

# Providing Antiretroviral Treatment in Southern Africa



*A Literature Review*

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[www.hst.org.za/publications/608](http://www.hst.org.za/publications/608)

February 2004

ISBN: 1-919743-81-2

Cover photograph: Graeme Williams, Southphotos

### **Published by Health Systems Trust**

401 Maritime House  
Salmon Grove  
Victoria Embankment  
Durban, 4001



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Funded by the Henry J Kaiser Family Foundation.

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## Acknowledgements:

Dr Lilian Dudley

Antoinette Ntuli

Vareshni Moonsamy

Jaine Roberts

“ARV provision is a must, coupled with basic, balanced diet, and we mustn’t forget malaria and TB. We can’t deal with one if we don’t deal with the others. ...It is time to be innovative and creative. This is either about the extinction of humankind or the rebirth of our people”

*Brigitte Syamalevwe  
International HIV/AIDS Alliance 2002a pp2*

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# EXECUTIVE SUMMARY

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The AIDS epidemic, which is estimated to have resulted in the death of more than 2.3 million people in sub-Saharan Africa in 2003, has the potential to cause profound negative social, economic and individual effects and has placed a particularly heavy toll on existing health care systems, particularly those already facing severe resource constraints. Research has shown that the vast majority of the over 38 million people living with HIV/AIDS in low and middle-income countries at the end of 2001 did not have access to even basic medications for treating HIV-related illnesses and for relieving pain.

In high-income countries, where combination antiretroviral treatment (ART) became widely available from 1996 onwards, AIDS related mortality declined markedly for two or three years and has since stabilized. The World Health Organization reported that in sub-Saharan Africa, in 2002, more than 4 million people needed treatment, but that only 50 000 (less than 1.5%) had access to it. Where ART has been provided, it has been credited with having a significant positive effect on the lives of people living with HIV/AIDS. It has been held responsible for emptying HIV/AIDS wards, for dramatic falls in AIDS related mortality and morbidity and for people returning to their homes, families and jobs.

Due to a variety of ongoing advocacy and lobbying initiatives, the prices of antiretroviral (ARV) drugs are now low enough to contemplate scaled-up treatment programmes in resource-constrained settings. A number of pilot programmes in developing countries have produced clinical results comparable to those in high-resource settings, with acceptable cost-effectiveness.

This report outlines experience with ART in a number of sub-Saharan countries. ART is provided through a number of different avenues, which include the public sector, the non-profit sector, the corporate sector and the private sector. ART programmes may involve collaboration between two or more sectors with such partnerships being encouraged in recognition that the magnitude of the task may exceed the capacity of any one sector. Particular attention is paid to Botswana, the first sub-Saharan country to provide ART on a wide-scale through the public sector.

Policy-makers and development agents face significant challenges as they plan for the delivery of ART. Adequate resources need to be made available, whilst attention needs to be paid to strengthening the overall health system. Communities also need to be involved in and prepared for ART programmes and clinical aspects of therapy such as adherence, resistance and toxicity monitoring. Broader development objectives such as poverty reduction and adequate nutrition also need to be addressed, as do issues related to equity.

The review highlights numerous shortcomings and gaps in the literature and areas that require further research. More robust indicators and data on the full costs of HIV and AIDS and the benefits of provision of ART need to be developed and routine monitoring systems need to be implemented. Alternative funding mechanisms need to be investigated. Numerous health systems and service issues need to be addressed, including the identification and evaluation of best practice. Different service delivery models, as well as issues related to human resource development and strengthening of support systems need further attention. Various issues related to the broader community, including methods of reducing stigma and improving adherence to ART, also need to be addressed. The provision of ART through the private and corporate sectors, as well as issues related to ART and children are identified as further issues which require investigation. The report concludes by highlighting the need for the response to HIV/AIDS to contain both an emergency response and a long-term development oriented response.

# Chapter One: INTRODUCTION

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# 1

In 2003, an estimated 2.3 million people in sub-Saharan Africa died of HIV/AIDS, whilst an estimated 3.2 million people acquired the infection. UNAIDS and WHO (2003) estimate that 26.6 million of the 40 million people living with HIV globally come from the region. HIV prevalence in the region appears to have stabilized, as high levels of infection are being matched by high levels of AIDS related mortality (UNAIDS and WHO 2003).

Southern Africa is home to approximately 2% of the world's population, yet contains 30% of all people living with HIV/AIDS. In South Africa in 2002, the average national prevalence rate of HIV in pregnant women attending antenatal clinics was 26%. Provincial variations were large, with the worst affected province, KwaZulu-Natal, reporting prevalence of almost 37%, compared with lower figures of 12-15% for the Western Cape (South African National Department of Health 2002). Overall it is estimated that at the end of 2002 there were 5.3 million South Africans living with HIV. As a relatively 'young' epidemic AIDS related deaths are likely to rise in the near future (UNAIDS and WHO 2003). It is estimated that between four and six hundred thousand South Africans currently need ART (South African National Department of Health 2003 and Johnson and Dorrington 2002). In four of South Africa's neighbouring countries, Botswana, Lesotho, Namibia and Swaziland, the HIV prevalence has reached high levels without signs of levelling off. Between 1992 and 2002, national HIV prevalence in Swaziland increased from 4% to 39% among pregnant woman aged 15-24 years. Botswana reports similar prevalence figures, while HIV prevalence in antenatal sites in Namibia rose to over 23% in 2002. Lesotho's 2003 data reflects a median HIV prevalence among antenatal clinic attendees of 30% (UNAIDS and WHO 2003). Malawi has an estimated HIV prevalence of 10% and it is estimated that 300 000 people are in need of ART. AIDS is the major cause of mortality amongst people aged 15-49 years in Malawi and it is estimated that life expectancy will fall below 40 years by 2010. Prior to the AIDS epidemic, life expectancy in Malawi was 52 years (Hills-Jones and Kanabus 2003).

The AIDS epidemic has the potential to cause profound negative social, economic and individual effects, and has placed a particularly heavy toll on existing health

care systems, particularly those of poorer nations. Loewenson and Whiteside (2001) estimate that the HIV/AIDS epidemic has increased the burden of disease up to seven fold in highly affected African countries, increasing the demand for and cost of public health care services, crowding out other conditions and doubling bed occupancy rates. They also suggest that AIDS distorts referral patterns as demands for quality of care and anonymity lead people to bypass primary care facilities for more expensive tertiary services. While this is more pronounced in insured, urban populations, it significantly increases costs of care to government and widens inequity in health expenditure.

The intention to fight the HIV/AIDS pandemic has been articulated in a variety of international documents. The Declaration of Commitment on HIV/AIDS adopted by the United Nations General Assembly Special Session (UNGASS) on HIV/AIDS in June 2001 commits Member States and the global community to taking decisive and urgent action to address the HIV/AIDS crisis. It calls for achieving a number of specific goals, including reducing HIV prevalence among young men and women, expanding care and support and protecting human rights. The Millennium Development Goals, adopted in September 2000, call for expanded efforts to halt and reverse the spread of HIV/AIDS by 2015. The Abuja Declaration and Framework for Action on HIV/AIDS, Tuberculosis and Other Related Infectious Diseases adopted at the African Summit in 2001, declare regional and national commitments to confront the epidemic (WHO 2002). However, it has been contended that the effect of HIV/AIDS remains the biggest single obstacle to reaching national poverty reduction targets and the development goals agreed on at the UN millennium summit (Loewenson and Whiteside 2001).

Progress towards achieving these goals requires action on a variety of fronts and includes expanding HIV/AIDS programmes to foster a supportive environment, preventing new infections, caring for those already infected and mitigating the social and economic consequences of the epidemic (Loewenson and Whiteside 2001, WHO 2002). Loewenson and Whiteside (2001) suggest that an effective response to HIV/AIDS must focus on all three areas of intervention; prevention, care and mitigation, in the context of a broader development agenda, forming a virtuous circle that will produce real and sustainable results.

Research has shown that the vast majority of the estimated 38 million people living with HIV/AIDS in low and middle-income countries at the end of 2001 lacked access to even basic medications for treating AIDS-related illnesses and

for relieving pain (UNAIDS 2002). In SA, access to Voluntary Counselling and Testing (VCT), the prevention of mother-to-child transmission (PMTCT), antiretroviral therapy (ART) and prophylaxis for opportunistic infections was very low (Ramkissoo *et al.* 2004). While progress had been made in some areas like blood screening, generally the level of care available to most people was limited. In addition, services were generally skewed in favour of urban, wealthier centres, effectively leaving rural areas underserved (Loewenson and Whiteside 2001).

This literature review aims to provide an overview of existing ART provision in southern Africa, to detail some of the more salient aspects of ART projects and programmes, and to identify areas for further research. The purpose of this document is not to provide a comprehensive list of ART pilot sites and programmes, but rather to identify and discuss important lessons and issues that will need to be addressed if ART provision is to be expanded. In compiling the review, a range of literature was consulted. Although peer reviewed journals were scanned for appropriate studies and articles, many of the documents and lessons from the limited number of ART programmes in sub-Saharan and southern Africa have yet to make their way into these journals. Much of the information was therefore sourced from “grey literature” including government communication documents, statements and reports in a cross section of media, interviews and meetings with key stakeholders, working documents, short reports, conference presentations, and seminar proceedings.

## 1.1 Provision of ART in developing countries

The provision of ART has been credited with having a significant positive effect on the lives of people living with HIV/AIDS. Where it has been widely provided, it has been held responsible for emptying HIV/AIDS wards, for dramatic falls in AIDS related mortality and morbidity and for people returning to their homes, families and jobs (Grubb *et al.* 2003). In high-income countries, where combination ART became widely available from 1996 onwards, AIDS related mortality declined markedly in the following two to three years, and has since plateaued.

However, provision of ART in developing countries has been limited due to a number of factors, most importantly the high costs of ARVs. For example, in Uganda in December 2002 the end-user price for one month’s treatment using a

generic three-drug combination of stavudine, lamivudine and nevirapine (Triomune) was 56 520 Ugandan shillings (US\$31), whilst a combination of zidovudine and efavirenz, cost 115 200 Ugandan shillings per month (about US\$63) (International HIV/AIDS Alliance 2002a). Since per capita income in Uganda was less than US\$ 250 per annum and an estimated 35% of Ugandans lived below the poverty line of less than US\$1 per day, these treatment costs remained beyond the reach of most people (CIDA 2004).

The provision of ART has also been limited by the poorly developed health care infrastructure in many developing countries (UNAIDS 2002). Concerns have also been raised about viral resistance developing if ARVs were to be improperly used on a wide-scale in African countries. Even where ARV services are available, fear and stigma associated with HIV/AIDS and human rights abuses of people living with HIV/AIDS have contributed to the ongoing reluctance among many people to come forward for testing and treatment (Parker and Aggleton 2001).

As a result of these constraints, some government leaders and a variety of other AIDS and public health commentators have argued that ART could not be introduced in developing countries, and have motivated that money could be better spent on preventing new infections (Hills-Jones and Kanabus 2003). Until recently dominant thought held that ART would, at least for the near future, remain financially and logistically beyond the reach of most HIV-positive people living in low- and middle-income countries. An International Monetary Fund policy discussion paper evaluating the impact of HIV/AIDS on health care services in southern Africa for example, held that "... with the possible exception of Botswana and South Africa (and there only to a limited extent) none of the countries in the region will be able to offer general access to highly active anti-retroviral therapies through the public sector service." (Haacker 2001: pp15). The paper further argues that "the scope for alleviating the impact of HIV/AIDS on the health sector through financial aid is limited".

In contrast, other individuals and groups have demonstrated the potential benefits of providing ART and have argued for its provision on moral, ethical and economic grounds. The Joint Health and Treasury Task Team (2003) set up in South Africa to investigate the feasibility of providing ART through the public sector demonstrated the likely effect of provision of ARVs on AIDS-related mortality and morbidity. The Team estimated that between 2003 and 2010, assuming a 20% ARV coverage scenario, an estimated 293,000 deaths would be averted until after 2010. If the 50% coverage model is applied, 733,000 deaths

would be averted, while the 100% coverage model could avert up to 1,721,000 deaths over the same period. 20% coverage of ART, by 2008, could defer orphanhood for 140,000 children, 50% coverage by 2008 would defer orphanhood for 350,000 children and 100% coverage by 2008 would defer orphanhood for as many as 860,000 children.

Other authors have postulated further social and economic benefits, but these are very difficult to quantify. These may occur at a macro level – such as reduced losses to the Gross Domestic Product, reduced levels of inflation (as measured by producer and consumer price indices) and improved investor confidence (Whiteside and Sunter 2000). Alternatively, benefits such as increased labour productivity and earnings or reduced costs for treatment, may occur at the individual and household level (Stover and Bollinger 1999). Nattrass (2004) believes that the overall positive impact of comprehensive treatment and care would more than compensate for the costs of such provision. The ASSA2000 model, used by the Joint Health and Treasury Task Team, allows for ARV's potentially reducing the number of new infections by reducing viral loads in infected persons. Others claim that ARV's will increase the pool of infected people through saving lives and therefore could increase new infections (Johnson and Dorrington 2002). However, the impact of ART provision on sexual behaviour remains unclear and while much literature on ART and behaviour emanates from Europe and the United States and relates to homosexual relations between men, to date there is little or no evidence of increased risk behaviour associated with ART in a heterosexual, developing country context (Nattrass 2004).

The Harvard Consensus Statement called for weak infrastructure in developing countries to be seen as a challenge to improve facilities and human resources rather than an excuse to deny access to HIV/AIDS treatment (Haacker 2001). It has also been argued that more drugs can, under certain conditions, catalyse better health care delivery systems, which in turn will promote greater capacity to deliver affordable medical technology (UNAIDS 2002).

