



UNITED REPUBLIC OF TANZANIA

HIV/AIDS Care and Treatment Plan 2003-2008

Business Plan 4.0
September 1, 2003

Developed in Collaboration with
The William J. Clinton Foundation

"The whole society must now wake up and fight together against this calamity. Unless we end this conspiracy of silence, all of us, the whole nation, shall perish"

- President Benjamin William Mkapa

"Treatment can turn AIDS from a death sentence into a chronic illness ... Now that we have the medical capacity to save and improve the lives of millions of people, there is no other moral or practical choice."

- President William Jefferson Clinton

"The way we deal with AIDS in Africa will determine Africa's future."

- Secretary General Kofi A. Annan

LIST OF ABBREVIATIONS AND ACRONYMS

AIDS	Acquired Immune Deficiency Syndrome
AMREF	African Medical and Research Foundation
ANC	Antenatal Clinic
ARV	Antiretroviral
CARF	Community AIDS Response Fund
CME	Continuing Medical Education
CMO	Chief Medical Officer
CO	Clinical Officer
CPL	Central Pathology Laboratory
CTU	Care and Treatment Unit
DAC	District AIDS Committee
DHHS	Department of Health and Human Services (US)
DMO	District Medical Officer
DOT	Directly Observed Therapy
FBO	Faith-Based Organisation
FTE	Fulltime Equivalent
GDP	Gross Domestic Product
GOT	Government of Tanzania
GTZ	German Agency for International Development
HAART	Highly Active Antiretroviral Therapy
HIV	Human Immunodeficiency Virus
IEC	Information, Education and Communication
KCMC	Kilimanjaro Christian Medical Centre
MAP	Multi-Sectoral AIDS Project
MCH	Maternal and Child Health
M&E	Monitoring and Evaluation
MNH	Muhimbili National Hospital
MoH	Ministry of Health
MoH&SW	Ministry of Health and Social Welfare (Zanzibar)
MoU	Memorandum of Understanding
MSD	Medical Stores Department
MTD	Medical Tender Board
MUCHS	Muhimbili University College of Health and Science
NACP	National AIDS Control Programme
NGO	Non-Governmental Organisation

NHLS	National Health Laboratory Services
OI	Opportunistic Infection
PEP	Post-Exposure Prophylaxis
PLWHA	People Living with HIV/AIDS
PMTCT	Prevention of Mother to Child Transmission
QA	Quality Assurance
RMO	Regional Medical Officer
RNO	Regional Nursing Officer
STD	Sexually Transmitted Disease
STI	Sexually Transmitted Infection
TACAIDS	Tanzania Commission for AIDS
TB	Tuberculosis
TFDA	Tanzania Food and Drugs Authority
TFNC	Tanzania Food and Nutrition Centre
TOT	Training of Trainers
UNDP	United Nations Development Programme
UNICEF	United Nations International Children's Emergency Fund
USAID	United States Agency for International Development
VCT	Voluntary Counselling and Testing
WHO	World Health Organization
ZAC	Zanzibar AIDS Commission
ZCTU	Zanzibar Care and Treatment Unit

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1. EXECUTIVE SUMMARY

Overview

Tanzania has been struggling for two decades now to understand and tame HIV/AIDS, from the first identified case in 1983 to its current epidemic status affecting every corner of the country, and all aspects of its economic and social life. This plan is best seen as an effort to take that struggle to a new level, offering the hope of comprehensive care and treatment to an extensive segment of the affected populace.

The HIV/AIDS Care and Treatment Plan replaces none of the careful planning and wide-ranging action which the United Republic of Tanzania has taken in the past 20 years to combat AIDS, most notably by the Ministry of Health and more recently by the Tanzania Commission for AIDS. Instead it adds to these labours, and complements the consistent and effective efforts of many donor countries and multinational agencies which have joined in the fight.

The plan's reach is broad, its goals ambitious, its schedule aggressive, and its challenge relentless. But the scope of the problem demands no less, and the promise of its success should energize the implementation as it has the formulation.

Table 1. Highlights of the HIV/AIDS Care and Treatment Plan (cumulative numbers)

	2004	2005	2006	2007	2008
Patients under treatment ('000s)	16	65	151	274	423
Total HIV+ Patients under care ('000s)	65.4	260.6	604.8	1098.0	1692.2
Budget for Drugs (\$MM)	6.6	25.5	67.6	138.4	237.1
Total Budget (\$MM)	26.0	79.9	178.1	332.7	539.3
Certified Facilities	23	78	141	204	247
Health Care Workers (FTEs)	459	1674	3632	6285	9299
Cost per HIV+ individual enrolled (\$)	398	207	162	141	122

Source: Team analysis

1.1 Clinton Foundation Approach

The William Jefferson Clinton Foundation of New York City has undertaken to help four African countries (Mozambique, Rwanda, South Africa and Tanzania) and several Caribbean countries develop plans to improve HIV/AIDS care and treatment. The Foundation will then raise funds to support these plans once country approval is received.

Each country's plan is being developed independently, and will reflect its unique social and political situation. Several common characteristics, however, guide the Clinton Foundation's HIV/AIDS work:

- The Foundation considers the HIV/AIDS crisis an international public health emergency, and believes speed is of the essence both in making plans and in implementing them.
- The Foundation practices a comprehensive approach, supporting programmes that reach all corners of its partner countries and that provide comprehensive care and treatment.
- The Foundation emphasizes antiretroviral treatment of HIV+ individuals both as a proven method to extend and improve life and as a necessary component of an effective prevention strategy.
- Since HIV/AIDS is a country-wide, long-term intractable challenge, the Foundation believes national governments must shoulder the responsibility for both planning and implementation of comprehensive programmes, and thus works primarily through government agencies in offering its assistance.
- Finally, the Foundation believes an important part of its work should be to strengthen the overall healthcare infrastructure of its partner countries for the long term.

1.2 Background of the Plan

This plan is the product of several months of collaboration and study initiated President Benjamin William Mkapa who asked President William Jefferson Clinton to have his Foundation assist Tanzania in developing a plan. The process began at a meeting of representatives of the Foundation and President Mkapa on February 5, 2003.

Several task forces were formed in March, including delegates from the Ministry of Health, TACAIDS and several other government agencies, faculty members of Muhumbili University College of Health Sciences, Tanzanian clinicians, PLWHA, leaders of NGOs active in AIDS activities, and representatives from several donor countries and international agencies. More than 50 individuals from Tanzania took part in the task forces' work. In addition, participants included several Clinton Foundation volunteers with backgrounds in business and health services and representatives of the Harvard AIDS Institute, one of the Foundation's medical partners

These task forces met on several occasions over the next three months, culminating with a three-day retreat in Bagamoyo at the end of May to complete the task force work and begin work on a first draft of the plan.

1.3 Cornerstones of the Tanzania Plan

A plan to offer care and treatment of the scope envisioned in this document necessarily must touch on a myriad of elements of the overall healthcare system. Before reviewing a summary of these findings, however, there are several cornerstones which should be appreciated:

- The plan builds on previous work, particularly the Health Sector HIV/AIDS Strategy for Tanzania, and is not a radical redirection of policy.
- The plan envisions a care and treatment programme for HIV+ individuals integrated into the existing healthcare infrastructure, both public and non-public, to the greatest degree possible consistent with quality, efficiency, and timeliness.
- The requirements for judging an individual facility's readiness to begin offering antiretroviral therapy should be as flexible as possible, while still ensuring quality and comprehensive healthcare for its HIV+ patients.

- The document is in the nature of a strategic business plan, and not a detailed work plan for implementation. It is a roadmap which leaves many decisions, policies and procedures to be worked out by the officials who will actually manage the implementation and their advisors.

1.4 Summary of the HIV/AIDS Care and Treatment Plan for Tanzania

At the final plenary planning session on May 31 in Bagamoyo, the combined task forces confirmed four goals for the plan.

Goal One: To provide quality, continuing care and treatment to as many HIV+ residents of the United Republic of Tanzania as possible, building on the careful planning already completed by the Ministry of Health and the Tanzania Commission for AIDS.

The operational elements have been designed to allow for more than 400,000 Tanzanian residents to be on treatment with antiretroviral drugs by the end of the fifth year of the programme. At the same time, some 1.2 million HIV+ persons not clinically eligible for HAART would be treated and monitored to track disease progression.

The success of the programme, however, should be judged first by the quality of the care and treatment it provides, and not by the number of people it treats. Whenever a choice must be made between treating more people or ensuring that the treatment is effective and safe; the only choice is to ensure that appropriate preparations (e.g. staff, training, logistical support, and adequate personnel resources) are completed before the programme is extended.

The plan recommends that treatment be available through care and treatment clinics established, over five years time, at virtually all public and non-public hospitals down through the district level. Treatment would be provided by teams composed of physicians, assistant medical officers, clinical officers, nurses, counsellors, laboratory technicians and pharmacists. Every team member would be required to complete a course of classroom and on-the-job training before assignment to a care and treatment team.

Maximum integration within the existing healthcare infrastructure, and the flexibility for local officials to design solutions most suited to their locales will aid rapid scale-up of the programme and ensure efficient use of available resources.

Additional support will be offered to increase the number of VCT centres, to speed the creation of PMTCT programmes in all antenatal clinics, and to greatly expand the routine counselling and testing of all patients in the healthcare system regardless of their reason for entry. These steps, along with close linkages with the TB and STI clinics, are intended to ensure a steady referral of HIV+ patients to the care and treatment clinics.

The buying power of the Clinton Foundation combined programmes, together with centralized purchasing and distribution by the Medical Tender Board (MTB) and Medical Stores Department (MSD) respectively, will ensure a steady flow of drugs and laboratory supplies to the clinics at the lowest possible prices.

Goal Two: To contribute to strengthening the healthcare structure of Tanzania, through expansion of healthcare personnel, facilities and equipment and comprehensive training in the care and treatment of PLWHA.

A strong management team at the national level, supplemented by additional programme managers working with the Regional Medical Officers (RMOs), will oversee a “strengthening and certification programme” designed to prepare facilities to prescribe ARVs and monitor their use, launch effective counselling and adherence efforts, and follow significant numbers of HIV+ patients not yet on HAART.

The Minister of Health will have overall responsibility for implementation. The key agency to establish and manage the care and treatment programme will be a newly created Care and Treatment Unit (CTU) within the National AIDS Control Programme (NACP), which itself will be given more visibility by an organizational elevation into the office of the Chief Medical Officer (CMO).

At the end of five years, the programme will result in a Tanzanian health system with thousands of additional employees with significant experience and training in the care and treatment of PLWHA, virtually the entire healthcare workforce trained in the basics of ART, modernized laboratories manned by an increased force of trained technicians, and a large number of refurbished or new clinic spaces.

On an equitable basis with the public healthcare system, the programme will invest in enhancing the voluntary, non-public sector of the healthcare system that accounts for up to 40% of the treatment provided in Tanzania.

Goal Three: To foster information, education and communication efforts focused on increasing public understanding of care and treatment alternatives, reducing the stigma associated with HIV/AIDS, and supporting ongoing prevention campaigns.

Framers of the plan recognize the importance of preparing the public for the introduction of large scale ART and educating them regarding both the promise and the shortcomings of HAART. The IEC programme will focus particularly on supporting the counselling efforts to educate patients, their families, and those who support them in the fundamentals of ART and the key role adherence plays in its success.

A major IEC programme will be launched to reduce the stigma associated with HIV/AIDS in order to encourage citizens to learn their serostatus, and PLWHA to enter the healthcare system for care and treatment.

Goal Four: To contribute in strengthening social support for care and treatment of PLWHA in Tanzania, through home-based care, local support groups, and treatment partners.

Local advisory groups will be utilized in every district which hosts a care and treatment clinic.

Encouragement and financial support will be provided to partnering organizations in the vicinity of certified ART facilities to strengthen existing and develop new social support networks. Maximum coordination with the Community AIDS Response Fund (CARF) created with a World Bank MAP grant will be encouraged.

Organizations will be formed or strengthened with a goal of empowering PLWHA to play a stronger role in monitoring and directing the HIV/AIDS care and treatment programme.

1.5 Budget Summary

The total budget to implement the plan is \$539 million over five years, with most of the cost (68%) occurring in the final two years of scaling up.

The cost of drugs, including ARVs and those for OI treatment, is \$237 million, or 44% of the total cost, and laboratory services is the second largest category of cost. Together, drugs and laboratory account for 67% of total cost.

Capital expenditures total \$44 million of the overall cost, of which the majority (56%) is for laboratory equipment.

Tanzania has an application pending before the Global Fund for about \$88 million for activities which are all part of the HIV/AIDS Care and Treatment Plan. In addition, the Government of Tanzania would assume responsibility for certain personnel costs totalling about \$6 million, as explained in detail in the plan. Subtracting these funds leaves \$441 million to be raised from other sources over the next five years. This objective assumes, of course, that the full Global Fund grant is awarded.

Table 2. Programme budget; values in '000s, except benchmark numbers

Budget summary	Year 1	Year 2	Year 3	Year 4	Year 5	Total	% Total
Drugs	\$6,552	\$18,919	\$42,107	\$70,858	\$98,697	\$237,134	44%
Laboratory & consumables	\$4,561	\$12,803	\$23,435	\$35,995	\$47,876	\$124,670	23%
Medical Staffing	\$1,017	\$4,037	\$9,190	\$16,273	\$24,111	\$54,629	10%
Training	\$2,759	\$4,845	\$5,974	\$9,318	\$10,641	\$33,537	6%
Facilities and Transportation	\$3,579	\$5,059	\$6,976	\$8,855	\$8,861	\$33,331	6%
Management & Administration	\$3,115	\$2,511	\$2,511	\$2,511	\$2,511	\$13,161	2%
Nutrition	\$642	\$1,967	\$4,073	\$6,961	\$10,041	\$23,685	4%
IEC/Mobilization	\$3,571	\$3,732	\$3,774	\$3,776	\$3,677	\$18,531	3%
Zanzibar (additional)	\$254	\$52	\$154	\$ 52	\$154	\$ 667	0%
Total budget	\$26,011	\$53,927	\$98,194	\$154,601	\$206,571	\$539,304	100%
Off-set funds							
Global Fund	\$10,933	\$13,918	\$17,684	\$22,556	\$22,797	\$87,888	94%
GoT share for Human Resources	\$ -	\$ -	\$337	\$1,546	\$4,106	\$5,989	6%
Annual off-set funds	\$10,933	\$13,918	\$18,021	\$24,102	\$26,903	\$93,877	
Annual fund-raising target	\$15,078	\$40,009	\$80,173	\$130,499	\$179,668	\$445,427	
Benchmarks							
Annual cost per individual on treatment	\$1,591	\$828	\$649	\$563	\$488		
Annual cost per enrolled HIV+ individual	\$398	\$207	\$161	\$141	\$122		

2. INTRODUCTION / GOALS AND OBJECTIVES

2.1 Introduction

Reflecting the leadership of His Excellency President Benjamin William Mkapa, the Government of Tanzania has taken strong and directed action in combating the HIV/AIDS pandemic. President Mkapa intensified these efforts in 1999 with a declaration of HIV/AIDS as a national disaster. The Ministry of Health has taken the lead in developing health sector responses, including the formation of the National AIDS Control Programme.

President Mkapa and the Parliament of Tanzania further focused national attention and energy on the problem in 2000 by expanding the nation's efforts to all entities and levels of Tanzanian government. This action included formation of TACAIDS with a mandate to lead the multi-sectoral response.

Two especially valuable documents have been produced this year to direct the nation's efforts in combating HIV/AIDS. In January, TACAIDS published the *National Multi-Sectoral Strategic Framework on HIV/AIDS*. This was followed a month later by MoH's *Health Sector HIV/AIDS Strategy for Tanzania*. Both of these important planning efforts benefited from considerable assistance from members of the Donor Assistance Committee HIV/AIDS Group and numerous other institutions active in the HIV/AIDS struggle in Tanzania

The Health Sector Strategy laid out an ambitious five-year plan of activities across all the responsibilities of the Ministry of Health, forecasting that a significantly increased budget would be required to support all of its objectives. It did not, however, foresee that sufficient funds and other resources would be available to launch a widespread treatment initiative during this time period.

Since the publication of the Health Sector Strategy, however, the Government of Tanzania has joined with representatives of the William Jefferson Clinton Foundation to develop a plan to amend the care and treatment sections of the strategy. Most importantly, the new plan envisions providing antiretroviral therapy to a significant portion of Tanzanians in need of treatment by the end of the five-year planning horizon.

The HIV/AIDS Care and Treatment Plan has been produced by a joint task force of Tanzanian government officials, Clinton Foundation representatives, and representatives of many other public and private groups which have been active in Tanzania's efforts to combat the HIV/AIDS pandemic.

2.2 Goals

This Task Force adopted four key goals for its work.

GOAL ONE: To provide quality, continuing care and treatment to as many HIV+ residents of the United Republic of Tanzania as possible, building on the careful planning already completed by the Ministry of Health and the Tanzania Commission for AIDS.

GOAL TWO: To contribute to strengthening the healthcare structure of Tanzania, through expansion of healthcare personnel, facilities and equipment and comprehensive training in the care and treatment of PLWHA.

GOAL THREE: To foster information, education and communication efforts focused on increasing public understanding of care and treatment alternatives, reducing the stigma associated with HIV/AIDS, and supporting ongoing prevention campaigns.

GOAL FOUR: To contribute in strengthening social support for care and treatment of PLWHA in Tanzania, such as home-based care, local support groups, and treatment partners.

2.3 Strategies and Tasks for Achieving Goals

Goal One: Expanding Care and Treatment

- Establish Care and Treatment Unit in MoH to manage a nationwide programme.
- Expand the identification of HIV+ individuals through expansion of national VCT capability, phased adoption of an “opt-out” counselling and testing policy for all users of the healthcare system, and creating strong linkages with other associated programmes (e.g., the National TB and Leprosy Programme).
- Create HIV/AIDS Care and Treatment teams to operate facilities throughout the country, beginning with referral hospitals and geographically important regional hospitals, and expanding to all regions and districts.
- Form a special partnership with the existing MoH PMTCT programme to increase its effectiveness and ensure its expansion countrywide within the first three years of the HIV/AIDS Care and Treatment Programme.
- Emphasize integration within the existing healthcare structure, while recognizing the advantages of a team approach to HIV/AIDS care and treatment, and that a rapid scale-up of this dimension requires some specialization.
- Encourage local initiatives in designing care and treatment programmes through certification process that combines flexibility with minimum standards of staffing, training and facilities.
- Emphasize the key role of private and voluntary hospital facilities as well as public facilities in providing HIV/AIDS care and treatment.
- Utilize centralized ordering and distribution, and the buying power of the combined Clinton Foundation programmes in Africa and the Caribbean, to lower the cost of drugs and make benefits of treatment widely available.
- Utilize innovative “collaborative” effort among healthcare providers in Tanzania to scale-up rapidly, effectively and efficiently.

Goal Two: Strengthening the Healthcare Infrastructure

- Train virtually the entire healthcare workforce in HIV/AIDS care and treatment fundamentals, with an emphasis on the uses of antiretroviral therapy.
- Recruit up to 10,000 additional healthcare workers and train them in the prescribing of ARVs, the evaluation of patients receiving ART, the care and monitoring of HIV+ individuals, counselling and adherence techniques, and other aspects of HIV/AIDS care and treatment.
- Give vital support to strengthening programme management resources and capabilities at the national, regional and district levels to ensure successful implementation and scale-up of the HIV/AIDS Care and Treatment Programme.
- Support infrastructure improvements including renovation and construction of clinical space, pharmacies with adequate and secure storage, and modernized laboratories.
- Make special efforts to upgrade the laboratory function throughout the healthcare network by recruiting and training of technicians, purchasing of testing equipment, assuring re-supply of consumables, and establishing a maintenance and repair infrastructure.
- Work with the government toward a phased movement of Clinton Foundation supported healthcare worker positions to government funded positions thus resulting in a better staffed health sector.
- Establish pragmatic monitoring and evaluation system to ensure continuous upgrading of the HIV/AIDS Care and Treatment Programme to reflect best practices and changes in technology and standard clinical procedures.

Goal Three: Expanding Information, Education and Communications

- Create an aggressive IEC programme to educate the general public about HIV/AIDS care and treatment, especially the role of antiretroviral therapy.
- Support a focused IEC effort to fully educate patients, their families, and those who support them in the fundamentals of ART with special emphasis on adherence.
- Support the effort to train all healthcare workers in the country in the fundamentals of ARV treatment and other elements of the comprehensive care of PLWHA.
- Enhance the existing HIV/AIDS de-stigmatization efforts currently underway in the country.
- Recognize that treatment is an important component of prevention, and be diligent in discovering additional opportunities to tie them together.

Goal Four: Strengthening Social Support

- Require certified facilities to link with local groups to strengthen existing and develop new social support networks in their catchment areas.
- Fund local or national organizations, preferably those composed primarily of PLWHA, to organize and educate PLWHA, enabling them to have a greater role in monitoring and directing the HIV/AIDS Care and Treatment Programme.

- Forge collaboration with CARF programmes and organizations and, where possible, funnel social support funds through these channels.

2.4 First Year Objectives and Facilities

The first year objectives of the plan are:

- To certify at least 19 facilities to begin operation of HIV/AIDS care and treatment clinics, and to supply them with necessary equipment and medicine.
- To begin ART for 15,000 HIV+ patients by the end of the first year.

