

# The complexities of implementing antiretroviral treatment in the Western Cape Province of South Africa

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The following article is by Fareed Abdullah, the head of the AIDS programme in the Western Cape Province of South Africa. It offers a unique account of treatment roll-out from the perspective of a programme manager in government. Abdullah's article illustrates that with sufficient will and ingenuity, and on the basis of genuine partnerships, antiretroviral treatment can be provided in a manner that both saves lives and improves the health system as a whole.

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## Introduction

The provision of antiretroviral treatment in South Africa has been shrouded in controversy over the last few years. Public discussion, emphasising policy aspects of this highly polarised debate, has neglected important technical and methodological issues that arise in the implementation of large-scale treatment.

In the mist of controversy, the Western Cape Department of Health has been able to steer ahead with a comprehensive programme to tackle AIDS that includes prevention, care and treatment components; arguing that all three components are needed to systematically tackle the epidemic.

In its sixth year of implementation of a PMTCT intervention, and after three years of pilot projects with HAART, the Western Cape has been able, for all intents and purposes, to roll out antiretroviral treatment throughout the province in the course of 2004. This article describes the complexities of implementing the treatment component of the programme and the measures needed to overcome systemic obstacles to successful treatment.

## Background to the Western Cape health service

The Western Cape health service comprises 252 fixed and 131 mobile clinics, 64 community health centres, 36 district and regional hospitals and three tertiary referral hospitals. The majority of clinics, though subsidised by the Province, are managed by local governments. The provincial Department of Health (DOH) is responsible for the community health centres and hospitals. These facilities serve a population of 4.5 million spread over 129 370 km<sup>2</sup>.

Almost two-thirds of the population of the province resides in the Cape Peninsula within the demarcated boundaries of the City of Cape Town. Ninety three clinics, 48 community health centres, the majority of regional hospitals and all three tertiary referral hospitals are found in the metropolis. The rest are spread through large and small towns in the rural areas. Higher levels of poverty and fewer opportunities compound the provision of health services in smaller towns. Although few in number, people living in small villages and farms are reached by mobile clinics and have to make their way to the nearest towns for treatment of serious illnesses or for more sophisticated health interventions.

Seventy two per cent of the population depends on the public health sector for their health care. The rest of the population has medical insurance and generally utilises private health care which is well-developed. There are 72.4 doctors per 100 000 population and just over 8 000 (acute and chronic) hospital beds. These rates are higher in the Western Cape than in other provinces but are skewed in favour of tertiary level care. The high number of medical staff (particularly specialists) and beds in the tertiary sector are the result of inheriting two medical schools and associated academic complexes.

At the level of the district health services, there is a severe shortage of health professionals including doctors, nurses and pharmacists. At this level there is great difficulty with the recruitment and retention of health professionals and many facilities suffer chronic staff shortages and poor organisation. The increase in access within primary care over the last eight years has resulted in a two- to three-fold rise in the number of attendances at district level facilities (particularly community health centres in the metro area) without a concomitant increase in resources or staffing levels.

Insufficient attention has been paid to the organisation and development of primary health care services and a severe lack of management capacity has arisen at the PHC level. Together with a lack of computerisation of these facilities and the neglect of physical infrastructure development, the primary health care service in the Province is comparable to similar services in other provinces, although not as underdeveloped as the PHC services in provinces such as the Eastern Cape or Mpumalanga.

## Demography and epidemiology

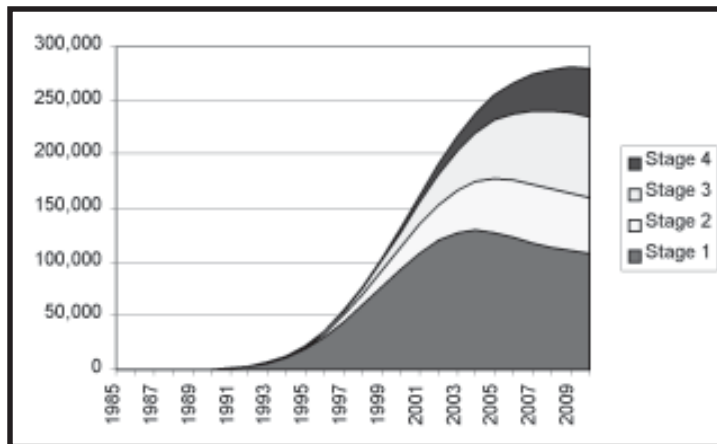
The Western Cape has a higher Human Development Index than the national average, reflecting higher levels of per capita income, employment and literacy. At the same time, the province has the highest Gini co-efficient reflecting gross disparities between rich and poor (Rasool, 2004).

