TREATMENT OF AIDS

A FIVE-YEAR PLAN

FOR

THE PROVISION OF ANTIRETROVIRAL THERAPY

AND

GOOD MANAGEMENT OF HIV-RELATED DISEASES

TO

HIV-INFECTED PATIENTS IN MALAWI

2006 – 2010

December 2005

Ministry of Health, Malawi

ACKNOWLEDGEMENTS

The Ministry of Health gratefully acknowledge the help and assistance of the following people, who under the chairmanship of Dr. Edwin Libamba, were responsible for the 5 Year ARV Plan (2006-2010).

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EXECUTIVE SUMMARY

AIDS Epidemic in Malawi: This is of such a magnitude and such a threat to economic and social stability that the country is proposing to continue with a bold and ambitious scale up and expansion plan for delivery of antiretroviral (ARV) therapy. Malawi's "aspirational" goal is to establish "Universal Access to ARV". A five-year vision is presented, along with a 2-year detailed and costed operational plan.

Numbers started on ART: Based on the reality under which the health sector functions, it is estimated that numbers of patients ever started on ARV therapy will be 35,000 by January 2006. Scaling up at the rate of 35,000 new patients in 2006, 40,000 new patients in 2007, and 45,000 each year in 2008, 2009 and 2010, the number ever started on ARV therapy will be 245,000 by the end of 2010.

ART Scale up strategy: These numbers will be achieved by continuing current scale up in the 60 sites in Round 1, by bringing 38 new sites in Round 2 into service delivery by April 2006, possibly having more sites in Round 3 delivering therapy by 2007, and by involving the private sector. Plans to reduce the burden of work in established clinics include less frequent follow-up, use of a lower cadre of health worker to follow-up patients, and decentralising to health centres.

Constraints to ART scale up: There are 5 possible constraints to such rapid scale up:

- Capacity of the health sector to deliver ARV therapy to people in need
- Uninterrupted drug supplies
- Adequate financial support
- Quarterly supervision monitoring and evaluation of ARV therapy
- HIV drug resistance and unacceptable side effects with first line ARV therapy

Risks of ART scale up: The risks to this large expansion of ARV therapy are similar to the risks outlined in the first scale up plan (2004-2005) and include:-a) drug security issues, b) drug adherence and risk of ARV drug resistance, c) impact on the health sector, d) equitable access to ARV therapy, e) overdue attention to care at the expense of prevention.

2-year operational plan (2006-2007): the plan includes the following activities:

- To review /revise/print/disseminate National Guidelines
- To build capacity for ART and HIV disease management
- To procure drugs for treating HIV and HIV-related diseases
- To implement ARV therapy in the public sector
- To implement Cotrimoxazole Preventive therapy
- To increase health worker and public education on ART and HIV
- To conduct enhanced monitoring and evaluation of ART and HIV-disease
- To assess new ART sites and supervise established ART sites
- To conduct ARV and HIV-operational research
- To manage ARV and HIV-disease at MOH Headquarters
- To implement ARV therapy in the private sector
- To link this scale up plan to other scale up plans (eg CT and PMTCT)

Budget: The total budget for the 2-year period is estimated at USD$47,273,500

INTRODUCTION

HIV and AIDS in Malawi:

Malawi has one of the highest HIV/AIDS prevalence rates in the world, with 14% of those aged 15 – 49 years infected. The National AIDS Commission estimated that in 2003 there were about 900,000 adults and children living with HIV/AIDS in the country. HIV/AIDS is now the leading cause of death in the most productive age group, resulting in an estimated 86,000 adult and child deaths annually. The cumulative number of orphans and vulnerable children, directly related to the AIDS epidemic, is approximately 700,000.

AIDS currently kills young adults in their most productive years, depriving the country of the skills and knowledge base so essential to human and economic development. AIDS leaves countless numbers of grandparents to bring up children. Many orphans cannot attend school, they suffer from poverty and malnutrition and become sucked into a spiral of crime, violence and commercial sex. AIDS retards development and creates the foundations for political instability.

Highly active antiretroviral therapy (HAART):

Highly active antiretroviral therapy (HAART) has dramatically improved the survival of patients living with HIV and AIDS in industrialised countries of the world. AIDS has been transformed from a fatal disease into a potentially treatable and chronic condition. In Malawi, it is estimated that 170,000 people at any one time may be in need of HAART. At the beginning of 2004, there were 9 facilities in the public health sector in Malawi delivering ARV therapy, and an estimated 3,000 to 4,000 patients were on treatment.