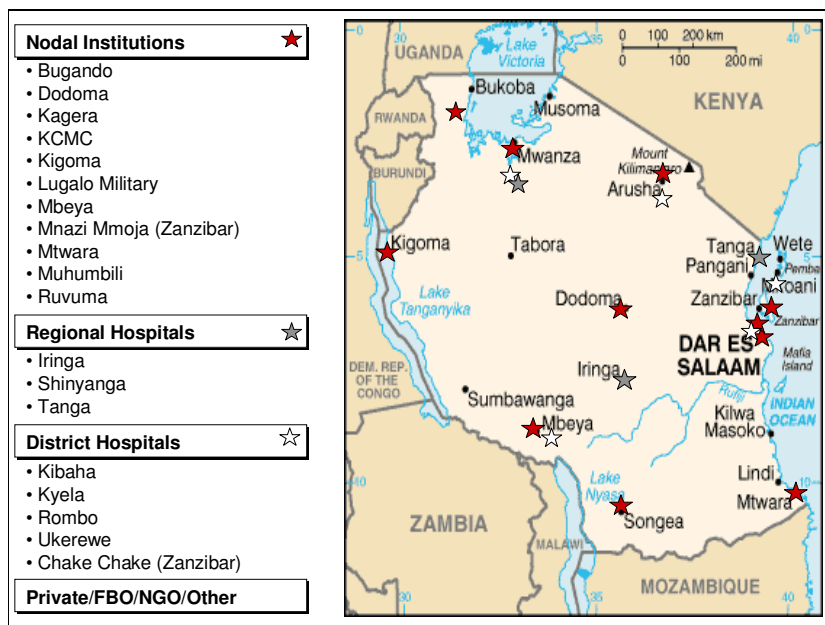
In order to accomplish these, a number of other objectives must be realized, including the following:

- Creating and staffing of the Care and Treatment Unit (CTU) in the MoH.
- Launching the distribution system for ARVs.
- Filling staff vacancies at target facilities.
- Training staff in the first year target facilities.
- Strengthening facilities, including building secure pharmacy, securing use of sufficient clinic space, and installing appropriate laboratory equipment.
- Adopting standards for laboratory services and ensuring all target facilities meet them.
- Establishing linkages with other elements of the healthcare system to ensure flow of treatment candidates, focusing especially this first year on symptomatic patients.
- Creating and implementing of an IEC programme.
- Preparation of model *Operations Manual for HIV/AIDS Care and Treatment* by the CTU, and local versions for each targeted facility.

Five types of facilities are being targeted for certification as participants in the HIV/AIDS Care and Treatment programme for the first year:

- Referral hospitals, to include Lugalo Hospital (the central military hospital) and Mnazi Mmoja Hospital in Zanzibar.
- Five regional hospitals to ensure geographic representation in major areas of the country.
- Four additional regional hospitals, to give added experience in smaller hospitals, particularly those not as advanced as the ones in group 2 above.
- Five representative district hospitals, paired with referral hospitals, to give the programme experience in operating at the district level, leading to better planning and execution in coming years.
- Participation by non-public facilities which self-select themselves to apply for certification.

Figure 1. First Year Target Locations



2.5 Five-year Scale-up Objectives.

During the second year of the programme, the objective will be to extend the programme to all regional hospitals and a greater number of district, voluntary and private institutions. The CTU will continue to encourage as many non-public hospitals as possible to participate in the strengthening and certification.

During the next three years, efforts will be made to extend the programme to all district hospitals and to other appropriate facilities.

Figure 2 shows how the programme might scale-up during the full five years of the plan.

Figure 2. Treatment Scale-up Model

Patients on treatment		POSSIBLE MODEL									
		Year 1		Year 2		Year 3		Year 4		Year 5	
Hospital type		New facilities	Total under treatment	New facilities	Total under treatment	New facilities	Total under treatment	New facilities	Total under treatment	New facilities	Total under treatment
Nodal* Facility (1000 new patients per year; 200 for Zanzibar site)		11	10,200	0	20,400	0	30,600	0	40,800	0	51,000
Regional** (600 new patients per year; 100 for Zanzibar site)		4	1,900	10	9,800	0	17,700	0	25,600	0	33,500
District, Voluntary*** and Private (600 new patients per year; 50 for Zanzibar site)		8	4,250	45	34,950	63	102,900	63	208,100	43	338,550
		16,350		65,150		151,200		274,500		423,050	
<p>Key assumption: Once certified, each facility is able to enroll a new cohort of patients each year while maintaining previous ones</p> <p>* Includes the 4 referral hospitals, 5 regional hospitals (Dodoma, Kagera, Kigoma, Mtwara and Ruvuma) to be upgraded to serve their region, the Military Hospital (Lugalo), and Mnazi Mmoja (Zanzibar)</p> <p>** Includes all other regional facilities and Chake Chake Hospital (Zanzibar)</p> <p>*** Includes Faith-based and NGO institutions</p> <p>Source: Team modeling</p>											

3. PROBLEM DEFINITION

3.1 HIV/AIDS Epidemiology and Impact

Tanzania is one of the poorest countries in the world with a GDP per capita of \$478 (2000), a ranking in the human development index of 140 among 162 countries, and 48% of the population living in absolute poverty.¹ Annual government expenditure is about \$6 per capita on health and \$15 per capita on primary school education. Recently however, Tanzania has been making significant economic progress, benefiting from a stable political situation and increasing foreign investment. These improvements are threatened by the growing impact of HIV/AIDS which is a considerable roadblock to continued improvement in the widespread poverty throughout Tanzania.

Although Tanzania is a regional success story in economic and political terms, AIDS-related mortalities are changing the demographic profile of the country, eroding past improvements. Without significant intervention, life expectancy will decrease from 61 years without HIV/AIDS to 46 years with the epidemic.² HIV infected patients occupy approximately 60% of all beds in urban hospitals, and TB, which was close to containment in the early 1980's, has risen from 11,753 cases in 1983 to 60,000 in 2000. TB is the leading cause of mortality among AIDS patients, accounting for 30% of all deaths.³

Tanzania has one of the higher national prevalence rates of HIV/AIDS in the world. As the largest country in East Africa, it bears the burden for a large part of the global epidemic along with the rest of Sub-Saharan Africa, which in 2000 had 70% of the global total of people living with HIV/AIDS (PLWHA). Out of a population of 34.5 million people, 2.2 million individuals above the age of 15 were estimated to be living with HIV in Tanzania in 2001.⁴ Ante-natal clinic surveillance results from 2002 place the prevalence of HIV at 9.6%; prevalence among blood donors in 2001 was 11.01%.⁵

The infection rate does not appear to have peaked, and has the potential to particularly affect the life span and quality of life of young Tanzanians under the age of 15, who account for 46% of the country's population.⁶ The rate of infection in this age group will directly impact Tanzania's productivity and ability to combat poverty in the coming years.

Current age and gender distributions of reported AIDS cases (Figure 3) reveal that the disease has the strongest impact on individuals in the prime of their working and child-bearing years, from 20-49 years, who thus have a limited capacity to make a productive contribution to society. The pattern shows early infection of young women, with reported cases peaking from age 25-34, while in men the majority of cases occur slightly later in life, peaking at 30-39 years. This group is unable to play an active economic role or provide for their families, and by 2001 they had left behind an

¹ *Health Sector HIV/AIDS Strategy for Tanzania, 2003-2006*, Ministry of Health.

² Dr. Geoffrey Somi, Tanzania Ministry of Health, 3/13/2003.

³ Ministry of Health, *Health Sector HIV/AIDS Strategy for Tanzania, 2003-2006*. Dar es Salaam, Feb. 2003.

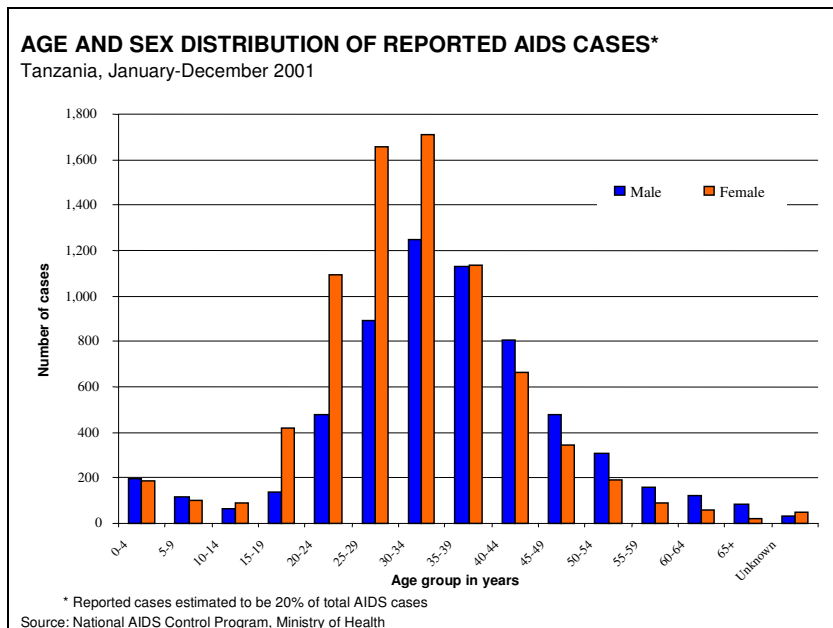
⁴ National AIDS Control Programme, *HIV/AIDS/STI Surveillance Report No. 16*, January-December 2001.

⁵ Surveillance of HIV and Syphilis Prevalence and Youth Behaviour from Antenatal Clinic Communities 2001 – 2002, MoH and Surveillance Report No. 16.

⁶ Census Bureau of Tanzania, 2002 Census

estimated 810,000 children orphaned due to HIV/AIDS, putting additional pressure on the limited resources of their extended families and communities.⁷

Figure 3. Age and Sex Distribution of Reported AIDS Cases



HIV/AIDS is gradually draining both management and professional personnel and the productive work force, with a negative macro and micro impact on the economy. Tanzania's future GDP is predicted to be 15-20% lower in 2010 than it would have been without the AIDS pandemic. Mortality rates are such that employers are facing shortages of skilled workers, and losing many of their more experienced personnel, as well as facing rising healthcare costs.

There is a serious effect on essential government services. The Minister of Education has noted that 114 teachers die of AIDS each month, leaving a gap in experienced teachers and, in many districts, no replacement.⁸ Young men who migrate to urban settings often become infected and cannot support their family, and the women left behind in rural areas have limited time for subsistent farming when they must care for the sick. Scarce resources are spent to overcome opportunistic infections, and children often leave school to care for sick relatives.

3.2 National Health System Response and Capacity

Despite limited resources, Tanzania has a well-developed basic healthcare delivery system which is 61% government owned, with the remaining 39% run by NGOs, parastatal organizations, voluntary agencies, and the private sector. There are approximately 5,000 healthcare facilities, geographically distributed so that 70% of the population is within 5 km of a facility and 90% is within 10 km.⁹ Services are organized in three levels, with six tertiary hospitals providing the most comprehensive care and predominately serving as referral hospitals. The secondary level consists of

⁷ UNAIDS, Tanzania Country Report Update, January 2002. <http://www.unaids.org>

⁸ Tanzania Situational Analysis, Ministry of Health, 2002.

⁹ Ministry of Health, Health Sector HIV/AIDS Strategy for Tanzania, 2003-2006. February 2002, p. 5.

regional hospitals, while the primary level consists of dispensaries, health centres and district hospitals.

Administratively, the health system is largely decentralized. The Ministry of Health has direct responsibility for the referral hospitals, and regulatory power over all health facilities, but facilities are independently run by the region or district. Zanzibar is administered independently, and its facilities are outlined in Chapter 13 and are not included in the above figures.

Table 3. Health Facilities in Tanzania

Number of facilities in 2000						
Facility type	Government	Parastatal	Voluntary/ Religious	Private	Others	Total
Specialized hospital	4	2	2	0	0	8
Regional hospital	17	0	0	0	0	17
District hospital	55	0	13	0	0	68
Other hospital	2	6	56	20	2	86
Health centres	409	6	48	16	0	479
Dispensaries	2450	202	612	663	28	3955
Specialized clinics	75	0	4	22	0	101
Others	90	6	15	228	1	340
Total	3151	211	778	1204	35	5054

Source: MOH Statistical Abstract

Increasing HIV prevalence imposes overwhelming pressure on the capacity and efficiency of Tanzania's healthcare system, leading to declines in the quality of care available to all citizens. The average HIV+ adult in Tanzania has an average of 17 illness episodes before death, leading to healthcare costs per patient which can be twice the Tanzanian GDP of US\$478 per capita.¹⁰

3.3 National Capacity and Response to HIV/AIDS

The first case of AIDS in Tanzania was reported in 1983, and two years later the Ministry of Health launched a "Short Term Plan" to address AIDS and announced the formation of the National Aids Control Programme (NACP). This Short Term Plan was followed by three five-year plans, predominately focused on information and educational campaigns aimed at persuading people to change their sexual behaviour in order to prevent infection. The latest five-year plan was introduced in 1999, with the goal of building a multi-sectoral response to HIV/AIDS that also involved patient care and impact mitigation, along with ongoing prevention campaigns.

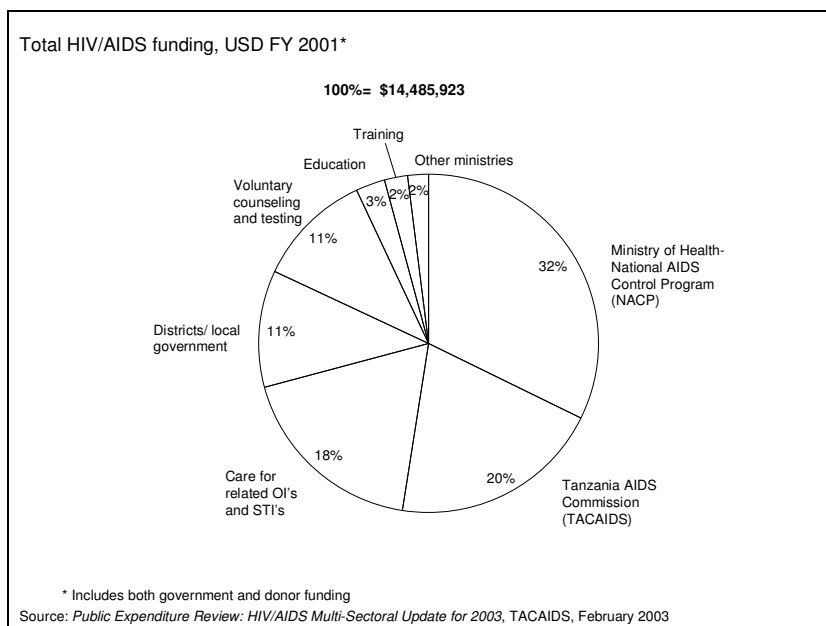
The President declared AIDS a national disaster in 1999 and launched the Tanzania Commission for AIDS (TACAIDS), a separate body from the NACP that reports to the Prime Minister's office, in December 2000. Although the NACP had made significant advances in areas such as blood safety, sexually transmitted infection (STI)

¹⁰ UNAIDS, Tanzania Country Report.

management, healthcare worker training, and education, it had limited capacity to coordinate a multi-sectoral response to the epidemic. The role of TACAIDS is primarily to lead a multi-sectoral response to HIV/AIDS by formulating related policy, ensuring coordination of governmental and non-governmental AIDS-related programmes, advocacy and resource mobilization.

In practice, the MoH, along with the regional and district councils, remains the implementing body for government provided clinical services. The NACP actively cooperates with TACAIDS, which focuses on the non-clinical aspects of AIDS management. They each in turn have strong links to the various healthcare providers, including NGO's, faith based organizations and the community.

Figure 4. Distribution of grants targeting HIV/AIDS in 2001



HIV/AIDS care is carried out to the extent possible at all levels of the healthcare system, with a focus on treatment of sexually transmitted infections (STIs), opportunistic infections (OIs), and prevention. ARVs have been introduced on a small scale through a programme aimed at preventing mother to child transmission (PMTCT), which has had limited uptake due to resource constraints, lack of community sensitization and hence male participation, social stigma, and other factors.

Highly active antiretroviral therapy (HAART) has recently become available to a small number of Tanzanians who can afford it. Overall, it is estimated that approximately 1,500-2,000 people fall into this category, with most of them residing in Dar es Salaam. Initially a HAART regimen cost \$86 per month or over \$1000 per year, a price few patients could afford. Adherence to appropriate medication regimes is often determined by family resources; patients who start treatment frequently drop one, two or all the drugs due to limited funds.

The MoH has begun planning to provide the country with HAART, and submitted Global Fund proposals to this effect. In February 2003 the National AIDS Control Programme put together a "Health Sector HIV/AIDS Strategy for Tanzania, 2003-2006" which proposed to put a cumulative total of 13,000 persons on HAART by the

end of 2006. The proposal was not funded, however, and a scaled down version has been resubmitted for consideration.

The Ministry of Health has issued HAART guidelines, but at this point few physicians are trained in the appropriate use of HAART, and use of the guidelines is *ad hoc*. Little is done to monitor patient adherence or track outcomes. Approximately eight companies have begun to provide workers on their health plans with HAART, and preliminary results show that their health expenditures are dropping due to reduced OIs.

For the most part donors have been reluctant to provide HAART in Tanzania, and other resource-poor countries, due to the following perceived barriers:

- High cost of medicines
- Difficulty in ensuring compliance with complex and at times unpleasant treatment regimes
- Perception that the healthcare infrastructure is insufficient to support a treatment initiative

However, the cost of basic HAART therapy recently dropped to its current price of \$30 per month, or \$360 for a year, and is expected to continue to fall rapidly.¹¹ Experience with treatment in similar developing settings such as Botswana, Haiti and Brazil is demonstrating that HAART can be effectively used in developing countries despite limited resources.

In the absence of significant new resources for AIDS treatment, Tanzania will not be able to close the enormous gap between the approximately 400,000 people who need treatment and those few who have the ability to pay for the drugs.

¹¹ Price reported at the Clinic for Sexually Transmitted and Infectious Diseases, Dar es Salaam, Feb. 2003.

4. CARE AND TREATMENT PLAN

Overview

It has been assumed by many observers that viable, large scale treatment programmes are impracticable in an African setting due to perceived problems with inadequate infrastructure, the inherent complications of the treatment, and prohibitive costs for drugs. The HIV/AIDS Care and Treatment Plan for Tanzania implicitly and explicitly rejects this reasoning.

Quality, effective and efficient care and treatment can be provided in Tanzania if careful attention is paid to a number of issues highlighted in this section, including aggressive efforts to identify HIV+ individuals, developing a team approach to treatment, strict observance of standard protocols by clinicians, and rigorous application of patient classification and treatment schedule models.

Other issues covered in the Care and Treatment Plan include patient monitoring, medical records, treatment and prophylaxis of opportunistic infections, and post-exposure prophylaxis.

4.1 Serostatus Determination

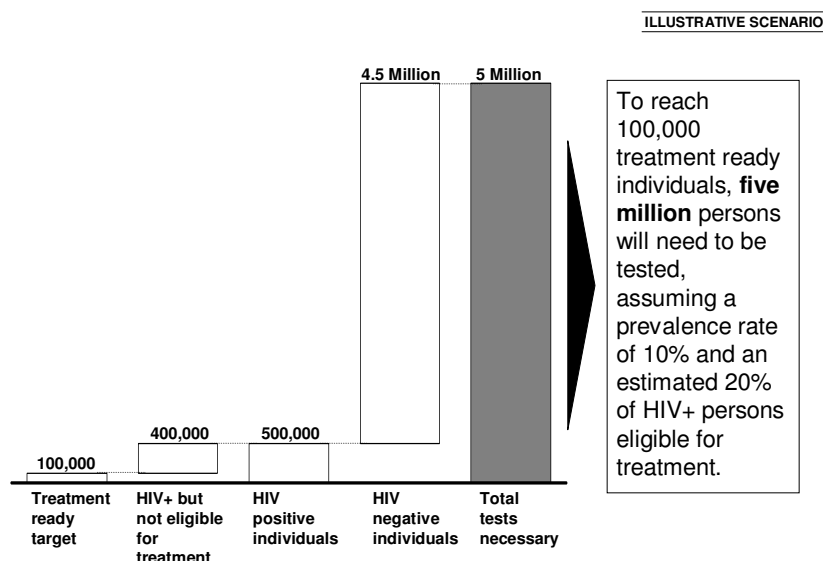
Meeting the goals of the HIV/AIDS Care and Treatment Programme will require a greatly expanded effort to identify patients in need of treatment. All segments of the healthcare structure in Tanzania will need to have a role in this effort. VCT centres, the National TB and Leprosy Programme (NTLP), antenatal clinics and STD clinics are key points of linkage because of the substantial overlap of clients. (See Chapter 5 for information about linkages to these programmes.)

Several efforts can contribute to expanding the coverage of VCT in Tanzania. Increasing recognition of the availability and effectiveness of treatment for HIV will encourage people who suspect they may be HIV+ to be tested. As HIV/AIDS treatment garners more public attention, stigma surrounding seropositivity, and the barrier it creates to testing, should be reduced. Improved education and sensitization of healthcare workers nationally will create a clinical care system that is more accessible and comfortable for patients with HIV. The MoH will encourage and work with partner organizations to improve the capabilities and coverage of VCT programmes.

In addition, it is important to begin examining options for a more rapid expansion of testing capability on a national level, including the feasibility of an "opt-out" policy for routine pre-test counselling and testing of at-risk individuals treated at all levels of the healthcare system.

To understand the magnitude of the effort required, consider that to enrol just 100,000 previously unidentified individuals in treatment it may be necessary to test up to 5 million people, assuming that 10% of those tested will be HIV+ and 20% of those will be eligible for treatment. (See Figure 5) The current capacity of VCT clinics is less than 1 million counselling sessions and HIV tests per year.

Figure 5. Identification of treatment-eligible HIV+ persons



The challenge of the Care and Treatment Programme will be both to increase the capacity for testing, and to strive for identification of the HIV+ segment of the population through methods short of population-based counselling and testing, although such efforts are important to aid in prevention efforts and should be part of the long term goals of the healthcare system.

4.2 Role of Routine “Opt-Out” HIV Testing

Greater routine serologic testing for HIV infection in varied clinical settings will be necessary to meet the ambitious patient identification goals of the programme. By taking advantage of the fact that the majority of HIV+ individuals present at a healthcare facility for some level of care before they require ARV therapy, it will be possible to identify HIV+ individuals who require care to slow disease progression and to detect those who require immediate treatment with considerably reduced effort when compared with instituting other large scale patient identification methods.

