23 ACCESS TO ANTIRETROVIRAL THERAPY

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Key Messages

- About 500 000 people in South Africa are in need of life-saving ARV medicines now, and the number is projected to rise to 1.4 million by 2009.
- Access to ARVs in SA is still minimal despite the fall in medicine prices.
- The key barrier to access is no longer the costs of ARVs and tests, but the capacity of the health system to implement the programme.
- Information on programme implementation needs to be communicated effectively and regularly by departments of health.
- The 2004 goal of at least one ART service point per health district is being delayed by the procurement process and the need to train large numbers of health workers.
- Access to ARVs is anticipated to be very uneven across the country, worsening existing health system inequities.
- Lessons learned from the PMTCT programme should be heeded to avoid similar problems with the ART roll-out.
- The development of monitoring and evaluation indicators requires careful consideration of international guidelines as well as local needs to monitor equity.

Framework for Monitoring and Evaluation

Global:

- WHO '3 by 5' initiative and associated guidelines
- Global Health-Sector Strategy for HIV/AIDS 2003-2007
- Abuja Declaration of HIV/AIDS Tuberculosis and other related infectious diseases
- UNGASS Declaration of Commitment on HIV/AIDS
- Maseru Declaration

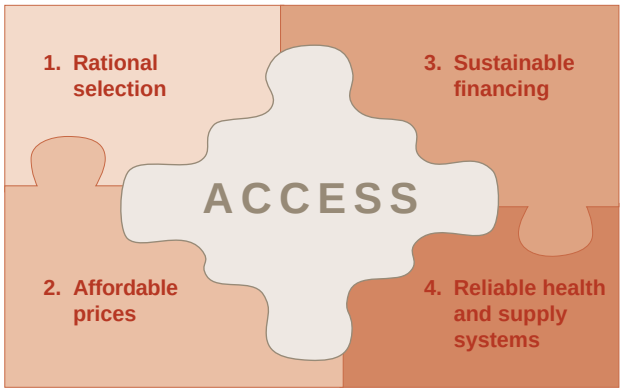
South Africa:

- Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment
- HIV/AIDS and STD Strategic Plan 2000-2005

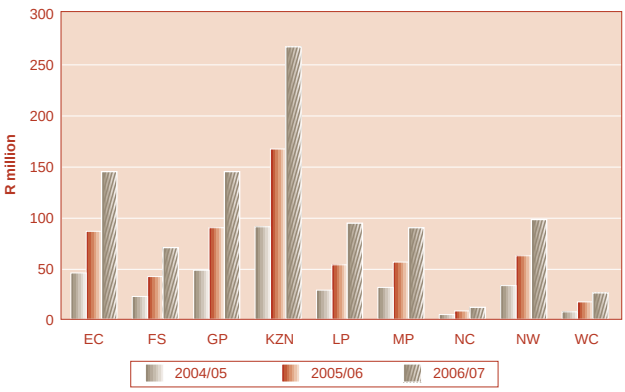
Key Indicators

Percentage of people with advanced HIV infection receiving antiretroviral combination therapy

WHO / EDM access jigsaw



ARV earmarked allocations by province, R million, real 2004 terms[49]



Introduction

Current estimates indicate that South Africa (SA) has the largest number of people living with HIV/AIDS in the world. Although estimates vary, it is broadly accepted that between 4 and 6 million people are infected and that HIV/AIDS is the leading cause of death in the country.[1] An estimated 600 South Africans are dying from AIDS daily.[2] The Medical Research Council (MRC) has predicted that the under five mortality rate will increase to twice current levels by 2008, and by 2010 the cumulative number of HIV/AIDS deaths will exceed 6 million.[1] In provinces with high HIV prevalence, HIV/AIDS patients account for about 46% of hospital admissions.[3] About 500 000 people in SA are in need of life-saving antiretroviral drugs now[4] and the number is projected to rise to 1.4 million (excluding those on medical schemes) by 2009.[5]

Although antiretroviral drugs (ARVs) have been available since the early 1990s, the widespread use of ARV combinations in a therapeutic setting, known as Highly Active Antiretroviral Therapy (HAART), has almost exclusively benefited industrialised countries, which bear only 5% of the global burden of HIV/AIDS.[6,7] The possibility of access to antiretroviral therapy (ART), particularly in Southern Africa where only 1 out of every 25 000 eligible people is currently on treatment, is quite recent. This is to a large extent attributable to a massive global social movement around access to essential medicines, accompanied by a profound reduction in the cost of antiretrovirals.[8] In SA, the demand for access to ARVs was most prominently articulated by the Treatment Action Campaign (TAC), starting in 1998 and intensified in 2001.[9] While demands for access are justifiable, given the public health threat HIV/AIDS poses to SA, the provision of ARVs in the public sector poses many challenges. For example, provision of HAART requires sustained technical capacity and represents a major challenge in under-resourced and under-served areas.[10]

In the 2002 South African Health Review, it was predicted that in 3-7 years, public sector access to HAART in SA would be a reality.[11] With the advent of the 'Operational Plan for Comprehensive HIV/AIDS Care and Treatment for South Africa' (the Operational Plan), which was approved by Cabinet on 17 November 2003,[12] this pediction has been given a chance of becoming a reality.

In December 2003, the World Health Organization (WHO) published a policy document outlining a plan to bring ART to 3 million people in developing countries by 2005.[13] The '3 by 5' strategy document outlines how WHO intends to work with other governments and groups to get treatment to where it is most urgently needed.

While both global and national plans have good intentions to strengthen the overall continuum of HIV/AIDS prevention, care and support, and reverse the socio-economic impact of HIV/AIDS, they pose major challenges. In the context of SA, the key challenge will probably be to expand access to treatment in ways that will not reinforce or accentuate existing health system inequities. Inequities persist across race, gender, age, geographical area, private / public health, primary / tertiary care and rural / urban sectors. A 'first come, first served' system has the potential to worsen this situation. The Joint Health and Treasury Task Team (JHTTT), which developed the Operational Plan, recognised this challenge and laid out a number of equity criteria for the programme:

- Provision for the rural poor must not be delayed until after urban areas have been served, but must commence concurrently.
- The South African government must have a clear, transparent and reasonable plan, which has the flexibility to address changing circumstances.
- Phased implementation of programmes is acceptable, as long as the State is working towards the realisation of a programme to which everyone in need will ultimately have access.
- Rationing on the basis of behaviour (e.g. poor adherence to treatment) is justifiable.
- A coordinated national programme is required to ensure equitable resource allocation roll-out across provinces.

This chapter briefly looks at both global and local frameworks / strategies for the provision of ART and examines the current trends and challenges of providing ART equitably in SA.

Framework for Monitoring and Evaluation

International Initiatives

The international response to HIV/AIDS has been guided by a number of United Nations (UN), WHO and Regional initiatives, some of which offer a framework for monitoring and evaluating HIV/AIDS global and national responses. These initiatives are summarised, together with other milestones in the history of ARV access, in Box 1.

