

PERSPECTIVES AND PRACTICE IN ANTIRETROVIRAL TREATMENT

ANTIRETROVIRAL THERAPY IN PRIMARY HEALTH CARE: EXPERIENCE OF THE KHAYELITSHA PROGRAMME IN SOUTH AFRICA

CASE STUDY



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About This Series

With 42 million people now living with HIV/AIDS, expanding access to antiretroviral treatment for those who urgently need it is one of the most pressing challenges in international health. Providing treatment is essential to alleviate suffering and to mitigate the devastating impact of the epidemic. It also presents unprecedented opportunities for a more effective response by involving people living with HIV/AIDS, their families and communities in care and will strengthen HIV prevention by increasing awareness, creating a demand for testing and counselling and reducing stigma and discrimination.

The challenges are great. Sustainable financing is essential. Drug procurement and regulatory mechanisms must be established. Health care workers must be trained, infrastructure improved, communities educated and diverse stakeholders mobilized to play their part. This series, Perspectives and Practice in Antiretroviral Treatment, provides examples of how such challenges are being overcome in the growing number of developing countries in which antiretroviral treatment programmes are underway. The case studies and analyses in this series show how governments, civil society organizations, private corporations and others are successfully providing antiretroviral treatment and care to people with HIV/AIDS, even in the most resource-constrained settings. In documenting these pioneering programmes, WHO hopes that their experiences will both inform and inspire everyone who is working to make access to treatment a reality.

INTRODUCTION

«People no longer accept that the sick and dying, simply because they are poor, should be denied drugs which have transformed the lives of others who are better off.»

– Kofi Annan, United Nations Secretary-General, 26 April 2001

Southern Africa is the epicentre of the worldwide AIDS pandemic. South Africa has over five million people living with HIV/AIDS, more than any other country. A comprehensive response to HIV/AIDS — including preventing new infections, preventing mother-to-child transmission, prophylaxis and treatment of opportunistic infections, dignified end-of-life care and, critically, antiretroviral therapy – is needed to adequately tackle the epidemic.

Since 1999, Médecins Sans Frontières (MSF) has been working in the Khayelitsha township, in Cape Town, initially supporting the first provincial government-run project to prevent mother-to-child-transmission in South Africa. Khayelitsha is a poor township with about 500 000 residents. More than half of the adult population is unemployed, and most live in informal housing (usually corrugated iron shacks). About a quarter of the women at Khayelitsha antenatal clinics test HIV-positive. Estimates indicate that more than 50 000 residents are infected with HIV.

In April 2000, in collaboration with the Provincial Administration of the Western Cape, MSF set up three HIV/AIDS dedicated clinics within Khayelitsha's primary health care centers. In May 2001, the HIV/AIDS clinics began to offer ARV treatment to people in an advanced stage of HIV infection.

The Khayelitsha ARV treatment project was initiated to demonstrate that treating HIV/AIDS with antiretroviral (ARV) drugs in a primary health care setting and in a resource-limited environment is feasible and replicable. In addition, it aimed to prove that developing countries can provide affordable HIV/AIDS care with low-cost ARV drugs. After two years, the programme has produced invaluable lessons, which are outlined in this paper.