The MoH should therefore consider a new national policy promoting routine counselling and testing of all ‘at risk’ patients entering a hospital or attending medical and specialized clinics, such as the NTL, ANC, and STI clinics. Attending physicians and nurses should be trained to provide the pre-test counselling, which might be abbreviated compared to standard VCT procedures, necessary to ensure patients are giving their informed consent to the test being ordered by the doctor.

It is recognized that institution of an “opt-out” counselling and testing policy constitutes a break with current practice and policies. The benefits of more HIV+ individuals knowing their HIV status, however, are overwhelming both in terms of preventing transmission of the virus and in initiating early treatment when patients will recognize the maximum treatment benefit. Individuals who test negative also will benefit from more widespread testing, because such tests often prompt people to reduce risky behaviour to stay free of HIV. Each encounter with a test counsellor is an opportunity to discuss risk reduction behaviour and to educate individuals about HIV transmission and HIV disease. The nature of this public health emergency mandates a more widespread effort by the healthcare community to ensure every at-

risk individual knows his or her status and is empowered to take action, whatever the test result.

During 2000, according to the MoH's Health Statistics Abstract 2002, more than 11 million outpatient diagnoses (and 322,000 inpatient diagnoses) were reported from healthcare facilities throughout the country. If a system could ensure the majority of the individuals behind these diagnoses learned their serostatus during their visits to a healthcare facility, it would be an important step forward in HIV/AIDS prevention and treatment efforts.

At the same time, this policy requires careful consideration and preparation of both healthcare workers and patients before widespread adoption. Implementation will likely be smoother as treatment becomes more widely available. It is recommended, then, that the MoH immediately examine the feasibility of such a policy with a goal of beginning implementation no later than the second year of the programme, although it could be phased into prepared facilities even earlier.

4.3 Scope of Care and Treatment

There are certain core elements of care and treatment that the programme will strive to provide for all persons who are HIV+. These core elements are designed to foster improved overall health and transmission reduction, with the aim of slowing the progression of disease on an individual and population level, and to maximize the benefit of available therapies. The core elements include:

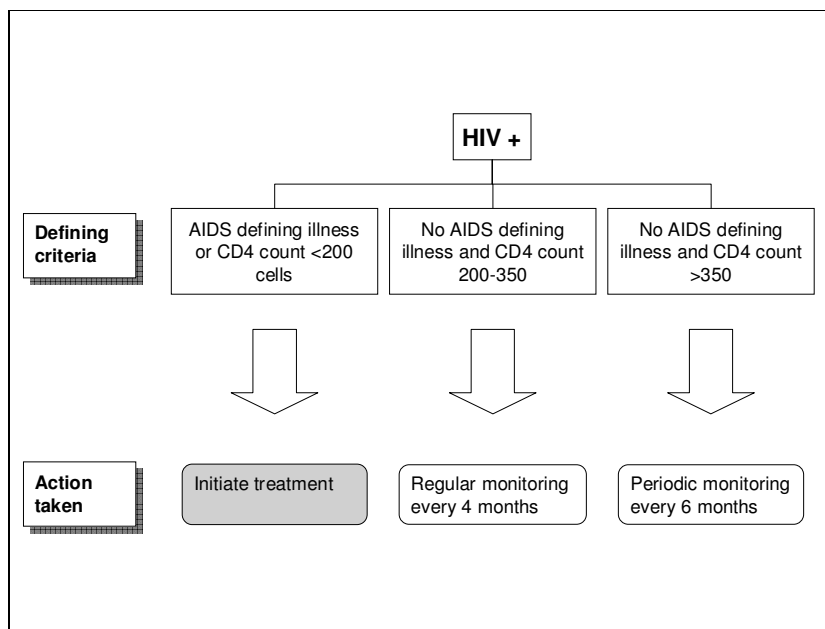
- Basic education regarding the mechanism of HIV infection and disease progression.
- Management of disease symptoms.
- Education about behaviours to reduce transmission of HIV.
- Orientation to the care and treatment programme.
- Counselling and education about actions that may delay progression of disease and reduce co-morbidities, such as attention to nutrition, food safety, and clean water.
- Routine clinical care and nutritional assistance to malnourished patients.
- Prophylaxis for OIs as indicated by the National Treatment Guidelines.

In addition to receiving the core elements of care and treatment, each patient will fall into one of three clinical categories with specific clinical goals of treatment as outlined below:

- **Mildly immuno-suppressed** - HIV+ individuals whose CD4 cell counts are above 350 cells/ml will come to clinic and have their CD4 counts determined every six months. The goals of care for these patients are to delay progression by treating opportunistic infections and to enhance the likelihood of success of future treatment by improving adherence to medications and visits.
- **Moderately immuno-suppressed** - HIV+ Individuals whose CD4 cell counts are between 200 and 350 cells/ml are at greater risk for progression to AIDS and will come to clinic and have their CD4 counts determined every four months. The goals of care for these patients are to delay progression by treating opportunistic infections and to enhance the likelihood of success of future treatment by improving adherence to medications and visits.
- **Treatment-ready patients** – These are patients with an AIDS-defining condition or a CD4 cell count below 200 cells/ml. The goals of treatment and

care for these patients are to reduce morbidity and mortality by aggressively suppressing viral load and treating opportunistic infections and to maximize the benefits of treatment by encouraging consistent adherence to antiretroviral therapy. These patients will come to clinic monthly to refill their medications and to meet with a counsellor. The clinician visit schedule is described below.

Figure 6. Categories of identified HIV+ individuals



Special considerations for children-or HIV+ children under 12 years old, where absolute CD4 counts are not an accurate measurement of immunological suppression, treatment will be recommended for all who fit any of the criteria below:

- Are under 1 year of age,
- Have a CD4 less than 15-20%, or
- Develop an AIDS defining condition.

Children who have a CD4 count of between 15/20% and 25% will be brought to the clinic every four months for evaluation and to have the CD4 measurements. Children with a CD4 count above 25% will be brought to the clinic every six months for evaluation and CD4 counts.

4.4 Care and Treatment for Those on Antiretroviral Therapy

- Patient Visits Plan

Once a patient with HIV is identified, he or she will be referred to the care and treatment clinic. At the initial clinic visit blood will be drawn for a confirmatory HIV test and CD4 count and patients will meet with a counsellor. Given that test results will typically not be available on the same day, the patient will be scheduled for a follow-up visit with a clinician to discuss the test results.

At the follow-up visit, after the clinical consultation with a prescribing clinician, patients who are recommended for and agree to initiate therapy will meet with a counsellor to discuss adherence, medication dosing, and adverse event management. They will have another blood sample drawn for tests which will help

inform the treatment protocol and to identify baseline values for monitoring toxicity. Patients will be scheduled for follow-up after two weeks, then monthly for the first six months for clinical care and monitoring of response to therapy (including toxicity management). During these visits, they will see an evaluating clinician, pick up their medication from the pharmacy, and meet with a counsellor (see counselling section below).

After six months, the patient will be requested to visit the clinic once a month for medication and counselling and as needed for clinical care. At four months intervals, CD4 counts and basic blood work will be performed and patients will see an evaluating clinician for clinical follow-up and to evaluate response to therapy.

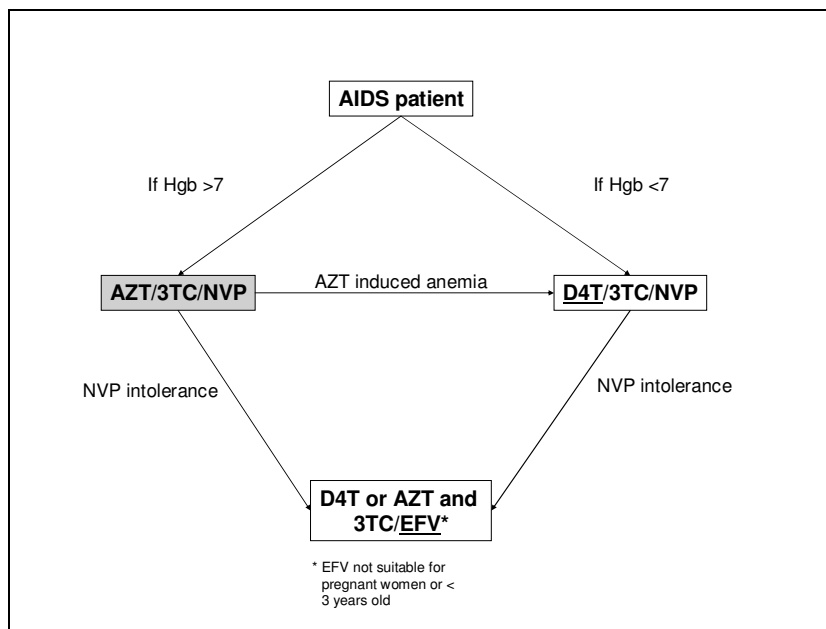
Patients who do not initiate therapy will continue to come to clinic regularly for clinical care and counselling as outlined in section 4.3 above and will be monitored regularly for disease progression.

- ARV Treatment Protocols

Specific treatment protocols for first and second-line HAART therapy have been approved by the MoH and HIV clinical experts of Tanzania and will be in agreement with the proposed Tanzania National HIV/AIDS treatment guidelines.

The first line regimen is AZT/3TC/NVP, with alternative regimens available for specific circumstances. Patients with severe anaemia (defined as haemoglobin less than 7 g/dl) will receive d4T instead of AZT while non-pregnant patients who cannot tolerate NVP will receive EFV.

Figure 7. First-line ARV prescription decision tree



The current recommended second-line therapy is ddl/tenofovir/Kaletra, although Clinton Foundation medical partners are still discussing the most appropriate second line in Africa and a different suggestion may be brought to the MoH in the future. Some issues concerning the current recommendations include:

- Kaletra requires refrigeration for long-term storage. Currently, the manufacturer’s guideline is that the drug can be kept unrefrigerated for two months at room temperature. The programme will need to evaluate whether

the drug remains viable if one-month supplies are dispensed under African weather and housing conditions, and to assure longer term refrigerated storage is available in the supply chain.

- Since Kaletra should be taken with food, and ddl should be taken ½ hour before or two hours after meals, the dosing schedule will be more complicated than with the first line. Again, the programme will have to monitor and evaluate the effects of this complication, and adherence counselling must emphasize the dosing schedule.
- Tenofovir currently is not available in a paediatric formulation, so Abacavir will be substituted for children.

The third line of therapy is under discussion. It is not practical to determine the regimen at this time, and appropriate treatment will be decided on a case-by-case basis after consultation with specialists at the referral hospital level. National HIV experts will have a small, but increasing variety of more expensive ARVs from which to choose. The repeated use of 3TC may be considered in subsequent lines in light of recent evidence that suggests the 3TC specific (M184V) mutation may lead to a less fit virus and possible increased susceptibility to other NRTIs. Saquinavir or indinavir boosted with low dose ritonavir may also be considered in third line regimens. As these subsequent third line regimens are more expensive, the use of ARV resistance assays may be considered on a limited case-by-case basis, as agreed upon by an HIV expert clinicians' panel.

- Lifestyle Counselling and Adherence Management

During their monthly visit to the care and treatment clinic, each patient will participate in a lifestyle counselling session. This time will be used to reinforce key behaviours relating to adherence strategies, disease management, transmission risk reduction, and adverse event management. Counselling will also focus on psychosocial issues such as disclosure of HIV status, assistance with social support, end-of-life care, and mental health.

HIV+ persons in Sub-Saharan Africa face significant social, economic, cultural, and medical challenges to access and adherence to ARV medications. Predominantly western experiences have shown that two factors, often interrelated, are critical to the success of ART. These factors are the development of drug resistance and consistent adherence to treatment regimens. Lack of adherence is believed to be the primary reason for virological failure and, in the presence of persistent viremia, can lead to more rapid emergence of resistant mutations. Therefore, routine assessment and reinforcement of adherence are extremely important. Each ARV Care and Treatment facility must have a comprehensive approach to adherence management.

Important lessons have been learned from Directly Observed Therapy (DOT) programmes, which maximize medication adherence in the treatment of tuberculosis. This type of adherence strategy can be adapted to HIV and AIDS treatment programmes. Research has shown that, like DOT programmes, the success of ARV programmes is directly related to the establishment of patient-oriented programmes and patient-provider relationships based on trust.

Given the high prevalence of HIV in Tanzania and the chronic daily dosing regimens for ARV regimens, direct observation of each ARV medication dose by clinic staff is not feasible on a large scale. Specific patients or settings may lend themselves, however, to this type of follow-up. These patients or settings will have to be determined at the institutional level.

The programme will initially follow a clinic-based model of patient adherence education. Adherence training and education is provided by clinic staff, which

includes medical officers, nurses, counsellors, pharmacists, and pharmacy technicians. Patients on ARV treatment will be encouraged to identify an adherence assistant. The adherence assistant is any person the patient chooses who agrees to help the patient take his or her ARV medications, e.g. a family member, friend, colleague, or community member. When necessary, patients with special needs can be assisted by counsellors and social workers. As counsellors and clinicians gain experience with ART in Tanzania, they will be able to tailor adherence strategies to meet the unique challenges that their patients present.

4.5 Treatment and Prophylaxis of Opportunistic Infections

The aggressive detection and treatment of opportunistic infections is important to reduce morbidity and mortality associated with HIV disease.

There will be adequate treatment and prophylaxis for the most common OIs. This includes cotrimoxazole for PCP (pneumocystis carinii pneumonia) treatment and prophylaxis, and fluconazole for treatment and prophylaxis of cryptococcal meningitis.

If a patient presents with severe immunosuppression and a severe opportunistic infection, like miliary TB, the initiation of ARV will often be more complicated and the outcome less favourable. Prescribing clinicians will decide on a case-by-case basis, in line with national and facility guidelines, the treatment regimen for patients such as these.

Some common OIs occur in a sequential manner as CD4 count falls in untreated HIV/AIDS, and should therefore be closely checked in patients within that category. Some characteristics of these OIs follow:

- Good to fair immunity (CD4 count 200-500 cells/ml): Herpes simplex, Herpes zoster, Kaposi's Sarcoma (cutaneous/palatal), pulmonary TB, thrush (oral candidiasis), self limiting diarrhoea, cervical cancer, and recurrent bacterial pneumonia.
- Compromised immunity (CD4 count less than 200 cells/ml): Cryptococcal meningitis, debilitating peripheral neuropathy, CMV retinitis, candida esophagitis, disseminated Kaposi's, PCP pneumonia, chronic or recurrent diarrhoea, miliary TB, wasting syndrome, and HIV dementia.

4.6 Post-Exposure Prophylaxis (PEP)

Post-Exposure Prophylaxis (PEP) is the application of ARV drugs to prevent HIV infection by blocking HIV replication after it has gained access to the human body. PEP will therefore be offered as per the national guidelines in accordance with international standards of care (WHO). The situations where PEP would be offered include likely exposure to the virus in an HIV negative person, particularly healthcare workers, as well as in the situation of rape. Standard regimens to consider would be the use of AZT/3TC in standard doses for a maximum of 28 days. This programme will include access to treatment counsellors and the use of appropriate HIV testing both of the source patient and the exposed individual.

4.7 Medical Records System

The medical record system will follow the lead of the current national medical record system, with some simple but important additions

Currently, most medical records are kept at the clinic site with a patient required to keep a card noting their medical record number and basic details. A proposed new chart system will be developed for the HIV/AIDS care and treatment clinic in which vital medical details are kept in the clinic setting with a duplicate, carbon copy kept by the patient. The duplicate patient-held chart will facilitate care at more than one site

so that a patient initiating ARV treatment or being followed at one site could receive care at a different site. This system would also meet the needs of a patient who moves to a different clinic's catchment area.

The medical record should provide all necessary information to allow quality, continuous care, but be simple enough to allow healthcare workers to accurately record this information in a timely manner under the constraints of a busy clinic setting. Some sample forms which might be used are shown in Annex 1.

A national computerized medical record system should be considered in the future to track patients as part of the proposed national medical record/pharmacy tracking systems. This system would allow the identification of a patient based on an ID # with name, birth date or other identifier, and could possibly include barcode scanning capability to track both medications and patient care. No funds are being budgeted for records computerization at this time, but could be considered at a later date.

4.8 Nutrition

Symptoms of HIV disease, such as anorexia, pain, nausea, vomiting, malabsorption, and diarrhoea indirectly contribute to poor nutrition. Opportunistic infections can limit food intake and also result in increased resting energy expenditure. The result is often inadequate nutritional intake leading to inability to maintain weight and lean tissue mass and micronutrient deficiency. Poor nutritional status also leads to a hastened progression of HIV disease to AIDS and death. The introduction of antiretroviral therapy is expected to reduce or eliminate many barriers to adequate nutrition. In cohorts in the US and Europe, HAART has led to reductions in opportunistic infections that may limit food intake and thus reduced wasting. In paediatric patients, the use of HAART has led to catch-up growth. Delayed disease progression and reduced morbidity due to HIV disease contribute to increased access to food by allowing individuals with HIV to be economically productive for longer. By improving symptoms of HIV disease that limit food intake, HAART should also reduce problems leading to decreased food intake.

In an effort to deliver a comprehensive treatment programme, the team has carefully considered the role of nutrition in HIV treatment. From a clinical perspective, adequate nutrition, appropriate micronutrient supplementation, and the treatment of clinical malnourishment are necessary components of the comprehensive treatment of HIV/AIDS and will significantly enhance the effects of pharmaceutical therapy. Additionally, given the fact that many antiretrovirals have food requirements, nutrition and antiretroviral therapy programmes often need to be linked together for maximum benefit.

Several licensed antiretrovirals have food requirements stemming from the effect of food on drug absorption through the gastrointestinal tract. Table 4 summarizes the food requirements for the drugs that have been selected as first and second-line regimens in Tanzania. All of the drugs selected for the recommended first line regimen can be taken without regard to meals.

Nutrition will be initially incorporated into HIV care through three specific interventions outlined below. These interventions may be changed pending new recommendations from the World Health Organization's Expert Advisory Group on HIV and Nutrition and feedback from the monitoring and evaluation component of the programme.

The Tanzania Food and Nutrition Centre (TFNC) will develop a curriculum and training materials for nutritional counsellors. These counsellors will be part of the treatment team and will focus on educating patients about the importance of nutrition and food and water safety and ways to maximize available food resources.

Table 4. Food requirements for antiretrovirals selected for use in Tanzania initiative

Line	Generic name	Trade name	Food requirement
1 st Recommended	Zidovudine (AZT, ZDV)	Retrovir	Take without regard to meals
1 st Recommended	Lamivudine (3TC)	Epivir	Take without regard to meals
1 st Recommended	Nevirapine	Viramune	Take without regard to meals
1 st Alternate	Stavudine (d4T)	Zerit	Take without regard to meals
1 st Alternate	Efavirenz	Sustiva	Avoid taking after high fat meals
2 nd Considering	Didanosine (ddI)	Videx	Take ½ hour before or 2 hours after meal
2 nd Considering	Abacavir (ABC)	Ziagen	Take without regard to meals
2 nd Considering	Lopinavir+Ritonavir	Kaletra	Moderate fat meal increases AUC of capsules and solution. Take with food.
2 nd Considering	Tenofovir Disoproxil Fumarate	Viread	Increased bioavailability when taken with food

Source: DHHS Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents, 2002

Nutritional education and counselling will be incorporated into the following services:

- VCT
- Monitoring of HIV+ individuals not eligible for ARV therapy
- Initiation and continuation of ARV therapy
- Paediatric follow-up appointments
- Home-based care programmes
- Family and community education activities

Elements to be included in counselling and education are:

- Basic nutritional education
- HIV-specific nutritional concerns including weight maintenance
- Food safety
- Food strategies that employ locally available foods
- Recipe provision

Pregnant women will receive a multivitamin supplement that contains vitamins B, C, and E, in addition to iron and folate. All children of at least six months of age, including those born to women who are HIV seropositive, will receive a vitamin A supplement every four months. Children under six months of age will not receive any supplement. All supplement protocols will be examined annually and updated to comply with current international guidelines.

The data regarding multivitamin supplementation for lactating women and other adults (non-pregnant women and men) does not show a conclusive comprehensive benefit. No supplementation is recommended at this time, but the issue merits annual re-examination as new data are available.

The budget for HIV care will include resources to treat severe clinical malnutrition, with an expected prevalence of about 5 to 10% among individuals with HIV. Healthcare facilities will be encouraged to develop an arrangement with local community groups (NGOs, FBOs, etc), to assist with the nutritional needs of patients of the care and treatment clinic.

Healthcare providers will evaluate the nutritional status of patients at each follow-up visit. Where appropriate arrangements can be made, clinicians will prescribe treatment for those patients who meet predefined clinical criteria for malnutrition (to be decided by TFNC in consultation with relevant partner organizations). The treatment will consist of a food basket designed to supplement a family of five until the next patient visit. The basket will include locally-purchased items such as maize flour, oil, etc. Health facilities may give the food basket directly or may provide referral with a voucher to a partner organization.

5. LINKAGES WITH OTHER INITIATIVES

Overview

The Tanzania HIV/AIDS Care and Treatment Programme can only be successful if it establishes successful linkages with a variety of partnering programmes and institutions. These linkages must be ensured by the Care and Treatment Unit through careful planning and coordination at the national level, but must be effective at the local and regional operational levels to be successful. This chapter touches on a few of the most important linkages to be pursued, although others will occur as the programme moves forward.

5.1 PMTCT Programmes

Tanzania has already embarked on an effort to extend PMTCT throughout the country. Five pilot programmes located at the four referral hospitals and one regional hospital (Kagera) were undertaken in April to September 2000, supported by UNICEF and GTZ. Two of the referral hospitals also supervised and supported two health centres in their implementation of PMTCT. An evaluation of those pilot programmes was completed by the U.S. Centers for Disease Control and Prevention and the published report highlighted some key issues:

- Referral hospitals have limited capacity to coordinate PMTCT activities at the regional and district levels, given their separate administrative systems. It is therefore necessary to establish strong national and regional coordination and management structures.
- There is significant rotation of staff manning ANC and labour wards. It is common to find staff untrained in PMTCT attending to the women. This underscores the need to have training geared to all healthcare workers in any institution and thus sensitize them, and their superiors as to the necessity of PMTCT.
- The voluntary “opt-in” strategy to counselling and testing impedes coverage, particularly when coupled with underlying stigma issues, and enthusiastic but unskilled and often poorly informed healthcare workers. Routine “opt-out” has therefore been proposed, along with the development and dissemination of information, guidelines and standards on a national scale.