Compared to the rest of the country, the Western Cape is further along the road of the demographic and epidemiological transition with an older population and a higher degree of chronic, non-infectious diseases including diabetes, heart disease, hypertension, asthma, arthritis and psychiatric illness. Infant and child mortality rates are lower than the national average and life expectancy is higher. The Province has an unusually high rate of tuberculosis (917/100 000). The rates of urban phenomena such as alcohol and drug abuse, violence and trauma, domestic violence and motor vehicle accidents are also much higher than in other parts of the country.

Given the higher socio-economic status of the population in this province, it is not surprising that HIV prevalence is lower than any other province and about half the national average. Still, at 13.1 per cent (antenatal prevalence) the HIV epidemic is well-established and accounts for the largest burden of disease in the province. Although not the largest single cause of mortality (except among children and women aged 15-49) the HIV epidemic is the single largest health crisis facing the Western Cape at the present time. This situation is expected to worsen over the next five years until the epidemic peaks at around 2010 when HIV disease will account for 25 per cent of all visits and admissions to health facilities in the Province.

The graphs below show the progression of the epidemic into its exponential phase and the likely trends until 2010. If this modelling is to be believed (and there is now evidence that these numbers may be overestimated) approximately 40 000 PLWAs will be eligible for ARV treatment in 2010. The current number needing treatment is likely to be closer to 10 000 to 12 000.

GRAPH 1: WESTERN CAPE PROVINCE HIV PROJECTIONS BY STAGE OF DISEASE



## Laying the foundations: the Western Cape's MTCT programme

In January 1999, the provincial department started its first PMTCT programme at two midwife obstetric units in Khayelitsha. In this programme, AZT monotherapy was provided to HIV-positive pregnant women with a view to reducing the risk of transmission of HIV from mother to child from a background rate of about 30 per cent to less than 15 per cent, a reduction of about 50 per cent.

Providing AZT to HIV-positive women in pregnancy meant setting up a voluntary counselling and testing service at the midwife obstetric units, and ensuring that the majority of women elect to test. Follow-up care for the mother and the infant had to be instituted at nine clinics in the area so that mothers could be advised about formula feeding (or exclusive breastfeeding for a small group who chose to do this) and that babies could be followed up to check for clinical signs of HIV so that they could be definitively tested for HIV at 9 and 18 months.

In the last five years more than 30 000 women have been counselled and tested in Khayelitsha. In this period, both the protocol for treatment and the overall efficiency of the programme have improved. Women now get dual therapy (AZT + Nevirapine) and babies also get both drugs. Babies are tested at 14 weeks with a definitive (although more expensive) PCR test, resulting in an improved overall management of the mother-infant pair, early referral for long-term treatment for any infant testing positive and a better all-round knowledge of the health status of the mother and infant pair. In 2002, the transmission rate, using AZT monotherapy, was recorded as 8.9 per cent. Results from PCR testing of babies whose mothers received dual therapy, in the last quarter (April-June 2004) showed that the transmission rate has further decreased to 5.5 per cent.

From 2001, the MTCT programme was steadily rolled out to all of the approximately 300 antenatal and child health clinics in the Province, including the majority of mobiles. By May 2003, all sites were on the dual therapy regimen described above. The same transmission rate demonstrated for Khayelitsha, of 5 per cent or less, can be expected for the whole province as results come in during the course of the financial year.

Further changes to the regimen are under way, not only in Khayelitsha but throughout the Province. Women with a CD4 count of less than 200 are referred, and fast-tracked,

for triple combination therapy (Highly Active Anti Retroviral Treatment, or HAART) during their pregnancy with a view to continuing treatment after the pregnancy. Women with CD4 counts above 200 are likely to receive AZT from 28 weeks pregnancy, AZT and Nevirapine in labour and Combivir for seven days after the baby is born (this latter component is aimed at reducing Nevirapine resistance). The infant will be given one dose of Nevirapine and AZT syrup for seven days.