Access to HAART is an important component of a strategy to support people living with HIV/AIDS as well as preventing transmission of infection. People may be more willing to undergo voluntary counselling and testing and disclose their HIV status if there is the possibility of getting effective treatment. By reducing viral load ARV drugs may from a biological view-point reduce the risk of sexual transmission. Sick people will be able to return to work. Parents will stay alive longer, thus delaying the time when children become orphans. The rate of mother-to-child-transmission will be reduced. It was clear that the response in Malawi in early 2004 was inadequate and a major scale up of treatment was needed.

Management of HIV-related diseases:

Good management of HIV-related diseases is intricately linked with provision of ARV therapy. HIV-positive patients who are eligible for ARV therapy are generally those in WHO Stage III and Stage IV, and they need stabilisation of their HIV-conditions before starting the specific ARV drugs. Patients in WHO Stage II are generally not eligible for ARV therapy, but can be assisted with good management of their conditions and cotrimoxazole preventive therapy (CPT).

The 2 year ARV Scale Up Plan (2004-2005):

Between January and February 2004, the Ministry of Health, working alongside its partners, developed an ambitious and bold 2-year scale up plan for 2004 and 2005. The main elements of this plan were as follows:- i) 60 hospitals and clinics in the public health sector were selected for ARV scale up, providing broad geographical coverage throughout Malawi; ii) ARV drugs were provided free of charge in the public sector; iii) scale up in new facilities involved the use of the first line ARV regimen only (stavudine+lamivudine+nevirapine = "Triomune"), but when health facilities showed capacity to properly deliver such treatment they were to be provided with alternative first line and second line therapy; iv) facilities were only provided with ARV drugs if they had been formally assessed by the clinical HIV Unit of the Ministry of Health as ready to deliver ARV therapy. It was agreed that ARV drugs must be provided within a structured framework, "a public health approach". The Malawi ARV Treatment Guidelines provided for such an approach, and the implementation of ARV delivery is based on this document.

Progress with the 2-year ARV Scale up Plan and HIV-disease managment:

The Ministry of Health, the National AIDS Commission, other national stakeholders and the donor body approved the scale up plan in February 2004. Implementation then started. In March 2004, all selected hospitals were briefed at three regional meetings about the scale up plan and the National ART Guidelines. Following the briefings, a classroom-training module of 5 days followed by a 2-week clinical attachment was developed. In May 2004, training sessions on ART were, and continue to be, conducted for clinicians and nurses in each of the 60 health facilities. The private sector was also brought on board, and by July 2005, 1100 clinicians and nurses in the public and private sectors had completed the training and passed the formal examination. In the latter half of 2004, the HIV Unit started structured assessments of all health facilities about readiness to start ART; by the end of March 2005, all the health facilities had been assessed as ready to start ART.

The procurement and distribution of ARV drugs was planned in a phased approach, with the 60 health facilities being given a "quota" of drugs according to whether they were low burden (starting 25 new patients per month on therapy), medium burden (50 new patients per month) or high burden units (150 new patients per month). ARV drugs were procured according to "Starter packs and Continuation packs", and these started to arrive in the latter half of 2004. By June 2005, all health facilities had received drugs and had started to treat patients.

A national monitoring system is in place and functioning. National and international stakeholders are kept briefed on progress by quarterly ART reports prepared by the HIV Unit. By the end of 2004, there were 13,000 patients who had ever started ART in the public sector in Malawi. By the middle of 2005, this number had increased to 23,000. Of those ever started, 82% were alive and on ART. By the end of 2005, it is estimated that 35,000 patients or above (adults and children) will have been started on ART.

HIV-related disease management training was integrated into the training on ART and is based on the National Guidelines on Managing HIV-disease, approved in 2004. A new policy on cotrimoxazole preventive therapy (CPT) was endorsed by MOH in mid-2005.