Khayelitsha

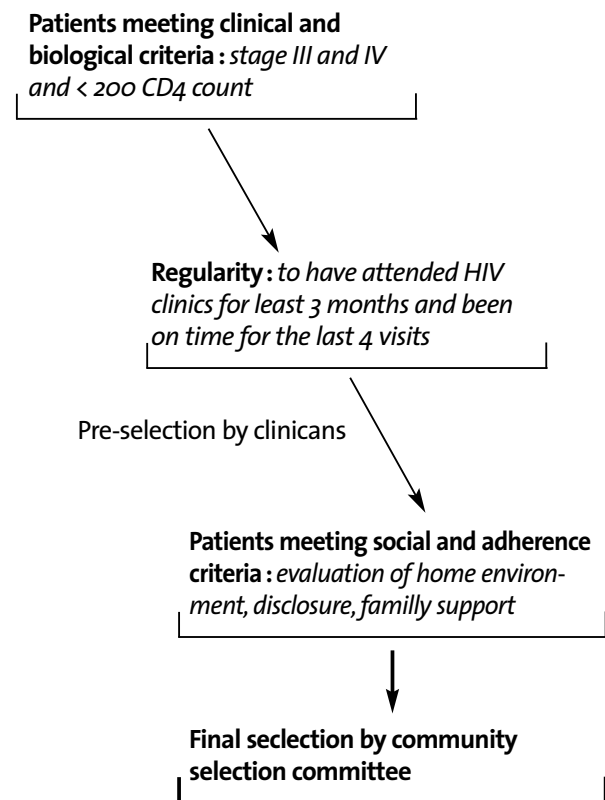
THE KHAYELITSHA ARV TREATMENT PROGRAMME : A BRIEF OVERVIEW

The HIV/AIDS clinics. The clinics are located within community health centres in Khayelitsha. They provide a comprehensive package of AIDS services that include counselling, support, prophylaxis, treatment of opportunistic infections, ARV treatment and referrals where necessary. The staff in each clinic initially consisted of one physician, one professional nurse and one lay counsellor. One nurse and one counsellor have since joined the clinic teams, to accommodate the increasing number of patients and to develop a nurse-based service model much more suitable to the reality of health services in Africa. The three clinics currently serve over 1800 HIV clients per month. Clients attend with different regularity according to clinical stage.

Eligibility criteria for ARV treatment. Initiating ARV treatment in a population with a high prevalence of infection and limited resources necessitates a patient selection process. Patient selection potentially challenges equity in the delivery of the services, and therefore requires clearly-defined and transparent procedures.

Eligibility for ARV treatment in the Khayelitsha programme is determined by criteria that combine an assessment of the clinical and social conditions of candidates, as well as of their anticipated ability to adhere to ARV treatment. Only people who attend the HIV clinics regularly and who live in Khayelitsha are considered for ARV treatment. To be eligible, patients need to be in WHO stage III or IV and have CD4 cell counts of less than 200/mm³. Adherence to co-trimoxazole prophylaxis and tuberculosis treatment and regular clinic attendance are used to assess ability to adhere to the therapy. After the patient has been counselled about ARV treatment, a clinic worker assesses the social and support structures available by conducting a home visit. The home visit also verifies the person's family environment and disclosure to at least one person who will act as a treatment assistant. Other factors considered in the decision about initiation of ARV treatment are history of alcohol abuse, and geographical instability (Fig. 1).

Figure 1. Selection of candidates for ARV treatment.



Enrolment process. Candidates' anonymous dossiers are presented to a committee of community members, people living with HIV/AIDS and clinicians not related to MSF who make the final decision on enrolment based on the clinical, social and adherence criteria. The presenting clinician is not involved in the final decision about enrolment. In a context where treatment is scarce but urgently needed, this removes some of the burden from the clinician and integrates the community into the process. Preference has been given to people living with HIV/AIDS based on their number of dependants (such as mothers versus single men); health status (very sick versus meeting the clinical criteria); income (very poor versus perhaps soon being able to afford treatment); and disclosure and activism (being open about HIV status and/or active in community organizations versus refusing to disclose).

Initiation of therapy. Once selected, the person is re-assessed by a physician. Appropriate laboratory tests are also performed to assess subsequent response to ARV treatment and potential adverse events. Subsequent laboratory monitoring is conducted according to a simplified schedule (table 1).

Table 1. Schedule of visits and laboratory monitoring prior and after initiation of ARV treatment

		M ¹ -0.5	M 0	M 0.5	M 1	M 2	M 3	M 6	M 12	M 18	M 24
All	Informed consent	X									
	Rx assistant	–	X	–	–	–	X	If VL detectable			
	CD4 cell count	X	–	–	–	–	–	X	X	X	X
	HIV RNA	X	–	–	–	–	X	X	X	X	X
AZT	FBC & Diff	X	–	–	X	X	X	X	X	X	X
D4T	FBC & Diff	X	Clinical reasons only								
EFV	ALAT	X	Clinical reasons only								
NVP	ALAT	X	–	X	X	X	–	X	X	X	X
PI	Cholesterol/Tryglyceride	X	–	–	–	–	–	X	X	–	–

¹M: months (M=0 refers to initiation of ARV treatment).