The MoH has set a goal of establishing PMTCT programmes in all antenatal clinics in the country by the end of 2006. Five additional regions have been targeted to begin the programme before the end of 2003: Dar es Salaam, Iringa, Kilimanjaro, Mtwara, and Tabora.

Programme management is currently in the Diagnostics Services Division of the MoH, and is administered by a minimal staff.

The inauguration of the HIV/AIDS Care and Treatment Programme will have important implications for the future of the PMTCT programme:

- There is considerable support, although not unanimous agreement, that pregnant women, who are HIV+ should be given the option of starting ARVs regardless of CD4 count, continuing through delivery and perhaps for six months of breast feeding. CTU leaders should ensure that appropriate advisory committees fully consider options in this line and issue a national advisory.
- ART availability will allow for expansion of the PMTCT programme into a PMTCT+ effort, with counselling aimed at enrolling the entire family in

continuing care and treatment offered by the ARV prescribing clinic most closely associated with the antenatal clinic.

- Availability of polymerase chain reaction (PCR) machines at reference laboratory facilities will allow for early diagnosis of the serostatus of children born to HIV+ mothers. The goal will be to allow the start of ARV therapy in all HIV+ children within the first four months of life. According to national and international guidelines, ARV therapy is indicated in all HIV+ children less than 12 months of age.

Close linkage and coordination between the PMTCT Programme and the Care and Treatment Programme will make each programme more effective and efficient. Provisions of the strengthening and certification strategy (See Chapter 9) require the CTU to ensure that each certified facility will have established linkages with appropriate antenatal clinics and their PMTCT components in their catchment area.

Specific recommendations include the following:

- Additional management and administrative resources should be provided to the PMTCT programme to ensure it is effective in scaling up to all antenatal clinics within the next three years.
- The PMTCT programme and the CTU should coordinate their scale-up schedules closely to ensure the most effective use of resources as both programmes strive to reach all areas of the country.
- The training curriculum of PMTCT and the Care and Treatment programmes should be structured to include information about how the two efforts complement each other, with specific instruction as to how referrals between the two programmes will be handled.
- Counsellors in both programmes need to be cognizant of the responsibility and expertise of other counsellors.
- Where appropriate, clinicians in antenatal clinics could become trained ARV prescribing clinicians and begin expectant mothers on HAART without having to refer them to the Care and Treatment Clinic. However, it will be important to screen and to enrol other family members for monitoring or treatment in the ARV clinic, and to ensure that the mother's care is transferred smoothly at the conclusion of her participation in the PMTCT programme.
- Record keeping and sharing will be essential to make the programmes work in an effective and efficient manner. The CTU and PMTCT managers should work out appropriate procedures as a high priority.

In addition to other provisions of the HIV/AIDS Care and Treatment Plan that impact the PMTCT programme, additional resources have been budgeted for expansion of the management effort for scale-up of the PMTCT programme.

5.2 VCT Programmes

Currently, there are approximately 250 VCT sites nationwide, of which 180 are government run, while about 70 are managed by various NGOs and faith based organizations. The MoH goal is to have six VCT centres with at least two full time counsellors in each of the districts in the country by 2006, a goal to be achieved by coordinating expansion plans of all participating entities. This proposal is not yet fully funded, even with the most recent Global Fund application that looks to cover 45 districts over the next three years. Recognizing the primacy of VCT centres in identifying HIV+ individuals, this programme provides for funding to meet the VCT site goals.

Significant progress has been made in the creation of national guidelines, not only of the operation of VCT sites, but also standard curriculum and training manuals for counsellors. To enhance these efforts, it is recommended that the MoH renew its effort to modify Civil Service regulations to create a cadre designation for counsellors. With thousands of new counsellors to be hired, both for VCT centres and in clinical settings, it seems imperative to professionalize a counselling career path to attract and retain qualified workers in these important healthcare positions. Planners in the Civil Service Department have demonstrated initial support for such a cadre.

Whether free-standing or hospital based, public or NGO sponsored, VCT centres will continue to play a crucial role in identifying PLWHA by confirming HIV infection, and therefore be a critical feeder of patients to the HIV/AIDS Care and Treatment Programme. Strong referral processes will need to be established between all VCT sites and the appropriate care and treatment clinic to ensure that HIV+ individuals are either enrolled for treatment, or have their condition monitored as appropriate.

In an ideal situation, the VCT site would draw additional blood from HIV+ individuals for transport to the care and treatment clinic for CD4 testing prior to the patient's first visit. This blood would most likely be drawn at the time of the individual's second visit to learn the results of the HIV test. Post-test counselling at this time would include information about when the client should visit the care and treatment clinic. Patient information would be transferred to the clinic along with the blood and the CD4 test result would then be made available during the patient's initial visit, allowing treatment to begin immediately if warranted. If the patient does not visit the clinic within a reasonable length of time, the clinic's follow-up system should attempt to find the patient and encourage him or her to enter the care and treatment programme.

5.3 Antenatal Clinics

The role of antenatal clinics will be twofold – as a testing centre for all expectant women, and as a PMTCT centre. The certification requirements (See Chapter 9) include a provision that any facility seeking to be certified for ART should establish a PMTCT programme in its antenatal clinic, if one exists. Close coordination between the two clinics is essential for effective treatment and prevention, and coupling of both services at the same centre should be explored wherever feasible.

At the very minimum, strong referral systems should be put in place to ensure that any HIV+ individuals seen at the antenatal clinic are appropriately enrolled by the HIV/AIDS care and treatment clinic. Counsellors in the PMTCT programme should also make an effort to have other family members screened for HIV. Likewise, care and treatment clinic clients who become pregnant should be referred to the PMTCT programme. Here too, efforts should be made to speed the process by sharing relevant medical records and also to follow-up any referred patients who do not show up at either site within a reasonable length of time.

5.4 STI Clinics

The NACP has made a major effort in the last five years to improve the diagnosis and treatment of sexually transmitted infections. STI clinics will clearly be key HIV+ identification locations, and facilities engaged in ART therapy should ensure that close coordination is developed among all medical practitioners involved in STI treatment. Because STIs increase the risk of transmitting HIV, all patients in HIV care should be monitored and treated for STI.

5.5 NTLP Clinics

With a 50% prevalence of HIV among TB patients, NTLP clinics will serve as an important channel for identifying HIV+ individuals. Though currently not done across

the country, two pilot projects are being conducted in Muheza and Iringa Districts to assess the feasibility of providing HIV treatment within the TB clinic setting. Irrespective of findings, testing and counselling of suspected patients will be encouraged at all NTLP clinics, as will be subsequent referral of HIV+ individuals to a care and treatment clinic for further follow-up.

5.6 Community Based Programmes

Continuous of care for PLWHA is an essential element of any care and treatment programme. The community, and its support for and enhancement of the clinical component of care, is the most important provider of non-clinical elements of the continuum.

This plan implicitly leaves many activities for primary attention by community based programmes, including such things as:

- Home based care.
- Basic support, such as food and housing.
- Secondary support for adherence.
- Psychosocial support.
- Family planning.
- Access to VCT.
- Community education in ART fundamentals.
- Prevention programmes.

When planning nationally it is very difficult to spell out in any detail how community collaboration should be manifested at the local level in widely varying circumstances across the whole country. The programme will closely coordinate with the CARF programme, managed by TACAIDS and funded by a World Bank MAP grant. The HIV/AIDS Care and Treatment programme budget allocates \$5000/year per facility certified by the CTU. These funds are intended to be additive to the community support grants managed by CARF and provided to community organizations to further the aims of the care and treatment programme.

In addition, the strengthening and certification model (see Chapter 9) requires that each facility entering the programme show that it has a plan in place to link with and support community organizations. Additionally, the strengthening plans will necessitate the designation of local advisory committees to consult with the certified facilities. These committees would be existing groups or formed specifically for this purpose.

5.7 DCAIDS

The Donor Assistance Committee HIV/AIDS Group has been, and continues to be, a key government partner in dealing with the HIV/AIDS pandemic in the country. Ranging from donating test kits to funding NGOs that establish and run VCT centres, the DCAIDS group has been intimately involved. This partnership and collaboration will be critical as Tanzania moves towards developing a continuum of care for all PLWHA across the country.

6. HUMAN RESOURCES DEVELOPMENT

Overview

Human resource capacity is a major constraint to scaling up comprehensive HIV/AIDS care and treatment, probably the most limiting factor determining how many PLWHA can begin ART within the next five years.

In the current system there is a shortage of trained manpower, from physicians and nurses to pharmacists, laboratory technicians and both hospital and community based counsellors. The MoH has worked under a hiring freeze in the public hospitals since 1991. The freeze was instituted to reduce salary costs and also due to the assertion that some healthcare facilities were overstaffed. In effect, however, many health facilities are now seriously understaffed and the freeze has made it difficult to address this issue.

The ARV treatment plan calls for significant additions in medical staff to expand the healthcare system capacity in order to provide quality care and treatment to PLWHA. The challenge will be to recruit, enrol and train healthcare workers fast enough to keep up with the demand which can be expected once the availability of treatment becomes generally known. However, it will be especially challenging to ensure that the necessary HIV/AIDS clinic workers are found without weakening the healthcare structure by pulling workers out of existing programmes.

It has not been possible during the planning process to adopt a detailed strategy for meeting the human resource needs of the programme in the outlying years, although it is assumed that first-year needs can be met without significant impact on the healthcare system. A key recommendation is that a thorough study be completed during the first year of the programme to develop a specific human resources plan for the programme.

6.1 Current Conditions

Detailed information on the current number of employed healthcare workers in Tanzania across public and private facilities is not readily available. There is, however, some data which give indications of the current state of employment.

The MoH Statistical Abstract for 2002 indicates that for 2001 approximately 36,000 healthcare workers are employed in public facilities. The ideal distribution of these workers is indicated in Table 5, which shows the number of workers in various categories authorized for each of the four major types of facilities. However, information suggests that the distribution is skewed, with referral hospitals being fully staffed in many areas of operation, while regional and district hospitals, particularly in more rural areas, are seriously understaffed.

Table 5. Authorised staffing levels for individual health facilities/institutions

Cadre	Referral Hospitals	Regional Hospitals	District Hospitals	Health Centre
Medical Officers	48	8	3	-
Assistant Medical Officers	10	-	5	1
Pharmacists	4	1	-	-
Pharmaceutical assistants	8	-	1	1
Laboratory technicians	25	-	3	-
Laboratory technologists	3	5	-	-
Laboratory Assistant	-	-	-	1
Clinical Officers	-	-	13	3
Nursing officers (General)	-	18	10	-
Public Health nurse A	4	1	-	-
Public Health nurse B	-	5	-	-
Specialist nursing officers	75	4	-	-
Nurse/Nurse midwife	328	58	33	4
Total	502	100	68	10

Source: MoH staffing levels for health institutions (1999)

The medical schools on the other hand have been generating graduates throughout the hiring freeze. Table 6 shows the incremental total output/graduates between 1998 and 2002. Since there have been few jobs for these graduates in the public sector, it is thought that there is a significant pool of unemployed or underemployed trained workers in some classifications. Particularly in the physician and nursing categories, however, there have been many opportunities for employment in the private sector and outside of Tanzania, and the pool of in-country healthcare workers in some classifications is probably not large.

Table 6. Total medical personnel graduates during a given year (1998-2002)

Main Cadres	1998	1999	2000	2001	2002	Total
General Practitioners/						
Medical officers	30	42	50	61	67	398
Paediatricians	1	2	2	0	2	14
Public Health	3	2	15	19	19	84
Pharmacists	14	17	19	14	21	162
Medical Laboratory						
technologists	10	5	8	4	10	88
Medical Laboratory						
technicians	24	37	28	33	35	285
Registered nurses	703	469	724	925	748	6604
Midwives	366	409	398	408	497	3839
Paediatric nurses	12		13		15	69
Public Health nurses	34	24		20	11	197
Other Specialized						
nurses	16		12		31	109

6.2 Basic ARV Treatment Team

The treatment of PLWHA can be deceptively straightforward, but in reality can be quite complex. Reasons for complexity include: the importance of adherence, the frequency of adverse reactions, the eventual onset of resistance, and the fact that it is life-long in nature. The nature of the treatment nearly always mandates a team approach, and the establishment of treatment teams in a clinic dedicated to treatment

and care of HIV/AIDS clients is the norm in most programmes. It is strongly felt that the team approach be the standard in Tanzania.

A recommended basic team structure has been adopted and is described below. Local variations to this structure are possible and in some cases may be preferable, particularly where greater integration with existing staff and programmes is possible. The Care and Treatment Unit should carefully review the proposals of target facilities, however, to ensure that the minimum standards of treatment, counselling, and other care can be provided by a structure which differs from that described here. Further, this basic team structure has been used to forecast human resource needs nationally, and to budget for these needs. It is expected that alternative structures will not materially change human resource planning or the budget on a national basis.

The recommended basic ARV treatment team would consist of:

- One Prescribing Clinician (PC) such as an MD or Medical Officer.
- Five ARV Evaluating Clinicians (EC), usually AMO or COs.
- Two treatment counsellors - nurse/counsellors who focus primarily on treatment related issues
- Five monthly counsellors - nurse/counsellors who focus on giving lifestyle and adherence counselling to patients every month.
- A health aide (to help with patient follow-up and social services related to adherence).
- A significant percentage of the following professionals are also required: a pharmacist, a laboratory technician, a nurse/phlebotomist, and a full-time clinic administrator.
- Support personnel for each ARV clinic setting would include a receptionist, a cleaner/messenger and possibly additional health aides to help follow-up lost patients. In larger clinics, it is expected that several treatment teams will be established with access to professional and administrative personnel supporting more than one team.

In sites without access to an MD/MO, such as some district hospitals and levels below, the team may utilize an AMO as Prescribing Clinician, two CO's as Evaluating Clinicians (EC), and the three nurse/counsellors, one health aide and other technical and support personnel noted above.

6.3 Staffing Needs

One way to determine staffing needs is to track the number of patient contact minutes for each staff member for each visit of a patient throughout the year. **Annex 2** shows the estimated time each patient would spend with a staff member during the first year of treatment and every year thereafter. Different scenarios are shown for patients on treatment and for those being monitored. This methodology allows for a good assessment of the total number of additional staff effort necessary to support the ARV treatment programme.

Table 7 shows the number of staff necessary for each of the first five years of the programme, expressed as FTEs (full time equivalents) assuming treatment of the number of patients each year estimated in the scale up model of **section 2.5** above, and monitoring of about three times as many HIV+ individuals not yet on treatment.

Table 7. Projected medical personnel requirements

Projected annual need of FTEs for the programme							
	Y1	Y2	Y3	Y4	Y5	Total	%
Prescribing clinician	31	74	111	142	150	507	5%
Evaluating clinician	136	345	534	705	776	2496	27%
Treatment counsellor	53	161	288	416	505	1423	15%
Lifestyle counsellor	164	432	693	937	1062	3287	35%
Pharmacist	26	73	121	168	195	583	6%
Phlebotomist	17	44	71	96	109	337	4%
Lab technician	32	86	140	190	217	666	7%
Annual Total	459	1216	1957	2654	3014	9299	100%
Cumulative Total	459	1674	3632	6285	9299		

On the advice of Tanzanian clinicians with extensive experience in the country, we have based our planning on a model in which all staff work 200 days per year. In each of those days, prescribing and evaluating clinicians see patients four hours per day while the remaining staff see patients for eight hours a day. It has been explained that paperwork, training, and other duties restrict actual clinician-patient contact hours in most cases to four hours. If facilities can significantly increase the number of hours clinicians see patients, it is clear that the human resource recruitment problems would be substantially lessened.

It is noteworthy that the largest category of healthcare workers needed is in the counselling area. In the VCT discussion (Section 5.2) it was observed that there is a need to develop a professional cadre for counsellors. These figures from the clinical side reinforce that conclusion.

6.4 Recruitment Strategies

To help ensure sustainability of lifelong treatment and care, the programme will focus on building indigenous human resource capacity in the healthcare sector. Given the scope of the needs across all healthcare activities, however, it will be a sizeable challenge to meet the needs of the care and treatment programme.

To determine how healthcare personnel can be recruited for delivery of ARV therapy without crippling other healthcare sectors, it is imperative to conduct a thorough healthcare human resources audit. By taking stock of the kind of personnel available in terms of their numbers, location and skills and qualifications, key gaps and opportunities can be identified.

At least three areas seem promising at this time, however, for recruitment in the early stages of the programme.

- The key potential group from which to source medical practitioners is among the trained who are not employed in healthcare professions. Given that the training of medical practitioners has continued through the hiring freeze, it is thought that there is a pool of personnel available for recruitment and further training.
- A second area for recruitment comprises the newly trained. This group is ideally brisk with new skills, part of which could be training in HIV/AIDS. They are also relatively easier to bring on board compared to the trained and employed but not currently in the health sector. This group is probably not particularly large, however.
- The third recruitment prospects are qualified Tanzanians currently out of the country. It is unknown how productive an effort to recruit these personnel will

be. Possibly some medically trained personnel have left the country because jobs were not available. However, it is believed that the promise of better salaries, working conditions, and benefits available in other countries was a major reason for many workers leaving their home.

Low salary levels are a major barrier to attracting healthcare personnel in most, if not all, categories. The Civil Service Department has adopted a plan to raise salaries over a five-year period, but success depends on annual appropriation levels approved by the Parliament. In the meantime, the Department has promulgated the Selective Accelerated Salary Enhancement (SASE) programme.

SASE allows selected public employees to receive immediately salary increases equal to the planned five-year level salary under a national plan to improve public sector compensation. Presently, it means about a 50% increase in salary for most positions. The programme, also known as “topping up” is supported in all cases by contributions from donor countries or agencies to cover the incremental increase in the first year, with the government covering an increasing proportion over the next four years such that the donor’s contribution is zero by the end of five years.

A requirement of SASE is that the “topping up” only be offered when it is tied to employee performance, with performance targets and reviews every six months. The Civil Service Department has recommended that MoH use SASE, with financial support from the HIV/AIDS Care and Treatment Programme, to help recruit healthcare workers for the programme.

The following strategic recommendations are made to address the human resource challenges:

- A thorough study should be initiated as soon as possible to audit the current healthcare human resource availability in Tanzania, project increases in availability of personnel under existing plans, and develop recommendations for meeting the human resource needs both of the HIV/AIDS Care and Treatment Programme and other segments of the healthcare sector. Funds have been budgeted to support such an effort.
- It is understood the WHO office in Tanzania, in cooperation with several donor countries, is undertaking a study of healthcare human resource issues. To the highest degree possible, the study recommended above should be coordinated with the WHO effort and be complementary in its goals and activities.
- Maximum use should be made of the SASE programme, consistent with the goal of not destabilizing other healthcare activities.
- For the first-year of the programme, MoH should make maximum effort to recruit new workers from the suspected pool of trained healthcare workers not employed in healthcare and from Tanzanians who have left the country. The results of this effort should help inform the audit/study which will be progressing simultaneously.
- The MoH should immediately begin discussions and plans with medical schools to increase the number of graduating nurses and other practitioners who could be available during the last two years of the programme, when needs are the greatest.
- As has been discussed in other sections, the CTU should encourage maximum integration with existing activities in healthcare facilities, consistent with the necessity of providing competent treatment to an increasing number of PLWHA. In some cases, greater integration should decrease the number of new workers needed.

- The CTU should work with target facilities and the MoH to attempt to increase the number of hours clinicians actually see patients during a single day.
- The MoH, in cooperation with other agencies, should strive for development of a meaningful career management system. All personnel, and in particular those dealing with treatment of HIV/AIDS, can be encouraged to develop long term careers in the area. This can be done both through further training and promotion on the basis of excellence in performance.
- To address the proportion of healthcare workers who are themselves HIV+, the MoH should develop workplace programmes to encourage early enrolment in care and treatment clinics. These programmes should also address issues of safety and protection for healthcare personnel, including PEP, to allay any reluctance to work in HIV/AIDS Care and Treatment clinics.
- The programme also should consider alternative reward strategies for retention, for example offering scholarships for further training, transport allowance and staff housing.

6.5 Sustainability of Additional Personnel

The HIV/AIDS Care and Treatment Plan has a five-year horizon, and as has been noted includes strengthening the overall healthcare infrastructure of Tanzania as one of its four major goals. It is therefore essential to ensure that the additional capacity developed through this initiative will be sustainable after the currently scheduled five years.

The sustainability imperative, combined with recognition that many healthcare facilities are currently severely understaffed, supports a plan that the government become fully responsible for worker compensation over a rolling five-year period. This will be achieved by adopting a phased approach: for the first two years of employment the programme will be responsible for the entire compensation of newly hired healthcare workers, and then starting in the third year, the government will begin a phased assumption of responsibility for compensation.

To achieve this, and recognizing that the largest number of personnel will be required in the latter years of the programme, the phased absorption would be done on a cohort basis with each cohort being defined as a person who is employed within the same year. For the first two years of each cohort's employment, the programme would cover the entire amount necessary for compensation. For years three, four and five, the government would take up 25%, 50% and 75% of compensation respectively, and then from the sixth year be fully responsible for compensation. This plan would require additional support from outside sources beyond the five-year period for workers hired after the first year. Strategies for managing a longer term need for outside funding are discussed in Section 11.6, Financial Management.

6.6 Training

Training healthcare personnel is critical to the success of the HIV/AIDS Care and Treatment Programme. This training must address the needs of all healthcare workers involved in the care and treatment of patients with HIV. Such training will have two key components: a "theoretical training" course and a "practical training" period in an ARV clinic. Lessons learned in other ARV therapy projects have taught that a training curriculum must be up-to-date internationally but relevant to the specific local situation in which it is implemented.