Box 1: Milestones in the history of ART[6]

Date	Milestone
March 1987	Zidovudine (ZDV or AZT), the first ARV drug, becomes available.
1996	Highly Active Antiretroviral Therapy (HAART), which uses a cocktail of antiretroviral drugs, is introduced.
November 1997	Launch of UNAIDS' Drug Access Initiative, designed to develop innovative, effective models to improve access to medicines to treat HIV and opportunistic infections in developing countries.
1999	*Médecins Sans Frontières* (MSF) launches a campaign for Access to Essential Medicines for neglected diseases, including HIV/AIDS, with the money awarded to the organisation for winning the Nobel Peace Prize.
May 2000	Launch of the Accelerating Access Initiative, a partnership between six UN organisations and five pharmaceutical companies, to address the lack of affordability of HIV medicines and to increase access to HIV/AIDS care and treatment in developing countries.
September 2000	The World Bank launches the Multi-Country HIV/AIDS Program for Africa to make funds available rapidly and flexibly to assist countries in scaling up their HIV/AIDS-related activities.
January 2001	The African Comprehensive HIV/AIDS Partnership between the Government of Botswana, the Merck Company Foundation, and the Bill and Melinda Gates Foundation starts with the development and implementation of a comprehensive HIV/AIDS strategy in Botswana, which includes large-scale access to ARV treatment in the public health sector.
April 2001	African leaders at the summit of the Organisation of African Unity in Abuja, Nigeria, endorse the need for greater efforts to fight HIV/AIDS on the continent, and commit their leadership to the cause. The Abuja Declaration on HIV/AIDS, Tuberculosis and Other Related Infectious Diseases pledges governments to set a target of allocating at least 15% of their annual budgets to the health sector, and to making available the necessary resources for the improvement of a comprehensive multisectoral response to the HIV/AIDS epidemic.
April 2001	The UN Commission on Human Rights adopts a resolution recognising for the first time that access to medications in the context of pandemics such as HIV/AIDS is "a fundamental element of achieving progressively the full realisation of the right of everyone to enjoyment of the highest attainable standard of health".
June 2001	UN General Assembly Special Session (UNGASS) on HIV/AIDS unanimously adopts the Declaration of Commitment on HIV/AIDS. Access to ARV drugs specifically recognised by the world's governments as an essential element in the response to the epidemic.
July 2001	The Global Fund to Fight AIDS, Tuberculosis and Malaria is set up. An initiative strongly supported by the UN Secretary-General, Kofi Annan, the Fund is an independent, public-private partnership designed to attract, manage and disburse new resources to fight the global crises represented by these three diseases. The Fund provides resources for comprehensive AIDS programmes, including the procurement of ARVs.
November 2001	The Doha Declaration on TRIPS and Public Health is adopted by members of the World Trade Organization (WTO), reconfirming the right of national governments to override patents, if necessary, in order to promote access to medicines by all.
April 2002	WHO includes 12 ARVs on its Model List of Essential Drugs, which is used by countries to develop essential drugs lists appropriate to their own needs.
June 2002	President Bush announces a $15 billion programme, the President's Emergency Programme for AIDS Relief.
July 2003	Heads of State at a SADC Summit on HIV/AIDS in Maseru, Lesotho, adopt the Maseru Declaration, reaffirming commitment to combating the epidemic as a matter of urgency through multisectoral action. Priority areas include access to testing, care and treatment, and the mobilisation of funds.
August 2003	Decision on implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health is taken by the WTO. This is the one remaining piece of unfinished business on intellectual property and health that was left over from the WTO Ministerial Conference in Doha in November 2001. WTO member governments agree on legal changes that will make it easier for poorer countries to import cheaper generics made under compulsory licensing if they are unable to manufacture the medicines themselves.
December 2003	WHO announces a commitment to the goal of having 3 million people on ARV therapy in low- and middle-income countries by the year 2005.

The 'treat 3 million by 2005' initiative

The goal of this initiative is for WHO and its partners to make the greatest possible contribution to prolonging the survival and restoring the quality of life of individuals with HIV/AIDS, advancing towards the ultimate goal of universal access to ART for those in need of care, as a human right and within the context of a comprehensive response to HIV/AIDS.[13]

As of November 2003, only 400 000 people in developing countries who were living with HIV had access to ARVs. This was just 7% of the total number of people who need treatment. The estimated total number who should be receiving ARVs is about 6 million people. In Africa, only 2% of those who need treatment are receiving it. This massive gap between need and treatment is why the WHO has launched a strategy to greatly increase the number of people who can access these life-saving medications. WHO hopes to see 700 000 people on ART by December 2004, 1.6 million people by June 2005 and 3 million by December 2005.

WHO's strategic framework for emergency scaling up of ART contains 14 key strategic elements. These elements fall into five categories – the pillars of the '3 by 5' campaign:

- global leadership, strong partnership and advocacy
- urgent, sustained country support
- simplified, standardised tools for delivering ART
- effective, reliable supply of medicines and diagnostics
- rapidly identifying and reapplying new knowledge and successes.

Current achievements

Since WHO's '3 by 5' initiative was first announced, a growing number of nations have taken the first steps towards scaling up the health care infrastructure needed to administer ART. As of February 2004, forty-two countries had formally requested participation in the '3 by 5' initiative, including India, SA, Zimbabwe, Malawi and Mozambique. Some will rely upon caregivers with only minimal training to administer simplified and standardised ARV regimens.

ARV regimes

Simplified and standardised first-line ARVs regimes are the basis of both the international and national ART roll-out initiatives. In 2003 participants at a workshop held in Nairobi by *Médecins sans Frontières* (MSF) concluded that an ideal first-line ARV regimen should be:

- effective and well tolerated with minimal side effects
- potent, even in patients with advanced disease, and robust (with a favourable resistance profile)
- free from troublesome interactions or contra-indications
- appropriate for use in TB co-infected patients and in pregnant or lactating women
- available in a fixed-dose combination (FDC), to be administered once or twice a day
- based on formulations that are stable in tropical conditions
- free from requirements for intensive laboratory monitoring
- affordable.[14]

Table 1: Summary of targets for the '3 by 5' initiative

Target description	Dates and targets to be attained			
	Jun 2004	Dec 2004	Jun 2005	Dec 2005
Countries using the AIDS Medicines and Diagnostics Service (AMDS)[i]	20	30	40	50
Countries with national implementation plans	25	35	60	60
Countries establishing ARV therapy targets	35	50	60	60
Additional WHO staff deployed to country offices	2000	400	440	480
Partnerships between ARV therapy outlets and community-groups	1 500	3 000	9 000	30 000
Health providers trained to provide ARV therapy	10 000	30 000	70 000	100 000
People receiving ARVs in developing countries	500 000	700 000	1 600 000	3 000 000

Note: i AIDS Medicines and Diagnostics Service is the access and supply arm of UNAIDS/WHO's 3 by 5 initiative.

FDCs are seen as important tools for scaling up access in resource-poor, high-prevalence settings. They are easier to distribute and take, and may be less expensive than combinations in which each medicine must be administered separately.[15]

A nevirapine/stavudine/lamivudine regime, taken as a twice-daily FDC, was deemed preferable to the other alternative regimens by the MSF workshop.[16] This combination was also endorsed as the first choice by a WHO-sponsored meeting in Zambia in November 2003, which sought to make operational recommendations on how to carry forward the '3 by 5' goals. Regimens in which efavirenz (EFV) replaces NVP are the preferred option in people who also require TB treatment alongside ARVs.[17]

WHO support to access drugs

A key element of the '3 by 5' strategy has been the creation of the AIDS Medicines and Diagnostics Service (AMDS). This is a new mechanism created to ensure that safe, effective and affordable medicines and diagnostic tests of good quality are more easily accessible. The AMDS will not directly purchase medicine or diagnostic test materials, but will assist national authorities and programme implementers to procure and maintain a reliable supply of medicines. Furthermore, the AMDS should eventually help countries to secure the best prices possible.[17]

Sufficient financial resources have not yet been mobilised to fully support the '3 by 5' initiative and national HIV programmes. By mid March 2004, WHO had raised $2.3 billion, only about half of the money required for the '3 by 5' initiative.[18]