Treatment regimen. Standardized triple therapy regimens are used. First-line therapy has until now included the combination of zidovudine, lamivudine and either nevirapine or efavirenz. The choice between efavirenz and nevirapine considers whether the person is receiving tuberculosis treatment, has abnormal liver function (in which case efavirenz is preferred) or is pregnant (in which case nevirapine is preferred). To date 60 % of clients have started therapy on efavirenz.

Until recently the second-line regimen has been stavudine, didanosine and lopinavir with ritonavir. It is likely that stavudine will soon replace zidovudine in the first-line regimen, with zidovudine replacing stavudine in the second-line. This will further simplify laboratory monitoring of the first-line regimen, and result in fewer adverse events on the second-line regimen.

Monitoring of progress. Everyone on ARV treatment is assessed clinically, weekly for the first 2 weeks, then every 2 weeks until the end of the second month, and monthly thereafter (table 1). Once people are stable on therapy, they can be assessed every 2 months. All laboratory tests are done at centers from the National Health Laboratory Services.



Nurse and patient during follow-up visit. Nurses do most of the follow-up work. Note the pill-box in front of the patient: a device to enhance adherence.

CLINICAL OUTCOMES

A preliminary analysis of those initiating treatment between April 2001 and late 2002 included 288 adults naïve to prior ARV therapy. The median age at baseline was 31 years (interquartile range 28–37) and 70% were women. The median follow-up time was 6.5 months.

Clinical measures at baseline. The median weight at baseline was 57 kg. The median CD4 cell count was 42 cells per mm³, reflecting that many people initiated ARV treatment at a very advanced stage of disease progression. The mean log¹⁰ viral load at baseline was 5.2. Half had a prior diagnosis of AIDS on initiating therapy.

Clinical measures after initiation of ARV TREATMENT. After 1 year on treatment, the mean weight gain was 10 kg. The frequency of opportunistic infections declined dramatically after initiation of ARV treatment. The incidence rate of tuberculosis and oral or oesophageal candidiasis – 2 of the most frequent opportunistic infections – declined by two thirds for both diseases when comparing for the same patients the period from before initiation of ARV treatment to the period on ARV treatment.

After 6 months, 88% of those on ARV treatment had undetectable viral load levels (below 400 copies/ml), and 83% had sustained viral load suppression after 1 year on ARV treatment.

The mean CD4 cell count at 12 months of treatment was 275 cells per mm³. The mean overall increase of CD4 cell count was 221 cells per mm³. Increases were higher in those with a lower CD4 count at baseline.

Treatment changes and adverse events. Most people tolerated the first-line regimen well. Fourteen percent changed one of the ARV drugs because of either adverse events or a contraindication to treatment with that drug. The incidence of adverse events severe enough to require change in treatment was uniformly low, with 8% of patients needing to change an individual drug due to adverse events (usually attributed to either zidovudine or nevirapine). Three patients had been changed to a second-line regimen by the end of 2002.

