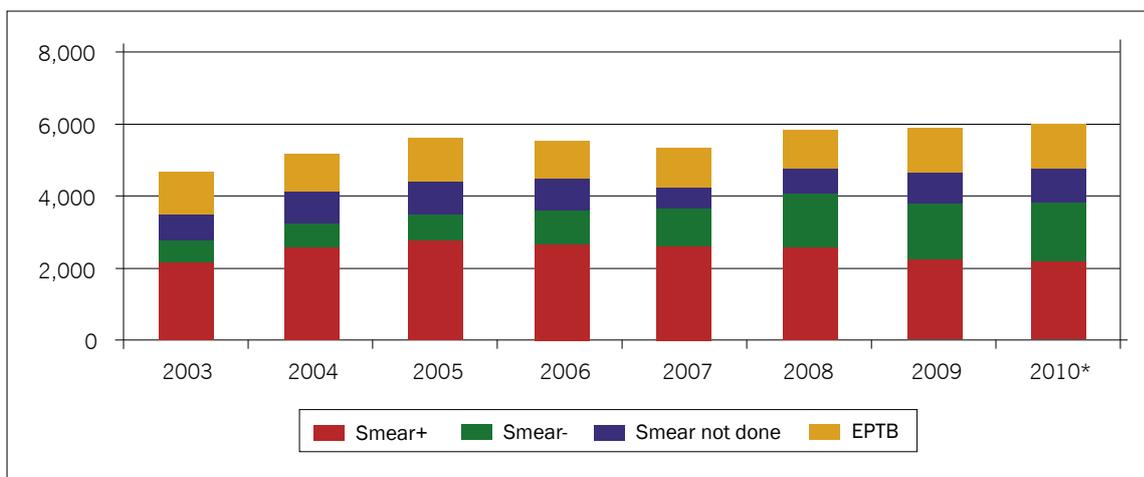


“Public health facilities are crowded with mothers and babies. Whilst women have many opportunities to test for HIV, are exposed to education and offered condoms, men feel unwelcome, stay away and are excluded from such programmes. The male clinic behind the CODETA taxi rank in Khayelitsha is a male-friendly setting where they feel comfortable to attend, are encouraged to test for HIV and learn how to avoid STIs. It provides men with a window into the public health system”

Dr Virginia de Azevedo -Khayelitsha Sub-district Manager

Better diagnosis of TB and stabilization of new case-finding

Khayelitsha 2010: TB Case-finding 2003-2010



- Case-finding appears to have stabilized despite increased case-finding activities:
 - Routine activities promoting smear-algorithm in HIV+ cases
 - Intensive case-finding projects i.e: IPT project in Ubuntu
 - Use of more sensitive diagnostic tools i.e: GenXpert
 - Systematic clinical TB screening in HIV patients
- % of cases reporting smear +ve has decreased significantly: fewer infectious cases spreading TB in the community
- % of smear -ve cases started on treatment has increased: diagnosis is pursued more vigorously & treatment started earlier with less patient morbidity/mortality
- % of diagnosed EPTB remains constant (~ 22%)

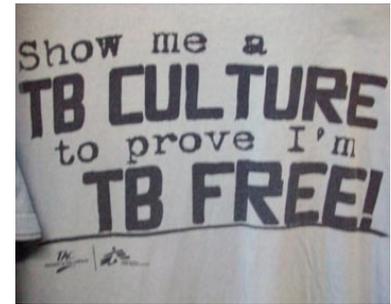


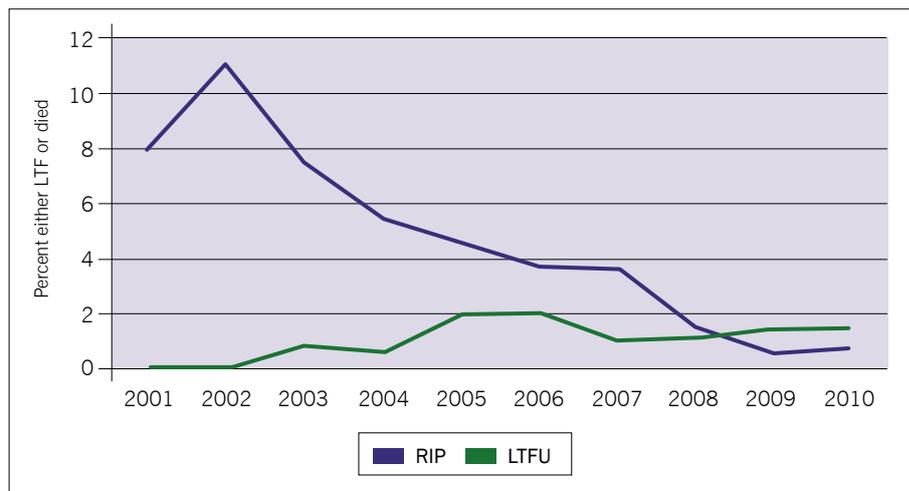
Photo Credit courtesy of TAC: TAC/ MSF T-shirt

DECREASING DEATH RATES

Adult mortality

Death rates of people on ART

Proportion adults LTF or died by 3 months on ART 3 Khayelitsha CHC's



Adult LTFU and mortality by 3 month on ART decreased over time

Death rates of people on ART have decreased steadily over the years, from 10% at three months on ART in 2002 to 2.2% in 2010. Loss to follow-up at three months increased from 0 to 3.5%. Linkages with the death registry revealed that for the period from 2005 to 2007, 50% of patients lost to follow-up during the first three months on ART had died¹. Corrected loss to follow-up in 2010 would thus be 1.7% and mortality 3.9%, still representing a six-fold decrease from the 2002 figure.

While the cumulative mortality at one year was 14.8% for patients started in 2001, it was 1.7% for patients started in 2009.

This is mostly because people are now starting ART at an earlier stage of the disease (see p 19) and at higher CD4 counts (see p. 20). This results in fewer severe opportunistic infections such as disseminated TB or cryptococcal meningitis, which are major causes of death in people living with HIV.

¹ Van Cutsem G, Ford N, Hildebrand K, Goemaere E, Mathee S, et al. (2011) Correcting for Mortality Among Patients Lost to Follow Up on Antiretroviral Therapy in South Africa: A Cohort Analysis. PLoS ONE 6(2): e14684. doi:10.1371/journal.pone.0014684

It is possible that improved screening for TB has also contributed to the reduced death rates on ART. Mortality could be further reduced by initiating people on ART even earlier.

The two key determinants to make this possible are:

1. To increase access to ART.
2. Adoption of the last WHO guideline, which recommends starting patients on ART when their CD4 is below 350 cells/ μ l.

The ART programme in Khayelitsha: model of care ²

In May 2001 the first patients were started on ART services at primary care level. By the end of 2001, 100 patients were initiated on ART and 300 by the end of 2002 (17 months since inception). The national HIV treatment and prevention plan was approved in late 2003 in South Africa.