This combination of interventions is almost certain to lead to transmission rates of below 1 per cent for the Western Cape. This should be achieved within the current financial year although its full impact might only be realised in the next year.

The PMTCT programme was an important starting point in the provision of antiretroviral treatment and in many ways it was the dress rehearsal for the implementation of antiretroviral triple combination therapy (HAART) for long-term treatment of adults and children living with AIDS. The die had been cast in the course of the PMTCT programme, mainly with the approach taken to involve partners in the implementation of the programme. This would be replicated in the HAART roll-out. The entire counselling service was outsourced to NGOs (though provided on site); there was a strong community involvement mainly through the involvement of the Treatment Action Campaign (TAC) at most of the metro-based services; and many partnerships with NGOs, local authorities, clinicians from academic hospitals and universities. This gave the staff and middle managers a sense of being special, and are positive ingredients for any successful programme.

## Phasing in a HAART programme

The HAART programme started in May 2001, once again in Khayelitsha. This time it was a joint effort between the Department and Médecins Sans Frontières (MSF) which, internationally, were looking to get more involved in treatment in the developing world. In the first three years the programme was implemented and run almost entirely by MSF at Community Health Centres in Khayelitsha. By the end of 2004, more than 1 500 patients were on treatment at these three sites.

During 2002 and 2003, the province entered into partnerships with at least six other NGO or research-based initiatives in public health facilities in the Western Cape. By December 2003 sites had been opened in Khayelitsha (3), Gugulethu, Langa, and at the G F Jooste, Groote Schuur, Tygerberg and Red Cross Hospitals.

Roll-out of the HAART programme began in earnest at the beginning of 2004, following the National Cabinet decision of November 2003 to implement and fund a national HAART intervention in all provinces. The pilot projects already in place by this time gave the Western Cape a head start on the rest of the country. Working with antiretrovirals, both in the MTCT programme and the pilot ARV sites, gave the provincial team a working knowledge of the numerous issues that arise in the provision of this intervention. Clarity, and an appreciation of the powerful results of successful treatment, created the right conditions for the phasing in of treatment at other sites.

The majority of treatment sites have already been commissioned, including those in outlying towns such as George, Worcester, Paarl, Beaufort West, Malmesbury, Stellenbosch, Robertson, Hermanus, Mossel Bay and Knysna.

More than 6 000 patients are already receiving treatment and at least another 6 000 are expected to be on treatment during 2005, accounting for the great majority of people who need treatment (See Graph 1, Stage 4).

### Preparation of the health service for HAART

For successful treatment at the individual level, a health service needs to be accessible to those in need of it. It needs doctors and nurses to assess patients and basic laboratory tests to assist them in their initial evaluations. It also requires physical space and equipment to make these evaluations. Patients need to be prepared for treatment readiness including education about their illness and drug literacy, and be given the tools to ensure that there is adherence to the medicines. Once treatment is commenced a reliable system of drug supply needs to be in place and also psycho-social support systems to ensure a high level of adherence. The system needs to be organised enough to retain patients, thus ensuring regular and reliable follow-up of patients on treatment.

At the system level, a treatment programme needs to cater for the multitude of individual circumstances leading to a wide and varied involvement with the health service. Pregnancy and childhood require special attention. Many others will require special expertise in their initial workup or for serious side effects. Some will have more than one opportunistic infection or other concomitant diseases such as TB, heart disease or diabetes. Some will require admission to various levels of the health service. At the system level there is a need for management, planning, budgeting, procurement, contract management and monitoring.

An antiretroviral treatment programme cannot be cost-effectively implemented as a separate stand-alone service, but must be integrated into the existing health service as almost all of its components are drawn from the health service. For such a programme to be successful, implementers will have to strengthen the health service and take special measures to overcome system weaknesses. These system weaknesses vary from country to country in the region and also from province to province within countries.

### The Province's strategic approach to HAART

According to the Provincial ARV Plan, HIV care is to be provided at all health facilities up to and including testing the CD4 count of the patient. These include clinics (run by nurses) or hospitals. Funding has been made available to all local authorities to allow for the performance of CD4 counts at clinics. If the CD4 count is above 200 and the patient does not have any major opportunistic infections, the patient should be managed at the facility for that condition or referred within the health service to an appropriate hospital for secondary or tertiary care. This is exactly the same as is the case for TB. If a laboratory diagnosis for TB is made at a hospital, the patient is then referred to a TB clinic for treatment and follow-up for between six months and two years, depending on whether the TB infection is new or a re-treatment or whether the patient has multi-drug-resistant TB.