Part of this funding crisis can be attributed to the existence of parallel, unilateral aid efforts. Notable among these is President Bush's $15 billion President's Emergency Plan for AIDS Relief (PEPFAR), launched in 2003. PEPFAR's goals are to treat at least two million HIV-infected persons with antiretroviral therapy, prevent seven million new infections in 14 countries in Africa and the Caribbean, and care for 10 million persons infected with or affected by HIV, including orphans and vulnerable children. The target countries, which are home to nearly 50 percent of HIV infections worldwide, are Botswana, Cote d'Ivoire, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda, and Zambia. Apart from the fact that this limits US contributions to the GFATM and '3 by 5' initiative, the US government has also come under pressure for calling into question the safety and efficacy of generics and FDCs. Although never formally stated, it became apparent that PEPFAR funds would only be used to buy US Food and Drug Administration approved ARVs, in essence those sold by the original patent-holding pharmaceutical companies. Even though these medicines are heavily discounted in developing countries, compared to prices in the US and Europe, they are still about twice as expensive as the medicines made available through a deal with SA and Indian generic firms, brokered by the Clinton Foundation.[19] The price for the most common first line formulation under these agreements is as low as $140 per person per year, one-third to one-half of the lowest price otherwise available in most settings.[20] Following the recommendations of a meeting on FDC Drug Products in Gaborone, Botswana, in March 2004, the US Department of Health and Human Services has proposed a fast track registration process for FDCs, co-blistered presentations and generics, which would not necessarily be sold in the US but could then be procured with PEPFAR funds.[21] The exact process is still being debated, but there remain concerns about possible delays in obtaining even limited 'registration' for key generic ARVs.[22]

Perhaps the most stinging rebuke for US unilateral action came from the 57th World Health Assembly, which resolved in May 2004 not only to support Member States' abilities to use the full range of TRIPS-related relief measures, but warned against the dangers of bilateral 'free trade' agreements which might restrict access to such measures, and also sought to strengthen the WHO prequalification project.[23] Globally, the means to ensure access to good quality, affordable ARVs therefore remains a contested terrain.

National Initiatives

HIV/AIDS and STD Strategic Plan for South Africa, 2000-2005

The South African national strategic plan for HIV/AIDS (the Strategic Plan) was launched in June 2000 by the national Department of Health (NDoH).[24] The aim of the Strategic Plan is to provide a framework for a multisectoral response to HIV/AIDS, at all levels of society. The overall goals are to reduce the number of new HIV infections (especially among the youth), and to reduce the impact of HIV/AIDS on individuals, families and communities.

The Strategic Plan is structured around four main areas:

- prevention
- treatment, care and support
- legal and human rights
- monitoring, research and surveillance.

The Strategic Plan had committed to offer ARVs for post sexual assault and universal access to nevirapine for the prevention of mother-to-child transmission only, but has in this regard been overtaken by the more recent Operational Plan.

Operational plan for Comprehensive HIV and AIDS Care, Management and Treatment for South Africa (the Operational Plan)[25]

Released in November 2003, the Operational Plan aims to accomplish two interrelated goals, which are to provide comprehensive care and treatment for people living with HIV/AIDS and to facilitate the strengthening of the national health system in SA. The following targets are articulated in the plan:

- Establish at least one service point in every health district (District Council or Metropolitan Council) in SA by the end of the first year of implementation.
- Provide all South Africans and permanent residents who require comprehensive care and treatment for HIV/AIDS equitable access to this programme within their local municipal area within five years.

It also involves 'upgrading our national health care system, recruitment of thousands of professionals and a very large training programme to ensure nurses, doctors, laboratory technicians, counsellors and other health workers have the knowledge and the skills to ensure safe, ethical and effective use of medicines'.[25] It is important to recall that this Operational Plan did not emerge from a simple government-led policy process. A number of key strategic actions by actors outside of government contributed to the environment that made its development inevitable, not least the following:

- The resolution of the court action taken by the Pharmaceutical Manufacturers' Association and others to block the implementation of amendments to medicines legislation in April 2001, which involved global social mobilisation.
- The Bredell Consensus Statement on the Imperative to Expand Access to Antiretroviral Medicines for Adults and Children with HIV/AIDS in SA, in October 2001.
- The National Treatment Congress held by the Congress of South African Trade Unions and Treatment Action Campaign in August 2002.
- The 'HAART projects: Getting Started in South Africa' meeting convened by the Nelson Mandela Foundation in November 2002.
- The NEDLAC Framework Agreement on a National Prevention and Treatment Plan for Combating HIV/AIDS negotiated between October and November 2002.
- The Treatment Action Campaign's 'Dying for Treatment' civil disobedience campaign, from March to May 2003
- The 'Scaling up Antiretrovirals in the public sector: What are the challenges?' conference convened by the University of the Witwatersrand's School of Public Health and Perinatal HIV Research Unit in August 2003.
- The South African AIDS Conference, held in Durban in August 2003.

Proposed indicators for monitoring '3 by 5' and national initiatives of ART programmes

WHO Guidelines

Based on WHO's lessons learned, the following guiding principles are recommended for the development of national indicators.[26]

- Firstly, the number of indicators must be kept to a minimum, as the effort and expense required to collect the necessary data can be daunting, especially for national monitoring and evaluation systems with limited capacity.
- Secondly, the indicators developed must be agreed by international and national partners to minimise the burden countries may encounter through having to collect different indicators, or different variations of the same indicator, for international agencies and donors who fail to coordinate their own monitoring and evaluation needs.
- Thirdly, indicators that can be compiled using data collection systems that already exist are preferable to those that will require special efforts to collect.

The WHO proposed indicators are detailed in Table 2.

Proposed National Indicators

The Operational Plan has outlined a number of possible output and outcome indicators (see the chapter on HIV/AIDS in this Review). At the time of writing, the national indicators had not been finalised.[a]

Challenges in monitoring ARV therapy

As with many complex and multi-layered interventions, monitoring and evaluation of ART is easier to depict graphically than it is to operationalise. A typical monitoring and evaluation pipeline is shown in Figure 1. The inputs into ART programmes are relatively easy to define, identify and monitor. Monitoring and evaluating the process, outputs, outcomes and impact of these interventions is far more complicated. The process of implementing ART programmes is difficult and open-ended; the programme outputs differ according to the implementation processes used. The goals and objectives of therapy are varied and they have not yet been agreed upon.[27]

a Ronel Visser, Member of the National Health Information System Committee of SA, February 2004, personal communication.

Table 2: WHO proposed core indicators for ART programmes[26]

Level	Area	Core indicator	Definition	Numerator	Denominator
Input	National policy and guidelines	**Existence of national policy and guidelines for ART programmes**	Existence of national guidelines for the provision of treatment with antiretroviral drugs in line with international or commonly agreed upon standards. Guidelines should be available for all aspects of the provision of ART, including the four Ss (starting, stopping, switching and substituting) as well as the provision of necessary care, support and follow-up.	N/A	N/A
Process	Human resources	**Number of health personnel trained to deliver ART services according to national / international standards**	The number and percentage of health personnel newly trained or re-trained to deliver ART according to national guidelines during the preceding 12 months. These guidelines should cover ART dispensing, administration, and monitoring. 'Re-trained' health personnel refers to those that have undergone in-service training. That is, they are already in the work force and have been practising for several years. Training includes both in-service and pre- service training.	No. of health care personnel newly trained or re-trained in ART provision, administration, and monitoring during the preceding 12 months.	Total no. of health care personnel working in facilities that provide ART.
	Drug supply	Percentage of ARV distribution nodes that report on inventory consumption, quality, losses and adjustments on a monthly basis (the standard in this regard are under development)	The percentage of ARV distribution nodes that report basic information on the logistics management system on a monthly basis. The information of importance is inventory consumption per month, quality and any problems with quality, losses from inventory stores, and adjustments made on a monthly basis. A node is a regionally or locally based distribution point, receiving its drugs from the central stores and providing them to the clinics, pharmacies and other recognised distribution points in the district. These nodes are the key to maintaining an uninterrupted drug supply that is secure, flexible and responsive to changing needs.	No. of nodes reporting on monthly basis.	Total no. of nodes
Output	Coverage of programme and access	**Percentage of districts with at least one centre that provides ART services in line with national standards**	Percent of districts or local health administration units that have at least one centre staffed by trained counsellors providing ART in line with national standards.[i] This indicator gives a crude idea of coverage of ART.	No. of districts with at least one centre that provides ART services in line with national standards.	Total no. of districts
		Percentage of designated facilities providing ART in line with national standards	The percentage of designated health care facilities at different levels of the health care system that have the capacity to provide ART in line with national standards.	No. of designated facilities providing ART in line with national standards	Total no. of designated facilities
Outcome	People on treatment	**Percentage of people with advanced HIV infection receiving ARV combination therapy *(ART Coverage)***	The percentage of people with advanced HIV infection currently receiving antiretroviral combination therapy.	No. of people with advanced HIV infection who receive ARVs combination therapy according to the nationally approved treatment protocol (or WHO/ UNAIDS standards)	No. of people with known advanced HIV infection (estimated to be 15% of the total no. of people who are HIV+)