KEY COMPONENTS OF THE KHAYELITSHA MODEL OF CARE FOR ART



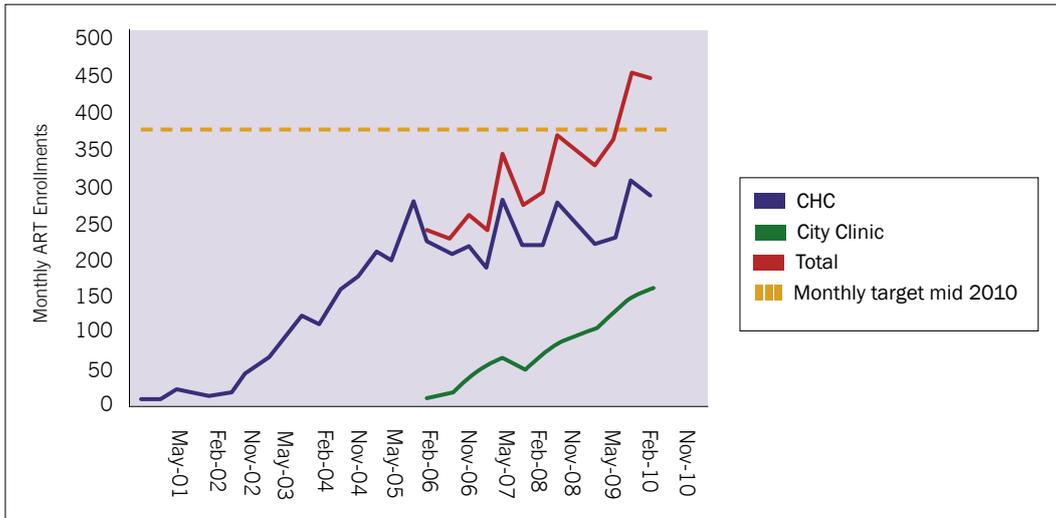
- Patient-centred “decentralization of ART” to all primary care clinics
- Integration of ART within TB services as a one-stop service
- Nurse-led care including ART initiation and clinical follow-up
- Back-up provided by doctor support and a good referral system
- A ‘three tier system’ for monitoring and evaluation: paper registers for small clinics, electronic registers for larger clinics and a complex database for sentinel surveillance, including monthly monitoring and evaluation meetings.
- Ongoing district-based training and mentoring
- Relevant operational research to provide evidence-based decisions

Decentralization of HIV care started in 2006 and by the end of 2006, ART care, including treatment initiation, had been decentralized to two city clinics. Annually, new clinics have become ART sites and by the end of 2010, all 11 clinics in Khayelitsha were providing ART.

Since late 2003, enrolment of new patients increased dramatically from 30-40 a month, to 100-120 in 2004, to 350 a month in 2009 and 430 a month in 2010, with a total of 4 625 patients enrolled during 2010. The total number remaining in care was more than 20 000 in May 2011, of which more than 1 000 were children. The three CHCs now have more than 13 500 patients in care, with the highest number at Ubuntu Clinic (5 065 patients).

² Khayelitsha 2008-2009 annual report. <http://www.msf.org.za/publication/khayelitsha-annual-activity-report-2008-09-providing-hivtb-care-primary-health-care-level>

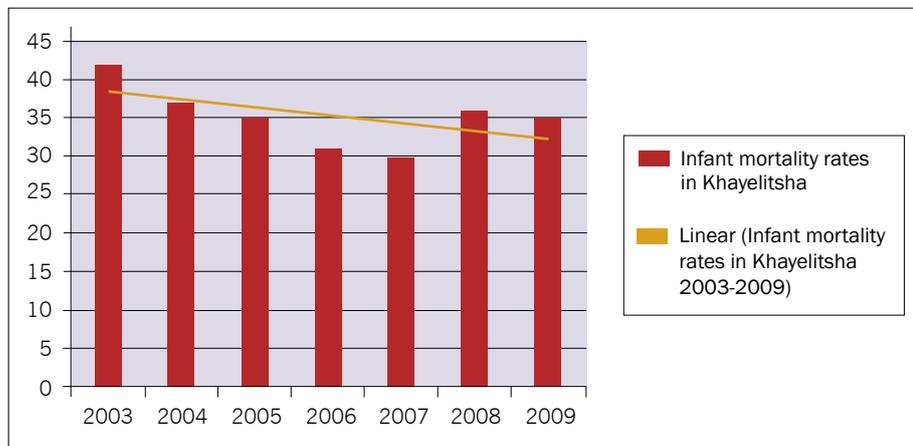
CHC: community health centre, City Clinic: City of Cape Town



This figure shows the saturation of initial ART services points at the end of 2006 and the impact of the newly opened City clinics, allowing the increase in the monthly enrolments toward the sub-district target in order to cover 80% of need.

Infant mortality

Infant mortality rates in Khayelitsha 2003-2009



Infant mortality rate: number of infants deaths <1 year of age for every 1 000 births a year.

Following the introduction of a prevention of mother to child HIV transmission programme in 1999, Khayelitsha has recorded a steady decrease in infant mortality, showing a clear impact at population level. During the last half of 2008 and the first half of 2009 there was a partial breakdown in the Home Affairs notification system for live births and deaths.

According to the City of Cape Town, the most notable difference in infant mortality in Khayelitsha during 2008-2009 was an increase in diarrhea cases. A similar increase

has been reported in several areas in the Cape Town Metropolitan area over the last three years, prompting a city-wide multidisciplinary effort during the Diarrhea Disease Season that is still under evaluation.

Now that WHO recommends safe options for breastfeeding, this increase in diarrhea cases re-opens the debate about formula feeding as the preferred infant feeding option in Khayelitsha.

PMTCT model of care

The first programme in South Africa to prevent the mother-to-child transmission of HIV (PMTCT) was initiated in Khayelitsha in 1999 by the provincial government in collaboration with MSF. The initial regimen used AZT from 36 weeks of gestation and during labour. In October 2003, in keeping with international protocols, the regimen was changed to the “Ditrame-plus” regimen with AZT and NVP given to all mothers and babies. This regimen, together with exclusive free formula feeding, reduced mother-to-child transmission to 3.1% in 2010. In Khayelitsha, most women have access to safe water.

Integration of ART within the midwife obstetric unit:

In December 2004, a pilot project was started, initiating ART for pregnant women with a CD4 count below 200 within the midwife obstetric units (MOUs) as a one-stop service. Women with CD4 counts below 200 were counselled and enrolled into a fast-tracking system of weekly visits in preparation for ART initiation. These included intensified adherence counselling and routine ART work-up.

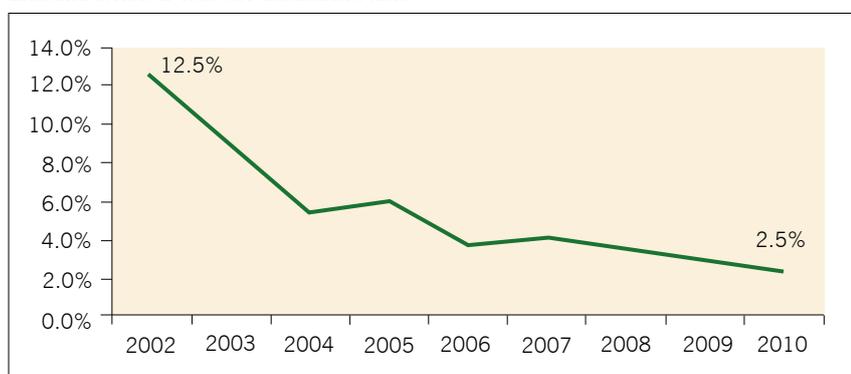
During the first years, because MOUs were not accredited to initiate ART, outreach teams from the ARV clinic initiated women on ART during weekly visits.