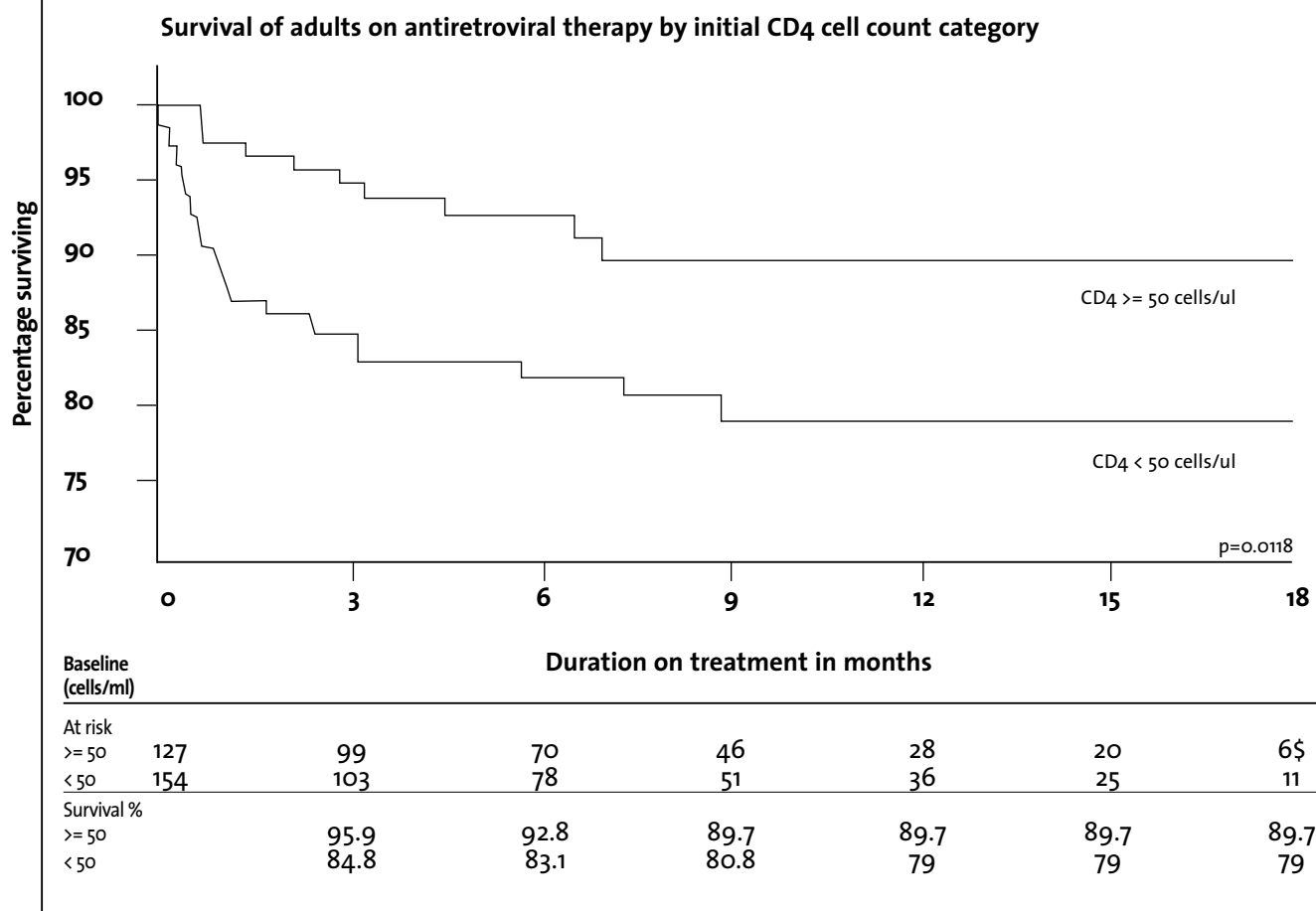
Health-related quality of life. An ongoing study is measuring pain and discomfort, anxiety and depression, mobility, self-care and usual activity in both the MSF clinics and the general population. At the start of treatment, all domains except anxiety and depression differed significantly between the cohort on ARV treatment and the community sample. Over time, the health-related quality of life of those on treatment approached that of the community sample in all domains, until at 6 months the ARV treatment and community populations did not differ significantly.

Survival. Survival at 18 months on treatment was 84% (95% confidence interval 79–89%). All deaths among people who had started ARV treatment were attributed to AIDS and none to treatment complications. Three quarters of the deaths occurred before 3 months on treatment, with dramatically reduced mortality rates after this time regardless of initial CD4 count (Fig. 2). This is primarily because treatment was initiated late, as many were already at quite an advanced stage of HIV/AIDS when they arrived at the clinics. Despite this, even the group that started treatment late did remarkably well.

Table 2 : Selected Treatment outcomes

	Duration on treatment	
	6 months	12 months
Mean weight gain (kg)	6.1	10.0
Proportion of those tested with undetectable viral load	88%	83%
Mean CD4 cell count change for those with serial measurements	+°133 cells/µl	+°221 cells/µl
Proportion surviving	88%	84%

Fig. 2. Survival of adults on ARV treatment by initial CD4 count category



ADHERENCE

ARV treatment requires good adherence to achieve sustained suppression of viral replication and to prevent the onset of resistance. Because ARV treatment is a life-long treatment, it requires commitment and a responsible attitude. In this programme, the key to achieving this commitment has been to implement two equally important strategies:

- ▶ using simplified and standardized regimens that minimize the burden of pills, the dosages and the risk of side effects; and
- ▶ implementing a solid patient-centered education approach that ensures a good understanding of the treatment by the patient and a strong support system.

To achieve good understanding of ARV treatment and sufficient support, MSF has developed an education programme focusing on the people living with HIV/AIDS that combines several components.