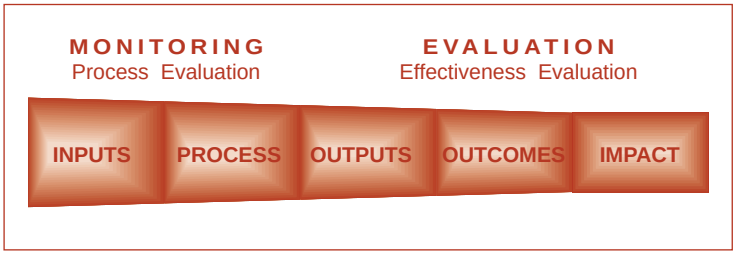
Level	Area	Core indicator	Definition	Numerator	Denominator
		Number of drug regimens distributed to patients per month	Number of drug regimens distributed to patients per month.	No. of drug regimens distributed through drug distribution points	N/A
		Twelve Month programme retention rate	Percentage of individuals still on treatment 12 months (and every 12 months thereafter) after initiating treatment.	No. of individuals still on ART 12 months (and every 12 months thereafter) after initiating it	Total no. of individuals initiating treatment in a given calendar year
Impact	Health status / Survival	Percentage of adults on treatment who gain weight by at least 10% at 6 months after the initiation of treatment	Percentage of adults on treatment who gain weight by at least 10% at 6 months after the initiation of treatment.	No. of adults on ART who gained weight by at least 10% at 6 months after initiating treatment	The total no. of adults who initiated treatment at around the same time
		Percentage of people still alive at 6, 12, and 24 months after initiation of treatment	Percentage of people still alive at 6, 12, and 24 months after initiation of treatment.	No. of individuals still alive after initiating treatment after 6, 12, and 24 months	Total no. of individuals initiating treatment at around the same time

Note: WHO recommends that countries with limited capacity start with the five indicators (marked in bold) or choose to stagger the implementation of monitoring and evaluation over time.

i Standards are:
a. Systems and items to support management of opportunistic infections and provision of palliative care (symptomatic treatment) for advanced care of clients with HIV/AIDS;
b. Systems and items to support advanced services for HIV/AIDS care;
c. Systems and items to support ART services;
d. Conditions to provide advanced inpatient care for clients with HIV/AIDS;
e. Conditions to support home care services; and
f. Post-exposure prophylaxis.

A health facility survey is required to measure the extent to which ART is being administered and monitored in line with existing standards.

Figure 1: The monitoring and evaluation pipeline



Source: Challenges in monitoring ARV therapy[27]

Data and Analysis

Locally available data are only now beginning to become available, as the ARV roll-out progresses. However, this section will focus on what is already known about ART coverage, and then concentrate on the data used to justify the decision to provide ART in the public sector, the means provided and the challenges facing that process.

ART coverage – international perspective

Two years after UNGASS, ART coverage for people in low and middle income countries remains extremely low, with only about 400 000 (7%) receiving ARVs in 2003 out of an estimated 6 million who need the therapy.[13] Cited reasons for poor access to ARVs in the developing world and particularly in sub-Saharan Africa include:

- financial constraints
- weak management systems
- weak health systems, including poor drug management and logistics systems; weak patient tracking and referral systems; understaffed health facilities; inadequate training, deployment and remuneration of health workers; inadequate physical space and need for rehabilitation of clinics, laboratories and pharmacies; and lack of medicines
- inadequate / too complex clinical guidelines
- weak laboratory standards
- poor coordination among players and stakeholders
- stigma and discrimination against people living with HIV/AIDS.[28]

Another way to view access is as an interlocking series of jigsaw pieces. Achieving progress on one aspect moves the emphasis on to the next. The pieces are (1) rational selection, (2) affordable prices, (3) sustainable finance, and (4) effective health and support systems. This applies equally to ART or any essential medicine. As progress has been made with selecting rational first-line options for resource-constrained settings, securing lower price and additional financing, so the focus now falls on the health infrastructure.

The estimated ART coverage of adults in developing countries at the end of 2003 is shown per WHO Region in Table 3, and for selected African countries in Table 4. In sub-Saharan Africa, only an estimated 100 000 people had access to antiretroviral treatment at the end of 2003, or about 2% of the 4.4 million people in need.

Table 3: Coverage of adults in developing countries on ART and estimated need, by WHO Region, as at Nov 2003[13]

Region	No. of people on treatment	Estimated need	ART Coverage (%)
Africa	100 000	4 400 000	2
Americas	210 000	250 000	84
Europe (including Eastern Europe and Central Asia)	15 000	80 000	19
Eastern Mediterranean	5 000	100 000	5
South-East Asia	60 000	900 000	7
Western Pacific	10 000	170 000	6
All WHO Regions	400 000	5 900 000	7

Table 4: The gap between the treatment need and treatment coverage in selected African countries, 2003[29]

Country	No. of people on treatment	Estimated need	ART Coverage (%)
Botswana	8 000	110 000	6
Malawi	800	300 000	<1
Nigeria	14 000	1 500 000	<1
South Africa	<5000[i]	500 000	<1
Uganda	17 000	110 000	15

Note: i In the public sector, out of 20 000 - 30 000 in total.

Although Uganda was one of the first countries to run a pilot ARVs project in Africa, Botswana was the first country in sub-Saharan Africa to offer ARVs through the public health system on a large scale, starting in January 2002.

Botswana's coverage and experience

Botswana has one of the highest prevalence levels of HIV/AIDS in the world, estimated at 40%.[30] Botswana started its ART treatment programme in January 2002. Although the country has invested heavily in the programme and has a committed leadership, and a relatively smaller number of people needing ART, the coverage after two years remains relatively small. By 15 September 2003, 12 000 patients had enrolled in the programme, 8 000 were on ARVs, and 786 had died. By February 2004, the number enrolled had grown to 19 675 and 11 660 people, including children, were on ARVs, and 1 106 patients on ARVs had died.

Critically, Botswana's experience has the potential to provide some key lessons for the SA ART roll-out.[31, 32, 33] These include the need to address several capacity challenges at the same time (e.g. chronic shortage of staff, a prevailing culture of silence, low knowledge of HIV/AIDS, lack of experience with ARVs, lack of appropriate storage and security facilities, lack of laboratories, adequate space and a functioning monitoring system), and that rapid expansion may compromise the quality of the programme, particularly in areas such as follow-up and monitoring. They have learned that, without substantial investments in the health system, HIV/AIDS may simply exacerbate existing deficiencies. They have shown that patient enrolment follows a sigmoid curve as exponential growth occurs only after initial capacity is developed. They have learned that ART needs to be implemented by teams of professionals. This means that each service site needs to have a team of professionals and a full time manager to manage schedules and systems. They have shown that adequate patient education on ARVs is essential, and that health workers need to build trust and prepare for a long relationship with their patients. Further, like the MSF project in Khayelitsha, they have shown the utility of all patients having a 'buddy', someone who knows the patient's status to assist with follow-ups, patient tracking and adherence, and that rigorous patient follow up in the first 3 months is crucial.