If the patient is considered to be a possible candidate for HAART, he/she is referred to one of 36 sites where HAART is provided. Patients referred to HAART sites are worked up and prepared for treatment, usually over a 4-6 week period, and commenced on treatment with a first line regimen.

There are trade-offs to be made with the selection of sites. From a patient's point of view it would be ideal to have HAART at every clinic, community health centre and hospital in the province. The expertise, however, does not exist at all facilities to provide HAART. A doctor trained in HAART care needs to initiate treatment and also needs to be involved in the detection of side effects or other complications of treatment. Follow-up visits can be shared with nurses but conventional wisdom dictates that doctors should be present; and in a Province such as the Western Cape, where there are almost 2 000 doctors in the public sector and funding for additional doctors, it would seem appropriate to engage this level of expertise.

Limiting the number of sites to 40 or 50 allows for pooling expertise into a smaller number of sites and for focussing management and training on a more manageable number of sites. Significant expertise exists at regional and tertiary hospitals and a



significant proportion of patients already initiated on HAART receive their treatment here. Treatment at regional or tertiary hospitals, in particular, where patients travel great distances, are likely to enjoy lower adherence as the linkages to psycho-social support programmes in the communities are fewer than district hospitals or community health centres.

Limiting the number of sites aids the effort to prevent drug resistance amongst patients. This is premised on the notion that having too many clinicians prescribing antiretroviral treatment encourages liberal prescribing practice, especially where there is patient and family pressure to initiate treatment when patients are not ready and at risk of non-adherence. Once again, the correct balance needs to be found between reaching as many patients as possible in the shortest time, and getting treatment right first time around. Patients who develop drug resistance are at risk of spreading resistant virus, thereby disabling treatment potential among new entrants onto the programme. Public health benefits of treatment are placed at risk with the widespread development of community-acquired resistance.

With this in mind, the protocol to be followed in the selection of patients for treatment initiation is crucial. This must, however, be balanced with the rights of patients to treatment. Psycho-social criteria such as geographic access to the site, disclosure, past history of adherence to treatment, and literacy levels become important in the decision to initiate a patient onto treatment. Other factors such as alcohol or drug dependency and mental state (for example, clinical depression) are also important in the selection of patients for treatment. None of these criteria are exclusive. A global assessment of the patient by the clinical team must be done before a decision is made.

There is anecdotal evidence that treatment initiated by private general practitioners outside of a comprehensive programmatic approach, including the organised provision of psychosocial support through community-based counselling and support groups, leads to a higher degree of treatment failure and increases the risk of the spread of resistant virus. Resistance is less of a problem in the treatment of paediatric AIDS where its effect is generally limited to individual treatment failure and less likely to lead to sexual spread of resistant virus.

A liberal approach has led to faster enrolment of children onto treatment in the Western Cape. The dramatic decreases in childhood infections, a result of the successful MTCT programme, have led to a high degree of coverage of treatment among children. More

than 60 per cent of an estimated 1 500 children needing treatment are already enrolled onto the programme and this figure is expected to exceed 90 per cent within a year.

## Lessons and challenges of expanded access

The logistics of setting up a HAART programme proved to be complex, related in large measure to the unpredictability of the demand for treatment. Global estimates of numbers of patients with AIDS needing treatment can be calculated from demographic, epidemiological and cost models. In the case of the Western Cape, we were able to predict the total number of patients needing treatment from demographic models developed by the Actuarial Society of South Africa which predicts the prevalence rates of HIV infection over time. The model is able to predict the proportions of HIV infected by stage of disease, allowing for global estimates of patients requiring treatment for each year of treatment over a number of years.

The task of converting these estimates into site-by-site estimates proved more difficult and required some guesswork. In the Western Cape, antenatal prevalence data was available for each health district following three years of district level prevalence studies, and this allowed for broad estimates of high, medium and low prevalence areas for AIDS.