Integration of ART into antenatal care services has been associated with a reduced maternal morbidity and mortality through a higher ART uptake and fast track for women presenting late in their pregnancies. The one-stop service saves time for patients and health services and a reduction in lost to follow-up can be expected.

In April 2010, the new ART guideline recommended ART initiation for all pregnant women with a threshold of < 350 CD4.

The rate of vertical transmission in Khayelitsha for 2010 as measured by HIV DNA polymerase chain reaction (PCR) at six weeks, dropped to 2.5%. This low rate of transmission is the result of 10 years of an aggressive and continued PMTCT programme which has led to a **testing acceptance rate close to 100%**, with provision of infant formula milk for the first six months (according to mothers’ choice) and the fast-tracking of mothers who need ART for their own health.

Estimated mother to child HIV transmission rates



Reduction in mother to child transmission over eight years

ART COVERAGE FOR PREGNANT WOMEN WITH < 350 CD4



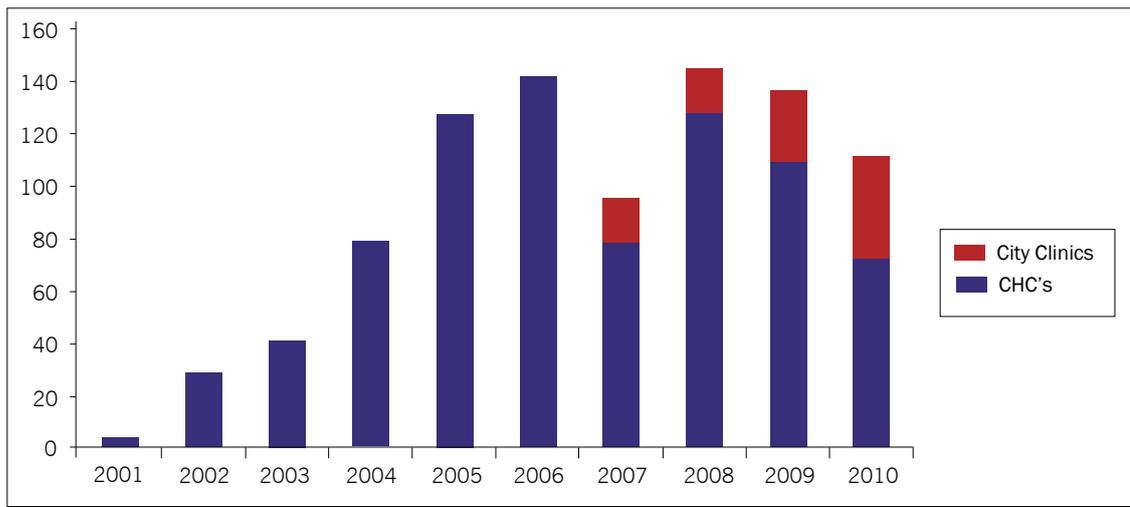
Photo courtesy of Pep Bonnet - children playing

- ART delivery **completely** integrated within antenatal consultations
- Midwife ART initiation
- Health staff training, human resources planning and task-shifting approach are required

Children on ART

Initially children were accessing ART at tertiary hospitals. From 2004, paediatric ART was decentralized to primary care clinics, resulting in a steady increase of children started on ART every year. The modest decline in 2007 was a consequence of active recruitment by tertiary hospitals for research purposes. These children have been referred back to primary care during 2008. However, since 2008 there has been a trend towards a decrease in child enrolment that can be potentially attributed to a successful PMTCT programme.

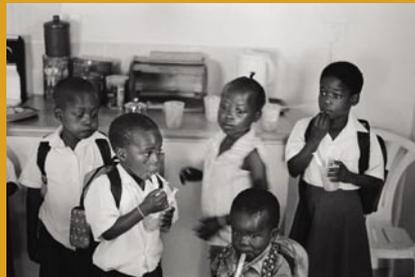
Children (0-5 years) initiated on ART



More infants and older children started on ART at PHC

The median age of children starting ART was around four years in 2001, but the range has extended over time to include older and younger children (range in 2001: 2 to 8 years; range in 2010: 2.4 months to 14 years). An increasing number of older children on ART are entering adolescence (section 2.2 youth), an age group known to be at higher risk of poor adherence and defaulting that requires adapted and innovative interventions.

PAEDIATRIC CARE AT PRIMARY HEALTH CARE LEVEL



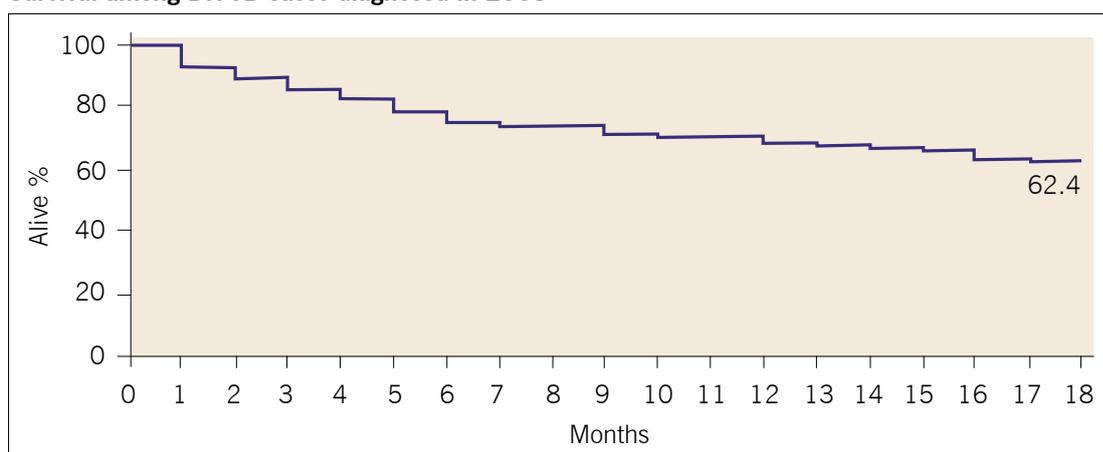
Programme outcomes show that 87% of children remain in care and 98% are alive at 5 years on ART

- Children and adults are managed by the same health staff team at primary care
- Nurse-led care with doctor support
- Tertiary hospitals provide telephonic and on-site weekly support to health team
- Specific weekdays are allocated for paediatric consultations
- Some clinics have a paediatric team consisting of a counsellor, a nurse and a doctor dedicated to children
- ART was simplified by replacing syrups with tablets
- Weight-based drug dosing chart has been standardized

Improved survival in DR-TB patients

Mortality among people with DR-TB in Khayelitsha, although remaining high, appears to be improving over time. Of those diagnosed with DR-TB in 2008, 62.4% are alive at 18 months after diagnosis. This means that overall mortality is 38%, which compares favourably with reports from elsewhere in South Africa³. Given that 76% of all DR-TB patients are HIV infected, this represents a significant improvement from results reported elsewhere.