ART Coverage in SA

Access to ART

Until recently, provision of ARVs in SA has occurred mainly through medical schemes, non-governmental organisations (NGOs) working through public and private facilities and through the corporate sector. Only recently has provision through the government-funded public sector commenced.

Medical schemes

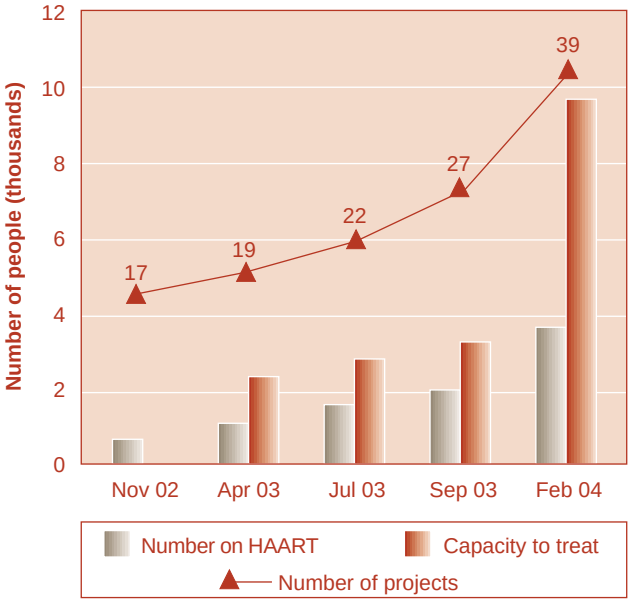
It is estimated that about 6.5% of the 7 million medical schemes beneficiaries in SA are HIV positive. By July 2002 about 22 500 members had enrolled for HIV/AIDS programmes out of an estimated 450 000 infected by the virus. Only 0.3% of medical scheme beneficiaries were thus making use of the HIV/AIDS programmes offered. This low participation is attributed to inadequate marketing of the programmes and to members' lack of awareness of these services.[34]

While the extent of treatment and care that can be accessed by HIV-positive clients may vary among medical schemes, it is generally the case that at least some treatment and care is provided by all private medical schemes, often (78%) through a 'Disease Management Programme' (DMP). Most beneficiaries in DMPs (90%) have access to triple therapy and the use of ARVs is accompanied by other services, including treatment of side effects, drug monitoring, and diagnostic measures. Currently the majority of the estimated 20 000 - 30 000 people on ART in South Africa are medical scheme beneficiaries. This, however, does not mean that medical scheme provision for HIV/AIDS is without *caveats*. Most medical schemes have a ceiling on how much HIV/AIDS-related treatment they will cover, which invariably means that people who have exhausted their medical schemes will either have to pay out of pocket or once again become the responsibility of the public health sector, thereby increasing the strain on an already overburdened system.[10]

Non-governmental organisations – public sector

From about the year 2000, various 'operational research' projects, primarily investigating the integration of HAART with existing public sector services, were started at different levels of care within the public sector and in different provinces of South Africa. An attempt was made, through the Generic Antiretroviral Procurement Project (GARPP) to improve access to HAART through the coordinated procurement of generic ARV drugs of good quality, at the lowest possible cost, for use in quality HAART projects in SA. The establishment of GARPP also provided an opportunity to assess the nature of such projects. Between December 2002 and February 2004, the number of such projects increased from 16 to 39 and the number of persons on treatment from 596 to at least 3 759 (based on figures from 26 projects). At that point the 39 existing treatment projects considered that they had the capacity to treat a maximum of 9 575 people with the resources then available (Figure 2). Ten projects were treating mainly HIV+ children. Six projects were located in rural health facilities, 15 in peri-urban township health facilities and 18 in urban health facilities. These continue to provide an invaluable repository of experience in the provision of ART in resource-constrained settings and have much to offer the national programme in terms of lessons learned. While initially set up to enable a large number of projects to procure generic ARVs, many of which would have had to be imported under special approval from the Medicines Control Council, GARPP has not been able to significantly reduce barriers to access to these essential medicines. The MCC insisted on project-by-project applications, rather than a single, coordinated approach. Changes in medicine pricing regulations also challenge the longer-term viability of a not-for-profit wholesaler. Nonetheless, the experiences gained remain invaluable.

Figure 2: Number of people on HAART, and number of people the current projects have capacity to treat with existing resources



Workplace schemes

Information on the provision of ART through workplace programmes in SA is limited. Therefore, a comprehensive assessment of these programmes is not possible. However, there are indications that despite companies having much to lose by not factoring the impact of HIV/AIDS into their planning, many do not take AIDS seriously and the response has not been commensurate with the escalating epidemic.[35]

Data produced by the South African Bureau for Economic Research[36] showed that, of the 1 006 companies sampled across various sectors, almost one-third reported a negative effect from HIV/AIDS on profits and more than half expected the epidemic to have an adverse effect on profits within five years. So far, only a small number of companies had started to provide their employees with ARVs. Furthermore, 30% of the 1 006 firms surveyed reported higher labour costs associated with HIV/AIDS, while 27% indicated they had lost experience and skills, and 24% had incurred recruitment and training costs. AngloGold found that providing HIV drugs to its workers with AIDS would add $4-6 – up to 2% – to the cost of producing an ounce of gold. But if no action was taken, that cost could rise to $9 per ounce.[37]

A study conducted by FutureForesight and the Wits Health Consortium suggests that poorly managed treatment programmes could be doubling the costs to companies. Factors contributing to higher than necessary costs, in particular productivity losses, include starting treatment when employees are already at an advanced stage of disease as a result of low uptake; poor clinical management and follow up resulting in failure to keep employees healthy; and a high proportion of patients failing therapy and developing resistance.[38]

Some companies have introduced ART programmes in the work place. However, there is evidence to suggest that companies who are providing ART to infected employees are finding it difficult to get employees to come forward to be tested. As a result, there are relatively small numbers of infected employees who are receiving treatment. In August 2002, Anglo American was the first to initiate a corporate-sponsored ARV programme in SA. Currently, it has 1 000 workers on ARVs and another 3 000 are in HIV wellness programmes. By the end of its first year of implementation, Anglo American had 58 sites with 60 doctors, 137 nurses and 40 counsellors. Of the employees treated, 97% were back at work and leading normal lives.[39] Other companies that have followed the lead of the mining companies include De Beers, Abbot, Alexander Forbes, Old Mutual, Vodacom, Multichoice, Coca-Cola, Diageo, Total, British Petroleum, Shell, Heineken and Daimler Chrysler.

A number of key contributory factors to poor participation in workplace ART programmes have been identified, and these can also be instructive to the national public sector response:

- Lack of adequate infrastructure – the infrastructure needed to implement a programme of this nature would not ordinarily exist in most companies' medical facilities; it is most often only the mining industry that has the required medical facilities for ARV roll-out programmes, whereas most other companies would have to outsource ART programmes to health management firms.
- Lack of knowledge
- Low uptake – perhaps due to stigma and fear of job losses
- Lack of capacity to monitor treatment on a regular basis – related to poor corporate health care infrastructure and lack of access to costly and sophisticated laboratories.
- Corporate discriminatory practices – although companies may feel that it is cost-effective to provide treatment to their highly skilled workforce (i.e. those who are highly paid, with extensive institutional memory and skills which are hard to come by), this would be considered discriminatory, and benefits should be made available to the entire workforce; few have extended this benefit to the employee's spouse and children, perhaps resulting in reduced morale at work and the possibility of drug sharing (thus rendering the drugs ineffective).
- Concerns about sustainability.