A process of consultation with site-based clinicians gave an indication of both capacity to take on patients and waiting lists at each site. Estimates for each site were then converted into site budgets for drug and lab costs. Staff requirements for each site were built up, taking into consideration the existing capacity and requested additional capacity and adjusting this for broad norms for different categories of staff at each site. Numbers of patients initiating treatment during each month were calculated to ensure that the expenditure generated fitted globally into the available budget. This was done with the full knowledge that budgets will have to be amended after a period of monitoring expenditure at each site. A mechanism was created to allow for funds to be redirected from low to high uptake sites. Staff costs were staggered to allow for a realistic prediction for the time taken to recruit and employ additional staff in the public service. Once again, a balance had to be struck between promising the provision of more staff in a credible manner and the willingness of clinicians to initiate a programme without such additional staff.

Significant numbers of additional staff, particularly doctors, nurses and pharmacists are needed for a HAART programme. In the context of a general shortage of health

professionals, staff recruitment becomes a major challenge. There is also the constant danger that the HAART programme will draw staff away from the already stretched primary health care system. This dilemma is difficult to address, and we cannot claim to have done this. The HAART programme is more attractive to doctors, nurses and pharmacists for a range of reasons, not least of all the better organisation of the programme and the great sense of fulfilment experienced by health professionals in the programme. The right balance has to be struck between employing dedicated staff for the HAART programme and using the programme as a means to attract staff more generally to the public service. Forcing staff at some sites to perform general duties at the facility may be a deterrent to new recruits; while preventing staff already in the service from applying to work in the HAART programme is an infringement of their right to work where they choose. The approach has been to make decisions on a site-by-site level, advertising dedicated posts where the general staffing situation is strong and insisting on dual functions where there are dangers of recruiting staff away from the general service, especially at primary care level.

Local managers and clinical co-ordinators have proven to be well-informed regarding the most appropriate choices to be made and it has been possible to capitalise on this local knowledge. Instead of recruiting staff specifically for the HAART programme, it is proving indispensable to addressing the entire staffing needs of the facility. This is greatly assisted by applying the globally available budget for the facility to the optimal mix of staff recruitment, thus allowing for the initiation of the HAART programme as well as the general needs of the facility. In this way, the HAART programme can be seen to be bringing resources to the whole facility, and this approach reduces the possibility of any resentment being felt about a programme which may appear to be better-resourced than others, and also gives credence to the view that the introduction of HAART can lead to the overall improvement of the public health service.

The same applies to the pharmaceutical service at facilities designated for the provision of HAART, which is a pharmacy-intensive programme. The high cost and volume of antiretrovirals and the strong dispensing component of a HAART programme call for a stable and well-organised pharmacy service in the facility, and it has not been possible to consider a separate pharmacy arrangement for HAART.

The pharmaceutical components of a HAART programme are integrally related to the general pharmaceutical services of the health service. In the Western Cape, where pharmacy services are weak at community health centres, especially in the metropolitan

area, this has proven to be a difficult obstacle to overcome. The central store (or Cape Medical Depot) often fails to supply medicines to institutions. Whereas hospitals are authorised to procure medicines directly from suppliers, community health centres possess neither the management capacity nor the logistical capacity (lack of computerisation, lack of access to budgets and lack of authorising personnel) to procure medicines other than from the medical depot.

The failure of the central store to supply to PHC institutions is related to the poor design of the building, insufficient shelf stock (capital stock), lack of computerisation as well as a lack of leadership, poor staff morale and low levels of productivity. A recurring excuse from the central store is that suppliers do not supply on time or that there are international shortages of certain products. It is a discussion point in the Department as to whether this is a valid excuse or whether suppliers are not being adequately managed when there are failures to respond to orders placed.

At the institutional level, pharmacies have been poorly planned and usually have insufficient space. There is a shortage of pharmacists and the lower salaries in the public service do not attract pharmacists; stock control systems are only manual; and there is inadequate managerial capacity at this level to address the problems. Security is an issue at most community health centres and criminal syndicates target public sector facilities, making security an important consideration in both the selection of sites as well as the number of sites identified. Theft of drugs is a complicated issue. Not only is it the responsibility of the department to prevent theft of medicines paid for by the taxpayer, but stolen antiretrovirals sold in the communities can lead to unstructured dispensing and increases the risk of community drug resistance and the spread of resistant virus.