A World Bank report (2003) indicated that there is no empirical evidence that viral resistance and non-adherence are more significant in developing countries than in developed countries. The report suggested that the current unregulated availability of ARVs in developed countries would accelerate the emergence of drug resistance and concluded that reduction of drug resistance is best achieved not by slowing down the introduction of ARVs in developing countries, but by ensuring that the distribution of ARVs occurs in the context of policies, practices

and procedures that promote rational ARV use and encourage patient adherence.

A number of recent studies and experiences in ART provision in low-income settings have also challenged the view that it is impractical, and even undesirable, to provide ART in these settings. Improvement in mortality and morbidity trends due to availability of ART is particularly notable in Brazil, and is expected to become visible in other countries in Latin America, the Caribbean and Asia in the next few years (UNAIDS 2002). In Brazil, an estimated 358,000 hospital admissions were avoided between 1996 and 2002, saving US\$2.2 billion (Teixeira *et al.* 2003).

At the same time, a number of small pilot programmes in various countries have produced clinical results comparable to those achieved in high-resource settings, and provided lessons regarding how these projects should be established and run. UNAIDS and WHO set up a Drug Access Initiative in 1998, which comprised pilot projects in Côte d'Ivoire and Uganda and, later, in Chile and Vietnam, to examine the impediments to the use of ART in resource-poor environments. Although involving small numbers of clients, the projects provided some significant lessons about evidence based treatment guidelines, patient compliance, stock management, and referral systems (Djoman *et al.* 2000). Other projects include the nine programmes established in seven countries in Africa, Asia and Latin America by Medecins Sans Frontieres (MSF). Preliminary findings from these pilot projects are that ART provision in the context of comprehensive district-based HIV care services in highly affected countries in Africa is both acceptable and feasible (Van Praag 2001).

Due to a variety of ongoing advocacy and lobbying initiatives, ARV prices are now low enough to contemplate scaled-up treatment programmes in resource-constrained settings. As a result, provision of ART has increasingly become a priority for both developing country governments and international agencies. The debate has shifted from whether or not ART should be provided in these settings, to considerations of how best it can be provided and WHO has set an ambitious target of ensuring that 3 million people globally are on treatment by the year 2005. Mechanisms for funding some of these initiatives are also available through the Global Fund for AIDS, Tuberculosis and Malaria and the President's Emergency Plan for AIDS Relief (PEPFAR).

## 1.2 Service delivery options and models

Initiatives to provide ART in developing countries make use of a number of service delivery models which utilise different financing mechanisms and service delivery options. These may be classified as follows:

1. Public sector provision where services are provided by the government using their own revenue or donor funds. Delivery may occur at provincial and regional hospital level, at district level, or at community clinic or community level
2. Non-Profit Sector – this includes local, national and international non-governmental organisations (NGOs), community-based organisations (CBOs) and faith-based organisations (FBOs)
3. Corporate sector – provision through private businesses or corporation
4. Private for Profit Sector – this covers private GPs, medical aids and pharmacists; and
5. Combinations of the above, sometimes referred to Public Private Partnerships (PPPs).

It is likely that a combination of approaches will be used to provide ART in most developing countries. It is important that different models are described and that best practice models are developed and shared with other role-players in an attempt to ensure that successful models are replicated and identified pitfalls avoided. Some degree of standardisation and legislative changes may be warranted in order to regulate the provision of ART and to ensure that the best interests of the public are served, although this issue requires further attention.

Ntuli *et al.* (2003) have argued that business and the private health sector need to be encouraged to develop mechanisms for minimising the impact of the epidemic on the public sector. The mechanisms adopted for shifting the burden of the disease to the public sector should become the subject of public debate with a view to encouraging business to take responsibility for providing treatment to all levels and categories of staff. Government should encourage the corporate sector to provide adequate employment assistance programmes as well as disability, death and sickness benefits that take into account the devastating impact of the epidemic. New ways of stimulating corporate social responsibility must also be explored. More vigilant and effective monitoring of labour and

equity promoting laws is required to ensure that people who are HIV positive are not being discriminated against when applying for and in maintaining their employment (Ntuli *et al.* 2003).

PPPs are gaining popularity and are being showcased as a way forward. Combining the knowledge and resources of two or more sectors may be a very powerful method to deliver essential services to the inhabitants of a country. However, the possible effects and benefits of local and global PPPs need further exploration and critics argue that the partnership models should be reviewed far more critically before being generally accepted (HAI Europe 2001).

### 1.3 Constraints to wide-scale provision of ART

Although there have been successful ART programmes in underserved and rural areas, the feasibility of replicating these on a wide-scale without the additional resources, external technical support, commitment and enthusiasm provided through academic and non-government support institutions that usually accompany these projects, remains questionable (McCoy 2003). Some commentators have suggested that targets such as those set by WHO are overly ambitious and that massive amounts of political will, money and action will be required if these targets are to be reached.

Obstacles to the delivery of large ART programmes in developing countries operate at a variety of levels, but can be summarized as follows (International HIV/AIDS Alliance 2002b, Parker and Aggleton 2001).

- Financial – the cost of providing ART, particularly the costs of ARVs
- Organisational – weak health care infrastructure and systems to deliver ART
- Physical – this includes the lack of transport and transport infrastructure for people with HIV to get to sources of testing, drugs, and monitoring, and
- Social – such as treatment providers discriminating against people with HIV by refusing treatment or offering sub-standard treatment, and the fear of stigma attached to the disease.

These and other challenges to wide-scale provision of ART in developing countries and specifically sub-Saharan Africa are discussed in more detail in Chapter III.

## Chapter Two: PROVISION OF ART IN SUB-SAHARAN AFRICA

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# 2

Despite the disproportionate burden of the HIV epidemic in sub-Saharan Africa, to date ART interventions in the region have been small scale. As of December 2002, there were an estimated 50 000 people accessing ARVs in sub-Saharan Africa. Given that it is estimated that 4 million people need ART, this translates into a coverage rate of less than 2% (Grubb *et al.* 2003) By contrast, North Africa and the Middle East have a coverage rate of 29%, while Latin America and the Caribbean have coverage rates of 53% (Hills-Jones and Kanabus 2003). In September 2003, UNAIDS indicated that the percentage coverage of adults with advanced HIV infection and in need of receiving ARV treatment was 7.5% in Botswana, 6% in Uganda, 2.5% in Swaziland and under 1% in South Africa (UNAIDS 2003).

The following table represents estimated number of adults in various treatment programmes in SADC countries (as of 2002) and the number of public and NGO treatment sites as of 2003. However, no comprehensive and updated database of treatment programmes is available to inform progress in southern Africa.

**Table 1: HIV prevalence and access to HIV services in sub-Saharan Africa**

	Population (Millions)	Est. no. of Adults Living with HIV (%)	No. of Clients – PMTCT	No. of Clients – ARV Therapy (2002)	Est. no. of Public/NGO ART Sites (2003)
Angola	12.8	5.5	0	0	0
Botswana	1.7	38.8	*	6 791	6
Lesotho	1.8	31	0	100	1
Malawi	11.6	15	*	1 000	3
Mauritius	1.2	0.10	8 500	35	6
Mozambique	18.2	13	0	0	0
Namibia	1.9	22.5	0	0	0
Seychelles	0.1	*	*	*	*
South Africa	44.4	20.1	38 168	30 000	48
Swaziland	1.1	33.4	*	*	*
Tanzania	35.6	7.8	1 961	0	*
Zambia	10.6	21.5	5 307	500	3
Zimbabwe	12.8	33.7	NA	500	4

\* - number unknown

Sources: Human Development Report 2003, WHO 2002, MSF 2003, Red Ribbon 2003, UNAIDS 2004.

As the devastating effects of the epidemic are felt in all spheres of life, many southern African countries, including Botswana, South Africa, Lesotho, Zimbabwe, Namibia, Mozambique and Zambia, are beginning to develop comprehensive HIV/AIDS strategies, which include ART.

## 2.1 Public sector provision

UNAIDS and the Ugandan Ministry of Health were responsible for the establishment of one of the first large scale ART programmes, known as the Drug Access Initiative (DAI), in Africa. The programme commenced in 1998 with the aim of examining how an ART programme could be set up and run in a developing country (Hills-Jones and Kanabus 2003). By the end of 2002, 10 000 people were receiving ART through the DAI (Okero *et al.* 2003) and an estimated 17,000 people were being treated through the combined efforts of the public,

civil society and private sectors. Plans are in place to expand public sector provision incrementally with 60,000 on treatment by the end of 2004 (Hills-Jones and Kanabus 2003).

With arguably the highest HIV/AIDS prevalence rates in the world of 39%, Botswana was the first country in sub-Saharan Africa to offer ART through the public health system on a large scale (Fredriksson-Bass and Kanabus 2003). The ART programme - known as "Masa", a Setswana word meaning "New Dawn" - was developed by the Ministry of Health, in partnership with the African Comprehensive HIV/AIDS Partnership set up jointly with the Bill and Melinda Gates Foundation, the Merck Company Foundation, and the management-consulting firm, McKinsey & Company (UNAIDS 2003). The ART programme was initially restricted to four central sites in 2002 (Government of Botswana 2003). It is estimated that of the 330 000 HIV-positive people in Botswana, about one-third require ART. By July 2003, 10 415 patients had enrolled in the programme, 6 791 were on ART, and 486 had died (UNAIDS 2003).

The Botswana experience has been invaluable in that it has highlighted a number of issues related to the successful provision of ART in a developing country setting. The main lessons learnt relate to the need for ensuring that the health system is able to cope with the additional requirement of ART provision and the need for adequate human resources. These issues are discussed in more detail in chapter three. However Botswana's AIDS programmes have been hampered by a reluctance of the Botswana to know their HIV status. Despite the provision of free, confidential, same-day testing only 65 000 people have made use of these facilities (IRIN Plus News 2003). This has resulted in a situation where people start ART much too late, and place further strain on public health resources.

In South Africa, it was estimated that as of February 2003, approximately 30,000 people were receiving ARVs, mostly triple therapy or Highly Active Anti-Retroviral Therapy (HAART). The majority had health insurance and were receiving treatment in the private or corporate sector through managed care schemes (UNAIDS 2004). In June 2003, ART was being provided in the public sector in eighteen projects across the country, three of which were in Gauteng, five in KwaZulu-Natal and ten in the Western Cape. These projects reached 890 people (Schneider 2003). By February 2004, the number of people receiving ART through public sector sites across South Africa had increased to about 3 800 across 39 sites. The Western Cape alone had 19 sites providing ART to an estimated 2 000

people. There were a further 82 sites listed as prospective (funded) which did not yet have patients on the antiretrovirals (Poole and Stewart 2004). Strict classification as either public or non-profit is increasingly difficult as many are forms of partnerships between the two or more sectors. In this instance public sector is defined as programmes where the HAART project provides full subsidisation of HAART drug-costs and routine monitoring tests to persons without medical aid and/or utilises existing public sector resources for the provision of a HAART service, and thus often incorporates sites assisted by MSF and or academic institutions.

In November 2003, the South African government released their “Operational Plan for Comprehensive HIV and AIDS Care and Treatment”. The plan focuses on providing comprehensive HIV/AIDS care including ART in at least 53 sites (one per health district) within 12 months from a non-specified start date. The target is to provide care within five years to all South Africans and permanent residents who require it, a number estimated to be 1.4 million. As of January 2004, sites for rollout were being evaluated for preparedness and selection. If rolled out as planned, the South African ART programme will represent the largest and most ambitious effort to combat HIV and AIDS to date. By the end of February 2004 a full accreditation tool had been developed by the National Department of Health and used to assess 110 sites for readiness to provide ART. Tenders had been requested for the provision of registered drugs and provincial task teams were developing provincial plans (Tshabalala-Msimang 2004, South African National Department of Health 2003). Additional pressures from civil society will likely ensure that at least some sites will provide treatment by then end of 2004, although it is likely the original deadlines and targets will be missed.

A number of other sub-Saharan African countries such as Zambia and Zimbabwe have established public sector ART programmes, albeit on a far smaller scale than those operating or planned in Uganda, Botswana and South Africa.

Zambia has introduced PMTCT-Plus as part of their national plan for scaling up access to ARV treatment. This involves the use of short-course nevirapine to prevent transmission of HIV from mother to child, plus ongoing ARV treatment for the mother and for the husband, if needed. As of 2001, there were no public or NGO sites providing ART and in January 2002 UNAIDS estimated that less than 1 percent of Zambians living with HIV/AIDS were receiving ART through private care (Garbus 2003). However, by 2003, initial rollout had started and in this phase of its ARV programme, the Zambian government planned to reach

approximately 10 000 people. It currently costs approximately US\$300 to buy a month's supply of ARVs on the open market in Zambia, while the government-sponsored drugs cost US\$9 per month after an initial payment of US\$15 for testing and counselling (Geloo 2003). However, the programme is surrounded by controversy and clinics have recorded a very low response to the programme. In outlying towns like Kasama in Northern Zambia, only three people have applied for ART. In the Western town of Mongu, 10 cases were recorded, while Livingstone, in Southern Zambia, had 22 applications. The University Teaching Hospital, the largest in Zambia, had recorded about 400 people on treatment (Geloo 2003). The Zambian government has attributed the low uptake rate to the fear of stigma and discrimination and has appealed to people to come forward and apply for ARVs. NGOs like the Network of Zambian people living with AIDS (NZP) have argued that the current system of drug distribution is open to abuse and favouritism and that there are only very limited treatment efforts made. One patient admits to having paid a US\$30 bribe to receive the ARVs and has suggested that such incidences are 'common' in the area in which she resides (Geloo 2003). The Zambian system of administering drugs through hospitals has also been criticised by the NZP, who suggest that this might not be appropriate as people usually only visit hospitals when they are very ill and use clinics more frequently (Geloo 2003).