Botswana's MoH has recently overseen the development of such a "theoretical training" course which began with international expertise but was adapted to the local situation. The ongoing HIV/AIDS/ARV training programme (KITSO), which has been improved through continuous field testing, will be adapted to the situation in Tanzania

utilizing Master Trainer Physicians and Senior Nurse Tutors, in a Training of Trainers (TOT) model. Permission has been obtained from Botswana to make the sharing of this existing training curriculum possible

The proposed training curriculum consists of 12 lectures each of which can be taught in about one hour. The current format is in PowerPoint slides but could also be copied into transparencies for use on an overhead projector. This format also can easily be printed and photocopied for use as trainee notes. Such formats are most easily used for teaching large groups of trainees, but other tools for small group or individual self-learning are also available such as CD-ROM with an audio track of the lecture paired with each slide. Finally, a lecture can also be transcribed to accompany each slide with written descriptive teaching notes, helpful for the development of new faculty familiarizing themselves with a lecture.

Valuable learning also takes place during the question/answer/discussion sections that follow each lecture for approximately 30 minutes. Additional time is devoted to discussing actual case presentations with open-ended questions based on recent patient situations. These case presentations, also presented in a PowerPoint slide set (adaptable to transparencies), serve to highlight important teaching points. This course is accompanied by a written examination designed to test practical information taught in these lectures and is indicative of a trainees' comprehension of the theoretical material presented. Competence in this course could be rewarded with an official MoH certificate and a qualification to proceed to practical training in an active ARV clinic.

The "practical training" programme depends on the availability of practicing HIV experts prescribing ARVs in a busy clinic setting. A new trainee requires experience with a minimum of 8-10 patients in various stages of ARV treatment (initiating, continuing and switching ARVs) who experience common management problems (ARV toxicity both manageable or requiring ARV changes, and ARV virological failure requiring ARV switches). The entire process can be done in as short as four weeks practicing under an experienced HIV clinician with sufficient patient exposure.

In order to meet the long-term needs of the Tanzanian medical education system, the theoretical curriculum could also be incorporated into the medical and nursing curriculum for all healthcare workers (i.e. schools for MDs, AMOs, COs, nurses, Pharmacists, and Pharmacy Technicians). An advanced theoretical HIV/AIDS curriculum is also being developed that is appropriate for the Continuing Medical Education (CME) of ARV providers, leading to a cadre of expert healthcare workers capable of updating the Tanzanian National HIV/AIDS education system as new advances in HIV medicine are developed throughout the world.

The theoretical programme will also be adapted to teach the fundamentals of HIV/AIDS care and treatment to healthcare workers not directly involved in the ART clinics, attempting to reach all workers in the country before the end of five years.

7. DRUGS AND CONSUMABLES PROCUREMENT AND DISTRIBUTION

Overview

The supply of drugs (both ARVs and those for OI treatment and prophylaxis), vitamin supplements, laboratory equipment and reagents, and other supplies is a critical portion of the project. Not only should their receipt by the end user be guaranteed and constant, but also given their high value, they need to be shipped and stored securely.

While determination of the purchasing entity and some of the relevant processes are still to be finalized, the Medical Stores Department (MSD) will play the critical role of clearing, storing and distributing the respective products to the end user facility. The current MSD inventory system is computerized and will be adopted to include any other necessary elements of tracking which become necessary.

To ensure the process runs smoothly, MSD will appoint an individual whose primary responsibilities will be limited to overseeing the procurement and distribution of drugs, supplies and equipment for the Care and Treatment Programme.

7.1 Purchase and Import

The entity that will purchase and import the necessary products will be determined by MSD and the Care and Treatment Unit, after consultation with the Clinton Foundation, based on an analysis of supply reliability, quality of goods, and cost effectiveness. The purchasing entity will ensure delivery of the goods to the port of entry into Tanzania and arrange for insurance as appropriate.

The Clinton Foundation, with its inherent purchasing power stemming from involvement in multiple country programmes, will negotiate lower prices with manufacturers of drugs, vitamin supplements, lab equipment and reagents than Tanzania could expect from single country negotiations. The Foundation is expected to arrange blanket contracts and purchase orders with several vendors that the Tanzanian government can avail themselves of for direct order of products.

Provisions guaranteeing fee-free clearance of all drugs, equipment and supplies designated for use in the Care and Treatment Programme will be included in a Memorandum of Understanding to be signed by the Government of Tanzania, the Clinton Foundation, and other participants in the Programme. The details of this MoU will be shared with the Tanzanian Revenue Authority to reduce delays at the port of entry and to ensure that no additional cost is incurred (e.g., importation duty, VAT).

The Care and Treatment Unit will consult with the Pharmacy Board to ensure products being ordered are registered in Tanzania, and thus can be legally imported. Should this not be the case, the Pharmacy Board has agreed to fast track any registration applications submitted by the CTU or the purchasing entity.

7.2 Clearing, Storage and Distribution to Healthcare Facilities

Once goods enter the country, MSD will be responsible for clearing them through customs, storing and distributing to the end user facility.

MSD was created by Parliament in 1993 with the objective of providing Tanzania with a more efficient, centralized medical supply and pharmaceutical procurement and distribution system. While controlled by the Ministry of Health, MSD operates as a private organization with an independent board of Trustees overseeing operations. MSD is fully supported by the fees it charges for services provided, and currently delivers goods in excess of 70 Billion Tanzanian shillings (USD \$ 70 million) in value.

Considering their current scale of operations, continuously developing expertise and central role in the MoH, MSD is the natural choice to handle clearing, storage and distribution operations. The HIV/AIDS Care and Treatment Programme fits into their current operations with just a few modifications. The discussion below highlights changes which MSD will make in the current method of operations to accommodate the special needs of the Care and Treatment Programme.

Distribution Model

In its current distribution procedures, MSD moves products from the port of entry, through its central warehouses in Dar es Salaam to eight zonal warehouses throughout the country, and then gives custody to the respective District Medical Officers (DMOs). The DMO is then responsible for the final of distribution of products to individual health facilities. There is a need for stricter controls over the products destined for the Care and Treatment Programme, particularly drugs, both because of their value and susceptibility to pilferage, and to ensure they reach their target locations on time. MSD, therefore, will bypass the normal role of the DMOs and deliver these specific products directly to certified health facilities. This process will include any voluntary and private providers that receive certification to be part of the programme.



* Zonal Store Locations

Air Transport

MSD maintains Zonal Stores in eight locations: Dar, Iringa, Mbeya, Moshi, Mtwara, Mwanza, Tanga and Tabora. These stores, as can be seen on the map, are distributed evenly across the country. Most of them are within a day's drive of the central warehouses in Dar es Salaam, so land distribution by truck is adequate. However, for three select zonal stores, Mwanza, Tabora and Mtwara, that are currently not accessible by road within 24 hours due to distance and conditions of the roads to those areas, airlifting of products, particularly ARVs, will be the prudent course of action. MSD, which handles the national vaccination programme in this manner, has agreed to airlift critical supplies, including all ARVs, for the Care and Treatment Programme to these three stores.

Security

As mentioned above, the security of goods at all points of transfer and storage is a primary concern, not only due to the value of products and thus the need to reduce any incidents of loss, theft or pilferage, but also due to the need for maintaining continuous supply available to patients at all times. Security at all points in the process will therefore be improved accordingly to meet the necessary standards.

At the central warehouses and zonal stores, special secure metal cages, similar to those currently used for narcotic products, are being installed to accommodate the increase in volume. Access to these secure locations will be limited to authorized personnel only, and an appropriate paper trail will be strictly enforced and audited.

Transfers both to zonal stores and finally to end user facilities will be done using the current fleet of MSD vehicles that already have a secure compartment installed in them for valuable and sensitive goods. Depending on the increased volume to be transported, these secure compartments will be upgraded accordingly. In addition, should the need arise, armed escorts can be arranged by the Ministry of Home Affairs for internal transfer trucks.

MSD also has a comprehensive insurance policy which covers the goods throughout their delivery chain and thus any financial losses incurred could be recouped. Despite this assurance, loss of product will be minimized as much as possible, owing to the recognition of the need to maintain constant supply to all facilities enrolled in the programme.

Cool Storage

Some of the products, in particular laboratory reagents, paediatric suspensions and proposed second-line drugs, need cool storage facilities. Cold boxes will therefore be provided as necessary for the trucks while each zonal store will be assessed for capacity to absorb additional products within their current cold rooms. Healthcare facilities will similarly be surveyed to ensure they have sufficient cold-chain capability.

7.3 Inventory Management

Given the value of products and the need to ensure no stock-outs, strict inventory management at all levels is necessary for the Care and Treatment Programme to be effective. All responsible personnel must be cognizant that even brief stock outs could have catastrophic consequences for patients reliant on these drugs.

Through the support of USAID, MSD has a computerized inventory system for all its warehouses that tracks products by batch numbers and expiry dates. MSD is now in the process of implementing an ordering system for all healthcare facilities which, when fully in place, will change the current “push” system of periodic, pre-defined distribution of medication kits to a “pull” system that reflects actual facility need. It is expected that this improvement will be fully operational by 2005.

In the first six months of the Care and Treatment Programme being rolled out for each facility, appropriate quantities of products will be pushed to the facility based on projections of the number of patients to be enrolled at the site. Frequent reporting of activity will be required to make close monitoring of available stock of products possible. This reporting will be sourced from a daily dispensing register which will be linked to patient records, a version of which currently exists for the TB and Leprosy programme. The data will then be shared with and captured by MSD for aggregation of overall national usage.

After the six-month mark, a point at which sufficient data should be available to project demand, each institution will then be responsible for ordering the appropriate levels of drugs needed. This will be a combination of quantity needed to sustain enrolled patients, along with a projection of new ones to enter the cohort, a number which will be dependent on the facility’s capacity to expand its treatment component. Once fully established, this system will be valuable in projecting overall national need.

7.4 National Drug Control

Again, recognizing the need for control of access to the ARVs, and trying to limit haphazard use in the public, the Pharmacy Board will issue a circular that any importers and wholesalers of ARVs in the country may sell them only to licensed pharmacies supervised by a registered pharmacist. This is in line with the Food, Drugs and Cosmetics Act 203 which establishes the Tanzania Food and Drugs Authority (TFDA) that will regulate the provision of safe, effective and good quality

pharmaceuticals across the country. In addition, any pharmacy selling ARVs to the public should only do so on presentation of a prescription from a prescriber in an accredited facility. The timing of the issuance of this circular will need to be well coordinated to ensure that an adequate number of facilities are accredited and thus those individuals currently on ARVs can still access the drugs.

It is not proposed to assume total control over the drugs such as in the NTLP programme, the only entity in the country that has access to TB drugs. Given that the HIV/AIDS programme is not undertaking to provide all possible combinations of drugs, and that there is a number of individuals (albeit small) who have already started on disparate regimens, access to the drugs they have already started on cannot be denied. It is therefore necessary to leave this window open and make possible the continued but strictly regulated importation and sale of ARVs in the country.

8. LABORATORY FACILITIES AND EQUIPMENT

Overview

Establishing and staffing adequate laboratory services throughout Tanzania will be one of the greatest challenges faced by the ARV Care and Treatment Programme. By the second year of implementation, approximately one million CD4 counts will need to be determined annually, building to 5.6 million tests by the fifth year if treatment goals are met.

Effective laboratory services are essential to screen the population at large to determine HIV status, to identify patients immediately eligible for treatment, and to monitor the condition of HIV+ patients so that timely treatment can be initiated. Nothing is more important for the success of the programme.

Presently, lack of sufficient trained personnel, outmoded or inoperative equipment, uncertain supply of reagents, and paucity of maintenance procedures and technicians hinder the provision of laboratory services.

At the national level, the Care and Treatment Unit will coordinate a comprehensive programme to supply new laboratory equipment, consumable supplies, and additional technicians trained in HIV-related lab procedures. The CTU will also plan for maintenance of equipment so that it can remain in constant use.

8.1 Current State of Laboratory Services in Tanzania

The Tanzania laboratory system is currently in a state of reconstruction. In 2002, a Ministerial Task Force was commissioned to review the state of national laboratory service, and develop appropriate recommendations. Its key findings were:

- The level of funding for labs is low and has continued to decline even though they are significant revenue generators for the hospitals in which they are located in. Lab equipment is therefore poorly maintained and serviced.
- Even if facilities were staffed at capacity, which they usually are not, many services are not available due to inadequate facilities e.g., broken down machinery and lack of continuously available reagents.
- The lack of an effective supervisory mechanism has taken its toll with standards not being maintained appropriately.
- As a result of poor services offered, clinicians generally have developed limited confidence in lab results.
- Procurement processes for lab equipment, maintenance and reagents are not managed by lab staff thus little coordination occurs. MSD is typically the channel for procurement and resupply, but has no laboratory expertise, thus adding to inefficiencies in the system.

Consequently, the task force's recommendations were:

- The creation of the National Health Laboratory Services (NHLS), an autonomous body that would own and be responsible for running national, zonal and regional labs administered independently from the hospitals. The NHLS would staff, equip and maintain these facilities. In line with Local Government Reforms that transfer power to local governments, district level labs and below would continue to be run by their respective local governments. Discussions to implement this recommendation are currently underway.
- The re-establishment of the Central Pathology Laboratory (CPL) as a central and autonomous entity from MUCHS

- Procurement processes for lab equipment and supplies should be coordinated and overseen by a competent body (e.g., CPL). MSD's storage and distribution channels across the country could then be leveraged to ensure efficient procurement and resupply.

The CPL is currently being reconditioned with support from Abbott Laboratories to become a state-of-the-art facility that will be able to adequately handle the increased workload and functionality required to support the HIV/AIDS care and treatment initiative. The CPL will likely be the centre for (re)training laboratory technicians for other centres across the country.

The CPL has CD4 counters and chemistry capacity that supports Muhumbili Hospital and other surrounding institutions (government, NGO and private). With the refurbishment effort currently underway, significant capacity will be added without requiring extensive input from the HIV/AIDS Care and Treatment Programme.

All other referral centres have CD4 counters (or are in the process of acquiring one) and necessary chemistry capability. However, due to a lack of reagents and technical support for training and maintenance of equipment, little use is being made of the CD4 machines at present. At the same time, it is recognized there has been little demand for use of these machines since treatment opportunities are very limited.

Regional facilities vary greatly. Some in urban areas offer a more complete range of services. Several have received support from foreign donors and/or NGOs and have fully capable chemistry and haematology capabilities.

At the district hospitals, testing is typically done using basic, non-automated procedures. Laboratory services in dispensaries and health centres are limited to manual haemoglobin and blood count tests.

Laboratories throughout the country have also suffered from a shortage of qualified personnel, partly due to the hiring freeze instituted in 1991. However, the available technicians and technologists are typically able to cope with the workload, due to factors such as the lack of functioning equipment (e.g. breakdowns or lack of reagents), and eroded clinician confidence in test results. An improvement of laboratory facilities will necessitate hiring more persons. It may be a difficult process to attract back to public service individuals who have entered the private sector and are likely earn a better salary compared to the government pay-scale.

8.2 Laboratory Requirements of the HIV/AIDS Care and Treatment Programme

The need to have laboratory services available to peripheral healthcare facilities does not necessarily mean having extensive laboratories at each level of the system. A good balance between centralization and decentralization needs to be struck, depending on the robustness of the blood samples, cost efficiency, ease of management and quality assurance. Laboratory requirements for the programme can be determined by the type of testing needed.

- **HIV testing**

Knowledge of one's serostatus is the entry point to the entire process. Given the programme's aggressive care and treatment goals, it is critical that HIV testing be available and performed at all levels of the healthcare structure. Considerable progress has already been achieved in Tanzania with the adoption of rapid tests for diagnosis across the board. This positive move needs to be augmented with supported expansion of VCT centres throughout Tanzania to reach the current goal of one VCT centre per 20,000 individuals. Funds have been budgeted to help accomplish this goal.

In addition, there are several established clinics that are capable of HIV testing. These include NTLP clinics, ANC facilities, blood donation and transfusion sites, STI clinics, and in-patient wards. The MoH has made strides in providing testing kits and training for those working in these facilities, and these will be augmented through this programme.

It is proposed that routine testing be provided free of charge and that it will become a normal part of healthcare for all individuals.

Currently laboratory facilities rely on local arrangements with organizations such as AMREF to provide quality assurance. To provide a national quality assurance programme, it is critical to establish and enforce universal guidelines, with appropriate testing algorithms and strict quality assurance programmes. HIV ELISA capability (relevant for both QA, resolving discordant rapid tests, and testing of children less than 12 months old) will need to be expanded across key hub locations, servicing facilities in their catchment areas, in line with the recommendation below to create centralized HIV reference laboratories across the country.

- **CD4 testing**

Once seropositivity is established, the next crucial step is to determine whether an individual is ready for treatment or if he or she will require periodic monitoring.

Two organizational options exist for CD4 testing. The first one involves having a centralized testing facility which collects samples from surrounding facilities, performs the tests and remits results back. The second one relies on decentralized testing with less sophisticated systems/equipment at lower level healthcare facilities.

In the Botswana HIV/AIDS programme, a large HIV reference lab was built, centralizing CD4 counts at a significant cost savings (about 5 to 10 times cheaper than de-centralized FACS count model). It was also found that the central lab was easier to manage not only in terms of logistics and maintenance, but also for quality control and assurance. CD4 samples have been shown to last at least 3 to 4 days without a significant drop in quality, thus making transportation to the lab possible from distant locations.

The laboratory task force, recognizing these advantages, as well as the problems associated with lower tech methods of CD4 counting (e.g., use of dyna-beads), recommends the establishment of hub facilities which will be equipped with automated machinery with high throughput and quality to satisfy the needs of the programme. While actual locations are still to be selected, important considerations include pre-existing capabilities, ease of establishment and scaling up, and the transportation network available. The referral hospitals, Muhimbili, KCMC, Bugando, Mbeya and Mnazi Mmoja are potential centres.

- **Haematology and Clinical Chemistry**

Constant monitoring of the patient's physiological status is necessary once therapy has been initiated. Unlike CD4 counts, clinical chemistry and haematology have to be done quickly and close to the patient. All laboratories, especially those at lower level institutions, will need to be strengthened appropriately by providing necessary equipment and possibly additional personnel. The strengthening of these facilities can have significant impact on the overall quality of healthcare delivery in the country since these tests are not limited to individuals with HIV/AIDS.

- **Viral Load and Resistance Testing**

Routine use of viral load and resistance testing is not planned unless new technologies become available that eliminate current high costs and difficulties in the protocols. Viral load and resistance testing will therefore be primarily used to

evaluate difficult cases, and measure the impact of the programme. Consequently, this capability will be established only at the reference laboratories, and possibly not at all of them.

- **Other tests**

Because HIV/AIDS frequently leads to opportunistic infections, capacity needs to be established to detect and treat OIs as they occur. Of particular interest is having robust TB testing capability, beyond current sputum based testing.

Also, given that efavirenz is an alternative in the first line for those who are nevirapine intolerant, pregnancy tests will be required for all women of child bearing age who cannot tolerate nevirapine.

8.3 Operational Plan for Laboratory Services to Support Care and Treatment.

- **Space and equipment**

Depending on the type of test, a tiered system of services will be established. Widespread use of HIV test kits will be encouraged and supported through all channels possible. Clinical chemistry and haematology testing will be necessary at all prescribing institutions. By year five all hospitals from the district hospital level and above will have the capability. CD4 counting, viral load and resistance testing will be primarily limited to top tier reference laboratories which will be established over the course of the programme. This is summarized in Table 8.

Table 8. Healthcare facility laboratory participation.

Test	HIV reference laboratory	Regional hospital lab	District hospital lab	Primary healthcare centre
HIV serology	+	+	+	+
HIV diagnosis in infants	+	-	-	-
CD4 cell count	+	-	-	-
Clinical Chemistry	+	+	+	+
Haematology	+	+	+	+
Viral load and resistance	+	-	-	-
Robust TB testing	+	+	+	-
Pregnancy test	+	+	+	-

Given the geographic distribution of the first year institutions, thorough analysis needs to be done to establish the full needs of each tier of facility and develop appropriate strengthening plans, particularly with the lead times necessary to order, transport and install new equipment, along with any necessary construction and training.

- **Training**

Training of all laboratory staff involved in the programme will be required both in the fundamentals of ARV medicine, and in specific areas of laboratory services. There are five main areas of concentration for training that will need to be addressed:

- Training of existing staff on new procedures
- Training of new lab technologists and technicians
- Training in lab management
- Training in lab data management, both paper based and computer based.
- Advanced in-service training for those who will be recruited.

The laboratory taskforce also suggests that the current training schools be supported to produce well trained lab technologists qualified in HIV/AIDS procedures. Both advanced and ordinary diploma levels need to incorporate HIV/AIDS procedures.

Such support could entail re-assessing various training curriculum to include HIV related testing, relevant training materials, equipment and reagents.

- **Quality assurance**

Manuals on standard operating procedures will be drafted by the MoH, being sure to leverage knowledge and experience gathered by the Harvard-Botswana Partnership project. The MoH is currently developing and recruiting laboratory inspectors to perform internal quality control that will include personnel and supplies, condition of equipment as well as adherence to established procedures.

For external quality control, all accredited labs will participate in a national quality control programme at least semi-annually. The Care and Treatment programme encourages cooperation with already existing support programmes, such as UK-NEQAS, ACP, WHO and QASI.

8.4 National Health Laboratory Services Proposal

The relevance of strong laboratory services within the healthcare delivery system is particularly underscored by the needs of this programme. Given its current state and the need for significant strengthening, a central body, such as the proposed National Health Laboratory Services (NHLS) will be important, not only to drive the process of improvement, but also monitor and ensure quality control for laboratory institutions. Even though no direct action has been taken yet to move from recommendation to actually establish such an entity, this programme would benefit greatly from it, and therefore supports such a move.

9. STRENGTHENING AND CERTIFICATION OF HEALTHCARE FACILITIES AS ARV PROVIDERS

Overview

In order to reach a significant portion of the more than half million HIV+ Tanzanians who are expected to require treatment over the next five years, it will be necessary to involve hundreds of healthcare facilities, public and private, of various sizes and capabilities spread equitably throughout the country.