Our approach to this difficult area of programme implementation was to take it on with a 'can do' approach and to take it step by step. As part of the accreditation process, a checklist of strengths and weaknesses was completed for each of the proposed sites and those sites with adequate pharmacy capacity or alternative interim arrangements were grouped into a set of sites scheduled for early roll-out.

The checklist took into account the physical space at the pharmacy, the staff capacity, security and basic organisation of the pharmacy with regard to operating procedures and stock control. A separate set of standard operating procedures was developed and pharmacy staff at all sites were trained in the use of these procedures.

The most important predictor of a successfully run pharmacy was the commitment, enthusiasm and ability of the pharmacist in charge, with the first two characteristics proving to be the most important. These characteristics have not been lacking among public sector pharmacists and this is a throwback from the deep frustrations experienced by health workers at our inability to provide life-saving medicines in a situation where these were available in the private sector. Enthusiasm, combined with relief, greeted the roll-out team whenever they visited sites to unplug the mechanics of treatment implementation at these sites. Preparing a pharmacy for ARVs afforded the opportunity to review and improve the overall functionality of the pharmacy more generally. As the ARV programme brought more staff and resources as well as opportunities for renovating and retooling pharmacies, it has generally led to an overall improvement. It should be noted that bringing ARVs into the pharmacy is a big change as the volume of drugs and the capital stock (value) of drugs grows significantly (by as much as 20-30 per cent) as does the workload of the pharmacists and their assistants. It appeared to be possible, in our situation, to use the introduction of ARVs into the pharmacies as a trigger to improve the whole pharmacy, given the substantial additional resources being added. In environments with limited resources, it is likely that another approach may be more appropriate.

Our approach to procurement was completely different. In this case our assessment was that our regular system of drug procurement and store capability would collapse under the pressure of adding the ARV load to it. There was not enough physical space on the shelves of the central store for 450m<sup>3</sup> of drugs (4 months' shelf stock). The risk of running out of stock with the current central store was too great and a decision was made to establish a separate procurement process and a separate store.

## Success factors

### Partnerships

Working with partners has been a major success factor in the ARV roll-out. This has been particularly important in the early days of the roll-out when the Department's capacity and experience with implementing and managing ARV treatment was limited. Three partnerships were important in this period – the joint initiatives with Médecins Sans Frontières (Khayelitsha), Desmond Tutu HIV Centre (Gugulethu, funded by Crusaid, City Bridge Foundation and Pangaea) and Kidzpositive (Groote Schuur Hospital, funded by the One to One Foundation).

Research projects, particularly at Tygerberg Hospital, were supported by the Department. All of these partnerships were framed as operational research projects aimed at working out best practices in the provision of ARVs in the public sector, and all documented their activities with a view to answering basic questions on how to organise the service within the system. The Khayelitsha and Gugulethu projects addressed similar questions: is it feasible to provide ARVs in the public sector; how do we ensure high levels of adherence in our setting; what is the best model for community psycho-social support; should treatment sites treat all patients with opportunistic infections or only those eligible for ARVs; how many doctors and nurses do we need for a cohort of 300 patients; which drug combinations should we use?

The stated objectives of the partnerships were important but what was read between the lines was probably more important. The Department was seen as credible and doing all in its power to initiate treatment. It was seen as innovative in its decision to make partnerships where resources were limited. We were all on one side – the virus on the other. This led to a positive spiral where all parties – government, local authorities, NGOs, international donors and clinicians – were working together to do their best in the circumstances, and the importance of this factor should not be underestimated. A programme that is seen as ahead of the rest, innovative, responsive and all-inclusive, will attract good quality staff, better resources and greater trust from the public and civil society and, of course, less criticism.

Over the last six months and in the course of the government-funded roll-out phase, the Department has entered into a unique partnership with a non-governmental organisation called Absolute Return for Kids (ARK), aimed at speeding up the commencement of new sites. ARK brings in a team of doctor, nurse and/or pharmacist (whichever is needed by the site) to rapidly upgrade that site's capability. Once the Department is able to recruit staff on a more permanent basis, as well as upgrade the systems in the facility, ARK will pull out of the operation. This is a model that is strongly recommended.