## 2.2 Non-profit sector provision

In southern Africa, ART is provided by a range of non-profit organisations. These include international, national and local NGOs, CBOs and FBOs. In South Africa, in many cases, non-profit organisations have partnered with the public sector. The MSF sites for example are one such partnership with MSF providing funding and management, while the public sector has provided facilities and some staff. Thus many of the 39 sites sometimes claimed to be non-profit sites are in fact partnerships between public, private and non-profit institutions.

Ray and Kureya (2003) identified a number of non-profit organisations providing ART in Zimbabwe. These included two mission hospitals, as well as a Harare-based NGO which provided advice on nutrition, psychosocial support and palliative care to people with HIV/AIDS and free ART to a small number of people.

Services are not always free, and in many instances a nominal amount is charged to cover administrative and/or drug costs. For example, The Lighthouse, an NGO

operating in Lilongwe, Malawi, charges patients 2,500 Kwacha a month (about US\$28) to cover the cost of the drugs. Uptake of the service has been low, and although the clinic attributes this to a reluctance of people to take the initial test, the cost of the service is probably too high for most people in Malawi, where 41% of the population lives on US\$1 or less per day (Hills-Jones and Kanabus 2003).

MSF has played an important role in establishing ART programmes in a number of southern African countries. In Malawi, MSF has implemented a well-designed district-based comprehensive HIV programme in partnership with local public sector institutions (McCoy 2003). In South Africa, MSF offers ART to residents living in the townships of Khayelitsha and Gugulethu in the Western Cape. The project was the first to use ARVs outside of clinical trials in South Africa, and has sought to develop a model of service based on primary health care that can be replicated elsewhere (Schneider 2003). Since the inception of the Khayelitsha programme in May 2001, more than 600 people have been placed on treatment. Adherence rates are reported to be high and a 70% decline in opportunistic infections (including TB) was noted (MSF *et al.* 2003). The programme has now been extended to Lusikisiki in the Eastern Cape where MSF is attempting to develop a model of implementation of HIV/AIDS care in a rural area. MSF reports that links with family and assistants are central to adherence to treatment regimens, while some degree of experimentation with eligibility criteria, particularly community involvement was necessary (MSF *et al.* 2003).

The practical effects of delivering treatment in resource-poor settings mean that many NGOs, CBOs and People Living With AIDS (PLWA) groups are trying to deliver ART through their own structures. Many such organisations struggle to sustain treatment programmes as they have very limited resources for purchasing medicines, and many find themselves relying on drug donations. They often experience problems with stock-outs of supplies, lack of drug information and receiving drugs that are close to expiry dates or inappropriate to local needs. These factors may limit treatment effectiveness and contribute to the development of drug resistance (Van Praag 2002).

NGO, CBO and PLWA group-based treatment activities should, at a minimum, adhere to WHO recommendations for managing donations and be based on the stated needs of the recipients. The International HIV/AIDS Alliance (2002b) argues that supplying or accepting donations of drugs and commodities on the basis of being “grateful for anything we can get” is not a sound strategy for safe and

effective HIV/AIDS-related treatment.

Non-profit organisations provide a valuable service to communities, and have played a role in developing models for wide-scale service provision. At the same time, it should be remembered that the projects are often small-scale and have access to resources (including financial resources and highly qualified technical staff) that are in short supply in the rest of the country (McCoy 2003).

### 2.3 Corporate sector provision

There are compelling moral, ethical and economic reasons for providing ARVs through the corporate sector. A number of large and small businesses in southern Africa are providing partly or fully subsidised ART through the workplace. However the impact of these programmes is limited by the fact that many employees work in the informal sector or hold low-level, non-unionised positions that do not offer medical assistance (Garbus 2003).

While corporate sector initiatives are to be welcomed, these can be implemented in an uncoordinated, unregulated fashion, usually by larger companies, which can lead to inequities. Loewenson and Whiteside (2001) argue that national and international frameworks are needed to support initiatives by smaller, less well resourced companies.

Corporate efforts are often characterised by cost sharing initiatives. One such example is that of the Coca Cola Company, which announced in May 2003 that 40 of its bottlers in Africa had committed to providing ARVs to their employees. Coca Cola is to cover 50% of the treatment cost, the bottlers 40% and employees will be required to cover the remaining 10% of costs. Although widely acclaimed, this announcement came approximately 18 months after Coca Cola had publicly committed to provide ARVs at the UNGASS sitting. After substantial lobbying and advocacy, Coca Cola also reversed its earlier decision to provide ART only to its administrative staff and has now agreed to provide treatment to any employee who requires it (James 2002). In 2000, the Bank of Uganda began to offer ART at subsidised cost to its employees. In this case the employees pay 25% of the drug costs and the Bank carries the cost of the laboratory tests. This initiative has since been followed by other private organizations offering various prevention and treatment packages to their workers (Okero *et al.* 2003).

The Debswana HIV/AIDS project in Botswana has been hailed as a best practice example that could stand as a benchmark for other companies. The initiative covers 90% of the costs of HAART for its workers and their spouses (George and Whiteside 2002). By 2002, it had provided HAART to 186 staff with AIDS. The company has also implemented a care and support programme that includes home based care services and has established a functional HIV/AIDS resource centre aimed at disseminating relevant information to employees and local communities (George and Whiteside 2002). In Zambia, the provision of ARVs is also being strongly promoted by the Zambia Federation of Employers and a number of corporations provide ART to a limited number of employees (Garbus 2003).

In South Africa, local subsidiaries of German auto giants DaimlerChrysler, BMW and Volkswagen have set up major HIV/AIDS programmes, encouraging voluntary testing of employees and offering support and treatment to those infected. DaimlerChrysler South Africa, whose motto is "HIV/AIDS Is Everybody's Business", spends about three million rand (US\$420,000) annually to provide ART to the estimated nine percent of its workforce already infected. The company employs about 6,000 people and retrenched workers receive ART for two years following retrenchment. Volkswagen South Africa, with an estimated workforce infection rate of six percent, has a similar programme (Journ-AIDS 2004).

However, such initiatives are isolated and do not represent widespread practices. A recent survey released by the South African Business Coalition Against HIV/AIDS (SABCOHA) indicated that of the companies surveyed, six percent currently provide ART at the workplace. Overall, it was found that smaller companies were struggling to provide even basic education packages and it was predominantly only the larger companies who were doing so (SABCOHA 2003).

Practical challenges for workplace HIV/AIDS programmes include achieving buy in from labour movements, overcoming the stigma attached to accessing VCT services as an entry point to treatment, and linking with NGOs and CBOs (Stewart *et al.* 2002). Further challenges in the policy environment of workplace ART provision include issues such as the fate of employees who are no longer able to work or are due to retire, extending ART to wives and partners especially in the context of polygamous marriages, as well as the company's policies with regard to provision of ART for the children of their employees (Report of the Expert Meeting 2003).

Vigilance is also required to ensure that private companies do not find disingenuous ways of shifting the burden onto the public sector. Possible methods of circumventing obligations to employees include pre-employment screening to exclude those with HIV from the workforce, reduced employee benefits, restructured employment contracts, selective retrenchments, outsourcing, and changes in production technologies that substitute capital for labour. For example, in Botswana, one company reduced the number of days of sick leave that employees were allowed to accrue and adopted a policy requiring anyone with a negative sick leave balance to accept medical retirement (McCoy 2003).

## 2.4 Private-for-profit sector provision

Private for profit provision includes treatment offered by private medical practitioners, either directly from the practitioner, usually a General Practitioner (GP) or through a pharmacy. ARVs offered through the private sector are either paid for through out-of-pocket payment by individuals or by medical aid companies. Medical aid companies tend to set limits on their benefits, which may result in people being diverted away from the private sector onto the often overburdened public sector.

The main concerns with private provision are that drugs may be supplied according to what the supply chain have in stock or want to provide, rather than what may be best for the patient. A lack of continuous care, counselling for adherence and irregular pricing are characteristics of this approach to provision. For example, in Zimbabwe, Ray and Kureya (2003) found that some pharmacies stocked HIV related medicines according to what wholesalers were offering rather than what their customers needed. The study also found that people bought ARVs erratically. Reasons for this included prohibitive costs, patients tending to stop treatment when they felt better; most patients scouted around for cheaper sources; and some clients had died. The pharmacy mark up for ARVs was lower than for other drugs – approximately 10% compared to up to 50% for other drugs – because of the high sourcing costs involved with ARVs. The study also ascertained that the number of people buying ARVs directly from pharmacies was low. Only one pharmacy reported that it had sold to more than 20 clients, and less than 10 of these were regular clients.

Brugha (2003) points out that the recent reductions in the price of ARVs and rapid increase in legal distribution in the public sector may increase illegal leakage into the private sector. He cites a 2000 study from Zimbabwe which reported that one-quarter of 68 private physicians were prescribing ARVs and one-quarter of 80 pharmacies were dispensing them to patients, although insurance companies did not reimburse for their use. The authors described prescribing practices as “therapeutic anarchy” with prescribers and dispensers using “any ARV that they could lay their hands on”. Monotherapy, stocked by 82 percent of pharmacies, was prescribed to 17 percent of patients (Garbus and Khumalo-Sakutukwa 2003).

While provision through the private sector is a vital ingredient in the provision of ART to all in need, there is a general lack of information and data on this sector and a paucity of data on people who make out-of-pocket payments for ARVs (Martinson *et al.* 2002). Continued lack of regulated and standardised protocols of treatment, the lack of practitioner knowledge and poor supply practices are ongoing challenges. The private sector needs to establish clear guidelines and training for practitioners to provide correct treatment, while medical aid and insurance packages for those infected may need to be revised to limit the potential crossing over to the public sector.

# Chapter Three:

## CHALLENGES TO SCALING UP ART PROGRAMMES

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# 3

A growing body of literature outlines the challenges involved in providing ART in resource constrained settings. A number of evaluations have identified a set of issues which will need to be addressed if ART programmes are to be successfully implemented, particularly on a large scale.

The International HIV/AIDS Alliance (2002a) identifies a number of key elements that influence the effectiveness of ART programmes. They argue that good information and strong support for patients and communities are essential before and during treatment. Families and communities have a key role in this, and commitment from local government is required. Other important elements include sustainable and affordable supplies of medicines and diagnostics, adequate training for health care workers, accurate information and continuing education for patients, supporters and providers.

A report by the World Bank (2003) based on a survey of experience in distributing ARVs in developing countries also identified a number of key components of a successful programme. These include:

- Simplified, standard regimens of fixed dose therapies
- Simplified clinical monitoring
- Provision of consumer friendly adherence support
- Maximum use of available human resources (including non-professional staff, families and community members)
- Active community involvement
- Integration and phased scale up.

As previously argued, the experience of implementing an ART programme in Botswana contains important lessons for all developing, and especially other southern African, countries. In Botswana the HIV/AIDS epidemic and its treatment exacerbated pre-existing structural and systemic deficiencies and led to the creation of new ones as the numbers of patients accessing the services increased

(Government of Botswana 2003). Thus health care infrastructure and systems have to be strengthened before widespread public sector provision ART can be successfully implemented (Hills-Jones and Kanabus 2003).

The shortage of health personnel has been cited as one of the critical challenges to the successful implementation of ART programme in Botswana. In its 2002 report on the status of its national response to the UNGASS Declaration, the Botswana government identified the need to strengthen the linkages and co-ordination between the central and the district levels, and integrate and mainstream HIV/AIDS programmes into broader health services. Further challenges were also noted, including the changing pattern of STIs with an increase in viral STIs; the inadequacy of ongoing and supportive counselling; inadequate integration of VCT into the health system; inadequate national policy on counselling and insufficient involvement of men in PMTCT (Government of Botswana 2003). The strengthening of monitoring and evaluation systems to inform programme design and to identify programmes appropriate for scaling up were also areas in need of urgent attention. The lack of adequate numbers of counsellors at facility level, inadequate access to drugs including generics, the high price of reagents for laboratory support and financing issues must also be addressed (Government of Botswana 2003). A number of socio-cultural barriers to widespread uptake of ART also emerged.

Based on the recommendation of the National AIDS Council and in an attempt to de-stigmatise the virus and introduce ARVs more widely, Botswana also plans to introduce routine HIV testing at all public health facilities in 2004. All clients will therefore be tested unless they “opt-out”, as opposed to the current system whereby clients have to “opt-in” to testing (IRIN Plus News 2003).

Common themes from the literature and from the examples of pilot programmes and initial phase rollout efforts may be summarised into broad categories as follows:

- Ensuring adequate resources are made available for ART programmes
- The essential overall strengthening of health systems
- The need to ensure community preparedness and involvement
- From a clinical perspective, adherence, resistance and toxicity must be monitored

- Broader issues such as poverty and nutrition need to be taken into consideration in ARV rollout
- Issues of equity to ensure provision of ART does not further skew the gap between rich and poor or increase gender inequality
- Monitoring and evaluation systems to better inform policy (WHO 2002).

## 3.1 Ensuring adequate resources

### 3.1.1 Financing

The cost implications of providing comprehensive treatment for AIDS are substantial (Geffen *et al.* 2003, Rollnick 2002). As the prices of ARVs decline, other associated costs such as CD4 and viral load tests and equipment become important drivers of overall cost (Cleary *et al.* 2003). UNAIDS and WHO (2003) warn that dramatic and sustained increases in resources and political commitment – including from hard hit countries – are needed in order to reach this goal.