Any consideration of HIV and AIDS in the workplace must however take account of underlying factors that might exacerbate the disease. As TAC's Mark Heywood has stated: "It is all very well to look at treatment, but the causal factors, such as the migrant labour system, or the single sex hostels (on the mines) which promoted the spread of the disease, must also be dealt with, as must prevention education."[40]

Public sector – implementation of the Operational Plan

Until recently the main thrust of the government's treatment initiative in the public sector has been directed towards improving the quality of life of people with HIV through the treatment of opportunistic infections (OIs) and through the provision of nutritional supplementation. The NDoH has developed and distributed a number of guidelines to assist health care workers in addressing HIV/AIDS, STIs and OIs.[10, 24] However, these have also perpetuated the 'exceptionalism' associated with HIV. Until the most recent issue of the Primary Health Care Standard Treatment Guidelines and Essential Drugs List, there was a lack of consistency between guidelines produced by the "vertical" programmes and medicine selection. An example was the suggestion that azithromycin be used for presumptive treatment of possible sexually transmissible infections following sexual assault, when this agent was not available in the State sector.

Cabinet's August 2003 directive to the NDoH to present a detailed operational plan for the implementation of HAART in the public sector changed the entire landscape of ART in South Africa.[12] Implementation of the approved Operational Plan commenced in December 2003. This included the designation of HAART service sites by provincial DoHs followed by a process of facility accreditation. Initial lists of proposed service points from provinces were forwarded to the NDoH and reviewed on more than one occasion. In January 2004, the then identified sites for HAART provision were assessed for accreditation utilising a different accreditation survey, with some identified sites being re-surveyed for accreditation. This process continues at the time of writing this chapter, and will continue over the months and years to come.[41] At the time of the President's State of the Nation speech, mention was made of 113 sites that had been designated for the provision of ART. Giving a detailed account of the sites accredited per province, and an account of where and to what extent the roll-out has actually started, is very difficult. This is a rapidly changing picture, made even more complex by the overlay of donor-funded programmes such the GFATM-funded Enhancing Care Initiative in KwaZulu-Natal. Donor-funded programmes that operate through the provincial departments should not be seen as separate from the national roll-out, but

as complementary or even integrated into that process. The following important milestones can be listed:

- Service points for comprehensive treatment, including ARVs, have been identified in all of SA's 53 health districts.
- The NDoH has visited more than 113 facilities in all 53 health districts to assess their capacity and develop urgent action plans to close the gaps where they exist.
- Various training efforts have been started, targeting medical, nursing and pharmaceutical staff. These have mobilised resources at the universities, as well as from abroad.
- Vacant posts at the service points have been advertised to strengthen their capacity, although to what extent these are being filled is difficult to say at this stage.
- The national treatment guidelines have been distributed to the provinces, and are in the process of being adapted and refined for local use.
- The tendering process to buy the necessary first and second–line medicines (nevirapine, stavudine, lamivudine, efavirenz, zidovudine, didanosine, lopinavir/ritonavir, ritonavir and indinavir) has started. A negotiating team to coordinate this work had been appointed.
- The NHLS has received R20 million to develop laboratory capacity.
- Two additional pharmacovigilance centres have been established at Medunsa and the University of the Free State, to work together with the national centre in Cape Town to monitor the effects of ARV usage.
- An electronic patient information system and a drug-tracking system are being developed with the private sector.

The situation with accreditation as at April 2004 is shown in Table 5. However, caution must be exercised in the use of these data, as the situation is extremely fluid.

In the Western Cape, phase 1 of the roll-out (to be completed by the end of June 2004) envisaged using 15 sites. These include 8 hospitals (Hottentot's Holland Hospital, Tygerberg Hospital, Red Cross Children's War Memorial Hospital, Groote Schuur Hospital, GF Jooste Hospital, George Hospital, Paarl Hospital, Worcester Hospital) as well as 7 primary care sites in Cape Town (Nolungile Community Health Centre (CHC), Khayelitsha Site B CHC, Michael Mapongwana CHC, Gugulethu CHC, Washington Road CHC, Hout Bay Main Road Clinic, Mitchell's Plain CHC). Although some progress has been made in more rural provinces (a launch in the Eastern Cape for example), the roll-out has predictably started in the more urban and better resourced provinces of the Western Cape, Gauteng and KwaZulu-Natal. The Western Cape is already providing treatment to more than 2 500 people. The ART programme commenced at 5 sites in Gauteng, beginning in April 2004.[43] KwaZulu-Natal has started providing ARVs at 8 sites.

It is recognised that, although the Western Cape has one of the lowest HIV prevalence levels in the country, it has the most progressive public sector ART programme. As documented in countries such as Uganda and Botswana, political leadership and open endorsement of the programme will remain key determining factors in the equitable delivery of ART.

Cost-effectiveness of ARVs

One of the major hindering factors in the provision of ARVs in the public sector has been affordability. High drug and test costs have made the provision of ARVs in high prevalence settings unaffordable, due to the risk that resources could be diverted from more cost-effective interventions. Several models of the cost of providing HAART in SA have been made. A model published in 2000, simulating the demographic impact of providing ARVs in SA, reported that if 25% of the HIV-infected adult population received triple therapy from 2000 to 2005, life expectancy at birth for the country would increase by 3.1 years by 2005 at a cost of US$15 000 per life-year gained. The total cost to the country estimated over the 5-year period was US$19 billion.[44] This study concluded that the intervention was not affordable.

In October 2002, TAC modelled the costs and benefits of phased-in introduction of HAART to adults with a CD4 count of less than 200 cells/ml. They estimated that by providing HAART, the life expectancy of the average South African will be extended by about 8 years by 2015 and the programme would cost between R14.1 to R18.1 billion depending on the cost of the first-line and second-line regimes used.[45]

A recent study carried out in Khayelitsha in the Western Cape indicated that it was cost-effective to treat opportunistic and HIV-related infections with ART, for HIV-positive adults with CD4 cell counts of less than 200 cells/μl.[46] The costing of both the ART and no ART options included all recurrent costs required to deliver ART, to treat opportunistic and HIV-related infections, to encourage adherence and to minimise transmission of the virus (including viral load, CD4 count and other laboratory testing, cotrimoxazole prophylaxis, ongoing palliative care, extensive counselling of patients, referrals for tuberculosis treatment and inpatient care, nutritional supplementation, and the provision of male and female condoms). The capital costs associated with infrastructure, medical equipment, furniture, and staff training were also included (annualised using a real discount rate). Lifetime costs were not insignificant. For patients on ART, these were calculated to be just over R93 000. In the absence of ART, the lifetime cost was on average just under R24 000 (for patients with CD4 counts less than 200 cells/μl). The average life

Table 5: Selected and accredited sites for ARV public sector roll-out by province as at April 2004[41, 42]

Province	District	Facility
Eastern Cape (38)[i]		No accreditation released yet
Free State (3)	Lejweleputswa (DC18)	Bongani Hospital
Gauteng (23)	Tshwane	Kalafong Hospital
	Johannesburg	Helen Joseph Hospital
		Coronation Hospital
		Johannesburg Hospital
		Chris Hani Baragwanath Hospital
KwaZulu-Natal (27)	eThekwini	King Edward VIII Hospital
		Addington Hospital
		Mahatma Gandhi Hospital
	Umzinyathi (DC24)	Church of Scotland Hospital
	Uthungulu (DC28)	Ngwelezane Hospital
	Ilembe (DC29)	Stanger Hospital
	Zululand (DC26)	Benedictine Hospital
	Sisonke (DC43)	EG and Usher Memorial Hospital
Limpopo (19)	Bohlabela (CBDC4)	Mapulaneng Hospital
	Waterberg (DC36)	Mokopane Hospital
	Vhembe(DC34)	Tshilidzini Hospital
	Sekhukhune (CBDC3)	St Rita's Hospital
	Capricorn(DC35)	Mankweng Hospital
Mpumalanga (6)	Ehlanzeni (DC32)	Themba Hospital
		Shongwe Hospital
	Nkangala (DC31)	Philadelphia Hospital
		Witbank Hospital
	Gert Sibande (DC30)	Bethal Hospital
		Evander Hospital
Northern Cape (7)	Frances Baard (DC9)	Kimberley Hospital
North West (5)	Southern (DC40)	Tshepong Hospital
	Central (DC38)	Bophelong Hospital
	Bojanala (DC37)	Rustenburg Hospital
Western Cape (16)		No accreditation released yet