There are many partners out there and many donors willing to fund treatment in sub-Saharan Africa, and governments should engage them. In the course of such engagement we have learnt to separate the partners who bring significant resources from those who have more enthusiasm than money. There are many partners who are looking for research material so they can complete their PhD or Lancet contributions, and are recognisable by the limited funding they bring with them. Partnership management can prove complex and difficult. Too many partners can be difficult to manage and some proposals must

necessarily be refused in order to avoid being overwhelmed by too many partners. Partners require time and direction, and failure to provide this will lead to partners possibly acting unilaterally. Partnerships must be carefully chosen, and should ideally be well-resourced, well-defined, well-administered, and bring with them additional clinical staff.

The stage has now been reached where discussions are being held with partners about taking over the operations and bringing partnerships to an end. All parties need to understand that such partnerships have a point of closure, in this case usually between three and five years. Over the next financial year the Department will take over all expenditure related to these partnerships. The termination of partnerships should be handled sensitively as deep attachments develop to the projects, and termination processes should be agreed in detail before being implemented.

## Management model

The management model of the ARV programme has been hailed as an important factor in the success of the programme, and while supporting this view, it is not easy to accurately describe the model. As the clinical and scientific information on the treatment of HIV/AIDS is constantly being updated it was necessary to bring clinicians closer to the policy-making process. This was made possible by combining managers and clinicians into a common decision-making structure that meets regularly and develops the main policies of the programme. Site managers and clinicians joined as new sites were activated. Managers learned about the clinical and 'coal-face' issues and clinicians began to appreciate the managerial issues relating to the budget, human resources, supply chain and the constraints of and need for building the health system infrastructure. Partners were brought directly onto the decision-making structure.

This management model led to openness and transparency, joint ownership of problem areas and joint credit for success. The role of clinicians in the Western Cape, as well as international partners such as MSF, in enhancing the reputation of the Western Cape ARV roll-out has been significant. Once again, this has added to the positive spiral.

## Weaknesses

There are also significant weaknesses to the Western Cape ARV programme that are well-known to the team, with some of these being the result of trade-offs that were made in deciding what components of the roll-out should be prioritised over others. In some cases, the policy framework was not in place to implement these component parts.

These weaknesses will be overcome as the policy vacuum is addressed. This has been the case with the nutrition support components of the programme and also the community adherence components.

### The importance of nutrition

In the case of nutrition support, the budget in the current year did not allow for the provision of nutrition support for all patients on ARVs and provision was made only for patients with a body mass index of 18.5 to access the Department's Protein Energy Malnutrition scheme, which is available to all patients with any chronic disease, including TB. A policy has now been clarified that will allow for nutrition support to all patients who request it at ARV sites, given the importance of proper nutrition in ensuring adherence to antiretrovirals. This will be budgeted for in the next financial year. Store space for large stocks of fortified foods becomes a necessity and sites will need internal reorganisation and renovations to accommodate these stocks. Food supplements are well-known as high risk items for theft and controls must be in place to ensure optimal use of these resources.

In the case of community-based psycho-social support, the policy work here is incomplete. There are different models for such support and it is difficult to draw conclusions about which of these are the best for the Province. In the case of Khayelitsha, patients are required to select a treatment coach who becomes the main individual in the psycho-social support component. This is backed up by site-based counsellors and support groups. Drug literacy programmes are also conducted with the patients and their treatment coaches. Good adherence has been shown after two years.

In Gugulethu, the model is very different, with lay counsellors who are community-based looking after up to 30 patients, doing home visits and unannounced pill counts. These counsellors are the patient's first port of call with any problems. The counsellors spend a lot of time at the site and are involved in the clinic-based management of the patient together with the doctor and nurse. The numbers of counsellors in this model is a lot higher than in the Khayelitsha model and is likely much more expensive. Two year adherence is also good here.

At the Tygerberg Hospital, patients are counselled by site-based counsellors and then referred to home-based care organisations in the community. This appears to be a weaker model although it tends to use up unused capacity in the home-based care sector. Theoretically, the need for home-based care should decrease substantially as



more patients are commenced on treatment and this should free up capacity for home-carers to play a greater role in ARV psycho-social support. These models are being evaluated and decisions will be made in the combined clinician-management-partner forum as to the optimal model at the best cost. The model will be carried through each site and financed in a way that allows for strong systems to be built at the community level.