A variety of models and costing systems upon which to base cost-benefit analyses and results have been developed. Each model relies heavily upon assumptions regarding various inputs to the treatment process. Applying a planning and costing model to over 80 countries, Kumaranayake *et al.* (2002) estimated that “wide-scale” ARV treatment coverage by 2015 would cost between US\$6.8 and US\$9.2 billion per annum. This does not include additional prevention and care costs valued at US\$8.8 and US\$5.8-7 billion respectively. In modelling the costs of different treatment scenarios of select population groups in India, Over *et al.* (2003), in Attawell and Mundy (2003), estimate that costs could range from US\$177 million to US\$744 million per year. This would comprise the majority of the health and social welfare budgets combined. In Botswana, the cost of medications, counselling and testing is estimated to be US\$600 per patient per annum (Rollnick 2002).

In South Africa, a number of cost estimates have been undertaken under different scenarios of provision and varying underlying assumptions. Each result in different projections and therefore the need to plan in terms estimated ranges of coverage needs and costs. The Joint Health and Treasury Team (2003) estimated that a 20% coverage scenario (by 2008) would allow for 200,000 people to be

treated, while raising this to a 50% coverage scenario would allow the treatment of 600,000 people. Full coverage would allow 1.2 million people on treatment by 2008. These different scenarios of coverage would incur scaled costs as outlined in the table below. Thus full coverage by the year 2010 would cost an estimated R16.9–R21.4 billion.

**Table 2: Additional Rands per year (billions)**

Scenario	2003	2005	2008	2010
No ARV	R5.4	R6.3	R6.7	R6.7
50% Cover	R5.5	R7.0	R9.6 – 10.5	R10.8 – 12.9
100% Cover	R5.6 – 5.7	R7.9 – 8.3	R13.4 – 15.7	R16.9 – 21.4

Source: Joint Health and Treasury Task Team (2003)

Boulle *et al.* (2002) estimate that by 2006/7, R4.9 million would be required in order to treat less than 118 000 patients per annum.

In South Africa, the national government has allocated almost R1.6 billion to treat an estimated 381 177 people by 2005/6 (South African National Department of Health 2003). Geffen *et al.* (2003) calculate that by 2015, comprehensive treatment would cost over R20 billion, about 1.74 per cent of GNP. The South African National Department of Health has recognised the importance of integrated care and the need to revamp much of the health system itself in order to provide adequate treatment. The requested budget per annum, in millions of rands, as submitted to Treasury in 2003, is shown in Table 3 below (South African National Department of Health 2003). Of note is that ARVs account for less than one-third of the overall costs over the five year period.

**Table 3: Estimated cost requirements for implementation of a comprehensive ART programme**

	2003/4	2004/5	2005/6	2006/7	2007/8
New Staff	21	322	432	662	1 027
Laboratory Testing	20	152	311	520	806
ARVs	42	369	725	1 118	1 650
Nutrition	63	343	421	532	656
Other Health System Upgrades	70	171	184	160	160
Programme management (national and provincial)	16	103	128	128	128
Capital Investment	30	75	100	100	0
Research	34	55	55	48	48
<b>Total</b>	<b>296</b>	<b>1 590</b>	<b>2 358</b>	<b>3 268</b>	<b>4 474</b>

Source: National Department of Health (2003)

For most southern African countries, with the possible exceptions of South Africa and Botswana, provision of ART through the public sector with government revenue alone is not a possibility and alternative methods of financing need to be investigated. McCoy (2003) suggests that one of the biggest issues relating to the financing of HIV/AIDS treatment in Africa is the question of who will pay for the medicines and the health care infrastructure that is required. He points out that if the responsibility for financing is left entirely up to households and individuals, poor households would be prejudiced due to their inability to afford care and treatment, or would access care at the expense of other needs. He recommends that finances be collected and pooled at a central level and distributed in a manner that supports the poor in accessing services. Optimal cross-subsidisation of the poor by the rich would take place if households contributed according to their ability to pay, rather than according to their risk of illness or need for health care.

Options for increasing financing for allocation of equitable health care resources include government taxation and donor funds. In southern Africa, the former option is constrained by high levels of unemployment, household poverty and a large informal economy that is not captured by the tax system. Consequently, government revenue makes a relatively small contribution to an already under-resourced public health system in most South African Development Community

(SADC) countries (McCoy 2003). Whilst government-subsidised provision of ART to poorer sections of the population may be an option, current thinking suggests that means tested access to treatment is not appropriate due to the bureaucratic and cumbersome nature of the instrument and the tendency of people to be less than frank about their financial status in order to access treatment (Ntuli *et al.* 2003).

Donors fund most of sub-Saharan Africa's health systems – and there has been an avalanche of publicly stated interest and intention of the North to fund HIV/AIDS prevention and treatment campaigns in poorer countries. However, much of the monies for this have yet to be received. For example, as of March 2002, the projected annual costs of the Global Fund were less than the pledges received from donor governments and corporations. The money promised by the donors at the end of 2003 was US\$1.371 million less than the money that the Global Fund needed (McCoy 2003). It is also not clear to what extent funds pledged to fight HIV/AIDS will be diverted from other programmes that were already earmarked for developing countries. Potts and Walsh (2003) suggest that money being put into treatment is money taken away from prevention and vice versa. Special conditions when using donor funds, such as the proposed ban on generics when using PEPFAR money, also have to be negotiated.

It is also debatable whether funding will be allocated to areas of treatment that are most in need. Diverse interests, including those of pharmaceutical companies and politicians, are often placed above recipient countries true needs. Thus strengthening of health systems as a real need may be overlooked in favour of interventions that yield immediate and visible results, such as provision of money for drugs. It is possible that a vertical approach to donor funding of health may re-emerge and funds allocated to the fight against AIDS may be placed inappropriately (Shevel 2004). Vertical programmes, established to achieve rapid delivery against unrealistic targets can bring about undesirable inefficiencies and wastage (Loewenson and McCoy 2004). As such, countries need to take cognisance of the underlying weaknesses in the health systems and ensure that the goal of longer-term health provision, across the board, is paramount in planning and allocation of funds. Such an approach may require challenging the existing paradigm of funding agencies, which are set to become even more significant players in health programmes in developing countries. TAC (2003) argues that further research into whether these donations create undue and onerous obligations on countries and their effect on the existing health

infrastructure is required. The effect of cooperative relationships entered into between countries and foreign institutions require further scrutiny.

Other financing options include health insurance/medical aid funding, out-of-pocket payments, corporate funding through workplace and outreach programmes or community-based health financing (CBHF). CBHF is a term used for various models of financing for health care including, community health funds, micro-insurance, mutual health organizations, revolving drugs funds and community involvement in user fee management (World Bank 2004). The essence of this approach, which is gaining popularity in developing countries, is to include normally marginalized groups into some form of scheme that assists in the payment for their health care services. Such a scheme may involve voluntary based community financing where households pay into a scheme to finance part of the basic health care services they receive from government, thereby complementing government efforts (PHRplus 2004). Hsi *et al.* (2002) suggest that while weaknesses such as lack of capacity, limited membership and financial instability are ongoing challenges for the CBHF approach, there may be a role for them in providing a supportive role to those taking ARVs. However, at present most of these organisations are prevention oriented and additional attention is required to develop capacity to play a greater role in care and treatment.

#### 3.1.2 Drug Procurement

Prohibitive costs of ARVs have been a major factor in limiting the implementation of ART programmes in developing country settings. Wealthy nations and multinational pharmaceutical companies seeking to maximise profits and preserve their intellectual property rights have, until recently, set ARV prices at levels that are unaffordable to most people in developing countries.

The rationale offered for such protectionist policies is that intellectual property rights and patents are necessary to provide a reward system that will promote and sustain the high cost innovation and research needed to produce new and improved medicines (McCoy 2003). t'Hoën (2003) however, points out that many ARVs were initially developed with public research institutes – including universities – and not by pharmaceutical companies alone. In order to back the argument, reference is made to the development of many of the most important AIDS drugs, including zidovudine, stavudine, zalcitabine, abacavir, and a number of protease inhibitors, in which public research institutes were key players. t'Hoën

also questions whether pharmaceutical innovation is synonymous with therapeutic innovation and cites the results of an assessment of 2 257 new “health market” products introduced in France between 1981 and 2000, which revealed that sixty-three percent of the new products were “me-too” drugs. These drugs offer no therapeutic gain over existing drugs. Only seven products introduced over this period (0.13%) represented a real therapeutic breakthrough.

The Doha Declaration on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement makes provision for public health needs to be placed above commercial interests in international trade negotiations. The Doha Declaration further states that “public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency for which governments can issue compulsory licenses authorising the use, subject to certain conditions, of patented products” (UNAIDS 2002 pp149). Member states can, in some circumstances, make use of generic medication. Despite this, a host of bureaucratic red tape, procedural complications and conditionality has hampered the use, manufacture and import of generic ARVs. MSF alleges that some World Trade Organisation members have attacked both the spirit and intent of the Declaration, putting the interests of their pharmaceutical industries ahead of the health of the world’s poor (MSF 2003). Others suggest that the issue of drug pricing has become an important litmus test of the global community’s commitment to a fair and humanitarian response to HIV/AIDS (McCoy 2003).

As a result of sustained and vociferous advocacy and lobbying initiatives, some major drug companies have agreed to adopt the system of differential or tiered pricing and sell ARVs at lower costs to developing countries. As a result sub-Saharan Africa has seen dramatic reductions in ARV prices by pharmaceutical giants. For example, in January 2001, the combination of d4T, 3TC and nevirapine on the Kenyan market cost about US\$450 per month, but by October 2001, it had fallen to US\$80, as drug manufacturers agreed to sell their products at large discounts. Other countries (e.g. Brazil and India) have started manufacturing their own ARVs that cost even less. Hence, the ARV drug market now includes a wide range of prices and offers opportunities for cost savings. This means that ART programmes can search for competitively priced ARV drugs. However, access to comparative prices and suppliers of ARV drugs remains a challenge for many ART programme managers (Tawfik *et al.* 2002).

MSF points out that while a few firms sell their drugs at competitive prices, most originator prices are still significantly higher than generic alternatives. For example, the best international price of Boehringer Ingelheim's nevirapine is US\$438, while a generic version costs US\$166 (MSF 2003). However, recent months have seen further developments on the drug production front. In late 2003 GlaxoSmithKline and Boehringer Ingelheim announced that they would allow the widespread manufacture of cheap generic versions of their patented AIDS drugs in South Africa. In addition, they have indicated that they would grant more licenses to generic firms to produce and import ARVs. This may extend the voluntary license granted to local firm Aspen Pharmacare in October 2001 for the production of ARVs. A second firm, Adcock-Ranbaxy, a South African affiliate of India's Ranbaxy Laboratories Ltd, has already been offered a license and GlaxoSmithKlein will consider applications for another two possible licenses for the manufacture of copies of other ARV drugs such as AZT and lamivudine (Reuters 2003).

## 3.2 Strengthening of health systems

The introduction of additional requirements into an already overburdened health system can potentially reduce the efficacy with which existing services are delivered; thus implementation of ART should be linked to and congruent with a broader health sector strategy (Prescott 1997). A better understanding of the existing health service is required, in order to ensure that both the existing and new services are strengthened by renewed attention and efforts.

WHO (2002) guidelines for ART provision requires that a number of services are in place. These include: HIV counselling and testing and follow-up counselling services to ensure psychosocial support and adherence to treatment; capacity to appropriately manage HIV related illness and opportunistic infections; a laboratory that provides tests for monitoring treatment; a continuous supply of ARVs and medicines for the treatment of opportunistic infections and other HIV related illnesses; and reliable regulatory mechanisms. Countries implementing ART programmes are also required to implement an HIV drug resistance sentinel surveillance system. Only facilities which meet minimum criteria should provide ART. Criteria for selection may include: the presence of trained medical officer/s; professional nurse/s and dedicated lay counsellors; an existing core package including adult curative care; TB; VCT; PMTCT and treatment of opportunistic

infections; a reliable and secure supply chain in place for ARVs and easy access to laboratory services (Schneider 2003).

### 3.2.1 Providing a Continuum of Care

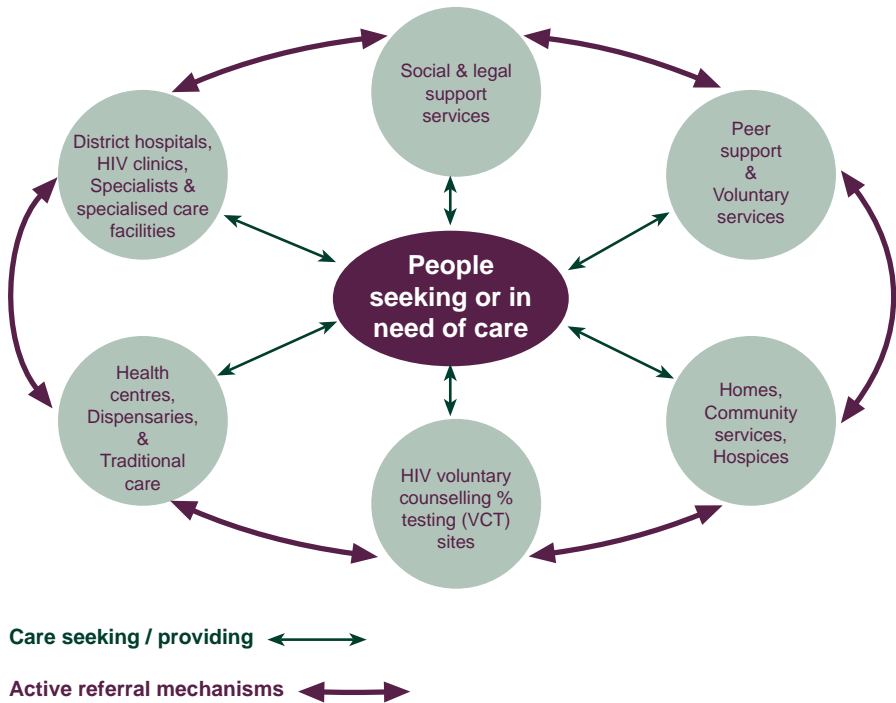
Both prevention and treatment are priorities if lives are to be saved, human suffering reduced and the future impact of AIDS on human development and poverty reduction efforts minimised (Loewenson and Whiteside 2001). A central element of a comprehensive HIV/AIDS treatment and care strategy is the effective integration of prevention and treatment interventions. Intrinsic to this approach is a move away from seeing prevention and treatment as two unrelated strategies (UNAIDS 2002). Treatment and prevention programmes also complement one another as the availability of lifesaving treatment is also a powerful lure for people to get an AIDS test as well as into safer sex and life-style enhancing education programmes (Rosenberg 2001).