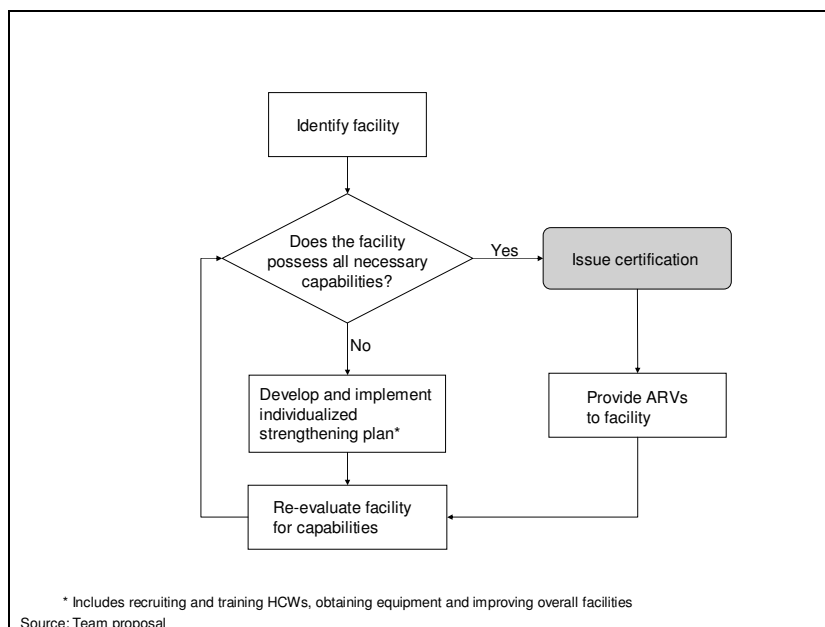
The engine that will drive this mammoth undertaking is a system to strengthen the ability of healthcare facilities to effectively treat patients, and when strengthened, to certify them as eligible to receive ARVs.

The certification process should be rigorous to ensure quality healthcare, but flexible enough to account for differences in facilities' size, organization and mission across the public-private spectrum and from the referral hospital level to the local dispensary level.

9.1 Selection and Strengthening Process

The Care and Treatment Unit will be responsible for developing a system to identify facilities as potential ARV providers and to manage the strengthening process. The objective will be to establish clinics to prescribe ARVs, monitor patient condition, and provide other care and treatment for HIV+ patients.

Figure 8. Preparing facilities for certification



In conjunction with other divisions of the MoH, the Care and Treatment Unit will target on an annual basis the public facilities where ARV therapy will be administered. This targeting will be undertaken in full consultation with authorities at the local and regional level. Section 2.4 indicates the facilities that have been targeted for the first year of the programme, and gives a conceptual plan for the number and type of facilities which might be targeted in successive years in order to reach the objective of providing ARVs to at least 400,000 Tanzanians by the end of five years.

It will be important to plan sufficiently far in advance to ensure that facilities can be strengthened to be full participants in the programme in time to meet the goals of the scale-up plan. This is especially true, of course, in the case of ensuring sufficient personnel will be available at the proper time and for facilities which cannot participate without major construction work.

The key tool in preparing facilities for participation in the ARV programme will be a Strengthening Plan, jointly prepared and agreed to by representatives of the Care and Treatment Unit and managers of the target facility, to assess the needs of the facility and correct any deficiencies. It is planned that Regional Medical Officers, working as extensions of the Care and Treatment Unit, will take a major role in the targeting of facilities as well as in the preparation of Strengthening Plans. The RMO's office will be given additional resources to carry out this function, as explained in Section 11.3.

Each Strengthening Plan will develop detailed strategies for dealing with issues such as:

- Designation of a facility leader to take responsibility for preparation of the strengthening plan and supervision of the facility's participation in the HIV/AIDS Care and Treatment Programme.
- Creation of a local advisory committee.
- The recruitment of personnel for the Care and Treatment Team and other supporting units of the facility.
- Training of Care and Treatment Team members.
- Orientation and training of other healthcare workers at the facility and in nearby facilities.
- Establishing appropriate clinic space.
- Laboratory plan.
- Inventory of existing equipment, and ordering of new equipment.
- Maintenance plan for equipment.
- Building secure pharmacy.
- Participation in PMTCT programme.
- Preparation for linking with NTLP, ante natal, and STI clinics.
- Linkages with other facility operations (wards, other clinics, support units etc.).
- Linkages with community resources (VCT, social support, etc.).
- Participation in locally based continuous care and IEC activities.
- Preparation of a facility-specific Operations Manual for HIV/AIDS Treatment and Care.

It is important to note that planning for strengthening should not be limited only to looking at the facility itself. For example, an analysis of the availability of VCT services in the area must be undertaken and preparations made for increasing the number (or effectiveness) of sites if necessary. These activities will require coordination with other sections of the MoH, community leaders and resources, NGOs and other providers of VCT services.

Other important activities outside the facility might include:

- Briefing local officials and leaders and organizing district or lower level advisory committees.
- Cataloguing available continuous care activities in the community, and making plans to increase where necessary.
- Enlisting resources to help educate families and communities about the basics of HIV/AIDS medicine, particularly the role that treatment can play and the difficulties inherent in lifelong treatment for affected individuals and their families.

The Strengthening Plan will spell out in detail the implementation steps which are necessary for bringing the facility to the point where it can be certified ready to receive, prescribe and distribute ARVs. The plan will also assign responsibility for each implementation step and develop a time line that will show when the strengthening process will be completed.

The Care and Treatment Unit will be responsible, again working closely with the Regional Medical Officer as its representative, to monitor progress in implementing the Strengthening Plan and ensuring adherence to the approved timeline.

9.2 The Certification Process

A major challenge for the Care and Treatment Unit will be to design a certification process that is rigorous enough to ensure quality care for patients at all levels, and yet is flexible enough to allow for creativity, initiative and reflection of unique local conditions on the part of the target institutions.

The key values the Care and Treatment Unit will look for in considering an application will include:

- **Quality** – Does the facility have a treatment system in place that will ensure quality health care for HIV/AIDS patients?
- **Quantity** – Is the facility prepared to treat a significant number of HIV+ individuals upon certification, and to increase the patient load as the staff gains experience?
- **Accessibility** – Will treatment be made available on an equitable basis to all Tanzanians regardless of ability to pay?
- **Accountability** – Are procedures and safeguards in place to ensure that funds, equipment, supplies, and medicines are properly used and accounted for?

With these values in mind, the strengthening plan should help prepare a facility to meet the minimum requirements outlined below. While this HIV/AIDS Care and Treatment Plan, particularly in Chapter 4, suggests specific methods for meeting the minimum requirements, the Care and Treatment Unit should encourage flexibility and maximum integration with existing healthcare resources. Target facilities should feel free to tailor the way they propose to meet a specific requirement in a manner which reflects the facility's individual needs and characteristics. In this way, best practices can be developed to aid in the scaling up efforts.

Certification Requirements

1. Designation of a leader for the facility's participation in the programme.
2. At least one trained Treatment and Care Team sufficient in scale to treat a significant number of HIV/AIDS patients, as determined by the Care and Treatment Unit.
3. Laboratory services in place including appropriate equipment, trained operators, and an effective maintenance plan. (And/or a plan to access laboratory needs from another facility)
4. Organization and appointment of a local advisory committee.
5. Demonstration that linkages have been made with VCT centres, antenatal clinics, NTLP clinics and STI clinics, and other sources to ensure a sufficient number of treatment-eligible patients are routed to the certified facility.
6. Secure pharmacy storage available with adequate ventilation, refrigeration, and sufficient storage space.
7. Preparations made for participation in a system for procurement of drugs.
8. Appropriate number of consultation/treatment/counselling rooms available.
9. Where the facility has an antenatal clinic, participation planned in a PMTCT programme.
10. A plan in place to link with and support organizations helping to ensure continuous care in the home and community, and the education of PLWHA, their families, and their communities.
11. A system in place to track patients and maintain/transmit medical records.
12. Systems in place to ensure funds, equipment, supplies and medicines are properly accounted for.
13. Adoption of a facility-specific *Operations Manual for HIV/AIDS Treatment and Care*.
14. In the case of non-public hospitals, a Memorandum of Understanding in place.

9.3 Participation by Non-public Facilities and Providers.

Private facilities of all types (FBO, NGO, for-profit), which receive some 40% of visits for healthcare in Tanzania, are key to the success of the HIV/AIDS Treatment and Care Programme. It is imperative that they be motivated and encouraged to participate in the strengthening and certification process.

It is expected that many private facilities will self-select themselves as target facilities, and the Care and Treatment Unit should develop a system to ease the application process. Some private facilities probably can be certified with minimal assistance from the Care and Treatment Unit. However, when appropriate, strengthening plans should be completed for private as well as public facilities. In those cases, voluntary facilities will have access to funds and other resources on an equitable basis with public facilities.

Very early in the development of the programme, outreach efforts should be undertaken by TACAIDS and the MoH to advance the participation of the non-public sector. Actions such as the following should be taken:

- As soon as this HIV/AIDS Care and Treatment Plan is approved, copies should be sent to all non-public facilities in the country, along with additional information giving clear guidance as to how they can participate.
- The Care and Treatment Unit should target non-public facilities as potential programme participants to ensure equitable availability of ART throughout the country and initiate contact with these facilities to promote their participation.
- Non-public facilities, and organizations which represent them, should be well represented on all steering and advisory committees at both the national and district level.
- Representatives of non-public facilities and organizations should be invited to all briefing and organizational meetings organized for members of MoH.

The certification process for a non-government facility to participate in the Care and Treatment Programme must include negotiation of a Memorandum of Understanding (MoU) between the Ministry of Health and the governing body of the facility. This MoU should describe the responsibilities of the MoH and the responsibilities of the governing body in implementing the Care and Treatment Programme at the specific facility.

As soon as possible, the Care and Treatment Unit should publish a model MoU which will give guidance to facilities and government negotiators.

10. INFORMATION, EDUCATION AND COMMUNICATION

Overview

The Information, Education, and Communication (IEC) component of the HIV/AIDS Care and Treatment Programme is focused on the dissemination of information to four key targets: the general public, healthcare workers, HIV seropositive individuals, and those who care for HIV seropositive individuals. The effectiveness of the IEC strategies should be assessed in the overall monitoring and evaluation efforts and the strategy should be revised accordingly as the programme moves forward.

The IEC interventions under this plan will be based on the following principles:

- Understanding the goals and objectives of the plan and working to accelerate the implementation process towards achievement of the set goals and objectives
- Understanding the major obstacles of ART and utilization of services such as VCT, HIV/AIDS care and treatment clinics, and STI clinics.
- Using the most effective and innovative communication approaches for each target population.
- Reinforcing parallel support activities to enhance understanding and uptake of the plan by the target audience and general community.
- Guided use of the media

The size and scope of the Tanzanian Programme Plan provides a unique opportunity to design innovative strategies to manage antiretroviral therapy. Some IEC activities may include pilot programmes to explore innovative approaches, such as the use of a telephone hotline for questions regarding disease and antiretroviral management and the development of a website to disseminate up-to-date training materials to trainers throughout the country.

Additional IEC activities may include:

- Promotion of VCT services
- Stigma reduction activities
- TB (DOT) Programme Coordination
- Promotion of adherence of both medication for those on treatment, and visits for all identified HIV+ individuals
- Education on prevention and risk reduction activities
- Nutritional campaign and supplement information

10.1 General Public IEC Programmes

The dissemination of information to the general public will be conducted through mass and local media outlets and will be staged to be compatible with the scale-up of the national programme. Key messages are envisioned to include the existence of a treatment programme for advanced HIV disease, public education about antiretroviral therapy (specifically the mechanism of therapy, eligibility for therapy, and the logistics of accessing therapy). Other messages will encourage those who do not know their serostatus to visit a VCT centre and opt for post test support networks expected to be established soon. The public campaign will be designed and developed in collaboration with many key stakeholders, including those organisations with experience in social marketing and related activities.

Since the plan is being implemented in stages, VCT promotion activities, nutrition education campaigns and stigma reduction will mainly dominate the initial IEC activities targeting the general public category of audience. Messages will aim to empower individuals, particularly PLWHAs, to promote respect for human rights in health and other social settings. Activities will also include the development of various IEC materials and messages that portray positive and hopeful images of HIV/AIDS in general and PLWHAs in particular. Other specific IEC interventions will include: -

- Aggressive campaigns to educate the general public (in the project area), about HIV/AIDS care and treatment, with emphasis on the use of ARVs
- Education for family members on importance of adherence and to support patients receiving ARVs in order to reduce the development of drug resistance.
- The fact that ARVs are part of preventive therapy will be given prominence throughout the campaigns.
- Promotion of VCT services through:
 - IEC materials development and dissemination
 - Mass media campaigns

Print materials

For the promotion of VCT and ARV access print IEC materials may include:

- Posters – distributed and posted at strategic areas within public structures – including health facility buildings, public offices and schools.
- Billboards along highways, major towns and cities
- Brochures – for distribution in health facilities, schools, NGOs and during special events (e.g. World Health and AIDS Days, International Trade Fairs, etc.).
- Regular Newsletters – circulated to service providers and other partners in the field. Newsletters are important tools for field workers and can be source of local HIV/AIDS news when readers are given the opportunity to contribute to the paper.
- Wall and table calendars – distributed to as many stakeholders as possible throughout the country.
- Books and booklets targeting health workers in public and private health facilities, AIDS service organisations, schools and public and private offices.
- Regular Newsletters for professional and other special groups.

For non-health workers, including patients and family members, relevant IEC materials will be developed consisting mostly of print media to take home and read. The main content of these materials will be:

- Importance of drug compliance and adherence
- Importance of good and balanced diet and nutrition
- Signals for drug resistance and or reactions
- Contact persons and institutions where patients can get help in the neighbourhood area and possible hotline contacts.

- Any other additional information for support network in the area.

Mass media programmes

The mass media programmes will reinforce major issues in the other media, but will specifically address issues, which require community and social change. It is anticipated that advocacy and promotional activities would be adequately addressed through the media. Special programmes on stigma reduction will be planned and aired on both radio and TV stations. Arrangements can be made with specific media houses for reduced rates, particularly for long-term arrangements with such stations.

10.2 Healthcare Workers

The dissemination of information to healthcare workers ties into the training programme, and should focus on basic knowledge regarding HIV disease and antiretroviral therapy as well as sensitisation to reduce HIV stigma and will be directed primarily towards healthcare workers who are not part of the antiretroviral programme. A curriculum of educational materials will be developed by the MoH (with potential collaboration with non-governmental partners) and adapted from existing curricula. As part of the site certification process, persons with key management and supervisory roles at each institution will undergo this training. Once they have completed their own training, the healthcare team will conduct training for other healthcare workers in their institution, using the educational materials developed by the MoH, and could assist with training of other healthcare facilities within their catchment area.

Support materials

The IEC programme will help prepare reference books or booklets in order to improve and sustain understanding of the different issues. These materials may include the following:

- National guideline books for the management of AIDS patients on ARVs.
- Booklets for quick reference on the management of drug reactions.
- Booklets on ARV drug interactions including pharmacological information for the different ARVs.

10.3 PLWHAs

IEC efforts directed towards HIV seropositive patients and those who care for them will be focused on empowering individuals to effectively manage HIV disease and therapy. The MoH (potentially in collaboration with non-governmental partners) will develop and adapt educational materials to be used in counselling visits at antiretroviral clinics. The MoH will also serve as an information resource, providing data and relevant reference materials for advocacy groups and other stakeholders who are developing programmes to assist persons with HIV disease or those affected by HIV disease.

During this period of ARV therapy being widely used in the country, key areas for education for PLWHAs will include the following:

- The issue of emerging ARV resistant HIV strains in the general population.
- The importance of adherence to ARV in order to reduce the occurrence of resistant strains and maintain a viable first line therapy.
- Safe sex.
- The issue or desire of PLWHAs to have children and raise a family.

- Other developments in the course of ARV use as well as surveillance and research findings.

It is anticipated that a wide range of information will be generated throughout the period that will require close follow up for purposes of sharing across the country for a co-ordinated approach. Many times PLWHAs are part of the solution and will be deployed to work with IEC experts at different levels and settings to enhance compliance, support and understanding of the plan and relevant processes.

11. MANAGEMENT AND ADMINISTRATION

Overview

If the ARV Care and Treatment Programme is to meet its goals, it will require recruiting and training several thousand new healthcare workers, building or renovating hundreds of new facilities, and obtaining and distributing millions of dollars worth of drugs. The proposed budget of \$26 million in the first year, growing to \$205 million by the fifth year would soon be larger than the current expenditures in Tanzania on all other healthcare activities combined, primarily due to the cost of drugs.

The management demands of such a programme are sobering, but the scope of the public health emergency it is designed to address and the positive economic and social benefits to Tanzania if it is successful, mandates that no less of an effort be expended.

The Minister of Health will have ultimate responsibility for success of the HIV/AIDS Care and Treatment Programme, ensuring that its goals and objectives are supported by and integrated into all elements of the MoH.

Direct management and planning for the programme will be lodged in the office of the Chief Medical Officer, enlarged to include the National AIDS Control Programme (NACP). A new Care and Treatment Unit (CTU) will be created within NACP to directly administer the programme. The CTU will need to establish linkages with all elements of the MoH, other government agencies, NGOs, donor countries, technical experts, and community resources. Financial management will be an important part of its responsibilities, shared with other government agencies.

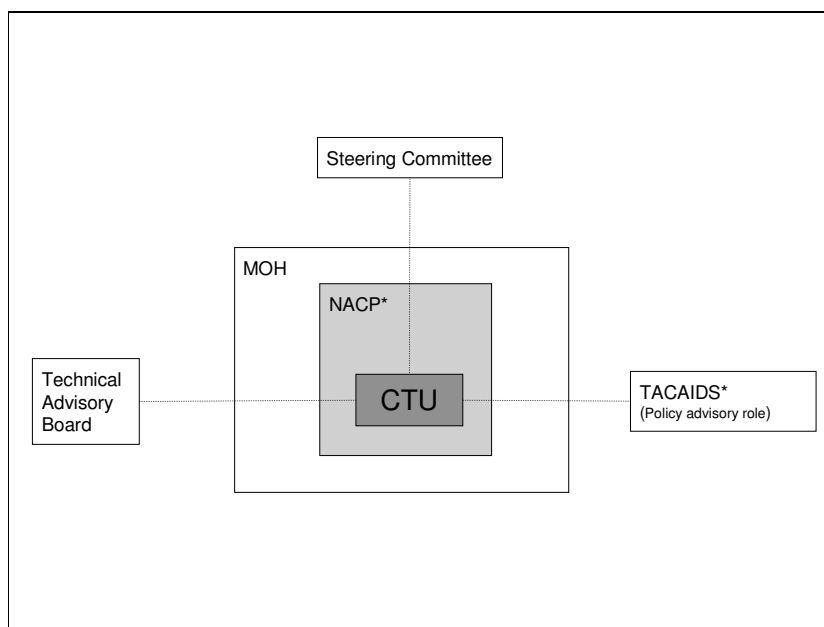
In addition to the national management structure, the programme will require participation by regional and district managers and the local government agencies that support them.

An important part of the administrative structure will be monitoring and evaluation procedures used by management to continuously monitor and modify the programme from lessons learned in the field and in response to changes in technology and methodology.

11.1 Management Structure

The CTU, to be established within the NACP, is proposed as the focal point of management control and coordination for the ARV Care and Treatment programme. (See Figure 9)

Figure 9. Location of CTU within MoH



A number of technical advisory committees should be formed by the CTU, including at least:

- Clinical Care Advisory Committee
- Laboratories Advisory Committee
- Information, Education and Communication Advisory Committee
- Training Advisory Committee
- Pharmacy and Drug Procurement Advisory Committee
- PMTCT Advisory Committee
- VCT Advisory Committee
- Social Support Advisory Committee
- Monitoring and Evaluation Committee

11.2 Care and Treatment Unit Organization and Staff

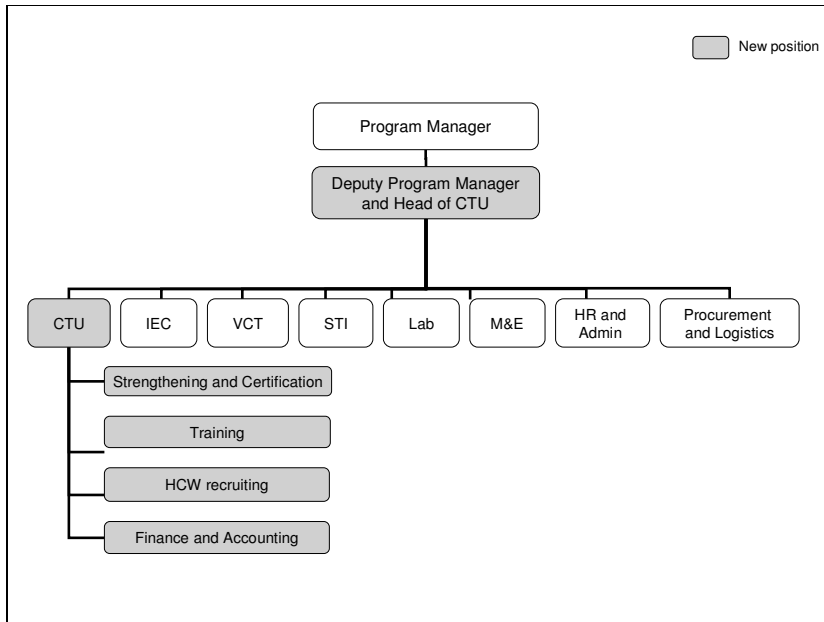
Organization of the CTU

The nature of the CTU will evolve over time, with two main phases:

- For at least the first five years of the programme, the CTU will function as a type of “implementation task force,” charged with establishing and scaling up a complicated, expensive, nationwide programme of services to clients who, without the programme’s intervention, are (or will become) terminally ill. Strong skills in change management, hands-on administration of a detailed planning and implementation process, and a sense of urgency are prerequisites for success in this phase.
- After the scale-up is complete, the nature of the CTU responsibilities will change in many respects. Careful coordination of a programme which is widely dispersed and managed by local authorities will be the primary function of the CTU in this phase. Coordination, including strong monitoring and evaluation skills, rather than hands-on management can be expected to become more pronounced as the Tanzania government’s decentralization initiative takes hold.