Survival among DR-TB cases diagnosed in 2008



Survival among DR-TB cases

BUSISWE BEKO AND OTHANDWAYO, KHAYELITSHA MDR-TBMSF COUNSELOR



“Two years previously I was found HIV positive, I had TB and I was pregnant. I started ARVs but my TB treatment did not work. When my baby was 2 months old I learned I had MDR-TB. My baby was found free of HIV, but she had to stay with me and she got MDR-TB. I finished my treatment in September and my baby continued till November. She spent most of her early years on a very harsh treatment. I’ve struggled a lot during that time, but we are now cured of MDR and happy and very proud.”

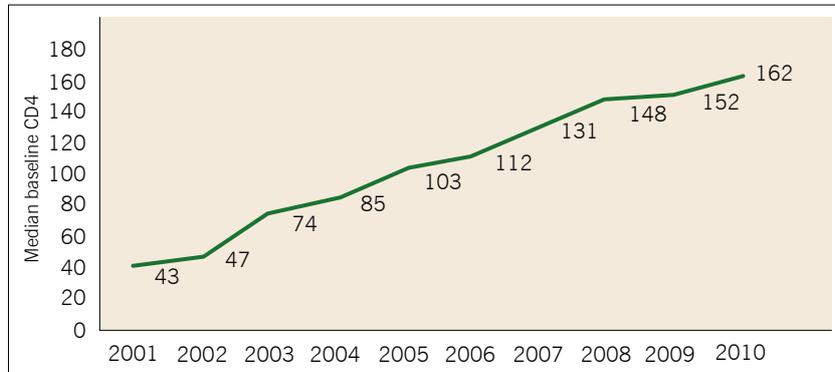
³ Gandhi, N.R., et al., HIV coinfection in multidrug- and extensively drug-resistant tuberculosis results in high early mortality. Am J Respir Crit Care Med, 2010.

DECREASING ILLNESS

Patients now start ART earlier

Increasing CD4 count at start of ART

Median baseline CD4 - adults (newly initiated only): 3 Khayelista CHC's



CD4 counts at initiation of ART increased from 43 cells/ μ L in 2001 to 162 cells/ μ L in 2010.
CHC: Community Health Centre

Decentralization and scaling up of ART has allowed the programme to start patients on treatment earlier. The baseline CD4 count of people starting ART has increased from 43 in 2001 to 162 CD4/ μ L in 2010. In the clinics where ART started in 2007, the proportion of patients with a baseline CD4 < 50 cells/ μ L dropped from 30% to 12% in 2010. Starting patients earlier means they are less likely to experience disease or side effects when they start ART.

This improvement is the consequence of increasing access to ART (through decentralization, task-shifting and TB/HIV integration) and the consequent decrease in stigma, resulting in increased HIV testing

and treatment-seeking. The impact of early initiation has helped to decrease early mortality and make patient management easier, which in turn made nurse-based services more sustainable.

On the basis of the available evidence, the new 2010 WHO guidelines recommended earlier ART initiation for all PLHIV with a CD4 count of ≤ 350 cells/ μ L, regardless of the clinical stage. In April 2010, the national ART guidelines recommended earlier ART initiation to special groups that include HIV-infected infants, pregnant women and people with TB /HIV at CD4 threshold of 350/ μ L. Despite this significant policy change, South Africa still has to adopt full WHO recommendations.

THE WAY FORWARD 'EARLY ART INITIATION' AT CD4 < 350 FOR ALL¹

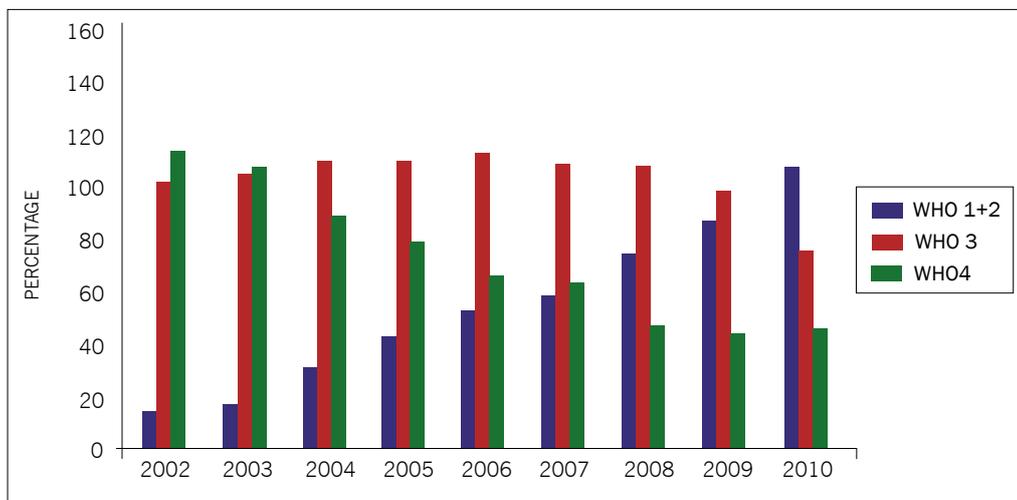
Benefits for patients and the health system

- Reduction in mortality and morbidity related to HIV/AIDS
- Reduction of the incidence of active TB by more than 50%
- Reduction in HIV transmission due to reduction in "community viral load"
- Expected reduction in HIV/AIDS and TB admissions
- Increased likelihood of achieving a normal CD4+ cell count
- Potential reduction in the lost to follow-up rate
- Reduction in the burden on the health services and consequent increase in patient and staff satisfaction
- Less intensive clinical support resulting in more sustainable nurse care

¹ Middelkoop, K; *Am J Respir Crit Care Med* Vol 182 pp 1080-1085, 2010 Ford, N; *AIDS* 2010, 24:2645-2650 *Lancet* 2010; 375:2092-2098 *Donnell D Kitahata MM, et al. N Engl J Med.* 2009; 360:1815-1826
Moore RD, et al. *Clin Infect Dis.* 2007;44:441-446.

Patients start ART at earlier clinical stage

WHO stage at the moment of ART initiation



Clinical stage evolution at ART initiation from 2002 to 2010

A similar impact of the evolution of the baseline CD4 count is reflected in the clinical stage of adults presenting for ART initiation, with a dramatic decrease in the proportion of patients in stage 4 (almost 50% in 2001/2 compared with 20% in 2010) and a parallel increase in stages 1 and 2 (16% in 2001/2002, compared with almost 50% in 2010) throughout the last 10 years. This successful achievement can be attributed to the progression in decentralized, community nurse-based ART services and the massive community awareness and education campaigns, including widespread testing campaigns.

Of concern is the stabilization around 20% of the proportion of patients starting ART in stage 4.