▶ **Individual support:** Everyone who enrolls in the ARV treatment programme is required to identify a treatment assistant. The treatment assistant is usually someone living in the household, aware of the person's status and willing to assist with medication as necessary. Lay counsellors – trained in HIV/AIDS and ARV treatment – are available in the clinics to help people living with HIV/AIDS with individualized adherence plans that respond to their specific needs. In case of serious adherence problems, a nurse-counsellor performs home visits as needed for more thorough follow-up.

▶ **Peer support:** Twice a month, the clinics host support groups attended exclusively by people on ARV treatment. Participants discuss barriers to adherence, adverse events, disclosure and other psychosocial issues that affect them. A counsellor regularly performs adherence workshops in the support groups.

► **Materials support:** People in therapy are provided with pillboxes and drug identification charts, daily schedules, diaries and educational materials explaining the risks and benefits of ARV treatment.

Combining simplified regimens with a low pill burden and a comprehensive individual support programme, beneficiaries of the Khayelitsha ARV treatment programme show high levels of adherence to the medication. A clinic-based self-reported evaluation of adherence to ARV treatment is currently ongoing, based on a 4-day recall period. Preliminary results show that 89% of respondents indicate adherence exceeding 95% at 3 months on treatment.

THE NEW SOCIAL CONTRACT: BREAK THE FATALITY AND WE WILL BREAK THE SILENCE

The HIV services in Khayelitsha in recent years were developed alongside strong civil society pressure and community-based education programmes. The Treatment Action Campaign (TAC), a grassroots HIV advocacy organization, has acted on a provincial and national level, mobilising the community to be aware of HIV as a political issue and pressuring the government to develop a comprehensive response. The community programmes of the TAC have educated many in the community about HIV/AIDS, prevention and ARV therapy (“treatment literacy”). In Khayelitsha, the link between education and treatment can best be described as a new social contract: the clinics provide effective HIV/AIDS care and life-saving treatment, and the community breaks the silence, fights stigma and discrimination and, through education, promotes understanding and prevention.

In Khayelitsha, TAC’s *Project Ulwazi* (“knowledge”) has brought people living with HIV/AIDS, some being treated through the MSF programme, into schools, clinics, churches and workplaces and on radio programmes. Through this programme, youth have been proactively involved in educating the community, provoking discussion, decreasing stigma and promoting disclosure. With a mobile exhibition, Project Ulwazi volunteers have guided hundreds of schoolchildren, support groups and community members through a travelling collection of banners, posters, videos and educational materials showing pictures and live stories of people living with HIV/AIDS. Project Ulwazi volunteers have also helped to establish AIDS Action Committees in secondary schools to continue in-school education beyond the initial workshops conducted by the volunteers.



HIV positive clients discuss their treatment and life experiences in a meeting

This education and awareness-raising has been critical in preparing the community to accept treatment, especially as the national government continues to offer mixed messages on the benefits of ARV therapy. Treatment, for its part, has motivated people to listen to educational messages and has promoted a more open climate for discussion, helping to provoke greater change on a broader scale.

TREATMENT AND PREVENTION: TWO SIDES OF THE SAME COIN

In 1999, a provincial initiative on the prevention of mother-to-child transmission in the Western Cape led to a dramatic increase in the number of women aware of their HIV status. Before such programmes existed in the Western Cape, few were aware of their status and even fewer were willing to disclose it. Prevention of mother-to-child transmission provided motivation for pregnant women to be tested for HIV. In 2000, the opening of the MSF dedicated HIV clinics provoked a similar effect. By providing effective treatment for opportunistic infections and, for those in the late stages of HIV/AIDS, ARV therapy, these clinics likewise provided an incentive for others to be tested: their own health and survival depended on acknowledging that their recurring illnesses were linked to a larger disease.

The Khayelitsha ARV programme is thus part of an increasing number of initiatives in the Western Cape responding to HIV/AIDS. The government programmes range from the expansion of voluntary counselling and testing sites, the development of youth clinics to respond to the distinct needs of adolescents, the availability of post-exposure prophylaxis for rape survivors in government clinics and the universal expansion of pro-

grammes in public health facilities to prevent mother-to-child transmission. The combination of all these initiatives has helped to create an environment where people feel cared-for. This has affected prevention, promoting openness and decreasing the stigma around HIV/AIDS.