The CTU will be a separate unit within the NACP, but at the same time will draw on other divisions within the NACP to take responsibility for many of the functions which are part of its charge. Since the HIV/AIDS Care and Treatment Programme will be, by far, the largest programme within NACP, this hybrid type of organization is appropriate and will ensure that the entire NACP is enlisted in ensuring the programme's success. (See Figure 10)

Figure 10. Location of CTU within NACP



The Coordinator of the CTU will have a dual role, also serving as Deputy Programme Manager of the NACP. This is a position which has been under discussion for sometime within the MoH, but has not yet been created. This aspect of the organization, again, will ensure that the NACP as a whole will be organized and motivated to support the implementation of the HIV/AIDS Care and Treatment Programme.

- **Care and Treatment Unit Staff**

CTU Coordinator and NACP Deputy Programme Manager - A senior level manager and administrator with successful experience implementing large and complicated programme or enterprises should be recruited to fill this position. Medical experience should not be required, nor should the position necessarily be filled by a person with government experience, although either would be a plus.

The person recruited should be asked for a minimum five-year commitment, with the realization that the person qualified to undertake this task may not be motivated to remain in the more static situation which the “second phase” of the CTU evolution will bring.

The importance of finding the right person for this position cannot be overemphasized. The success of the programme will depend on this person being a strong manager, an effective leader, and an entrepreneur within the government structure.

Other key staff members:

- Strengthening and Certification Coordinator

- Drug Procurement and Distribution Coordinator
- Construction Coordinator
- Training Officer
- Accountant and Financial Management Supervisor

Other NACP staff who would play key roles:

- Information, Education and Communication Coordinator
- Monitoring and Evaluation Coordinator
- Counselling and Support Coordinator
- Laboratory Coordinator
- Administration

Essential linkages within MoH:

- PMTCT Coordinator
- Laboratory Coordinator

In addition to the above managers, the HIV/AIDS Care and Treatment Programme will provide financing for the establishment of several other positions within the CTU, the other divisions of the CTU, and the PMTCT and Laboratory offices under the Head of Diagnostic Services. (See Annex 3 for a line-up of new staff and their roles.)

11.3 Regional Medical Officers' Management Role

The nature and scope of the ARV Care and Treatment programme make it unlikely that it could be successfully managed throughout the nation from a centralized office without additional help in each of the regions.

Regional Medical Officers will have an important role in coordinating the strengthening and certification process, and other activities of the programme, at the regional level. To assist the RMOs, the programme will sponsor the creation of a position of Regional HIV/AIDS Care and Treatment Coordinator in each of the regions. In some larger regions, an assistant coordinator may be advisable. Funds have been budgeted to provide an assistant in a third of the regions.

The RMOs responsibilities to the programme will include:

- Identification and scheduling of targeted facilities to become strengthened and certified.
- Assisting the targeted facilities with preparation of the strengthening plan, acting as the liaison between the facility and the CTU Strengthening and Certification Coordinator.
- Supervising implementation of the strengthening plan.
- Assistance with technical and logistical advice to the leader and staff of the HIV/AIDS Care and Treatment Clinic, and where necessary, liaising with the NACP.

11.4 Recruitment Strategies

Timely recruitment of a competent management team, prepared to start work with minimal need for training or other preparation is necessary if the programme is to meet its first year goals. Several impediments to timely recruitment have been noted, including:

- The length of time necessary to arrange for new job titles and descriptions with the Civil Service Department and prolonged delays in authorization to create and fill new positions.
- The difficulty of recruiting top-level administrators with significant experience at current government salary levels.
- Delays inherent in the normal recruiting policies and procedures, and difficulty in conducting a widespread search within a short time period.

For these reasons, it has been suggested that the Clinton Foundation (or its designee) could fill a valuable role by taking charge of the recruiting effort, hiring the management team, and contracting their services to the MoH for the first 2-3 years of the programme. Tanzanian government officials, however, could be fully involved in the actual search and selection process of the individual managers.

11.5 Counterparts

One of the major goals of the Clinton Foundation is to strengthen the overall infrastructure of the health sector in countries where it sponsors HIV/AIDS Care and Treatment Initiatives.

The Foundation, therefore, would not suggest a plan to manage the initiative in Tanzania with the use of expatriates or non-government consultants for the long term. However, in addition to the length of time necessary to recruit management personnel, concerns have been expressed that it may be difficult to find Tanzanians who have had experience managing large-scale programmes to fill the key leadership roles.

The Clinton Foundation proposes, then, a system of “counterparts” to provide overall management for the programme. Under this system:

The Foundation (as proposed above) would recruit Tanzanian leadership and contract it to the MoH to get the programme started. These positions should be phased into regular government service as soon as possible.

The Foundation would recruit and hire, through a designee organization with expertise in ART and management of complex medical programmes, a “counterpart” for each of several key positions. These counterparts would most likely be expatriates, whose primary qualification would be experience in programme management and expertise in a particular discipline (e.g. laboratory management, human resources, accounting, procurement and distribution etc).

The MoH manager and the counterpart manager would work as a team, with the counterpart acting as a partner, a mentor and an advisor, to establish and manage the programmes during the early years.

The designee organization which would recruit and hire the counterparts, would also be retained to provide services as a “team leader” for the counterparts. One important aspect of this role would be to ensure that the counterpart is truly imparting skills and experience to his or her partner as the programme progresses, and not just exerting management control in place of the partner.

By the end of the third year of the counterparts’ employment, a plan would be agreed upon for a schedule to phase out the counterpart position.

12. MONITORING AND EVALUATION

Overview

A comprehensive monitoring and evaluation plan is critical for the successful implementation of the proposed HIV/AIDS treatment and care programme. In this section of the business plan, we describe the M&E plan for each phase of the implementation cycle that involves provision of resources and inputs for the planned activities, measures to determine the extent to which the planned activities are realized, and documentation of the immediate programme outputs, as well as programme outcomes and long-term impact.

During the planning phase, members of the multidisciplinary task force worked together to define realistic programme goals and objectives. Later, team members developed a detailed and comprehensive implementation plan, and appropriate indicators for monitoring programme implementation and evaluation of the long-term impact were identified. The indicators were selected on the basis of their ability to reliably measure the programme goals and objectives, while realistic targets and benchmarks were selected taking into account the scope of the proposed programme and resource availability. The final M&E strategy was developed to address the following main questions:

- To what extent are the planned activities implemented in a timely way and within the allocated budget?
- Does the programme reach its goals of providing quality services to the target population?
- Has the programme succeeded in minimizing the occurrence of severe side effects and emergence of drug resistance?
- Has the programme resulted in improved quality of life and survival among people living with HIV/AIDS?

12.1 Routine Evaluations

Three main types of evaluations will be performed:

1. Process evaluation will focus on monitoring the availability of resources and other inputs for each goal/objective, implementation of the planned programme activities, and documentation of the immediate programme outputs. During the implementation of the proposed programme, information about the availability of the required resources and inputs will be collected. Since human resource development is important for the successful implementation of this programme, detailed information about staff positions filled at each Care and Treatment Unit (CTU) and personnel performance will be routinely collected.

Other aspects that will be monitored as part of the process evaluation include development of a training programme for members of care teams, identification of institutions which will be involved in the implementation of the planned programme activities, development of treatment guidelines, number of staff trained, number of healthcare teams formed, number of health facilities certified to provide HIV/AIDS care and treatment, and the number of health facilities providing treatment and care at defined time points.

2. Programme Outcome measures: The immediate programme outcome measures will be the number of PLWHA who are seen at the health facilities certified to provide treatment and care for initial screening to determine their eligibility, and the number of PLWHA who are enrolled in the various treatment and care packages.

Another important programme outcome is information about the distribution of CD4+ lymphocytes count among patients seen at treatment centres for initial screening to determine their eligibility and those enrolled in the treatment programme. As described previously, subjects with CD4 counts less than 200 cells/ml will be started on HAART, while those with CD4 counts above 200 cells/ml will be followed regularly for prevention of OIs and monitoring disease progression. Information about the distribution of CD4 among subjects not eligible to initiate therapy will be used to estimate the number of patients that will require treatment at various time points during the implementation of the programme.

3. Impact evaluation: Provision of treatment and care for PLWHA is expected to be associated with improved quality of life and survival. Hence, measures of quality of life and survival will assume a central role in the programme impact evaluation. However, it is not possible to estimate the programme impact as relates to each specific programme goal/objective. Because of this, the overall programme impact will be assessed by using a few indicators that might be related to more than one programme goal/objective.

As part of the services to be provided, detailed information about the status of health of patients prior to initiation of therapy will be collected. This information will be updated regularly during the follow-up visits. Appropriate measures of quality of life and survival will be developed and used to assess the impact of the treatment programme. Quality of life measures at baseline will be compared with measures at follow-up visits to assess improvements over time.

12.2 Long Term Programme Assessment

There are other cross-cutting long-term measures of impact that are of direct interest to the programme and the international community. It is unlikely that the routine M&E that will be implemented by this programme will collect information that could be used to assess long-term programme impact. Specialized studies will be required to provide information that will help to assess the impact of the proposed programme on the following areas:

- What are the minimum laboratory tests required to ensure safety and effectiveness of antiretroviral treatment?
- Emergence of drug resistance and whether this differs by HIV-1 subtypes.
- AIDS-related hospital admissions and disease burden in the context of ART.
- Economic impact of HIV/AIDS treatment and care.
- Decreased HIV/AIDS stigma and increased discussions and openness.
- Changes in sexual behaviour among patients receiving treatment and in the general population, and how this might be associated with HIV transmission.
- Overall programme impact on HIV transmission.

It is envisioned that the implementation of a comprehensive M&E plan will require well-developed data collection systems and plans for analyses, as well as the use of multiple data sources to provide the required information. Existing data sources will be identified and integrated in the proposed M&E system.

This strategy will help to minimize new data collection efforts, and increase utilization of data that is being collected by different institutions in Tanzania. As part of the planning process, institutions willing to collaborate in data collection activities and participate in the analyses and report writing will be identified. Members of the Clinton Foundation and Harvard School of Public Health will contribute in this effort and provide long-term technical support.

13. ZANZIBAR PARTICIPATION

Overview

Zanzibar will be a full participant in the HIV/AIDS Care and Treatment Programme, beginning in the first year with clinics established both on Unguja and Pemba. Although sero-prevalence rates are much lower in Zanzibar than on the mainland, the Zanzibar AIDS Commission (ZAC) and the Ministry of Health and Social Welfare (MoH&SW) are dedicated to preventing increases in prevalence and providing effective treatment for patients who are HIV+. While controlling their own programme, Zanzibar officials will work closely with the CTU to ensure that they have access to the latest clinical information, for the procurement of drugs, equipment and consumables, and to coordinate joint IEC efforts.

13.1 Problem Definition

Zanzibar is made up of two sister islands (Unguja and Pemba) and several smaller ones. The population in the 2002 was estimated at slightly less than 985,000.

A careful study of prevalence rates was completed in June 2003, a collaborative undertaking by the MOH&SW with participation and support by WHO, UNDP, UNICEF and MUCHS. This study projected a fairly low prevalence rate of 0.6% for the general population, but with women at 0.9% and men at 0.2%. Prevalence was highest among young adults 25-34 years of age at 1.5% and nearly as high in the 35-44 age group at 1.3%. This population-based study was also compared to existing ANC sentinel surveys and the findings were found to have a high correlation.

The healthcare system in Zanzibar is administered by the MOH&SW through a three-level structure of hospitals and primary healthcare facilities. At the top of the pyramid is Mnazi Mmoja Hospital in Stone Town on Unguja, which serves as the referral hospital for Zanzibar. There are three district hospitals in Pemba, 2 cottage hospitals on Unguja, and 2 on Pemba, and 104 primary healthcare facilities (72 on Unguja and 32 on Pemba).

Private healthcare facilities, both non-profit and for-profit, play much less of a role in the overall provision of healthcare services in Zanzibar than on the mainland. It is expected that only one private hospital would have the scale to establish an HIV/AIDS care and treatment clinic. Nevertheless, private facilities should be encouraged to play a supporting role wherever possible.

An HIV/AIDS clinic has recently been established at Mnazi Mmoja, providing VCT services, laboratory analysis consistent with its limited equipment capabilities, treatment of opportunistic infections, and other care of PLWHA as it can, given its restricted access to drugs. About 20 patients on HAART were being managed by the clinic in 2003, most of whom initiated treatment on the mainland and all of whom purchase their own drugs.

13.2 Care and Treatment Plan

HIV/AIDS care and treatment clinics will be established at Mnazi Mmoja and Chake Chake hospital on Pemba during the first year of the programme. For budgeting purposes, it is assumed that each facility will have a full care and treatment team as outlined in Section 6.2. It is expected, however, that the number of personnel in each team will be phased in as patient loads increase, and the full team may not be required for some time. These teams will manage a clinic substantially in line with the guidelines contained in Chapters 4 and 5 of this document, modified as appropriate to fit any special circumstances in Zanzibar.

Since current prevalence levels indicate only about 6,000 Zanzibar residents are HIV+, it is probable that two clinics can handle all of the HIV+ residents which would

be identified and referred to the clinics within the next several years. The plan provides for a third clinic in the third year, and a fourth in the fifth. The funds budgeted for these clinics, however, could be reallocated to establish additional part-time clinics in several locations.

Currently, Zanzibar has three free-standing VCT sites and 11 hospital-based VCT sites. Significant increases in counselling and testing of youth are being provided by a recently awarded Global Fund grant. It is expected that these facilities, plus aggressively pursuing linkages with ANC, TB, STI clinics and referrals from general healthcare facilities will provide a steady flow of HIV+ patients to the clinics. Resources have been provided in the plan, however, to establish up to 10 additional VCT sites in the first two years of the programme.

Drugs and other consumables will be requisitioned through the MSD as Zanzibar currently uses this channel for many of its supplies. Laboratory testing for CD4 levels will be conducted at the referral hospital level only, but other laboratory equipment for routine testing will be purchased for each clinic location.

Initial training of clinicians and counsellors should be completed through attendance at courses established on the mainland by the CTU. There should be ample funds in the overall training budget to accommodate the Zanzibar students. As the clinics on Zanzibar become more established, it should be possible to provide at least the clinical portion of training at the Mnazi Mmoja clinic.

It will be important in Zanzibar as elsewhere to train the entire healthcare workforce in the fundamentals of ART and other care and treatment topics. Resources have been provided for this training.

The Global Fund grant includes initiatives to involve community service organizations and religious education sites in the fight against HIV/AIDS. Zanzibar authorities should ensure these organizations are fully aware of the care and treatment programme and that they are encouraged to help with support for patients and their families and communities.

13.3 Management and Administration

The HIV/AIDS Care and Treatment Programme will be administered in Zanzibar by a small care and treatment unit (ZCTU) located within the MOH&SW. The unit will be directed by a senior level clinician who will be charged with both overall management responsibilities as well as direct responsibility for the strengthening and certification process, training and recruitment of healthcare workers, liaising with other ongoing activities in Zanzibar such as IEC efforts, laboratory services, and VCT services.

Because of the size of the overall programme, consideration should be given to combining this leader's activities with a role in the Mnazi Mmoja clinic.

The ZCTU head will be assisted by an associate director who should take direct responsibility for procurement and other logistical activities, and by a half-time IEC coordinator. A clerk will fill out the unit.

The ZCTU, although independent of the programme on the mainland of Tanzania, should work closely with the CTU to ensure it is kept abreast of latest changes in the programmes and so that it can benefit from the experiences of the many clinics which will be operating throughout Tanzania.

13.4 Budget Summary

It is proposed that Zanzibar have a separate budget for personnel, capital expenditures, and miscellaneous expenditures. Funds have been budgeted within the overall budget, however, to account for drugs and other consumables for the comparatively small number of patients who will be enrolled in the Zanzibar portion of

the programme. Arrangements should be made by the CTU to ensure that Zanzibar is able to requisition these drugs and supplies through MSD at no further cost. Zanzibar should also have access to training courses on the mainland.

Table 9. Summary of Zanzibar budget (\$000)

	2004	2005	2006	2007	2008	Total
CTU Personnel	\$22	\$22	\$22	\$22	\$22	\$ 111
Treatment team personnel	\$44	\$44	\$44	\$66	\$88	\$287
Facilities upgrade	\$88	\$ -	\$57	\$ -	\$57	\$201
Lab equipment	\$238	\$ -	\$64	\$ -	\$64	\$366
HCW training	\$92	\$ -	\$92	\$ -	\$92	\$276
Other	\$110	\$41	\$51	\$47	\$62	\$312
Total Zanzibar budget	\$595	\$107	\$330	\$135	\$385	\$1,553
Funds flowing to Zanzibar directly	\$214	\$52	\$154	\$52	\$154	\$627

14. BUDGET AND FINANCIAL MANAGEMENT

Overview

The total cost to implement the plan is \$539M over five years, 68% of the cost realized in the final two years of the plan. The costs of drugs, including ARVs and OI treatment, and laboratory services amounts to 67% of the total cost. (Seen Annex 4 for a detailed look at the budget model and assumptions.)

The most important thing to emphasize about the budget is that it results from a best effort to determine how a care and treatment plan in Tanzania might be structured; and then to estimate how much it would cost to implement such a plan. There are no delusions on the part of the framers that the plan will be implemented exactly as written. Implementation will be impacted by a number of factors, including:

- The CTU and programme managers in the field will learn from the successes and failure of actual clinical experience on the ground, and accordingly readjust future plans and activities on a continuous basis.
- Changes in technology, clinical practice techniques, and ARV pharmacology will result from research and development activities and be incorporated into to the programme.

Table 10. Programme budget; values in \$000, except benchmark numbers

Budget summary	Year 1	Year 2	Year 3	Year 4	Year 5	Total	% Total
Drugs	\$6,552	\$18,919	\$42,107	\$70,858	\$98,697	\$237,134	44%
Laboratory & consumables	\$4,561	\$12,803	\$23,435	\$35,995	\$47,876	\$124,670	23%
Medical Staffing	\$1,017	\$4,037	\$9,190	\$16,273	\$24,111	\$54,629	10%
Training	\$2,759	\$4,845	\$5,974	\$9,318	\$10,641	\$33,537	6%
Facilities and Transportation	\$3,579	\$5,059	\$6,976	\$8,855	\$8,861	\$33,331	6%
Management & Administration	\$3,115	\$2,511	\$2,511	\$2,511	\$2,511	\$13,161	2%
Nutrition	\$642	\$1,967	\$4,073	\$6,961	\$10,041	\$23,685	4%
IEC/Mobilization	\$3,571	\$3,732	\$3,774	\$3,776	\$3,677	\$18,531	3%
Zanzibar (additional)	\$254	\$52	\$154	\$ 52	\$154	\$ 667	0%
Total budget	\$26,011	\$53,927	\$98,194	\$154,601	\$206,571	\$539,304	100%
Off-set funds							
Global Fund	\$10,933	\$13,918	\$17,684	\$22,556	\$22,797	\$87,888	94%
GoT share for Human Resources	\$ -	\$ -	\$337	\$1,546	\$4,106	\$5,989	6%
Annual off-set funds	\$10,933	\$13,918	\$18,021	\$24,102	\$26,903	\$93,877	
Annual fund-raising target	\$15,078	\$40,009	\$80,173	\$130,499	\$179,668	\$445,427	
Benchmarks							
Annual cost per individual on treatment	\$1,591	\$828	\$649	\$563	\$488		
Annual cost per enrolled HIV+ individual	\$398	\$207	\$161	\$141	\$122		

Because this programme is unique in terms of its scale, scope and application, there is limited precedent to use for estimating patient demand, facilities requirements, human resource utilization, and the demand for certain cost items, particularly ARVs, OIs and some laboratory services. Budget amounts will likely shift as programme patterns emerge.

14.1 Budget Summary

Drugs

Drugs is the largest single budget category, totalling \$237M over the 5 years of the initiative. Of this amount, 91% goes directly towards ARV purchase for enrolled patients while OI drugs and PEP for healthcare workers account for 9% and 0.1% respectively. All these amounts also include distribution costs that will be incurred within Tanzania.

Drug costs were computed using a current annual cost estimate for first-line ARVs of \$350/patient, discounted 20% per year to account for expected downward pricing adjustments. At the same time, patients will migrate from the first-line ARV regimen to more expensive second and third lines, leading to an overall decrease drug cost per patient of about 9% annually. The second-line regimen is assumed to start at \$1,285/patient annually, again discounted 20% per year. Third-line regimens, not yet determined, were assumed to be 150% of second-line costs.

Table 11: Cost of Drugs (\$000)

	2004	2005	2006	2007	2008	Total
ARVs	\$6,048	\$17,313	\$38,467	\$64,570	\$89,669	\$216,068
OI drugs	\$388	\$1,498	\$3,535	\$6,186	\$8,927	\$20,535
PEP for HCW	\$57	\$47	\$41	\$37	\$35	\$217
PMTCT	\$59	\$61	\$63	\$65	\$67	\$314
Total	\$8,556	\$20,924	\$44,113	\$72,865	\$100,705	\$237,134

Laboratory Services and Consumables

Laboratory is the second largest component of expense, totalling \$125M for the five years. The annual lab test costs which include all tests and consumables associated with both those on treatment and the HIV+ individuals being monitored account for \$62.3M, \$39M of which is for CD4 count tests, with normal blood work (full blood count, liver function, and lipids) accounting for \$19.1M and viral load tests at \$4.1M HIV testing for the general population, a total estimated by working backwards from the treatment targets, totals about \$28M which would provide about 17 million tests over the five years. CD4 count costs have been discounted 5% annually.