A comprehensive service for management of HIV-related illness needs to build on an integrated approach which focuses on providing a continuum-of-care. This continuum should encompass all levels of the health care system and include VCT services, management of STIs, family planning and reproductive health care, TB services and outreach, PMCT programmes and linkages to support groups. Community-based Home Care (CBHC) is also an important component of the continuum. CBHC includes “any form of care given to ill people in their homes. Such care includes physical, psychosocial, palliative and spiritual activities” (WHO 1993 pp6).

Clients and patients should be provided with information at every point as to what other services they should link to. This is generally difficult to achieve due to resource shortages and the fact that health staff have seldom been adequately trained to use this integrated approach (Ray and Kureya 2003).

The graphic below provides an overview of a continuum of care cycle.

### HIV/AIDS continuum of care and support



Source: Van Praag SynergyAids.com

Clearly strong referral systems are necessary to ensure that patients and those assisting them can access appropriate services as and when required. However, one study in Kenya found that referrals for family planning services were very low, occurring in only 10 percent of observed client-provider interactions. This was even lower for women who were HIV-positive, even though effective contraception to prevent pregnancy and subsequent vertical transmission of the virus were important components of care for these women (Family Health International 2003).

Community structures and civil society organisations also need to be part of the continuum-of-care. The creation of community-workplace and site-community linkages using NGOs as intermediaries can help to alleviate the strain on families. These intermediaries may be one method of ensuring that other household members, particularly vulnerable women and children, are able to access health care and nutritional support, particularly if access to ARV for some members results in reallocation of resources and increases household inequality. Such services for families and children should preferably be located in the community, avoiding institutionalisation and involving other community members where necessary (International HIV/AIDS Alliance 2002b). The appropriate mix of services will depend on a variety of factors, including workplace services, employment levels, existing NGO and CBO structures and may have to be determined at a local level (Stewart *et al.* 2002).

VCT and TB control programmes are important entry points to ART programmes, and are discussed in more detail below.

### **VCT as an entry point for ART**

VCT is a vital entry point for treatment (Oberzaucher and Baggaley 2002) and failure to establish successful VCT programmes will limit uptake of ART. Research has shown that many people who undergo VCT change their sexual behaviour to protect themselves and/or their partners. However, simple access to VCT does not guarantee successful sexual behavioural change and there are a multitude of factors to consider, such as the HIV status of the individual, couple or individual counselling, counselling content and client/patient motivation (Coates *et al.* 2001). Furthermore, success rates must be interpreted with care due to the bias away from VCT by those who fear they may be positive (WHO 2002).

Although many countries have VCT programmes, these tend to be concentrated in urban areas and leave out vulnerable sections of society. Overall, it has been estimated that VCT is available to only about 12% of people in developing countries (WHO 2002). Mechanisms need to be explored for expanding VCT services at the same time as ART programmes are introduced and scaled-up. VCT should be available in different settings (antenatal clinics, TB clinics, STI clinics etc.) and issues such as longer-term counselling options, as well as ongoing training and support for counsellors, who are likely to face larger case loads, should be addressed (International HIV/AIDS Alliance 2002a).

#### **Integrating HIV/AIDS and TB care**

Globally, levels of HIV and TB co-infection are high and continue to increase rapidly. UNAIDS and WHO data indicate that one-third of all people with HIV have TB co-infection and that up to 70 percent of TB cases are HIV positive. TB is one of the leading causes of death among people with HIV. Preventing and treating TB would significantly improve the quality of life of people with HIV, would lead to reduced morbidity and mortality, and would help control the spread of TB (International HIV/AIDS Alliance 2002b, WHO 2004c).

Experiences and lessons learnt from the TB Directly Observed Treatment programme can provide useful lessons for HIV treatment and care. The scale of the TB epidemic, the need for long-term combination therapy, and issues related to monitoring requirements and drug resistance and adherence are similar for TB and HIV/AIDS (Schneider 2003). However, TB therapy is a relatively short intervention while ART is life-long.

Research on TB treatment programmes in South Africa outlined a number of lessons, which may be extrapolated to ART programmes. Barriers to treatment included: a lack of money for transport to the clinic, insufficient money for food, perceived and real side-effects, beliefs that medicines should only be taken with food and when ill and the views that “western” drugs should not be taken with traditional medicines. The researchers identified strategies to rectify these programme weaknesses which included:

- Improving access to health facilities
- Addressing clients’ concerns about side-effects
- Counselling patients about the risks and benefits of treatment
- Implementing reliable drug supply systems
- Involving traditional healers
- Establishing and sustaining support groups for people living with TB and HIV; and
- Monitoring and reporting adherence by integrating a simple recording and reporting system into existing health information systems (Hausler and Godfrey-Faussett 2002).

In many instances health services, such as HIV/AIDS and TB services, exist in

parallel, resulting in a loss of valuable resources. It is critical that the synergies between different services are exploited by integrating services more effectively (International HIV/AIDS Alliance 2002b). However, where general medical and TB services themselves are weak, integrating HIV/AIDS treatment could result in greater dysfunction. In Tanzania, joint HIV/TB clinics are being planned and it has been proposed that AIDS and TB programmes, including testing facilities, health worker training and public sensitization, be linked from district to national levels. However, there is the possibility that stigma associated with both diseases might lead to the under-utilisation of services (Semali and Kimambo 2002).

### 3.2.2 Human Resources

A shortage of adequately skilled health staff across all levels is a major impediment to successful implementation of ART programmes in southern Africa. Lack of human resources has been an important limiting factor for Botswana's ART programme, where the problem has been compounded by the fact that 90% of the doctors involved in the programme are foreign, do not speak the local language and are unfamiliar with the local culture (Fredriksson-Bass and Kanabus 2003). The shortage is further compounded by the HIV epidemic itself in that many health care workers themselves are infected. In South Africa, it is estimated that over 16% of health workers are HIV positive, while up to 6 000 may be dying each year due to AIDS related illness (Shisana *et al.* 2003). In Botswana, the lack of a medical school, high attrition rates due to migration as well as illness and death, regional restrictions on recruitment of health professionals, lengthy recruitment procedures and low staff morale have limited the ability of the government to recruit, train and retain staff (Government of Botswana 2003). Staff trained as part of the ART programme have also become more marketable, which has contributed to high attrition rates.

Both Botswana and South African policy have recognised that comprehensive human resource development plans which address issues related to staff recruitment, retention and development are an integral part of scaled-up ART programmes. In Botswana, the following have been suggested as possible interventions to address human resources shortages (Government of Botswana 2003):

- Influencing international partners to fund or provide staff and technical experts

- Creating faster parallel recruitment channels
- Increasing the efficiency of existing systems e.g. hiring staff on a temporary basis and processing application for permanent positions when they are already in the system and making same-day offers to interviewed candidates
- Hiring entry level staff to minimise internal discord regarding pay and schemes of service
- Ensuring parallel systems created match government pay scales and do not set a destabilizing precedent
- Exploring ways of devolving responsibility to lower level staff.

The Ugandan national delivery model anticipates that, in the long-term, tasks customarily performed by physicians will have to be shared and involve other health care providers, such as clinical officers and nurses, who exist in greater numbers. Community organisations and family members will also need to be enlisted to provide ongoing support to people living with HIV/AIDS (Okero *et al.* 2003). In Botswana, a system of lay counsellors has been developed to ease the workload of the nurses (Fredriksson-Bass and Kanabus 2003).

Other commentators, such as MSF (2003), also advocate treatment models that rely heavily on nurses and simplified regimens and management guidelines. It has also been suggested that well-trained community health workers (CHWs) can play a crucial role in scaling-up ART programmes due to their accessibility to community members, their ability to conduct home visits without abandoning vital functions in a formal health care setting, and their ability to link communities to resources and services. They also provide a vital service in educating communities about health problems, can play an important role in mobilising communities and in identifying community needs and priorities, and can act as agents for change (Friedman 2003).

#### 3.2.3 Training of and Guidelines for Health Care Workers

Health workers who provide ART need to have appropriate knowledge, understanding and information about new treatments, side effects of drugs, HIV transmission, nutrition and drug storage (Fredriksson-Bass and Kanabus 2003). The widespread lack of experience with ART across the entire supply chain, combined with the lack of pre-existing curricula for rapid training of health

workers, is a significant challenge for public health sectors in developing countries. Additional training, even if fast-tracked, requires staff to be released from their routine duties. This can be very difficult in the context of staff shortages, heavy workloads, and numerous other competing training programmes.

**Table 4: Sites and personnel in South Africa required to ensure 100% ARV coverage by 2008**

	2003/04	2004/05	2005/06
Number of New Sites Joining Programme	120	236	0
Number of Staff to be trained	8 040	15 812	0
Cost of Training	R12.1 million	R 23.8 million	0

Source: Joint Health and Treasury Task Team (2003)

The table above provides an indication of the estimated number of staff that would have to be trained in order for South Africa to achieve 100% coverage by 2008, and the associated costs for the period 2003 - 2006. This table only looks at professional staff and does not include lay-counsellors and other non-professional staff.

Possible suggestions for meeting training needs include using existing training materials to rapidly develop a “bare essentials” curriculum; training entire facilities as a unit using a treatment team approach rather than training discrete groups of individuals; providing on site facility-based training through placement of a senior HIV treatment specialist who acts as a mentor for treatment teams; and developing an integrated training package (e.g. ART training is provided together with PMTCT and TB training) to reduce time away from work (Government of Botswana 2003).

In Uganda, a countrywide training programme was undertaken to ensure that staff were appropriately equipped to provide ART. This focused on ART and the use of sophisticated drugs for opportunistic infections at the referral and district levels, drugs logistics, stock management and other clinical management issues (Okero *et al.* 2003). The attitudes of people providing treatment are also critical. In Zambia, for example, people perceived the quality of medication they received from a home based care project to be superior to those provided by hospitals because of the caring and supportive attitudes found at the home based care project (Fredriksson-Bass and Kanabus 2003).

Training of GPs and other private sector providers is also an important issue. For example, in Zimbabwe, as in most southern African countries, any doctor can prescribe ARVs, regardless of whether or not they have received specific training. As a result there is no central register of doctors with expertise in prescribing ARVs and quality of care is variable. Ray and Kureya (2003) suggest that standardised treatment guidelines should be developed, that only accredited doctors should be allowed to prescribe ARVs and that systems for monitoring services should be introduced. They argue that this would ensure a better quality of service and address the danger of developing resistance to ARVs. However, they caution that the development of appropriate treatment guidelines could be a long process and guidelines alone will not change the clinical behaviour of medical practitioners, unless supported by advocacy and other mechanisms to ensure effective monitoring and accountability.

#### 3.2.4 Drug Supply Management

The proper management of supplies of appropriate ARVs and diagnostics is vital to the sustainability of an ART programme, and is a prerequisite for increasing community confidence in the public health system as a regular and reliable source of HIV and other health related treatments (International HIV/AIDS Alliance 2002a). Systems for drug procurement, as well as storage and distribution systems which ensure the required level of security and accountability for ARV drugs across the entire supply chain, need to be in place. ARVs are valuable commodities and corruption and leakages can occur. Ensuring appropriate temperature and storage conditions for drugs, particularly in very hot countries, is also important (Government of Botswana 2003).

Different supply approaches have been used in different settings. For example in MSF's Khayelitsha Clinic in South Africa, ARVs are procured and stored separately from other drugs, while in another clinic, supplies of ARVs are delivered to the facility pre-packaged and labelled with patient names. Drug stock outs in both sites are reportedly unusual. MSF also report from their Khayelitsha pilot programme that investing in and special attention to ARVs has resulted in improved drug supplies for all conditions in the facilities, indicating the positive spin-offs that ART delivery can have on the broader health system (Schneider 2003).

Experience in Botswana suggests that the following actions might be useful:

- Purchasing covered, lockable trucks with air conditioning for transportation
- Using and reinforcing existing 'habit-forming drug' protocols for ARVs
- Limiting the number of people with access to pharmacies
- Increasing security at storage sites; and
- Ensuring patients take drugs as prescribed (e.g. pill counts, monitoring dates of prescription pick-ups) (Government of Botswana 2003).

### 3.2.5 Laboratory Infrastructure

Reliable laboratory support to diagnose HIV and common opportunistic infections, to determine biological eligibility for ART and to monitor side effects and effectiveness, must be available to any facility providing ART (Van Praag 2002). However, testing and laboratory infrastructure in most southern African countries is sub-optimal and presents significant challenges to roll-out and scaling-up of ART.

There are only two centres in Zambia for CD4 and viral load testing. In Lesotho, laboratory capacity in meeting the demand for HIV testing and monitoring of patients on ART is limited and most of the HIV infected persons on ARVs obtain treatment from South Africa, where facilities for monitoring of CD4 lymphocytes cell count and viral load estimation are more readily available for those able to pay the associated costs (Government of Lesotho 2003). In South Africa, the national ART programme envisages that viral load and CD4 counts will be done at baseline, 3 months, 6 months and 12 months in the first year of treatment, then 6 monthly or yearly thereafter. The availability and turn-around times of tests are a crucial capacity issue.