A 2002 study conducted by the Centre for AIDS Development, Research and Evaluation and the South African Department of Health targeted nine commuter sites in South Africa, including Khayelitsha, and found that Khayelitsha residents reported the highest levels of condom use, willingness to use a female condom, willingness to have an HIV test and desire to join an AIDS club¹. This difference can be largely attributed to the comprehensive approach to AIDS care, and critically to the inclusion of ARV treatment which has seen increase in uptake of voluntary counselling and testing in the district from fewer than 1000 HIV tests in 1998 to more than 12 000 in 2002. The number of HIV support groups in Khayelitsha has also increased dramatically: from 4 in 1998 to 22 in 2002.

The availability of ARV treatment in Khayelitsha has demonstrated that treatment is important for prevention because it :

- ▶ provides a motivation for HIV-positive people to be aware of their status : without treatment as an option, knowledge that one is HIV-positive can be seen as offering little more than stigmatization;
- ▶ promotes openness and reduces stigma, as HIV is no longer an inevitable death sentence;
- ▶ can fuel educational initiatives supported by a pool of HIV-positive people open about their status;
- ▶ improves the morale of health care workers who can offer something beyond temporary treatment for opportunistic infections; and
- ▶ helps to keep families intact and economically stable, thereby protecting the most vulnerable (women and children) and minimizing at-risk populations.

¹ Parker W et al. *On the move: the response of public transport commuters to HIV/AIDS in South Africa*. Johannesburg, Centre for AIDS Development, Research and Evaluation, 2002 (<http://www.cadre.org.za>, accessed 31 May 2003).

AFFORDABILITY OF ARV TREATMENT

Aiming in part to demonstrate the affordability of providing ARV treatment in a resource-limited setting, the Khayelitsha ARV treatment programme is implementing strategies to minimize costs. The importation of generic drugs from overseas manufacturers dramatically reduced the costs of treatment. As few generic ARV drugs are registered in South Africa, MSF obtained permission from the South African Medicines Control Council under the Medicines Act (Section 21) for the use of unregistered generic ARV drugs. Authorization required sufficient evidence about drug quality.

Following a collaboration agreement between MSF and the Brazilian government, MSF started to source generic versions of ARV drugs for its Khayelitsha project from the Brazilian state manufacturer, FarManguinhos, in January 2002. The price of the first-line regimen (zidovudine/lamivudine and nevirapine) was then US\$ 1.55 per person per day. This price was half the cost of the lowest possible price offered by the proprietary companies to governments (US\$ 3.00 per person per day) and nearly a quarter of the price in the private sector (US\$ 5.50 per person per day). Later in 2002, the price of this Brazilian combination dropped further to US\$ 1.08 per person per day.

MSF recently received authorization from the South African Medicines Control Council to source drugs from different manufacturers worldwide, opening the chances to get the lowest prices.

Simultaneously, we have worked with the National Health Laboratory Services to reduce the price of laboratory tests, especially viral load and CD4 count. The development of the pan-leucogating protocol (AffordCD4™) and its immediate implementation at the National Health Laboratory Services allowed a price reduction from US\$ 24 per test to US\$ 8.30 per test. Negotiations between the National Health Laboratory Services and the proprietary companies that produce viral load kits led to a slight decrease of the cost of viral load testing in the public sector (US\$ 45 per test). MSF believes that the price of viral load testing can still be cut dramatically when companies apply the offers to which they have committed. The target cost for the package of two viral loads and two CD4 counts in the public sector is US\$ 70 per year.

By using generic ARV drugs and reducing the price of laboratory tests, MSF has cut the annual real cost per person of ARV treatment from US\$ 1366 in January 2002 to US\$ 536 in April 2003 (adjusted to fluctuations of exchange rate). This price is based on the regimen zidovudine/lamivudine and nevirapine, and two viral load tests and two CD4 tests per year.

LESSONS LEARNED: ESSENTIAL COMPONENTS OF AN EFFECTIVE HIV/AIDS TREATMENT PROGRAMME

«The doubters said it was impossible, too expensive or impractical. Let them say that to our patients who are under ARV treatment and thriving in Khayelitsha. The challenge now is to repeat this and to use successful pilot programmes as a guide to scale up.»