New laboratory equipment would cost \$24.6M, which would provide CD4 testing equipment at regional sites and normal blood work equipment at each clinic site. Equipment maintenance and replacement, data management and QA round out the section at \$6.4M and \$3.1M respectively.

Table 12: Cost of Laboratory Component (\$000)

	2004	2005	2006	2007	2008	Total
Lab test costs (incl. consumables)	\$1,063	\$4,427	\$10,299	\$18,348	\$28,178	\$62,315
Data management and QA	\$53	\$221	\$515	\$917	\$1,409	\$3,116
HIV tests for general population	\$1,089	\$3,249	\$5,729	\$8,209	\$9,890	\$28,167
Lab equipment	\$2,142	\$4,265	\$5,682	\$6,647	\$5,932	\$24,668
Equipment maintenance /replacement	\$214	\$641	\$1,209	\$1,874	\$2,467	\$6,404
Total	\$4,561	\$12,803	\$23,435	\$35,995	\$47,876	\$124,670

Medical Staffing

For the five-year programme, \$54.6 has been budgeted for medical staffing. Generally, this figure was determined from the analysis of FTEs necessary to provide the clinical and counselling services recommended in the care and treatment plan (Chapter 4). Latest salary data provided by the MoH was then applied to the FTE data. Additional adjustments included:

- Salaries for doctors (MD, AMO, and CO cadres) and nurses (treatment counsellors and phlebotomists in the FTE analysis) were topped up 50% under the SASE programme.
- The government was assigned responsibility for gradual assumption of certain salary obligations, as explained in Section 6.5.

The amount budgeted, enough to support some 9,000 additional healthcare workers in several classifications, may be greater than will actually be needed for two major reasons:

- Facilities structuring their individual strengthening plans will determine how to integrate the HIV/AIDS Care and Treatment Programme with their existing staff and programmes. This will affect the total number of new personnel needed.
- Widespread use of ART will reduce the impact of seriously ill HIV+ patients on the system as a whole with estimates that as many as 60% of existing hospital inpatients are suffering from HIV+ complications. This may allow resources to be shifted to the HIV/AIDS Care and Treatment Programme.

On the other hand, it is recognized that salary levels throughout the healthcare system are very low in Tanzania, exacerbating the difficulty in adequately staffing facilities and programmes. It is hoped that the government will continue to improve salaries over the five-year horizon of the plan, even beyond the 3% per year currently build into the budget. If so, this would increase the funds necessary to support the plan.

For these reasons, it was felt prudent at this time to budget the full amount necessary to staff all the FTE positions reflected in the plan.

Table 13: Medical staffing (\$000)

	2004	2005	2006	2007	2008	Total
Total HR costs	\$1,017	\$4,037	\$9,190	\$16,273	\$24,111	\$54,629
GoT share	\$ -	\$ -	\$337	\$1,546	\$4,106	\$5,989
CF share	\$1,017	\$4,037	\$8,853	\$14,727	\$20,005	\$48,640

Training

Training is a key part of the entire programme, and is estimated to cost \$33M over five years. The major effort will be training new clinic members, accounting for 67% of the total. Costs in this category range from \$3,000 for each doctor trained to \$1,500 for each counsellor. Funding is provided for each clinic worker to receive five days of refresher training each year.

Additionally, training for all healthcare workers outside of the actual HIV/AIDS care and treatment clinics is provided for, totalling about \$4M. A three-day, primarily worksite training course is envisioned.

Table 14: Training (\$000)

	2004	2005	2006	2007	2008	Total
New training	\$1,392	\$3,194	\$4,967	\$6,552	\$6,440	\$22,545
Refresher training	\$ -	\$303	\$ 1,002	\$2,089	\$3,524	\$6,918
Training of all HCW	\$1,317	\$ 1,344	\$ -	\$672	\$672	\$4,004
Training of Trainers	\$25	\$ -	\$ -	\$ -	\$ -	\$25
Curriculum Development	\$25	\$5	\$5	\$5	\$5	\$45
Total	\$2,759	\$4,845	\$5,974	\$9,318	\$10,641	\$33,537

Facilities and Transportation

The largest expenditure in this category is for renovation or construction of clinical facilities. It is assumed that the average clinic will cover 149 square meters and that construction cost will be \$400/SM. This is at the high end of construction costs experienced for such projects, particularly outside major urban areas, and should provide for quality facilities. Furniture is also accounted for, totalling about \$365,000 over five years.

Other major categories include some \$9M for transport of laboratory samples, estimated at \$1 per sample transported; and \$1 per new patient for medical records, totalling \$3.7M.

A total of \$448,000 is provided in the first year to construct a building to house the CTU. Alternatively, this money could be spread over more years for lease payments if new construction is not the chosen option.

Table 15: Facilities and Transportation (\$000)

	2004	2005	2006	2007	2008	Total
Clinics build out	\$1,371	\$3,278	\$3,755	\$3,755	\$2,563	\$14,721
CTU building	\$448	\$ -	\$ -	\$ -	\$ -	\$448
Maintenance	\$27	\$49	\$56	\$56	\$38	\$227
Furniture	\$34	\$81	\$93	\$93	\$64	\$366
Transport and logistics	\$1,257	\$889	\$1,752	\$2,994	\$4,504	\$11,397
Medical records	\$65	\$261	\$605	\$1,098	\$1,692	\$3,721
VCT	\$377	\$501	\$715	\$858	\$ -	\$2,451
Total	\$3,579	\$5,059	\$6,976	\$8,855	\$8,861	\$33,331

Capital Expenditure Budget

The plan foresees spending about \$44M on capital fixtures, improvements and equipment; a little more than 8% of the total cost of the programme. More than half of this amount is for laboratory equipment, with facility construction or improvement accounting for most of the remainder.

Table 16: Capital Expenditure (\$000)

	2004	2005	2006	2007	2008	Total
Lab equipment	\$2,142	\$4,265	\$5,682	\$6,647	\$5,932	\$24,668
Clinical space build out	\$1,371	\$3,278	\$3,755	\$3,755	\$2,563	\$14,721
Care and Treatment Unit (CTU) building	\$400	\$ -	\$ -	\$ -	\$ -	\$400
Cost of purchase of vehicles	\$840	\$ -	\$ -	\$ -	\$ -	\$840
Furniture	\$92	\$85	\$97	\$97	\$68	\$440
VCT set up	\$377	\$501	\$715	\$858	\$ -	\$2,451
Total	\$5,221	\$8,129	\$10,249	\$11,357	\$8,563	\$43,519

Management and Administration

The total budget for Management and Administration is \$13.2M, of which the largest item is support for the CTU, primarily for personnel, at \$6.1M. The CTU cost includes the salaries and other costs including a housing and home travel allowance for counterparts for the entire five years, although it is expected that at least some of the counterparts may be released beginning at the end of the third year.

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Although a detailed monitoring and evaluation plan has not yet been developed, \$1M per year has been budgeted for M&E activities. It is expected that additional M&E related activities, particularly research, can be supported from funds raised from other sources. In addition \$200,000 per year has been allocated for quarterly financial audits.

A total of \$1.0M over the five years has been budgeted for other technical assistance activities, most of which are expected to be channelled through the counterpart operation. Finally, Just over \$500,000 has been set aside in the first-year for start-up consulting assistance. This amount is intended to finance the major human resource study called for in the plan, assistance with developing new cadres for counsellors, and for other assistance to ensure a rapid and effective start-up of the programme.

Table 17: Management and Administration (\$000)

	2004	2005	2006	2007	2008	Total
Care and Treatment Unit (CTU)	\$1,265	\$1,211	\$1,211	\$1,211	\$1,211	\$6,111
Monitoring & Evaluation	\$1,000	\$1,000	\$1,000	\$1,000	\$1,000	\$5,000
Operational and Financial Audits	\$100	\$100	\$100	\$100	\$100	\$500
Start up funds	\$550	\$ -	\$ -	\$ -	\$ -	\$550
Technical Assistance	\$200	\$200	\$200	\$200	\$200	\$1,000
Total	\$3,115	\$2,511	\$2,511	\$2,511	\$2,511	\$13,161

14.2. Financial Management

Several models are possible for controlling the flow of funds into the programme. It is expected that some variant of the existing "basket funding" or "rapid funding envelope" processes will be used to manage the flow of funds into the country and the financing of the programme. Whatever the model to be used, the plan foresees formation of a board to oversee financing matters and monitor implementation of the plan. This board would be composed of representatives from each of the donor countries, international agencies, and other funders who choose to assist in supporting the programme, plus a representative of the Clinton Foundation.

The final identification of funders who will decide to support the HIV/AIDS Care and Treatment Plan as adopted by the Government of Tanzania (GoT) cannot be completed until after potential participants have had an opportunity to review the approved plan. Therefore, although discussions with GoT officials should continue regarding appropriate funding mechanisms, a decision on the detailed plan can be postponed until after identification of the funders and formation of the board.

An important tool for both financial management and administration of the implementation process will be a Memorandum of Understanding (MoU) completed between the relevant GoT agencies and the Clinton Foundation. Negotiation of this document should begin as soon as the plan is officially adopted by Tanzania, during the roughly three-month period which is expected to be necessary to secure the necessary funding commitments to begin implementation. At the appropriate time, the essentials of this MOU should be shifted to a new document which the donors, through the board structure, will also be parties to.

Finally, it is important to recognize that it is not envisioned that it will be economically feasible for Tanzania to assume the commitments of this programme at the completion of the five-year planning horizon adopted for planning purposes. At the same time, PLWHA who are enrolled in ART during the first five-years of the programme should be given reasonable assurance that treatment will be continued beyond 2008, the final year of budgeting under the current proposal.

It is recommended that the GoT and the donors committed to the present programme undertake a comprehensive review of the programme and the prospects for continued support during the second quarter of the third year of the programme. If it is determined that future support is questionable, adjustments should be made in growth rates to ensure that available funds carry HAART patients enrolled in the current programme as far as possible.

15. ANNEXES

Annex 1: Sample Medical Records Forms

HIV & CUMULATIVE MEDICAL HISTORY

Date of first HIV positive result, clinic: _____	
Baseline CD4 _____	Viral Load _____
Previous Exposure to ARV	<input type="checkbox"/> yes <input type="checkbox"/> no
Supplied by & date : _____	
PMTCT	<input type="checkbox"/> yes <input type="checkbox"/> no
Supplied by & date : _____	
PEP	<input type="checkbox"/> yes <input type="checkbox"/> no
Supplied by & date: _____	

History of PTB	<input type="checkbox"/> yes <input type="checkbox"/> no
Dates of Treatment: _____	
Treatment medications: INH/Rif/PZA/EMB/STP other: _____	
History of:	
<input type="checkbox"/> Relapse <input type="checkbox"/> MDR-TB <input type="checkbox"/> Extra-Pulmonary TB (specify site)	
<input type="checkbox"/> INH Prophylaxis Therapy (IPT)	
details:	

Medical History (circle if present and describe details)
Asthma
Diabetes
Epilepsy
Heart Disease
Hypertension
Malignancy
Peripheral Neuropathy
Psychiatric
Alcohol
STDs
Other:

Opportunistic Infections/Diseases	(dates)				
Cryptococcal Meningitis					
Cytomegalovirus (CMV) Retinitis					
Pneumocystis carinii pneumonia					
Recurrent Bacterial Pneumonia (>2 episodes in past year)					
Kaposi's Sarcoma					
Candida Esophagitis					
Candida Stomatitis					
Confusional State/Memory loss					
Lymphoma					
Invasive Cervical Cancer					
Herpes (severe)					
Wasting Syndrome					
Failure to Thrive					
Loss or delay of Milestones					
Other :					

LONGITUDINAL PATIENT VISIT

Date: _____

LMP _____ Contraception _____

Adequate ART Adherence: YES _____ NO _____

Brief Medical Summary:

PHYSICAL EXAM/REVIEW OF SYSTEMS

Wt (kg) _____ Temp _____ BP _____ Pulse _____ Respiratory Rate _____

General
HEENT headache/oral sores/thrush
Respiratory cough/dyspnea
Cardiovascular
Skin rash/ mucosal involvement/Stevens Johnson Syndrome
Endocrine/Lipodystrophy
GI diarrhea/nausea/vomiting/pain/jaundice/hepatomegaly
GU / women's health
CNS/PNS cognitive/weakness/dysaesthesias
Other

ASSESSMENT AND PLAN

Regimen/Dose change _____

ART Prescription: YES _____ NO _____

Next Appointment date: _____

MD Signature (LEGIBLE) and date : _____

Annex 2: Patient Time Visit model

Patient Visits schedule																														
	Pre 1	Pre 2	0	0.5	1	2	3	4	5	6	7	8	9	10	11	12	Y1 mins total/ patient	13	14	15	16	17	18	19	20	21	22	23	24	Y2 mins total/ patient
CD4<200, symptomatic																														
Prescribing Clinician	-	-	30	20	20	-	-	-	-	-	-	-	20	-	-	-	90	-	-	20	-	-	-	-	20	-	-	-	40	
Evaluating Clinician	-	30	-	-	-	20	20	20	20	20	-	-	-	-	-	20	150	-	-	-	-	-	20	-	-	-	-	20	40	
Treatment Counsellor	30	-	-	-	-	-	-	-	-	-	30	30	-	30	30	-	150	30	30	-	30	30	-	30	30	-	30	30	240	
Lifestyle Counsellor	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	480	30	30	30	30	30	30	30	30	30	30	30	30	360
Pharmacist	-	-	25	10	10	10	10	10	10	10	10	10	10	10	10	10	155	10	10	10	10	10	10	10	10	10	10	10	10	120
Phlebotomist	5	5	-	5	-	-	5	-	-	5	-	-	5	-	-	5	35	-	-	5	-	-	5	-	-	5	-	-	5	20
Lab technician	10	5	-	5	5	-	5	-	-	15	-	-	5	-	-	15	65	-	-	5	-	-	15	-	-	5	-	-	15	40
CD4 200-350, asymptomatic																														
Prescribing Clinician	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Evaluating Clinician	-	20	-	-	-	-	20	-	-	20	-	-	20	-	-	20	100	-	-	20	-	-	20	-	-	20	-	-	20	80
Treatment Counsellor	10	10	-	-	-	-	10	-	-	10	-	-	10	-	-	10	60	-	-	10	-	-	10	-	-	10	-	-	10	40
Lifestyle Counsellor	30	30	-	-	-	-	30	-	-	30	-	-	30	-	-	30	180	-	-	30	-	-	30	-	-	30	-	-	30	120
Pharmacist	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Phlebotomist	5	-	-	-	-	-	5	-	-	5	-	-	5	-	-	5	25	-	-	5	-	-	5	-	-	5	-	-	5	20
Lab technician	10	-	-	-	-	-	10	-	-	10	-	-	10	-	-	10	50	-	-	10	-	-	10	-	-	10	-	-	10	40
CD4 >350, asymptomatic																														
Prescribing Clinician	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Evaluating Clinician	-	20	-	-	-	-	-	-	-	20	-	-	-	-	-	20	60	-	-	-	-	-	20	-	-	-	-	-	20	40
Treatment Counsellor	10	10	-	-	-	-	-	-	-	10	-	-	-	-	-	10	40	-	-	-	-	-	10	-	-	-	-	-	10	20
Lifestyle Counsellor	30	30	-	-	-	-	-	-	-	30	-	-	-	-	-	30	120	-	-	-	-	-	30	-	-	-	-	-	30	60
Pharmacist	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Phlebotomist	5	-	-	-	-	-	-	-	-	5	-	-	-	-	-	5	15	-	-	-	-	-	5	-	-	-	-	-	5	10
Lab technician	10	-	-	-	-	-	-	-	-	10	-	-	-	-	-	10	30	-	-	-	-	-	10	-	-	-	-	-	10	20

Annex 3: New CTU Personnel – Peak staffing levels

Division	New employees	Counterpart
CTU		
Overall	Head of CTU/Deputy NACP manager 2 staff members 1 assistant	??
Strengthen and Certification	Coordinator 5 staff members 1 assistant	Yes
Drug procurement and distribution	Coordinator 1 assistant	Yes
Training	Coordinator 2 staff members 1 assistant	Yes
Accounting and Financial Management	Coordinator 4 staff members 1 assistant	Yes
Strengthening other NACP Units		
IEC	3 staff members	Yes
M&E and Epidemiology	2 staff members 1 assistant	Yes
Counseling and Social Support	4 staff members 1 assistant	Yes
Office Admin and HR	3 staff members	Yes
Laboratory	3 staff members	Yes
Other MoH offices		
PMTCT coordinator	3 staff members	Yes
Laboratory	TBD	??

Other:

- Office messengers
- Drivers

Annex 4: Budget Model Details

Budget Summary (\$000)

	2004	2005	2006	2007	2008	Total	% Total
Drugs	\$ 6,552	\$ 18,919	\$ 42,107	\$ 70,858	\$ 98,697	\$ 237,134	44%
Laboratory & consumables	\$ 4,561	\$ 12,803	\$ 23,435	\$ 35,995	\$ 47,876	\$ 124,670	23%
Medical Staffing	\$ 1,017	\$ 4,037	\$ 9,190	\$ 16,273	\$ 24,111	\$ 54,629	10%
Training	\$ 2,759	\$ 4,845	\$ 5,974	\$ 9,318	\$ 10,641	\$ 33,537	6%
Facilities and Transportation	\$ 3,579	\$ 5,059	\$ 6,976	\$ 8,855	\$ 8,861	\$ 33,331	6%
Management & Administration	\$ 3,115	\$ 2,511	\$ 2,511	\$ 2,511	\$ 2,511	\$ 13,161	2%
Nutrition	\$ 642	\$ 1,967	\$ 4,073	\$ 6,961	\$ 10,041	\$ 23,685	4%
IEC/Mobilization	\$ 3,571	\$ 3,732	\$ 3,774	\$ 3,776	\$ 3,677	\$ 18,531	3%
Zanzibar (additional)	\$ 214	\$ 52	\$ 154	\$ 52	\$ 154	\$ 627	0%
Annual budget	\$ 26,011	\$ 53,927	\$ 98,194	\$ 154,601	\$ 206,571	\$ 539,304	100%
Cumulative budget	\$ 26,011	\$ 79,938	\$ 178,132	\$ 332,733	\$ 539,304		
Yearly distribution	5%	10%	18%	29%	38%		

Benchmarking data

Benchmarking					
	Year 1	Year 2	Year 3	Year 4	Year 5
Number of pple on treatment at year end	16,350	65,150	151,200	274,500	423,050
Drugs	401	290	278	258	233
Laboratory & consumables	279	197	155	131	113
Medical Staffing	62	62	61	59	57
Training	169	74	40	34	25
Facilities and Transportation	219	78	46	32	21
Management & Administration	191	39	17	9	6
Nutrition	39	30	27	25	24
IEC/Mobilization	218	57	25	14	9
Cost per individual on treatment (annual)	1,591	828	649	563	488
	Year 1	Year 2	Year 3	Year 4	Year 5
Number of HIV+ enrolled at year end	65,400	260,600	604,800	1,098,000	1,692,200
Drugs	100	73	70	65	58
Laboratory & consumables	70	49	39	33	28
Medical Staffing	16	15	15	15	14
Training	42	19	10	8	6
Facilities and Transportation	55	19	12	8	5
Management & Administration	48	10	4	2	1
Nutrition	10	8	7	6	6
IEC/Mobilization	55	14	6	3	2
Cost per enrolled HIV+ (annual)	398	207	162	141	122

Demand Projects of patients by class (000s)

	2004				2005				2006				2007				2008			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Adults																				
CD4 <200, symptomatic																				
new starts less deaths	4	4	4	4	12	12	12	12	21	21	21	21	30	30	30	30	36	36	36	36
continuing less deaths	-	4	8	12	16	27	39	51	63	83	104	125	145	175	204	234	264	299	335	370
total	4	8	12	16	27	39	51	63	83	104	125	145	175	204	234	264	299	335	370	406
CD4 200-350, asymptomatic																				
new starts less deaths	4	4	4	4	12	12	12	12	21	21	21	21	30	30	30	30	36	36	36	36
continuing less deaths	-	4	8	12	16	27	39	51	63	83	104	125	145	175	204	234	264	299	335	370
total	4	8	12	16	27	39	51	63	83	104	125	145	175	204	234	264	299	335	370	406
CD4 350+, asymptomatic																				
new starts less deaths	8	8	8	8	23	23	23	23	40	40	40	40	58	58	58	58	70	70	70	70
continuing less deaths	-	8	15	23	31	54	77	100	122	163	203	244	284	342	400	458	516	586	656	726
total	8	15	23	31	54	77	100	122	163	203	244	284	342	400	458	516	586	656	726	795
Pediatrics																				
CD4 <15%, symptomatic																				
new starts less deaths	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1	1	1	1	1	1
continuing less deaths	-	0	0	0	1	1	2	2	3	3	4	5	6	7	9	10	11	12	14	15
total	0	0	0	1	1	2	2	3	3	4	5	6	7	9	10	11	12	14	15	17
CD4 15-25%, asymptomatic																				
new starts less deaths	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1	1	1	1	1	1
continuing less deaths	-	0	0	0	1	1	2	2	3	3	4	5	6	7	9	10	11	12	14	15
total	0	0	0	1	1	2	2	3	3	4	5	6	7	9	10	11	12	14	15	17
CD4 >25%, asymptomatic																				
new starts less deaths	0	0	0	0	1	1	1	1	3	3	3	3	4	4	4	4	4	4	4	4
continuing less deaths	-	0	1	1	2	3	5	6	8	10	13	16	18	22	26	29	33	37	42	46
total	0	1	1	2	3	5	6	8	10	13	16	18	22	26	29	33	37	42	46	51
Grand total of HIV+ individuals under treatment																				
new starts less deaths	16	16	16	16	49	49	49	49	86	86	86	86	123	123	123	123	149	149	149	149
continuing less deaths	-	16	33	49	65	114	163	212	261	347	433	519	605	728	851	975	1,098	1,247	1,395	1,544
total	16	33	49	65	114	163	212	261	347	433	519	605	728	851	975	1,098	1,247	1,395	1,544	1,692