MZIKAYISE NTSHONGONTSHI

is 44 years old and has one son Siviwe who is HIV negative. "I am from the Eastern Cape, and moved to Khayelitsha in 1991 with my father. I work in a petrol station. In 1998, I felt chest pain and was treated for TB for 6 months. I was asked to take an HIV test, and refused because I was too scared. The word AIDS was terrible at the time, AIDS=Death. I had several girlfriends at the time, and I knew how the virus was transmitted, but I told myself, this couldn't happen to me. In 2000, I got TB again, and went on treatment for 9 months this time, that was when I tested for HIV. When the nurse told me I was positive, I stayed calm, but wondered why this was happening to me. The first person I disclosed to was my brother, because I needed a treatment buddy. I then advised my girlfriend to go get tested, and at first she refused. In 2001, she was diagnosed with TB and tested positive for HIV. When I was first diagnosed with HIV, treatment was not

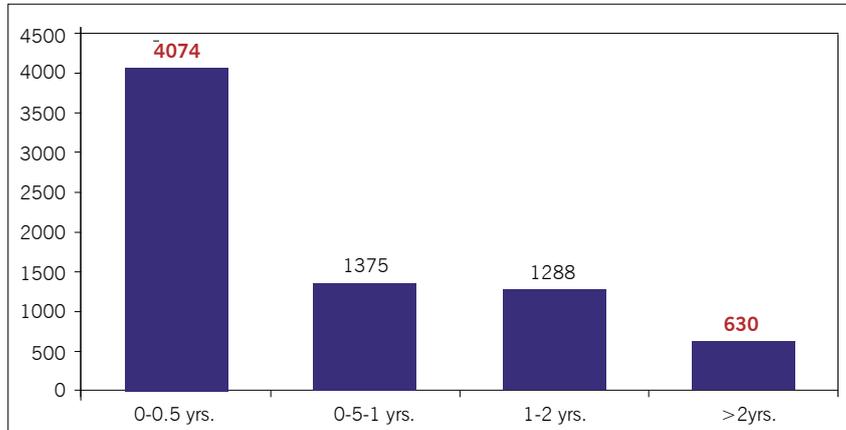


available. I was only given treatment for TB and cotrimoxazole. I started HIV treatment in March 2002, at the time I had a CD4 of 18. I was thin like a stick of grass, it was difficult even to find the veins to collect blood from me. I didn't experience many side effects from the treatment. I have never defaulted, or thought to stop my treatment. This is my life. I used to use my mobile phone as a reminder, but now it is no longer necessary. I take my treatment at 7 am and 7 pm every day. When I decided to have a child with my partner, we joined the PMTCT programme. Although life is not always easy in Khayelitsha, I can't leave. This is where I started my second life, thanks to treatment."

Decreasing TB rates in patients on ART

The TB and HIV epidemics are closely intertwined in Khayelitsha, with a co-infection rate of 70%.

TB incidence (per-100.000 person years) of patients on ART at different times since treatment initiation



Khayelitsha TB incidence is decreasing over time in patients on ART. Khayelitsha TB Program.

The tremendous rise in TB incidence rates over the past decade in Khayelitsha (and across the region) is directly related to the increasing HIV prevalence, along with improved TB case-finding. HIV increases the risk of a person developing and dying from active TB; thus prevention and treatment of HIV is an extremely relevant factor in reducing the burden of TB.

TB/HIV integration as a “one-stop shop”

In 2004, Ubuntu Clinic at Site B was established as a pilot site for TB/HIV integration, where co-infected patients could access both TB and HIV services at the same clinic; this effectively created a ‘one-stop’ service for the many people living with HIV and co-infected with TB.

There are a number of important advantages to TB/HIV integration:

- to improve detection of both TB and HIV
- to improve treatment outcomes (i.e. decrease morbidity and mortality from TB and HIV)
- to reduce the burden of both diseases in the community
- to make delivery of these (usually separate) health services more efficient and reduce health staff burden

The successful experience at Ubuntu Clinic has led to TB/HIV integration being extended to other clinics in Khayelitsha. Data from 2008 showed that 99% of TB patients in

integrated clinics were receiving HIV testing and counselling (HTC) and 95% of them were being tested for HIV (as part of an opt-out strategy). In addition, 99% of co-infected patients had a CD4 count result recorded, >95% were started on cotrimoxazole preventive therapy (CPT).

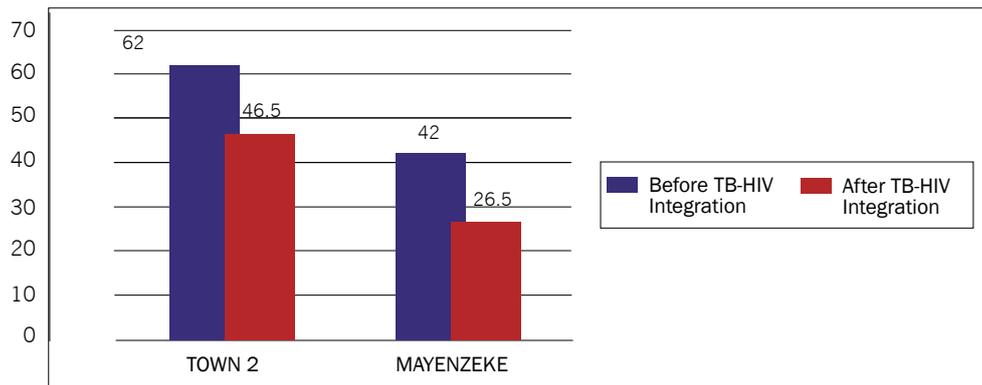
Since the same clinician is now responsible for managing both infections, detection rates of smear-negative pulmonary TB⁴ and extrapulmonary TB (EPTB) have improved. In one clinic, the proportion of EPTB cases (out of all TB cases diagnosed) increased from 23% to 39%. TB/HIV integration also encourages earlier ART initiation of TB patients co-infected with HIV: data from two clinics has shown that the median time from the start of TB treatment to ART initiation decreased from 62 to 46.5 days in Town 2 Clinic and 42 to 26.5 days in Mayenzeke Clinic respectively before and after integration of services. This is an important finding, as earlier ART initiation significantly reduces mortality.



Photo Credit: Joce Cendon

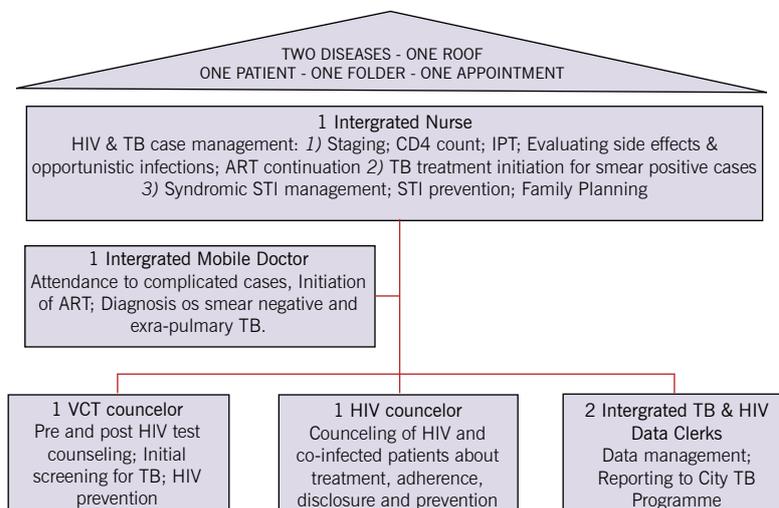
4 Smear-negative pulmonary TB r[]

Median numbers of days from TB treatment start to ART initiation



Median waiting time from start of TB treatment till ART initiation before and after TB-HIV service integration in two primary health care clinics in Khayelitsha

Town 2, City of Cape Town HIV/TB Integration model



There is additional evidence to show that TB/HIV integration has improved:

- Documentation related to other components of HIV-related disease
- Screening for possible medication-related side effects
- Screening for STIs and oppportunistic infections (OIs)

THE DUAL TB AND HIV EPIDEMICS

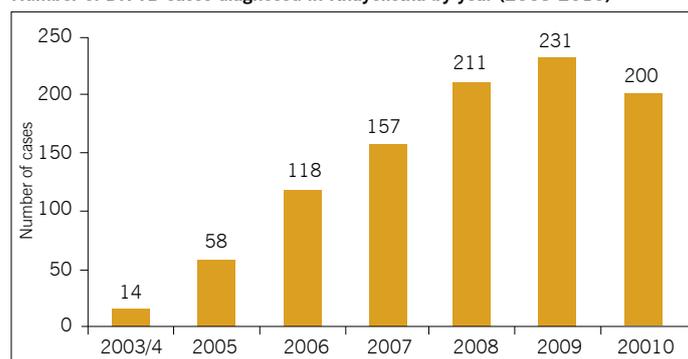
- The rising HIV prevalence has been the driving force for the increased burden of TB
- TB is by far the most common cause of sickness and death in PLHIV
- TB is more difficult to diagnose in PLHIV, increasing the risk of dying from undiagnosed TB
- Better TB diagnostics (i.e. molecular methods) allow for more accurate and earlier detection of TB in PLHIV and a reduction in the time to initiation of proper TB treatment
- The burden of TB is being reduced by:
 - Better access to ART (which prevents the development of active TB in PLHIV)
 - Earlier detection and treatment of cases of active TB

IMPROVING DIAGNOSIS AND TREATMENT OF DRUG RESISTANT TB

Increasing DR-TB case detection

Since the inception of the DR-TB community-based programme, the number of cases diagnosed in Khayelitsha has increased from 14 in 2003-2004 to 118 in 2006, to 200 in 2010. This is the result of intensive training to increase awareness of DR-TB, improved case-finding, initiating treatment early and effectively managing DR-TB patients at the primary care level

Number of DR-TB cases diagnosed in Khayelitsha by year (2003-2010)

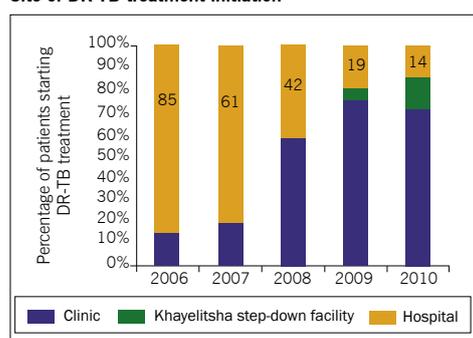


Number of DR-TB cases diagnosed in Khayelitsha by year (2003 to 2010)

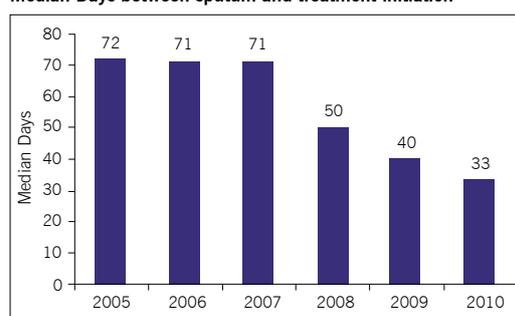
Reduced time to treatment initiation and decentralization of DR-TB treatment

More than 80% of patients with drug-resistant tuberculosis (DR-TB) diagnosed in 2009 and 2010 were started on treatment. The median time to treatment initiation has decreased from 71 days in 2007 to **33 days in 2010**, partially due to decentralization of the DR-TB programme. In 2010, only 14% of cases from Khayelitsha were admitted to the centralized specialist DR-TB hospital at the time of treatment initiation and **71% started treatment through their local clinic.**

Site of DR-TB treatment initiation



Median Days between sputum and treatment initiation



DR-TB COMMUNITY-BASED MODEL OF CARE

- Drug-resistant tuberculosis (DR-TB) refers to TB that has become resistant to first-line treatment and requires longer and more difficult treatment with second-line anti-TB drugs
- Instead of attempting to hospitalise all DR-TB patients, the Khayelitsha model of care uses a patient-centred approach with community-based treatment through existing primary care services
- Using lessons learned from the decentralization of HIV care, diagnosis and treatment of DR-TB has been integrated into the routine TB and HIV programmes in Khayelitsha since early 2008



Gradual evolution towards improved first line regimen

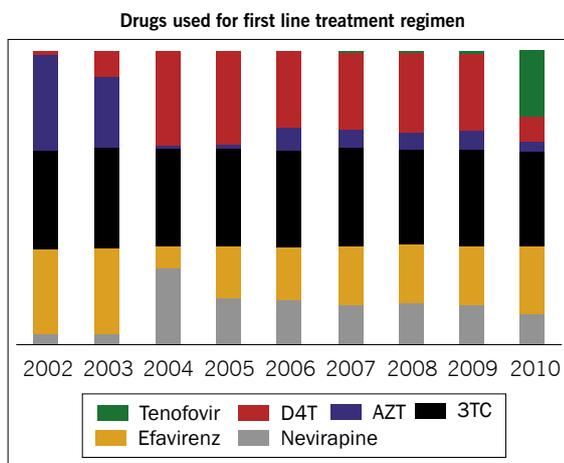
During 2003, the programme progressively switched from an AZT based to D4T based first line. This change somewhat simplifies monitoring for side effects and eliminated the risk of short-term side effects related to AZT. EFV has been increasingly used since 2002, however at the end of 2003 NVP has been used in preference to EFV for availability in fixed dose combinations and a cheaper generic.

Since August 2004 ARV drugs have been supplied by the Provincial ARV depot which resulted in a major regimen change from the previous one supplied by MSF in order to contain costs : AZT was substituted by D4T as was Efavirenz by Nevirapine, mostly for cost saving reasons. In October 2004, a number of first and second line locally manufactured ARVs became available. The national tender for ARV drugs was awarded in March 2005.

D4T has been a cornerstone for treatment for thousands in Khayelitsha and has allowed programmes to initially scale-up treatment considerably, but resulted in high rates of severe side effects such as lactic acidosis and peripheral neuropathy. Documentation of this led to reduction of the dose of D4T and later to recommendations against its further use when it became obvious that short term savings might present a different picture in the long run.

Tenofovir (TDF) is as effective as AZT or D4T and provides additional advantages of being less toxic and it is available as a once-daily regimen, which improves patient adherence. The cost has been pushed down through strong advocacy that led to the routine use of TDF since April 2010. As we have now come to a once daily regimen, the obvious next step is to get access to a 3 in 1 fixed dose combination. This will offer one pill, once a day with much reduced toxicity and ensure all 3 drugs are taken daily.