## How can everyone be reached?

The most important weaknesses relate to the slowness of commencement of patients onto treatment at most of the sites. Patients have their clinical workup fairly quickly and if the CD4 count is below 200, they fall into the group to be commenced onto treatment. The actual initiation onto treatment is a longer process, taking between four and six weeks to prepare the patient, and possibly longer if the patient is not ready for treatment. As a result, most sites have between 20 per cent and 40 per cent of their patients waiting to start treatment. This is compounded by the shortage of doctors and nurses at most sites. These backlogs are the most difficult part of a clinician's experience at an ARV site, as there is a concern that a patient may develop a serious opportunistic infection in this period. Large backlogs lead to a delay in the commencement of treatment. The mean CD4 count for patients initiating treatment in Khayelitsha during the first two years of the programme was 50, which is too low. This generally leads to a situation where patients on treatment have a high degree of acuity of illness and more complications, a greater number of hospital admissions and a higher mortality rate on treatment.

The addition of four doctors to the service in Khayelitsha has led to an increase in the mean CD4 count of patients commencing HAART to 89. Doctors and nurses here report that the patients are generally easier to manage now that treatment is started earlier, and that less time is spent on patients who are already on treatment; this means that many more patients can be seen, leading to an overall improvement of care at these sites. The backlogs create other difficulties. Pregnant women with CD4 counts of less than 200 cannot wait four to six weeks to commence treatment, but need to start immediately. When they are referred to ARV sites with large backlogs, clinicians are placed in an ethical quandary about whether pregnant women should 'jump the queue' in place of patients already worked up and waiting for treatment. This has led to a slow start to providing HAART in pregnancy. Fortunately, the backlogs will be temporary, since in the case of the Western Cape these should be made up over the next 6 to 12

months, after which patients will be initiated earlier onto treatment; those patients who need to be fast-tracked, such as pregnant women, will not be delayed in the commencement of treatment.

## More complexities...

There are many more complexities that need to be understood and unravelled in the course of implementing an ARV treatment programme. As many as 10 per cent to 15 per cent of patients requiring ARVs will need referral to a specialist centre for specialised investigations before they commence treatment, or for the management of Immune Reconstitution Inflammatory Syndrome (IRIS) or serious side-effects. Secondary and tertiary expertise is also crucial in providing clinical support, outreach clinics and training to staff at the community health centre or district hospital level where the majority of patients should be on treatment.

The lack of infrastructural readiness of the facility has also been an issue at almost every site. This has mainly related to the need for additional (preferably private) consulting rooms, counselling facilities and pharmacy infrastructure (additional space, systems, staff and equipment and fittings). As the public service is notorious for its slow response to building works, this is a problem most sites live with and it is generally two to three years before renovations are done or new facilities built. In this regard, there is no substitute for an organised and systematic approach to documenting needs and following up building works needs on a regular and dedicated basis.

## Conclusion

After three years of pilot projects and another full year of rapid scale-up to the level of a province-wide HAART capability, the Western Cape has learnt many important lessons about the challenges of such an addition to the package of care offered in the public health service.

We are certain that HAART is more effective at community health centres or district hospital levels where the synergies of providing treatment by skilled doctors and nurses can be combined with all-important community-based psycho-social support programmes aimed at enhancing adherence. We have also learnt that HAART cannot be provided independently of the myriad of other health interventions and that all component parts of a health service need to be geared up for such a programme intervention.

We have also made a commitment to the view that the provision of HAART provides us with an opportunity to address system anomalies within the public sector. The early impact of the HAART roll-out has been on pharmacy services. There has also been an impact on staff recruitment and retention strategies for both the HAART and general PHC services, particularly in respect of doctors, nurses and pharmacists. As part of this latter issue, the HAART programme has shown the significant short-term benefits of well-planned and high quality training programmes for staff, and their impact on staff morale.

The most important lessons that have been learnt from the HAART roll-out in the Western Cape include the importance of flexibility, the importance of trust established through partnerships, communication with and involvement of clinicians and other health workers in the roll-out effort, and the impact that the availability of HAART has had on the morale of the clinicians throughout the public health sector.

South Africa is in a unique position in the developing world in that government has committed the resources needed to have the largest antiretroviral treatment programme in the world. The Western Cape is determined to lay the basis for a successful programme throughout the country and to set a trail-blazing path in that regard.

We have tried to show that the task is a difficult one and yet, with the correct combination of actions and dedicated effort, a universally available treatment programme is achievable.

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