Building the necessary laboratory infrastructure and capacity will require substantial financial and technical resources. Although Brazil was able to rapidly build a capacity of 44 laboratories nationwide to cater for additional virological monitoring, this approach may not be feasible for most African countries, which lack both the finances and human resources to build and staff such facilities. Continued research is needed into cost-effective and simple methods of clinical monitoring (Van Praag 2002).

In addition to the lack of CD4 and viral load testing capacity in many countries, the logistics of transporting samples to central laboratories from widely distributed geographical sites within required time limits and on sometimes non-existent roads requires careful planning and execution. The accurate and timely communication of test results back to facilities, including those lacking direct phone lines and fax machines are added considerations (Government of Botswana 2003). The use of e-access and enhanced Short Messaging Service (SMS) technology should also be explored (Schneider 2003). The planning for wide scale treatment must therefore be located within the broader context of logistical and infrastructural requirements of the country in question.

#### 3.2.6 Patient Information Systems

A recent study conducted in South Africa showed that a weak Patient Information System was an impediment to ensuring ongoing and correct treatment, increased staff workloads and led to unnecessary duplication of efforts and time (Shisana *et al.* 2003). Ensuring that a single electronic information system is in place to assist in treatment of patients, regardless of where they present is an essential, yet often neglected, aspect of the health system.

In Botswana, the implementation of a new health information system necessitated the training of more than 95% of health workers in basic computer skills. The longstanding familiarity with, and dependence on, paper-based systems needed to be challenged. The lack of software packages appropriate for understaffed, high workload, high volume settings with low levels of computer literacy and the need to ensure that each patient would be uniquely identifiable regardless of the site at which they presented were further impediments identified (Government of Botswana 2003).

Some key aspects of successful introduction of Patient Information Systems, as suggested by the Botswana government, include: the development of simplified software packages; accomplishing a basic degree of computer literacy for all staff; using staff who have already been trained to train their colleagues; the provision of consistent onsite support/trouble-shooting visits; refraining from making too many sudden changes to the information system; and allowing people time and practice to develop familiarity with the system (Government of Botswana 2003).

### 3.3 Adherence and the development of resistance

An often cited concern regarding widespread provision of ARVs in both low and middle-income countries is the ability of health systems to ensure patient adherence to potentially complex ARV regimens. Adherence is a serious issue in all countries, because of the potential emergence of drug-resistant HIV. A United States study found that successful virologic suppression through the use of combination ART was highly associated with 95% adherence (i.e. persons taking their medication as prescribed by their doctors over 95% of the time), and that failure to suppress viraemia increased dramatically as adherence decreased (International HIV/AIDS Alliance 2002b). Development of resistance to a specific ARV agent may confer resistance to other drugs within the same class and can significantly limit future treatment options. Continued exposure to the same or a different type of HIV may compound this problem (Schneider 2003).

In the United States, a recent national survey revealed that 14% of newly acquired HIV infections were highly resistant to at least one HIV drug, and 5.5% were highly resistant to two or more drugs. In 1995–1998, the corresponding figures were 3.5% and 0.4%, showing a significant increase in resistant strains over time (International HIV/AIDS Alliance 2002b). Although little is known about resistant patterns in countries that will implement ART programmes in line with the 3 by 5 target (WHO 2004a), Zambian health officials have recently warned of the emergence of HIV strains that are resistant to current ARV drug treatment, albeit on a very minor scale (Plus News 2004). Alternative treatment options for resistant HIV generally require extra drugs and much higher costs than first-line treatments (International HIV/AIDS Alliance 2002a).

Management of supplies of ARVs and diagnostics, prevention of corruption and leakages, and the questions of cost and cost sharing can be expected to have direct effects on adherence rates and drug resistance. If supplies are interrupted for any reason, adherence will fail and drug resistance is more likely to develop.

Despite arguments that it would be unsafe to use ARVs in Africa for fear that incomplete pill taking would speed up the mutation of drug resistant strains that could spread around the world, recent evidence has suggested that ARV users in Africa are better at following their pill regimens than Americans. Surveys carried out in Botswana, Uganda, Senegal and South Africa, have found that, on average, there is a 90% adherence rate. The average figure in the United States

is 70%, dropping even lower among sub-groups such as the homeless and drug abusers (World Bank 2003, MSF 2002, Anglo America 2004).

The AIDS Healthcare Foundation stresses three factors that enhance ARV adherence: on-site support by NGOs, ongoing education by peers who are also on ART, and involvement of family members before and during treatment (Mascolini 2002). In MSF's programmes in Khayelitsha and Chiradzulu, adherence support involves trained counsellors, adherence plans and a treatment assistant (usually someone living in the same household) that could assist with adherence issues. Support groups on ART enabled discussions relating to barriers to adherence, adverse events, disclosure and other psychosocial issues and served as a tool for health promotion and education (Grubb *et al.* 2003).

Depression and substance abuse have been shown to be significant predictors of poor adherence in a number of studies in high-income countries (International HIV/AIDS Alliance 2002b). Similarly, in South Africa, one of the lessons learnt from the Operational Research on ART (OPERA) project at Chris Hani Baragwanath is that socio-behavioural factors, like alcoholism, can impede adherence (Schneider 2003). These findings underscore the need for ongoing psychosocial support before and during treatment.

Other mechanisms to ensure adherence include requiring potential candidates to sign consent for ART and agreeing to take on the responsibility of adherence, and individual counselling support at each clinic visit. The provision of adherence materials such as pill boxes, daily schedules and forms for self-monitoring of side effects, providing simplified regimens, and providing continuity of care through a dedicated service and staff are further tools that may be used to assist in adherence (Garbus 2003). Practical issues related to the ART regimens themselves, including the number of doses per day, the number of pills per dose and dietary restrictions, also contribute to people's ability to adhere (International HIV/AIDS Alliance 2002b). Compliance has become easier due to the availability in some countries of triple therapy cocktails in as few as two generic tablets a day.

Different programmes have also developed different methods for monitoring adherence. The OPERA project in South Africa makes use of questionnaires completed at every visit, as well as pill counts. Assessing adherence in children, particularly if the caregiver is ill or has died, poses more difficult challenges (Schneider 2003).

In settings where access to ART is limited, adherence also has a direct relationship with choices about who is eligible for treatment. Psychological, social, material and economic support is needed to optimise treatment, and choices about eligibility must therefore take into account all of these factors in order to achieve effective treatment outcomes (UNAIDS and WHO 2003). WHO recommends that in ARV treatment programmes in resource-limited settings HIV infected adolescents and adults should start ARV therapy when they have confirmed HIV infection and one of the following conditions:

- Clinically advanced HIV disease
  - WHO Stage IV HIV disease irrespective of CD4 cell count
  - WHO Stage III disease with consideration of using CD4 cell counts  $<350/\text{mm}^3$
- WHO Stage I or II HIV disease with CD4 cell counts  $<200/\text{mm}^3$  (WHO 2003)

MSF in South Africa have also created additional eligibility criteria for their sites. Patients are only considered for treatment if they live in the geographical catchment area, have social support to assist in adherence, are willing to disclose to those around them, and are active in the community (MSF 2002).

The involvement of people with HIV and other members of the community in the development and application of eligibility criteria and monitoring thereof may also help to mitigate allegations of unfairness and favouritism. Community understanding about ART may also develop and strengthen the voices of those who see that it can have beneficial effects on the community and individuals (UNAIDS and WHO 2003). The use of community structures to assist with patient selection decisions can also be of use in applying quasi-clinical selection criteria. For example, some projects have devised criteria that are considered to be predictors of good adherence to treatment and follow-up. These include pre-therapeutic evidence of regular clinic attendance and evidence that the patient has taken steps to improve his/her own level of treatment literacy (McCoy 2003).

### 3.4 Ensuring community preparedness

There is increasing consensus that involving community groups and representatives, peers and family members is a crucial component for successful large-scale roll out of public health programmes. Lessons from TB and river blindness control programmes have shown that systematically engaging these groups can improve treatment outcomes and generate effective local responses (Grubb *et al.* 2003). With the rapidly changing political and economic climate around the provision of ART in resource-poor settings, community preparedness for ART is essential (International HIV/AIDS Alliance 2002b). The growing availability of affordable ARV drugs may raise public expectations of a cure far beyond the current ability to reduce morbidity and mortality rates. In this regard, community preparedness to manage and mitigate unrealistic expectations and dashed hopes will be essential, especially as HIV treatment sites will have to refuse treatment to patients who do not meet minimum ART eligibility criteria (Van Praag 2002).

CHBC is a key HIV intervention which draws on two core elements, namely families and communities, and places families in the centre of the care team. Communities are places where people live, and a source of support and care to individuals and families in need (WHO 1993). Experience indicates that uptake and adherence are superior if people living with HIV and AIDS and their families can help to overcome barriers to accessing treatment, especially discrimination and stigma (WHO 2003). The involvement of family members to encourage participation in VCT, disclosure, reduce stigma and fear, improve adherence and encourage openness is essential (MSF 2003, Attawell and Mundy 2003). In a workplace study in South Africa, couple counselling was identified as a priority need by workers and their sexual partners (Stewart *et al.* 2002). Furthermore, counselling is also important for family members, particularly youth, who may have lost or will possibly lose family members.

Partnerships with affected communities, including people living with HIV/AIDS, critically determine how people living with HIV/AIDS understand ART, their health-seeking behaviour and the acceptability of treatment. CHBC provides an opportunity to include those living with HIV/AIDS, their families and communities in helping to assist people with HIV/AIDS and will help to overcome some of the key obstacles to an effective response, including denial, stigma and discrimination (Grubb *et al.* 2003).

However, care must be taken, as over-reliance on CHBC is potentially fraught with problems. The notions of “family” and “community” are frequently poorly defined and romanticised, and used as generic catch all phrases. In countries or regions with a history of significant social disruption and migration, traditional familial-based structures have often been fragmented, and replaced by arrangements based on factors other than kinship or blood ties (Cross *et al.* 1998). Furthermore, households already in poverty may not have the resources to deal with the additional burden and costs of care. In some cases, children may drop out of school to either care for the sick member or work, while other productive activities, such as agricultural production, may suffer (Breslin 2003, Moser 1997).

Community preparedness will also involve an ongoing process of understanding community beliefs and needs around the drugs, facilitating dialogue, conducting consumer education on HIV/AIDS-related treatment, and monitoring and evaluation. It will also involve encouraging and facilitating collaboration among various stakeholders, including those outside of the health sector. The potential role of NGOs, CBOs, faith-based organizations, PLWA groups and community advisory boards in building relevant community-level knowledge, understanding and skills should be maximised (International HIV/AIDS Alliance 2002b).

Other crucial issues include ensuring that community members understand the importance of continuity of supply and the ways in which supply interruptions can be prevented. Means should be found to include community voices in the planning and management of supplies and cost-sharing mechanisms, and to include community feedback in whatever monitoring and patient support systems are used. This will encourage transparency and community consensus and help to prevent the corruption and mismanagement that are often the cause of interruptions in supplies of vital drugs and materials (International HIV/AIDS Alliance 2002a).

There are few incentives for health care workers to work in partnerships and they seldom have the benefits of doing so explained to them. Communities, too, may lack the necessary structures, be unfamiliar with medical terms and be apprehensive about engaging in debate and dialogue with government health professionals. Programmes therefore, must be explicit about the mechanisms and methods that will be used to overcome these obstacles and should include community education and capacity-building as a key component of budgeting and planning for HIV/AIDS treatment and care (Grubb *et al.* 2003).

### 3.4.1 Ensuring that Adequate Information is Available

Good treatment information is essential for ensuring safe and effective HIV/AIDS-related treatment. Each person needs to know enough about what treatment is, how it is likely to help, how drugs are used and possible side effects. Good treatment information affects adherence and without the right information for all participants, there is a risk of inappropriate treatment, treatment failure or no treatment (International HIV/AIDS Alliance 2002b). Information about how treatment fits in with daily routines, such as timing of drug doses or availability of food, how and where to get treatment, availability of supplies and follow up visits is required (International HIV/AIDS Alliance 2002b). Information should be provided in local languages. Methods will also need to be found to supply ongoing, updated and accurate information (International HIV/AIDS Alliance 2002a).

Knowledge regarding ART has been shown to be poor in a number of settings. In Zambia, for example, very few pregnant women had heard of short-course treatment with nevirapine for prevention of mother-to-child transmission, how it works or how to access it. Those who had some information about it were often surprised to hear that HAART was available for long-term treatment of HIV infected adults (International HIV/AIDS Alliance 2002a).

People with HIV, especially those who are successfully using ART, have special credibility as sources of information and treatment support (International HIV/AIDS Alliance 2002a). In 2003, a series of HIV/AIDS related educational videos designed to educate people about the impact of HIV/AIDS and ART was released in Botswana. Messages include the importance of knowing one's status, the need for condom usage, the hope offered by ART and the importance of adhering to therapy regimes for the rest of one's life. Shown in patient waiting areas in approximately 120 clinics and hospitals (UNAIDS 2002), the videos used Botswana people to tell their stories in their own languages.

Health care workers at all levels also require clear and relevant information to carry out their work and to educate their colleagues and the public about ARVs. This need is amplified by the fact that many health care workers or their family members need treatment themselves. Information should not be confined to only those health personnel working directly with HIV/AIDS, as health care workers working in non-HIV-related services are often the first point of contact for patients. Ignorance or incorrect information about HIV/AIDS can operate as barriers to diagnosis and effective care of HIV/AIDS.

### 3.4.2 Addressing Stigma

Methods to better understand the dynamics surrounding stigma and approaches to counteract stigma need to be developed, as they can be a major obstacle to uptake of VCT and other HIV prevention and treatment services.