Note: i The numbers in brackets indicate the number of selected provincial sites for ARVs roll-out, but not all of them have been accredited by the NDoH.

expectancy was 8.33 years on ART, and 2.27 years for patients not on ART. ART thus led to an average gain in life expectancy of 6.06 years. In quality-adjusted terms, life expectancy was 6.79 QALYs on ART and 1.59 QALYs on no ART, as patients reported higher Health Related Quality of Life (HRQoL) on ART than without ART, a gain of 5.2 QALYs. The study concluded that the incremental cost per quality-adjusted life year (QALY) gained on ART was R13 621. The study concluded that ART is efficient in economic terms, and ought to be pursued if economically feasible and desirable to society. Importantly, when the lifetime cost was broken down into its key cost components, over 50% of the cost of the ART option related to the cost of the ARVs. Although the prices of some ARVs have fallen recently (the research used October 2003 prices), second-line ARV regimens are still expensive, as is efavirenz, which is an important component of the first-line regimen. Critically, a voluntary license to manufacture a generic version of efavirenz has recently been awarded to Thembalami Pharmaceuticals, a joint venture between the local Adcock Ingram company and the Indian firm Ranbaxy. Laboratory tests at the clinic level for the ART option are also relatively expensive, and accounted for 9.2% of the lifetime cost. For the non-ART option, the most important component was the cost of inpatient care.

Government's decision to embark on the ART roll-out was based largely on work done by the Joint Health and Treasury Task Team (JHTTT), established in July 2002 to review what would be needed to deliver ART and other HIV treatment and care in SA. The team looked at the cost of four options, assuming that ART would extend illness-free life by 3.6 to 4.4 years:[47]

- 'No ARV' – Providing comprehensive access to current standard treatment guidelines for all who need it, but with no ART for people with AIDS.
- '20% ARV coverage' – Working up via phased implementation to provide ART for 20% of all new AIDS cases in 2008, with full access to non-ARV care for all those who need it. On this option, 200 000 people would be on treatment by 2008. Between 2003 and 2010, the 20% ARV coverage scenario would result in 293 000 deaths being delayed until after 2010 (i.e. deaths of individuals who, without ART, would have died prior to 2010).
- '50% ARV coverage' – Working up via phased implementation to provide ART for 50% of all new AIDS cases in 2008, with full access to non-ARV care for all those who need it. This option would see 600 000 people on treatment by 2008. The 50% ARV scenario would result in 733 000 deaths being deferred until after 2010.
- '100% ARV coverage' – Working up via phased implementation to provide ART for 100% of all new AIDS cases in 2008, with full access to non-ARV care for all those who need it. On this option 1.2 million people would be on treatment by 2008, and would defer 1 721 000 deaths by 2010.

The team calculated incremental costs per death deferred of between R 23 674 (20% scenario) and R 26 238 (100% scenario) beyond 2010. The assumed cost of treatment, including all monitoring and care, would be R8 139 in the first year, falling to R7 611 in each subsequent year of treatment. The precise drug costs within these sums were unclear, but as the report had anticipated, the prices of generic ARVs have continued to fall. The JHTTT cost estimates are summarised in Table 6.

Table 6: Total AIDS treatment and care costs by scenario (R billion/year, target year 2008)

Scenario	2003/04	2005	2008	2010
No ARV	5.4	6.3	6.7	6.7
20% cover	5.5	6.6	7.8 - 8.1	8.2 - 9.0
50% cover	5.5	7.0	9.6 - 10.5	10.8 - 12.9
100% cover	5.6 - 5.7	7.9 - 8.3	13.4 - 15.7	16.9 - 21.4

Under all scenarios, a comprehensive health sector prevention programme would be required, which would cost an additional R550 to 570 million per year for the rest of the decade. It was expected that other socio-economic benefits would be forthcoming from expanding access to ART, but these could not be modelled. For example the calculations did not include externalities such as orphans averted. Without ART, it was estimated that 1.8 million children would become orphans between 2003 and 2010. At 20% ARV coverage, this could reduce by 140 000 children; at 50% coverage by 350 000; and at 100% ARV coverage by as many as 860 000 children. The team concluded, however, that there was currently no compelling evidence that ART would lead to any reduction in the number of new HIV infections occurring.

Following the costing exercise, a number of events have added to anticipated cost savings. The Clinton Foundation HIV/AIDS Initiative has the potential to bring the prices of generic ARVs down. As of April 2004, an acquisition cost of US$140 per year for a first-line regimen was suggested. This is less than half the price of the cheapest brand-name medicines, even at discounted prices.[19] In addition, the generic companies involved in this agreement are already or have the potential to produce FDCs, which can be taken in the form of one pill twice a day, promising even greater efficiency in logistics and therapy. Reduced cost CD4 cell and HIV viral load testing kits will also be made available through the deal. What is however unclear at this point is to what extent the SA government is intending to use the Clinton Foundation to aid procurement, or alternatively,

to what extent the intended tender process will achieve similar cost savings.

Public Sector Funding of ARV provision

With appropriate first- and second-line options for developing country settings identified, and medicine and diagnostic test acquisition costs tumbling, the next barrier to overcome is that of sustainable financing. In his budget speech in February 2004, the Minister of Finance made a commitment to boost the budget for fighting HIV/AIDS by R2.1 billion for the next three years. This addition will bring the total spending on fighting AIDS provincially and nationally to R12.4 billion over the three years of the medium-term expenditure framework (MTEF).[48] The government has put aside funding for ARVs as indicated in Figure 3.

The challenge now is to make sure the budgeted amount is spent – that it is moved to the provinces quickly, spent transparently and efficiently and accounted for effectively. There has been a pattern of under-expenditure of money dedicated to HIV/AIDS. For example, in 2000/01 the provinces spent 36.5% of the total HIV/AIDS conditional grant allocations. This proportion increased to 85% in 2002/03. Increased monitoring of the provincial government budgets and patterns of expenditure on HIV/AIDS, and in particular ART, will be needed.[50]

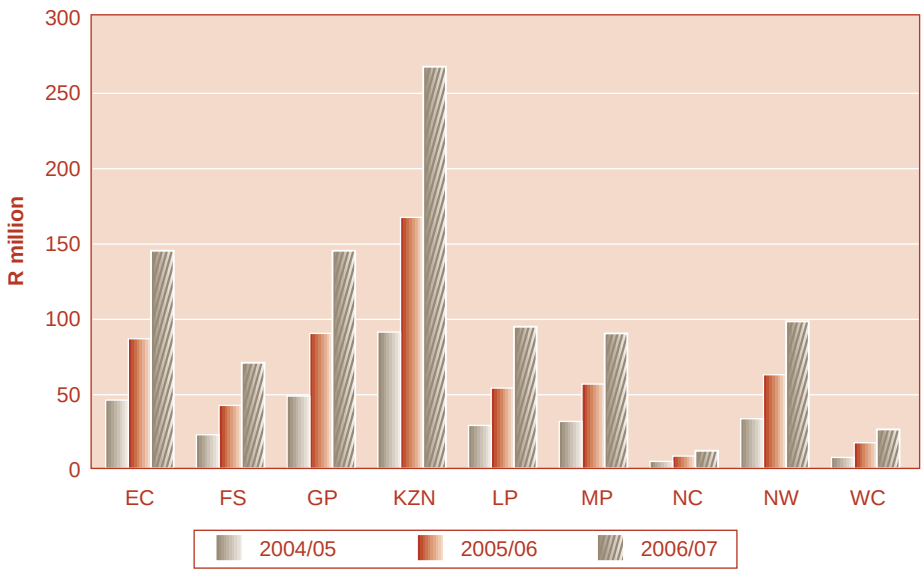
Key Challenges to Scaling up the ART Programme in the Public Sector