A simpler, more robust, less toxic and better tolerated 1st line can support improved ART adherence and less risk of interruptions and defaulting, leading to long term ART success



The evolution of main drugs used at ART initiation

CHALLENGES OF LONG-TERM ART PROVISION

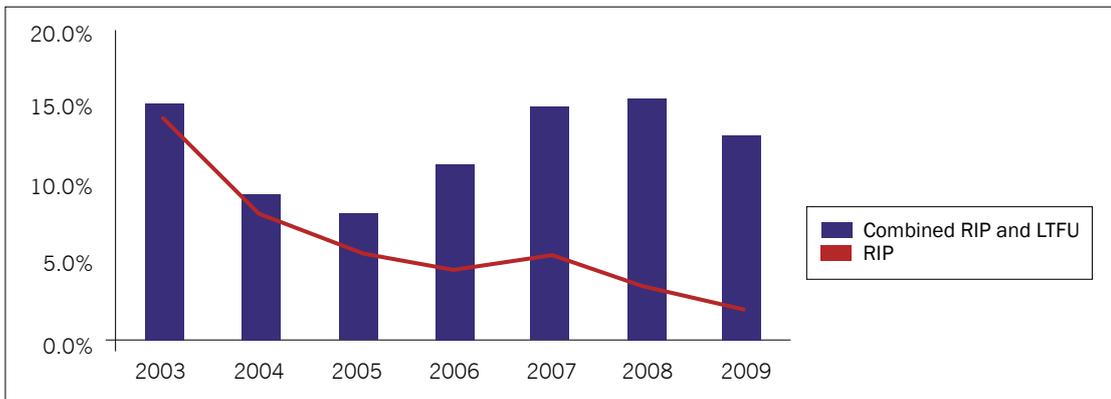
RETENTION IN CARE

ART provision resulted in dramatic improvements in patients' survival and today HIV has become a manageable chronic disease. To gain the maximum benefit from ART, patients need to remain on treatment for life.

The NSP target for retention in care at 12 months on ART is 85% and this rate has been maintained over the years. This target has

been reached in the largest CHCs. The higher mortality in the smaller and newer city clinics is due to a higher proportion of patients with low CD4 counts starting ART (up to 35% of eligible patients with a CD4 < 100 at baseline), which represents a backlog of patients in advanced stages of the disease who did not get earlier access to care.

RIP and LTFU after 12 months of ART



Mortality at one year on ART decreased, while total loss to care increased between 2005 and 2008 due to increasing loss to follow-up, before decreasing again. RIP: dead; LTFU: lost to follow-up; ART: antiretroviral therapy

While mortality at one year on ART in Ubuntu Clinic decreased gradually over time, losses to follow-up increased from 2005 to 2008, due to the saturation of services. From 2009, loss to follow-up decreased again, probably resulting from successful adaptation of services to manage the high load of patients more efficiently (refer to section 3.1). The proportion of patients

LTFU at 12 months after ART initiation in city clinics was comparable to the larger clinics, with more than 83% of the patients remaining in care.

Overall, 87.3% of people were alive and on ART at 12 months, 75.2% at 36 months and 65.1% at six years on ART. This highlights the need for improved strategies to retain patients in care.

SHIFTING FROM FEASIBILITY TO SUSTAINABILITY

Tremendous progress has been achieved in terms of patients treated, as the programme scaled up since 2001, with remarkable clinical and survival outcomes over time. However, ensuring good retention in care continues to be one of the biggest challenges and new interventions are urgently needed to retain an expanding and ageing number of patients in care, on ART and at the same time free up capacity to increase enrolment.



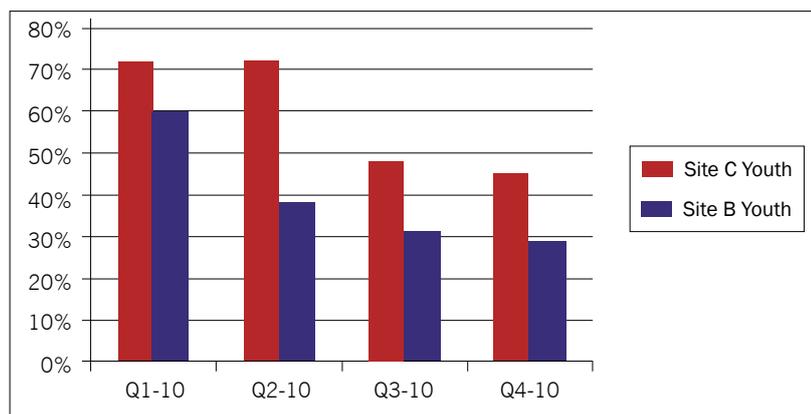
YOUTH CARE AND YOUTH CLINICS

The NSP states that: “Young people represent the main focus for altering the course of the epidemic” and recognises this population as one of higher risk that needs the focus of all specific interventions. HIV testing and ART enrolment of youth is low and defaulter rates on ART are higher than in adults. An increasing number of HIV-infected children on ART are surviving to adolescence and are transitioning from paediatric to adult services

Since 2005 the City of Cape Town and MSF have worked together at 2 Youth Clinics to provide youth-friendly, integrated services with the aim of providing services adapted to the needs of youth. These included provision of family planning (FP), diagnosis and treatment of sexually transmitted infections (STI), voluntary counselling and testing (VCT), management of early HIV-infection, and general curative care.

In 2010, up to 70% of eligible youth defaulted before starting ART; 60% of these defaulted immediately after HIV testing. This trend improved during 2010, possibly as a result of support interventions specifically targeting young people.

LFTU of treatment eligible pre-ART patients



Pre-ART loss to follow-up in the youth clinics remains high despite decreases seen in 2010.



Adherence interventions and in special cases, intensive adherence, need urgent reinvestments and redefinitions according to patients’ needs.

TREATMENT FAILURE

An analysis of virological outcomes⁵ at five years on ART in patients starting ART at the three CHCs, found a cumulative proportion of 14% had virological failure and 12% had been changed to a second line regimen.

Satisfactory short-term outcomes have been demonstrated and support the rapid scaling up of ART programmes. As access to, and time on, ART increases, so will the expected number of patients in need of second-line regimens.

Patients on 2nd line ART

After 10 years of ART provision the cumulative number of patients on 2nd line ART is 705 (5.8%) and 50 (1.1%) in the three CHCs and the newer city clinics respectively.

Patients on 2nd line were less likely to be virologically suppressed, compared with patients remaining on first line at an equivalent duration on ART. These findings highlight the importance of understanding why patients are failing in their 1st line treatment before considering a switch to 2nd line ART.

A special consultation for patients who are failing 2nd line ART has been established in one of the CHC's, consisting of an experienced counselor and a doctor with a special interest in these complex patients. Within seven months, 32 patients have been enrolled in the programme.

Preliminary data shows:

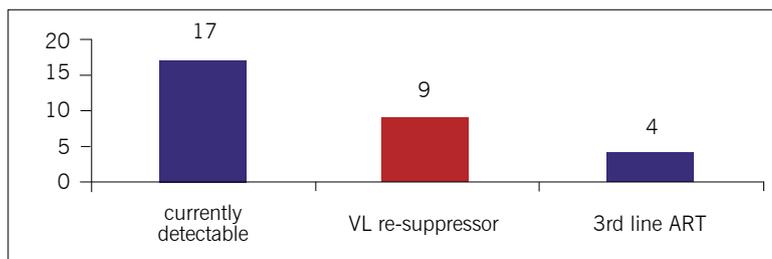
- 60% showed "chronic adherence problems" and were not ready to adhere to the treatment

- 30% returned to undetectable viral load after enhanced adherence support was provided and were transferred back to normal care
- Only four patients (12.5%) qualified as treatment failure and were changed to 3rd line ART.