Mann (1987) identifies three main phases of the HIV epidemic. Phase one is infection, while phase two is AIDS and the syndromes that appear in those infected. The third phase, potentially the most damaging of all, is the collective social and political response to AIDS, reactions characterised by high levels of stigma, discrimination and denial. Stigma is believed to be one of the greatest barriers to HIV treatment. It has been said to foster the growth of the epidemic as prevention efforts are undermined due to people's reluctance to get tested, and unsafe and risky behavioural patterns are perpetuated (UNAIDS and WHO 2003). It has been suggested that the provision of ART as part of a comprehensive treatment package would signify a move towards people becoming more open and combating stigma.

Stigma is in itself a difficult concept and even more difficult to measure. Stigma manifests in a multitude of ways, sometimes enacted, sometimes felt, sometimes applied to oneself. Discrimination is often the physical action undertaken as a result of stigma existing. It may occur within the household, in the workplace, in the community or even at the health service site (Parker and Aggleton 2001). In a study undertaken in a workplace in South Africa, health care workers reported experience of stigma due to their involvement in treating those thought to be HIV positive. Similarly any worker showing an interest in the epidemic would be cross-questioned as to why they were interested and whether they were HIV positive (Stewart *et al.* 2002).

Shame and secrecy works against adherence to ART because privacy is sought and medicines have to be kept hidden. It therefore makes it difficult to take doses at the right time of day, especially for those who feel the need to hide their status from people at work or in the home. Successful adherence to ART is largely dependent on a culture of acceptance and openness, which makes good treatment outcomes much more achievable (International HIV/AIDS Alliance 2002b). In Zambia, efforts to involve families have been constrained by the sense of shame that a person who has contracted HIV is perceived to bring upon the family. The fear of being burdened with orphaned children has added to this concern and shame. Such concerns can lead to people with HIV/AIDS being

shunned or abandoned (Grubb *et al.* 2003).

People infected with HIV may also face significant discrimination from health care providers. In a survey conducted among 1 000 physicians, midwives and nurses in four Nigerian states in 2002, one in ten doctors and nurses reported having refused to care for someone with HIV/AIDS, or had denied such a person admission into hospital. Forty percent thought that a person's appearance indicated their HIV status, while 20% believed that people infected with the virus had behaved in an immoral fashion and subsequently "deserved" their fate (UNAIDS and WHO 2003). In Côte d'Ivoire, it was found that impoverished patients are often given sub-standard treatment because they could not afford full courses of drugs. Similarly, in Burkina Faso people in an advanced stage of illness were turned away from hospitals due to perceptions that nothing could be done for them (International HIV/AIDS Alliance 2002). Provision of ART may however encourage more positive attitudes amongst health workers once they realise that they are able to treat HIV/AIDS patients effectively (Naidoo 2003, Van Gorkom 2003).

There have also been incidents where family support has been revitalised due to effective ART, as family members became more hopeful and less anxious about an increasing economic burden and the workload of caring for the sick and for orphans. It is therefore possible that scaled-up ART programmes, if handled correctly, could reduce strained family structures, reversing the breakdown of family life in high-prevalence, low-income, stigma-dogged settings (Grubb *et al.* 2003). Community involvement is also likely to contribute to the reduction of stigma by encouraging people to come forward for testing and treatment (International HIV/AIDS Alliance 2003).

#### 3.4.3 The Role of Traditional Healers and Leaders

In Africa, it is estimated that approximately 80% of people make use of traditional medicine for their health care needs, both in urban and rural settings. The term traditional healer is used to describe a great range of traditional health care providers, including spiritualists and herbalists (King 2000). It is estimated that 60% of South Africans consult traditional healers, usually in addition to using modern medicines. There are an estimated 200 000 practicing healers, and at least 3 500 documented plants used for a range of ailments (Van Wyk *et al.* 1997).

However, there is a dearth of solid and reliable research on the potential role of

traditional healers in providing care and treatment to those infected with HIV and AIDS. Research which has been conducted, has produced contradictory results. For example, Steinberg *et al.* (2002) concluded from their study of households in South Africa that there was a high level of dissatisfaction with traditional healers. Over two-thirds of respondents gave traditional healers a low rating because of the ineffectiveness of the treatment they received. Typical comments included “never got better”, “came back worse” and “medication didn’t work”. The same respondents rated local clinic services highly.

In contrast, research conducted by the Medical Research Council (MRC) in the Hlabisa District in KwaZulu-Natal, South Africa showed that traditional healers were acceptable, effective and convenient as supervisors for directly observed TB treatment. Involvement of traditional healers achieved a 98 percent treatment completion rate in 47 patients, compared with other supervisors who achieved a 67 percent treatment completion rate in a sample of 157 patients. Further research conducted in the region indicated that 84% of 100 TB patients interviewed said that they would consider choosing a traditional healer as a supervisor, while 92% percent of the healers interviewed said that they would be willing to act as treatment supervisors (Clarke 2004).

Many public health experts conclude that it makes sense to build collaboration between the formal health systems and traditional healers, and providers of traditional health care have a key role in community care-seeking behaviour and in information programmes (Van Praag 2002). Traditional healers can also play a key role in helping to dispel the many myths that prevail in some low-and middle-income countries about the causes of HIV/AIDS, as well as countering false claims about miracle AIDS cures (International HIV/AIDS Alliance 2002b). Methods must be found to include traditional healers in partnerships with western medical practitioners and in the network of treatment. Further research is required to determine how this may be managed to ensure that the available resources are used to best effect.

In South Africa, the government’s Comprehensive Plan for Treatment and Care of HIV/AIDS recognises that traditional healers may play an important role in referrals to ART sites, as well as counselling and support. At present a draft bill, the Traditional Health Practitioners Bill, has been developed for approval. A traditional indigenous knowledge arm of the MRC has also been established and provides a forum for the MRC and healers to evaluate and develop

standardized treatment and care efforts. Within the National HIV/AIDS Directorate, two traditional healers are fully employed by the sub-unit to work with traditional healers, while eight provincial chapters also work closely with government (Simelela 2004). Such an approach recognises the important role that traditional healers can play in ART programmes, whilst acknowledging that more formalised structures are required to make healers' roles more effective and safe.

Traditional leaders can also play a significant role in defusing stigma. In the Zambian district of Lundazi, chiefs have led by example and taken HIV tests. They have also forbidden widow inheritances and other practices that discriminate against women and leave them more vulnerable to infection (UNAIDS and WHO 2003).

#### 3.4.4 Greater Involvement of People with AIDS (GIPA)

People with HIV are not just passive "recipients" of treatment and have a vital role to play in accelerating and sustaining treatment. In Zambia for example, it was found that the involvement of the Salvation Army's Chikankata Health Services in care and prevention teams helped people with HIV to identify infections at an early stage and seek medical attention as soon as they became sick (International HIV/AIDS Alliance 2002b). People Living with AIDS (PLWA) also have a crucial role to play in treatment information literacy and advocacy.

Formal involvement of people living with HIV in solving various health systems problems will be essential. PLWAs can assist in planning for appropriate training for health providers, and education and capacity building for communities (WHO 2003).

In South Africa, civil society organisations, such as the Treatment Action Campaign (TAC) and the National Association of People Living with AIDS, have played an important role in advocating for ART and other HIV services and in educating communities about HIV/AIDS and treatment issues. Preparing communities in this way has been critical for both uptake of, and adherence to, treatment by patients attending the MSF clinics (WHO 2003, MSF 2003).

Additional dimensions to the involvement of PLWAs that need to be explored include treatment-adherence support (for example, through adherence counselling, ARV treatment support groups, and through direct-observation

treatment programmes), involvement in decision-making about eligibility for treatment, and involvement in the planning and management of treatment and services. Involvement of people with HIV in planning and decision-making about treatment and treatment services, on the principle of “nothing about us without us”, may enable patient-centred treatment and care to become a reality. The perspectives of people with HIV would help to focus discussions and clarify targets to be more time and cost-efficient (International HIV/AIDS Alliance 2002a).

In Uganda, GIPA is reported to have guided and assisted ART projects. PLWA groups have worked with individuals seeking diagnosis or disclosing their serostatus and have provided clients with referrals to numerous support groups. They have also played an important role in educating the public and assisted communities and individuals to set realistic expectations about comprehensive care and ART (Van Praag 2002).

### 3.5 Minimising ARV toxicity

Short and long-term toxicities have emerged in high-income countries as a further complicating factor in the delivery of ART. While short-term side effects, such as diarrhoea, nausea, fatigue and rash can be managed with relatively close monitoring of patient response to treatment, longer-term toxicities may require complex monitoring technologies and other treatment interventions. Central among these potential long-term complications of ART are imbalances in blood lipids, liver and kidney damage, and diabetes. The potential toxicities of ART further underscore the need for well-developed health care infrastructure (International HIV/AIDS Alliance (2002b).

However, while cognisant of the possibility of toxicity, research conducted in Botswana, concluded that HAART is extremely well tolerated among HIV-1C infected individuals (Wester *et al.* 2002). More research needs to be undertaken to identify how side-effects can be identified and treated in resource-poor settings.

### 3.6 Ensuring adequate nutrition

The relationship between nutrition and HIV/AIDS is complex and multi-faceted. Physical wasting and increased nutritional needs are characteristic of HIV/AIDS and TB (International HIV/AIDS Alliance 2002b) and people with HIV infection are more at risk for malnutrition due to reduced food intake, poor nutrient absorption, changes in metabolism, chronic infections and illnesses, anorexia, diarrhoea, fever, nausea, oral and oesophageal infections, thrush and anaemia (FANTA 2001). Nutritional deficits make people with HIV more susceptible to disease and infections of all kinds, and supplementation with multiple micronutrients has been shown to reduce mortality among HIV-infected individuals (Jiamton *et al.* 2003).

At the household level, HIV/AIDS and food security are closely linked. An HIV-affected household increasingly risks food insecurity and malnutrition through declines in labour, income and time available for care of younger children, together with increased expenses for health care. Food insecurity may in turn further increase both the risk of being exposed to HIV and a household's vulnerability to its increasing impact as the disease progresses (UNAIDS 2002). Clean water supplies are also important to reduce the burden of household chores and avoid additional illness (Steinberg *et al.* 2002).

The current focus on increasing access to ART in low and middle-income countries should not obscure the fact that for much of the world's population living with HIV, the need for access to food remains an overwhelming priority. Most of those infected are among the poorest populations, whose immunities are already compromised by lack of food supplies, sanitation and clean water (International HIV/AIDS Alliance 2002b). An assessment of HIV/AIDS-related treatment in Zambia identified lack of food as the most common and urgent barrier to treatment. Many people were hungry and could not afford to divert resources to other health care needs. Even amongst those who could afford drugs, outcomes were sub-optimal due to poor nutritional status (International HIV/AIDS Alliance 2002b). A review of ART provision in Zimbabwe also highlighted the challenge of maintaining food supplies as taking ARVs without adequate food could be dangerous and counter-productive (Ray and Kureya 2003).

Provision of nutritional support is an effective intervention that is fundamental to other HIV/AIDS care activities. Adequate food supplies are both preventative, in that they support healthy immune systems, and curative, in that they are

essential for drug treatment to be effective and to reduce viral replication and re-infection (International HIV/AIDS Alliance 2002b). Good nutrition may result in increased resistance to infection and disease, improved energy and a person who is stronger and more productive.

The goal of nutritional support programmes for people living with HIV/AIDS may vary from prevention of nutritional depletion to the provision of nutrition care and support for people with AIDS and for the families who care for them (WHO 2004b). Nutritional care and support should ideally go beyond simple provision of food parcels and include many components, such as nutrition education and counselling in health facilities, water, hygiene and food safety interventions to prevent diarrhoea, adequate quality/quantity of food and food aid.

The costs of providing nutritional support will vary according to services provided. In the short term, provision of food aid will likely be less costly than providing services aimed at income generation, education and training. Projects providing food assistance in several African countries cost less than US\$ 1 per day per person (WHO 2004a). While initially more costly, activities focused on education, training and income generation may decrease the need for food assistance in the long-term.

The need for nutritional support for households and individuals threatened by food insecurity reflects the important role for organizations and institutions outside of the immediate health sector to assist in interventions which can have a considerable impact on the health of people living with AIDS. As such, cross-sector and inter-department collaboration becomes critical in the comprehensive treatment of HIV and AIDS. This is recognised in the South African government's rollout plan, which provides for involvement of the Department of Social Development in the provision of nutritional supplements and packages (NDOH 2003).

Food assistance is believed to be a powerful means of attracting clients to other HIV services, including VCT. The World Food Program has used food aid to provide an incentive for children to stay in school. Building on the success of its take-home rations and school-based feeding projects for girls, the programme is implementing a similar strategy for orphaned children (Hills-Jones and Kanabus 2003).

### 3.7 Issues related to equity

The International Society for Equity in Health (ISEqH) identifies equity as: “the absence of potentially remediable, systematic differences in one or more aspects of health across socially, economically, demographically, or geographically defined population groups or subgroups” (ISEqH 2004). Seeking equity in health implies “addressing differences in health status that are unnecessary, avoidable and unfair. In southern Africa, these typically relate to disparities across racial groups, rural/urban status, socio-economic status, gender, age and geographical region” (Ray and Kureya 2003: pp 12). McCoy (2003) suggests that an equity approach is different from a “basic needs approach” or “poverty approach”, which focuses on the poor and the disempowered without relating their condition to the rich and the powerful. Equity implies an approach that gives more to those who have little, and less to those who have much. Rather than the allocation of equal shares, equity implies the allocation of fair shares. Equity-motivated interventions should aim to allocate resources preferentially to those with the worst health status (vertical equity), to address the power and ability people and social groups have to make choices over health inputs, and their capacity to use these choices towards health. Planning for equity requires identification of groups disadvantaged in terms of health status or utilisation of services (Ray and Kureya 2003).