At scale, the roll-out will be the largest of its kind in the world, an ART programme both massive and unprecedented in a resource-constrained setting. That it is still, many months after the Cabinet approval, still in the planning stages of implementation in many provinces is perhaps also true. With the exception of the Western Cape, Gauteng and KwaZulu-Natal, the remaining provinces have not enrolled significant numbers of patients in the ART programme. The challenges faced are not new and to a large extent they had been debated and were anticipated. The view of the NDoH and Minister is that the delays encountered are caused by deficiencies in the health system as whole. Through the accreditation process these deficiencies have became more obvious and must now be addressed with urgency.

The challenges include:

- The continuing lack of human resources such doctors, pharmacists, nurses, nutritionists, dieticians and counsellors. While not all of these are appropriate to be placed on a full-time basis at the most accessible level of care (i.e. primary health care facility level), over time the first point of contact must also have the necessary capacity to manage the continuing care for patients placed on ARVs. Necessarily, provision of ARVs is happening mainly at hospitals in the initial phase. There is a concern that the trend towards staff movement from primary to tertiary, and from rural to urban facilities could increase as selected sites recruit staff, thereby undermining PHC in surrounding areas. The scarcity of human resources could possibly be exacerbated by the high prevalence of HIV among health workers, estimated to be around 16%.[3] The human resource issues may well present the greatest challenge, given that a strong health system requires the continued presence of a skilled human resource base.

Figure 3: ARV earmarked allocations by province, R million, real 2004 terms[49]



- The lack of adequate infrastructure, including water, sanitation, electricity, communication and consultation rooms, and weak support systems, such as laboratory services, transport and medicines supply. Without infrastructural and systemic improvements, it will be extremely difficult to provide an adequate ARV programme. Failures in ARV supply, in particular, could have serious consequences for the effectiveness of therapy.[51] In addition to concerns about the reliability of supply, there are significant backlogs in the provision of adequate air-conditioned storage space, fridges and a suitable computerised inventory management system at the hospital level. Considerable effort is being made to address the lack of necessary laboratory infrastructure, for example to provide for comprehensive viral-load testing – of 7 NHLS facilities designated to provide this service, 6 are already doing so.
- The lack of essential services such as accessible voluntary counselling and testing (VCT) and effective prevention of mother-to-child transmission (PMTCT) programmes, particularly in rural and semi-rural areas. Unless HIV-positive people can be identified and given treatment at the WHO recommended stage,[52] the ART programme may not add value to the fight against AIDS and could possibly deplete resources needed for other important public health interventions.
- The lack of capacity to monitor and evaluate the ART programme at all levels of delivery, starting at the facility level. Such an unprecedented programme requires extensive use of relevant, real time information that can be fed back into the therapeutic environment. Failure to develop and fully utilise comprehensive monitoring and evaluation systems will limit the ability of the health system as a whole to respond appropriately.
- The current situation of fragmented Patient Information Systems. The ability to track and treat patients regardless of where they present is key to ensuring suitable levels of adherence and monitoring of treatment outcomes. Developing an integrated data platform that allows for a decentralised health system, yet meets the needs of both the patient and the national health information system, will prove to be one of the most challenging aspects of ongoing universal provision of care and treatment using ARVs. Although a recent study by the Khayelitsha MSF team has indicated that good levels of adherence to treatment can be achieved in resource-poor settings, there is a need to verify these findings in other settings, as well as at scale.[53]

Conclusion and Recommendations

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There is clear evidence of a major shift not only in policy but also in the allocation of the resources necessary to provide universal access to ART in South Africa. The key barriers to equitable access are no longer the cost of ARVs and associated testing materials, nor perhaps access to sustainable financing, and certainly not which ARVs to use, but rather the capacity of the health system to implement an ART programme. This is even more important when one considers the capacity necessary to effectively provide ART outside of the larger and better-resourced sites in the metropolitan areas of the wealthier provinces. While a strong commitment to moving forward is evident, these challenges need to be overcome to ensure that the goals of this highly ambitious programme may be met.

South Africa's ART programme will be the largest public health intervention of its kind in the world, and as such it is drawing a lot of attention. It is therefore essential that information on the implementation of the programme (i.e. progress, challenges and solutions to the challenges) is communicated collectively and regularly by both national and provincial departments of health. To date this information has at times been scanty, unclear and even contradictory, thus creating confusion among the general public. Access to information on ARV provision in the private sector and workplace programmes is still minimal. Sharing of information and resources between the private and public sector is crucial in order to monitor access, programme outcomes, and resistance to ARVs and to avoid duplication of work and wastage of resources. Currently available information indicates that access to ARVs will be very uneven across the country. For example, 6 months after the Cabinet's approval of the plan, only Gauteng, the Western Cape and KwaZulu-Natal had started providing ARVs in public sector facilities – the first two are the richest provinces, and the Western Cape has one of the lowest HIV prevalence levels in the country. This may be construed as signalling a worsening of already existing health systems inequities, but may also merely reflect the realities of infrastructural and other enablers at an early stage of an ambitious programme – a programme that includes a strong commitment to an equity-based approach. The development of monitoring and evaluation indicators should take into account the WHO guidelines. However, if the intent is to monitor equity in accessing ART, data may need to be disaggregated in specific ways, for example by gender, age and race.

It is worthwhile learning from the PMTCT project and avoiding the same mistakes. Three years after it was first introduced to SA, nevirapine-based PMTCT is still not reaching many HIV-positive pregnant women, particularly in rural areas. This is due

to stigma, inadequate physical infrastructure, and shortage of trained and motivated health workers. Nevirapine itself is not in short supply, but if orders are not placed, or facilities continue not to be designated as capable of providing the service, nor provided with the necessary equipment, access to this highly effective intervention will remain constrained. Equally, as new data emerge of alternatives to nevirapine-based PMTCT, the programme needs to be adapted and strengthened. Over time HAART should become an option.

According to the Operational Plan, within a year there will be 'at least one (antiretroviral) service point in every health district (53 districts) across the country, and within five years, one service point in every local municipality'. In February 2004, the NDoH admitted that delays in the procurement process and the lack of trained personnel were still delaying the roll-out of ART. Experiences in Botswana has shown that, even if sufficient funding is available, implementing ambitious plans quickly can be very difficult. Given the current status of the ARV roll-out and the Botswana experience, it may be necessary for the NDoH to revise the original targets of the plan.

Demands for access to treatment have been effectively articulated by civil society groups such as TAC. However, treatment can only occur if people have access to adequate and functioning health systems. Therefore, the increasingly powerful and progressive demands for treatment access need to be reinforced by equally powerful demands for adequate health systems. This requires not only resources but also unequivocal political commitment. Indeed this does appear to be happening. In his State of the Nation address in May 2004, President Mbeki clearly expressed an unprecedented political commitment to the provision of ARV-based treatment. He stated: "We have already started with the implementation of our Comprehensive Plan on HIV and AIDS. 113 health facilities will be fully operational by March 2005 and 53 000 people will be on treatment by that time".[54]

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