This analysis highlights the importance of a good adherence support, including routine access to viral load to support the early identification of patients who are in need of special attention.

The low number of patients with resistance to 2nd line is reassuring. However, the emergence of patients in need of a third line regimen is an early warning of what is to come. Third line regimens used in Khayelitsha contain drugs which are not available in the public sector due to their high cost. The price of Darunavir, Raltegravir and Tipranavir is R978, R798 and R2 030 per patient per month, respectively, compared to the price of the combination of Tenofovir-Lamivudine-Efavirenz which is R116 a month.

Patients on second line ART who have or had detectable VLs



Preliminary analysis of the patients failing 2nd line ART: 30% re-suppression rate

5 Boule A, Van Cutsem G, Hilderbrand K et al. (2010) Seven-year experience of a primary care antiretroviral treatment programme in Khayelitsha, South Africa. AIDS. Vol 4(24).

CHALLENGES AND INNOVATION FOR THE NEXT 10 YEARS

Existing Khayelitsha health facilities have now demonstrated the capacity to achieve 80% coverage of patients enrolled on ART at a CD4 threshold of 350. As already shown in the paediatric cohort, the number of clients eligible for ART is now slowly decreasing and therefore future challenges will include keeping patients in care in the long run and reducing the incidence of TB/HIV co-infection.

A WAY TO KEEP PATIENTS IN CARE: THE ADHERENCE CLUBS

At the end of 2007, Adherence Clubs were established in Ubuntu Clinic, with the objectives of improving clinic efficiency, keeping up with enrolment targets and improving long-term adherence by providing more patient-friendly services. Each group shares the club sessions to encourage a dynamic of mutual support.

Adherence Clubs are group clinic visits run by lay health workers who dispense pre-packed ARVs. Adherence Clubs are available on a voluntary basis for adult patients who are stable and have adhered to ART for 18 months or more and with the two most recent viral load results being undetectable. One club consists of 30 patients who meet every two months and are reminded of their appointment by SMS the day before. On club days the group meets and patients are weighed and screened for opportunistic infections and adverse events. A talk is given from a list of topics prepared in advance; in some cases, the group asks for a particular topic to be discussed. If blood for monitoring is required, patients are first referred to the nurse for blood samples to be taken and then given their pre-packed medications. The clubs aim to allow patients to be in and out of the facility within two hours. Should a patient develop a problem, whether an opportunistic infection, a serious adverse event or a detectable viral load, or in the event of the patient missing two or three consecutive club dates, they are referred to a clinician for more intensive follow up.

At the end of 2010 there was a total of 30 clubs, 23 of them in the community, with more than 750 people enrolled. In late 2010, the first



club was transferred to the community, followed by other clubs. Club activities are run in a library, allowing more clubs to be formed. Since January 2011, more than 25 clubs has been implemented in other clinics in Khayelitsha. However, the model will need to be widely expanded to achieve good geographic coverage of Khayelitsha. New National regulations regarding community health workers will allow this new cadre to be fully empowered in the management of such clubs. Drug distribution systems need to be further adapted to provide a service compatible with legally guaranteed and quality assured chronic drug dispensing units.

An evaluation of the clubs revealed that since 2008, 755 patients were enrolled into Ubuntu clubs. Only five (0.7%) patients died and eight (1.1%) became LTFU with 99.2 % of the patients alive at one year and 97.5% at two years of club care.

Data on mortality and retention in this community-based approach in an urban setting compares favourably with facility-based care, proving that clubs do not allow patients' outcomes to deteriorate and optimise patients' and health staff resources.



Ubuntu Team in the first Community Club.2010

REDUCING HIV AND TB INCIDENCE FURTHER

Reducing HIV incidence

Despite the early signs indicating reduced incidence of HIV infection in Khayelitsha, the initial target of 50% reduction in incidence, which was the aim of the current NSP in adults, has not been achieved. A noticeable exception is PMTCT where transmission has been reduced by 250 % since the beginning of the programme thanks to an effective bio-medical intervention. This makes the objective of 'an HIV-free new generation' with vertical transmission < 1 % achievable within the next 5 years.

Whilst waiting for an effective vaccine to be developed, it is necessary to continue with sustained behavioral interventions in order to achieve a reduction in HIV incidence in adults. Interventions such as high level condom distribution would also need to be complemented with alternative bio-medical interventions targeting mostly young women and older men.

LOOKING INTO 10 YEARS: INNOVATION AND WIDE IMPLEMENTATION

- Further out-of-facilities community base testing (in schools , taxi ranks, community halls)
- New PREP strategies targeting young female adolescents combined with development of new long acting ARV formulations (like TMC 278) combined with other bio-medical preventive interventions
- Higher CD4 threshold, potentially up to 500 CD4 and/or high viral load threshold to further reduce viral circulation and infectiousness at community level (Treatment As Prevention, i.e. TASP)
- These strategies will have to be supported by new drug formulations and technologies including:
 - Fixed dose combinations (FDC) for first and second line regimens
 - Semi-quantitative point of care (POC) viral load dipstick to monitor adherence and identify early treatment failures
 - POC CD4 devices to reduce lost to follow-up pre-ART, mostly among adolescents
 - More robust and forgiving regimens, including drugs like Darunavir, which maintain a low toxicity in the long term once the viral load has become undetectable.

Improve TB/DR-TB case detection (ICF)

For both TB and DR-TB, the paradigm of treatment as prevention has already been established. Early diagnosis and treatment initiation reduces the risk of ongoing transmission, as treatment (for both TB and DR-TB) dramatically reduces the infectiousness of patients. Currently the TB programme in Khayelitsha is achieving good outcomes, and although TB case notification may be stabilizing, more intensive efforts will be required to control the epidemic and reduce TB incidence. Similarly, although dramatic improvements in case detection for DR-TB have been shown in Khayelitsha, only a half of all estimated DR-TB cases are diagnosed – case detection will need to be increased if we are to reduce further transmission of DR-TB in the community.

Access to molecular diagnostic (HAIN/ Gen Xpert) shows very promising results in that direction such test should become common practice for all TB suspects in Khayelitsha, it would trigger much wider TB detection, including DR-TB detection while altogether offering a very sensitive screening tool to allow for INH prophylaxis in TB negative patients.

ERIC GOEMAERE – MSF SOUTH AFRICAN MEDICAL UNIT

“Looking back 10 years ago when we first arrived in Khayelitsha, it was striking to see that people were dying everywhere, from a disease whose name was forbidden to name at the time, because no solution for it existed. There was such intense community denial about it all, even among the nurses. 10 years down the line, over 55, 000 people test for HIV a year; people understand that HIV is no longer a death sentence. Community buy-in is the beginning of the solution. Buy-in happens because there is a reliable service within the community, supported through partnerships with many local and international organizations, complimented by widespread treatment literacy. The key to success is willingness on all service providers, working along with the City, Province, and NGOs. The political adversity faced in the early years reinforced strengthened partnerships with organizations such as TAC and the Province to tackle the challenges. Khayelitsha is proof that with concerted efforts, despite limited resources, universal coverage can be achieved. The challenge ahead will be to reduce HIV transmission, although some early signs of this are seen in Khayelitsha. We are still lagging behind in making a major impact in this area however, especially with adolescents and older males. We have our work cut out for us.”



Photo Credit: Francesco & Noor – MSF





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