Adopting an equity approach to ART provision thus entails identifying those most at risk of HIV infection in order to target prevention activities, and to identify those in need of care and treatment of HIV-related illness. Critical elements in implementing an equity related approach to ART includes considerations of age, race, gender, employment status and the nature of the work, and whether people live in urban or rural areas. Indicators to this effect may be included in eligibility criteria and selection procedures (Ray and Kureya 2003).

Access to ART must therefore be accompanied by an improvement in the delivery of adequate, reliable health services for the poor. Yet, even basic services, such as treatment of opportunistic infections, are not provided equally to all those in need (WHO 2002). Care must be taken to ensure that ART programmes do not reinforce existing inequities. Regular and consistent monitoring of the effect of ART programmes on broader development and equity goals is needed to ensure that these do not reinforce inequities and prejudice broader health sector and country development objectives. For example, in Zimbabwe, greater

concentration is placed on providing treatment in Harare and Bulawayo, which have much lower HIV prevalence rates than many of the outlying areas (Ray and Kureya 2003). This tendency to situate treatment in urban centres with superior resources reinforces and perpetuates inequities.

The provision of free medication in itself does not necessarily result in equitable outcomes. There are a variety of “hidden costs” associated with accessing care and treatment, which must also be considered. Travelling costs, including time taken to get to treatment centres and the distance some are required to travel to treatment centres, also exert a strong influence on decisions to take-up and continue with treatment. In one setting in Malawi where all public health facilities are within 6 km of the population and where care is provided free-of-charge at the point of delivery, it was found that on average, patients spent up to US\$13 accessing a TB diagnosis (Mann *et al.* 2002 in McCoy 2003), while in Zambia average indirect costs related to pre-diagnosis of TB were close to US\$27 (Needham *et al.* 1998 in Russell 2003). Additional studies are required in order to clarify the real direct non-treatment (i.e. transport, time off work, loss of productive time) costs to households affected by AIDS in southern Africa.

Ntuli *et al.* (2003) speculate that at least initially, provision of ART will exacerbate existing inequities. They further recommend that the strengthening of services necessary to provide ART must take place in a way that benefits disadvantaged areas and strengthens primary health care services generally. This will require the restructuring, re-organisation and redistribution of existing resources to facilitate reform of the underlying issues of the health system, and will need to be supported by increased financial, infrastructural and human resource allocations.

### 3.8 Structural issues

Many researchers have documented some of the structural factors that facilitate HIV transmission and its concentration within particular geographic areas and populations. These can generally be grouped into three interconnected categories:

- Poverty and economic underdevelopment
- Mobility - including migration, seasonal work, and the social disruption due to war and political instability; and

► Gender inequalities (Schneider 2003).

In spite of the uniqueness of each local epidemic, the same general structures and processes have been found to shape transmission in areas as diverse as Africa, Asia, and Latin America, as well as amongst certain groups in Europe and North America (Schneider 2003).

In the case of HIV, individual interventions, such as drug treatment, need to be accompanied by interventions at the structural level. While interventions such as ART are important in the short term, they should not dominate the debate to the exclusion of broader intervention strategies. It is suggested that provision of HIV care, including ART, requires both an emergency response and a long-term development response. The former should seek to relieve individual suffering, enable people with HIV to remain productive for longer, control ARV use to prevent drug resistance and provide hope and counter the stigma surrounding HIV. The development approach seeks to address systems related factors that underline general ill-health, such as poverty and inequality (Hargreaves and Harries 2002).

An ART programme is one necessary and important component of a wider social response to HIV/AIDS. If unchecked and unbalanced, it has the potential to dominate the energy and attention of the public sector and its partners, and become the standard by which success or failure is measured. The HIV epidemic represents both a crisis and an opportunity for the region. In this context, a commitment to scale-up ART must be viewed alongside a measured and multi-dimensional approach to HIV. A renewed commitment to prevention and to a broader social response to the structural conditions that influence vulnerability to HIV infection is required (Schneider 2003).

#### 3.8.1 Gender Dimensions of ART Provision

African women are considered to be at least 1.2 times more likely to be infected with the HIV virus than African men (UNAIDS and WHO 2003). The impact of HIV/AIDS and access to treatment are markedly different for men and for women. Typically, women are more stigmatised and discriminated against, often being denied access to health care services, especially if they present for diagnosis or treatment of STIs without a male partner (International HIV/AIDS Alliance 2002a).

According to Ntuli *et al.* (2003), the epidemic is fuelled among women for a number of reasons. Many women exchange sex for material favours and as a means of

daily survival. An institutionalised system of patriarchy and financial dependence on men often means that women cannot control when, with whom and under what circumstances they have sex. In addition, women are not expected to discuss or make decisions about sexuality. It is difficult for women to request, let alone insist on using a condom or any form of protection. If they refuse sex or request condom use, they often risk abuse, as suspicion of infidelity may arise. The many forms of violence against women mean that sex is often coerced. Women are frequently expected to have relations with or marry older men, who are more experienced and more likely to be infected. Men seek younger and younger partners in order to avoid infection (WHO 2001). The practice of 'dry sex' (Mill 1999) and the biological fact that HIV is generally more easily transmitted by men to women than vice-versa are further predisposing factors (UNAIDS and WHO 2003).

Sex workers are at a particular disadvantage in negotiating with male clients for safer sex and attempts to do this usually result in loss of income. Since sex workers could also be rejected by their families and society, loss of their own income can result in further poverty. In some instances sex workers are also discriminated against in terms of their access to treatment, since some clinics providing diagnosis and treatment of STIs insist that treatment will only be provided if the partner also comes for treatment (International HIV/AIDS Alliance 2002a).

It has been observed that many women, especially during the pre- or post-natal period, are willing to undergo counselling and testing once they know what can be achieved for both themselves and their babies. However, it is not ideal for them to undergo testing without their husbands or partners. In order for an ART programme to be successful, both partners, if concordantly positive and eligible, must have access to ART. Counselling on careful behaviours is required to reduce the incidence of partner infection (International HIV/AIDS Alliance 2002a). PMTCT-Plus, which is part of the national plan for scaling up access to ARV treatment in Zambia, entails the use of short-course nevirapine to prevent transmission of HIV from mother to child, plus ongoing ARV treatment for the mother and for the father if needed. Such an approach can assist in meeting family needs and reducing stigmatisation of the women by husbands or partners (International HIV/AIDS Alliance (2002a).

The issue of gender equity in access to treatment and care needs special attention within the context of workplace initiatives to provide or subsidise ARVs. While

some formal sector employers are considering providing ART for their employees, it is mostly men who will benefit from this kind of initiative, as they are more likely than women to be employed in this sector (Statistics SA 2002). Ray and Kureya (2003) point out that implicit in the equity approach in treatment and care is the need to address the issue of gender. They further point out that in the context of workplace schemes, it is still unclear whether partners and children with AIDS will be provided with treatment.

Given that HIV is in itself creating a downward spiral of poverty, there is urgent need for poverty alleviation and food security measures to be taken that will lessen the burden of HIV on the poorest sectors of society, particularly women and children (Ntuli *et al.* 2003).

# Chapter Four: ISSUES FOR FURTHER RESEARCH

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# 4

Literature on ART provision in a developing country context remains limited. While there are examples of pilot sites and experiences of initial roll-out, these have not always been comprehensively documented. In the process of developing this paper, a number of gaps in the literature and knowledge base have been identified and are outlined below for possible future research.

## 4.1 Impact monitoring and evaluation

More robust indicators and data on the full costs of HIV and AIDS and the benefits of provision of ART need to be developed in order to better measure the true impact of the epidemic at various levels, as well as the benefits of providing ART on a wide-scale.

In order to assess the effects of an ART programme, it is crucial that routine monitoring systems be established. A set of routinely collected indicators needs to be developed. A degree of standardisation of these indicators across countries would facilitate comparisons. At country level, decisions need to be taken as to whether a national ART registry is necessary, and whether an electronic or paper-based system should be used. Attention also needs to be paid to developing the capacity of the system for data collection, collation, analysis, use and dissemination.

Selected studies, such as the impact of ART on sexual behaviour, also need to be undertaken in developing country contexts. Much literature on ART and behaviour emanates from Europe and the United States and relates to homosexual relations between men. To date there is little or no evidence of increased risk behaviour associated with ART in a developing country, heterosexual context. Such a study will assist in determining the interaction between ART, risk behaviour and gender relations.

In order to begin the process of research it would be useful to establish a centralised database which lists progress to date across the sectors involved in the provision of ART.

## 4.2 Financing of ART provision

Scaling-up of ART programmes in countries such as Botswana and South Africa should allow for more reliable estimates of the costs associated with these programmes.

Both the availability and effect of donor funding for HIV/AIDS prevention and treatment should be monitored. Alternate mechanisms for funding of ART provision in resource poor settings also need to be investigated.

## 4.3 Health systems and service issues

Provision of ART has the potential to facilitate or hinder overall development and strengthening of the health system and health service delivery. It is essential to monitor the effect of introduction of ART on the provision of both other HIV-related and non-HIV-related services to ensure that other programmes are not negatively impacted upon by the introduction of ART services.

### 4.3.1 Service delivery models

ART is provided in numerous different settings, and it is important to identify and develop knowledge around best practice within these settings. Developing models of provision will better inform future initiatives and provide a framework within which development practitioners may work and evaluate schemes. Issues such as staff mix, integrated versus dedicated care, on site support and referral, community mobilization, public-private interactions and linkages between prevention and care should be described and evaluated.

### 4.3.2 Human Resources

Provision of ART requires adequately trained doctors, nurses, laboratory technicians, pharmacists, counsellors and clerks. However, the appropriate mix of and number of personnel is less clear. Countries seeking to implement ART programmes could benefit from information regarding the numbers, competencies and mix of personnel required to successfully implement different models of ART provision. Further investigation is required into the potential role of CHWs and traditional healers in ART rollout.

Assessments of the number of skilled health personnel needed must also be accompanied by an exploration of the policies, strategies and infrastructure required to recruit, retain and develop such workers. Strategies and mechanisms to promote and sustain the interest and commitment of staff to ART programmes should also be developed and evaluated. Attention must be paid to whether the curricula of higher education institutions are adequately equipping students with the knowledge and exit competencies to deal with prevailing public health issues, including ART and primary health care.

Aligned to this is the question of who should be allowed to prescribe and dispense drugs. The role of pharmacy assistants in the absence of pharmacists, and that of nurses in the absence of doctors and pharmacists also needs exploration.

### 4.3.3 Support Systems

Further investigation is required on what essential support systems are required at sub-district, district, provincial and national levels. Laboratory services are key to ART provision. Issues related to simplifying laboratory monitoring and ensuring prompt communication of laboratory results to ART sites need to be explored. Best practice models for drug procurement and supply management should also be described. Issues related to patient information systems, including the collection, collation, analysis and use of information need to be investigated.

## 4.4 Community issues

The broader community is often left out of planning and implementation of services intended for their benefit, and mechanisms for enhancing community participation and involvement of people living with HIV/AIDS need to be developed and tested. Target groups need to be identified and clear and practical methods to facilitate elections of representatives need to be developed. These representatives need to be trained to inform the process and appropriate communication flows need to be maintained.

Interventions which prepare communities for ART, especially those that successfully address stigma and result in improved adherence to ART need to be documented and the findings disseminated. Information, education and communication materials and programmes also need to be evaluated and shared.

## 4.5 Broader development issues

The impact of ART on poverty and resource allocation at an inter and intra-household level needs to be explored. Issues related to intra-household inequity, vulnerability and power need to be taken into account. Research needs to be conducted into how ART links to broader health sector and country development issues, and how the introduction of ART in a limited number of sites affects inequities. This is more likely within a framework of decentralization, whereby areas within one country are able to pursue their own agendas and funding sources. As such the introduction of donor funds in some areas and not others may introduce a regional bias. Alternatively, conditionality of such funds may facilitate a treatment bias and introduce unnecessary dynamics, particularly if good results are needed for continuity of funding.

Issues related to the effect of ART provision on women and gender inequalities need to be explored further.

## 4.6 ART provision within the corporate and private sectors

The private sector, both through private providers and workplace programmes, is likely to play an important role in ART provision, particularly in countries which lack wide-scale public sector programmes. Whilst this is to be welcomed, it is important that adequate regulatory and co-ordinating mechanisms are in place. There is currently a lack of information and data on the activities of the corporate and private sectors.

Adequate labour legislation to ensure non-discriminatory policies in the workplace needs to be in place and implementation monitored. Key policy issues which need to be resolved include: the fate of employees who are no longer able to work or are due to retire; extending ARVs to partners, particularly in the context of polygamous marriages; and company policies with regard to providing ART for the children of their employees.

Workplace practices also need to be monitored to prevent 'dumping' onto the public sector.

Private sector issues that need to be addressed include unregulated and non-standardised treatment approaches and the fact that drug availability is often

determined through supply-side rather than demand-side factors, and as such may be inappropriate. Medical insurance and medical aid packages may need to be revised in order to make ART more affordable and to prevent crossing over to the public sector.

## 4.7 Children and ART

HIV/AIDS research has often been guided by the disease burden of wealthier countries. Paediatric HIV/AIDS, which is uncommon in these countries, has tended to be neglected and there is a paucity of information on appropriate paediatric interventions. For example, little effort has been put into simplifying paediatric formulations. Given the high number of current and potential AIDS orphans in southern Africa, it is important that a better understanding of treatment challenges is developed and that psychosocial issues related to paediatric HIV/AIDS are addressed. Methods for targeting children for ART (especially in the context of the growing phenomenon of child-headed households), ways of monitoring and promoting adherence, the development of treatment guidelines, identifying special nutritional needs, the effect of HIV/AIDS on the girl-child, schooling and on education, are some examples of issues that need to be explored and improved.

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