- Tito August, physician working in the township of Khayelitsha



Demonstration for treatment access at the opening of parliament, 19 February 2003. Note participation of ANC member (wearing party vest)

The experience of the Khayelitsha ARV treatment programme in South Africa yields several lessons. Although individual contexts necessitate different models, an effective HIV/AIDS treatment programme is defined by its capacity to quickly and effectively treat a substantial number of people living with HIV/AIDS.

In the most-affected countries, this can be achieved if:

1. the public health system is mobilized and AIDS treatment activities are integrated into the basic package of care, including voluntary counselling and testing (VCT), prophylaxis of opportunistic infections, and psychosocial support;
2. treatment services are decentralized down to the primary care level to assure both coverage and community involvement;
3. simple regimens with standardised clinical guidelines sequencing the use of drugs and managing adverse events encourage ease of adherence for the patient and follow-up for the health care professionals;

PERSPECTIVES AND PRACTICE IN ANTIRETROVIRAL TREATMENT

4. multidisciplinary teams, including nurse-based care with a major emphasis on psychosocial support, utilises available resources and forces a holistic management of HIV/AIDS;
5. comprehensive approach to adherence includes counsellors, support groups and significant treatment literacy;
6. a community-based educational programme, incorporating basic HIV/AIDS education and a treatment literacy component, explaining the value and use of ARV drugs, complements a treatment programme;
7. the cost of ARV treatment can be made more manageable by for example use of generic drugs and inexpensive laboratory monitoring techniques minimize the cost of treatment, allowing more to receive ARV treatment at a manageable cost.

In Khayelitsha, many challenges remain ahead as the programme extends into its third year of treatment provision.

1. **Consolidation of nurse-based care:** Because of human resource availability, a developing country treatment model must rely heavily on nurses. This can be successfully achieved with simplified regimens and management guidelines. In Khayelitsha, clinics were initially managed by a team of one doctor, one nurse, and one counselor. The teams currently consist of one doctor, two nurses, and two counselors.
2. **Strengthening of training activities:** Training activities targeting clinical staff at the primary care level are needed to ensure that an HIV/AIDS patient is properly cared for from an early stage. MSF in Khayelitsha has organized two annual trainings of nursing staff in the community health centers, to educate about opportunistic infections and referrals, and to encourage a unified response to HIV/AIDS.
3. **Integration of HIV/AIDS and TB services:** According to the World Health Organization, tuberculosis is at «emergency» levels if the incidence is above 400 per 100,000 p-y. In Khayelitsha, the incidence of TB is more than four times that figure, with more than half of the TB sufferers co-infected with HIV. An effective intervention to address TB and HIV necessitates an exploration of the possibility to integrate both services. The Khayelitsha clinics are currently aiming to develop a model of integration.

4. *Development of an education programme to support long-term adherence to ARV TREATMENT:*

The adherence-support programme used in Khayelitsha up to now has proven to be effective to achieve high levels of adherence and viral suppression in the first year of treatment. Later stages of treatment might require a different approach to adherence-support as patients begin to feel healthier and more distanced from the negative effects of their illness. Counselors in Khayelitsha are implementing separate support groups to respond specifically to the issues affecting patients on treatment for one year or longer.

5. *Addressing the specific challenges of paediatric AIDS.*

In wealthy countries paediatric HIV/AIDS is virtually non-existent, largely due to the success of antiretroviral therapy. With research priorities shaped by the disease burden of wealthier countries, there has been relatively little effort into simplifying paediatric formulations. Currently available formulations hardly include any fixed-drug combination, which complicates administration and thus adherence. They also pose problems of adjusting and measuring dosages. On the psychosocial component, paediatric AIDS needs specific adherence support programmes to address the challenges faced by care givers and children. These issues are currently being explored in Khayelitsha.

6. *Development of a model of implementation of ARV treatment in a rural remote setting in SA:*

The development of a successful ARV treatment program in the poor peri-urban setting of Khayelitsha is a significant achievement, yet many of those infected with HIV in South Africa live in rural areas. Implementing a comprehensive HIV/AIDS programme with antiretroviral therapy in a rural area brings unique challenges, most notably infrastructure constraints and limited human resources. Using the experience of Khayelitsha and that of other MSF programmes elsewhere in rural Africa, MSF is currently developing a model of implementation of HIV/AIDS care, including ARV treatment, in a rural area of the Eastern Cape province.

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