SECTION 1: GENERAL STRATEGY

1.1. FRAMEWORK FOR ANTIRETROVIRAL DRUG DELIVERY

This framework lays out the public health approach for the wide scale delivery of antiretroviral (ARV) drugs in Malawi. The framework is based on that developed in the previous 2-year Plan and the Malawi ARV Treatment Guidelines. It consists of the following:-

- Goal
- Objectives and targets of ARV therapy
- Strategy for ARV therapy
- ARV Policy Package
- Key operations involving ARV therapy
- Indicators to measure progress with ARV therapy

1.1.1. Goal

The goal is to reduce morbidity and mortality of HIV/AIDS in adults and children.

1.1.2. Objectives

The principal objectives of antiretroviral drug delivery are:

- To provide long term ARV therapy to eligible patients
- To monitor and report treatment outcomes on a quarterly basis
- To attain individual drug adherence rates of 95% for patients on ARV therapy
- To increase life span so that over 50% of patients on ARV therapy are alive and ambulatory after three years of ARV therapy
- To ensure that over 50% of patients on ARV therapy are engaged in their previous employment or any other productive activity within 6 months of starting ARV therapy

1.1.3. Strategy

The strategy is to mobilise all existing ARV delivery sites and identify new ARV delivery sites to provide standardised combination ARV therapy to HIV-positive persons who present to health facilities and who fulfil the eligibility criteria (see Chapter on Patients Eligible for ARV Therapy), using wherever possible guardian supported treatment.

1.1.4. ARV Policy Package

The success of the ARV delivery framework depends on the implementation of a 5-point policy package:

- government commitment to ARV delivery
- detection of eligible cases (adults and children) who have undergone voluntary counselling and HIV testing and have a confirmed HIV-seropositive result and who fulfil eligibility criteria
- standardised combination ARV therapy to HIV-seropositive eligible patients (adults and children) under proper case management conditions with high levels of drug adherence
- regular, secure and uninterrupted supply of ARV drugs to units which are administering ARV treatment
- monitoring system for supervision of ARV therapy, effective patient tracing and follow-up and regular evaluation

1.1.5. Key Operations

- There is an HIV/AIDS Unit in the Ministry of Health, which has overall responsibility for the management of ARV therapy in the country
- The ARV treatment guidelines for adults and children are available in every treatment unit which administers ARV therapy, with these guidelines being updated at regular intervals based on national experience and new international knowledge
- There is a standardised registration, recording and reporting system
- There is a combined training and examination programme covering all aspects of ARV delivery, which all staff involved in ARV delivery must have attended and must have passed the formal examination
- There is a counselling and HIV testing service (CT) linked to every unit providing ARV therapy, which is subject to regular quality assurance and quality control
- ARV treatment units are provided within the general health services, at hospital and also at health centre level
- There is a regular supply of ARV drugs and HIV testing materials
- There is a plan of supervision, mentorship, monitoring and evaluation
- There is a plan of regular reporting and evaluation
- HIV / AIDS research is fully regulated to support patient care and implementation of the ARV treatment guidelines
- There is a process to develop long-term and medium term plans with budget details, funding sources and responsibilities

Other important key operations essential to strengthen and sustain ARV delivery include information, education, communication and social mobilisation, involving private and voluntary health care providers, and operational research.

1.1.6. Indicators and Targets to measure progress with ARV delivery

Input indicators:

- An ARV treatment guideline manual (reflects government commitment)
- Number of districts providing ARV therapy (cumulative by year)
- Number of HIV-ARV Clinics administering ARV therapy in public sector
- Number of HIV-ARV Clinics administering ARV therapy in private sector
- Number of staff trained and accredited in use of ARV drugs in the public sector
- Number of staff trained and accredited in use of ARV drugs in the private sector
- No stock-outs of ARV drugs and HIV test kits, and uninterrupted supplies of ARV drugs to patients

Output indicators:

- The number of new patients (adults and children) started on ARV therapy each year
- The number of patients (adults and children) who have ever started on standardised ARV therapy
- The number of those starting ART who are alive and taking therapy at any given time (ie, under care)
- The number (and proportion) of those starting ART who have died
- The number (and proportion) of those starting ART who have defaulted (ie have been lost to follow-up)
- The proportion of patients alive and on ART who are ambulatory
- The proportion of patients alive and on ART who are engaged in their previous employment (or in the case of children engaged in age-related day time activities)
- The proportion of patients alive and on ART who show 95% adherence to ARV therapy
- In a sample of specimens assessed, the percentage of patients with undetectable viral load 12-15 months after the introduction of HAART

The targets linked to these indicators are shown in **Annex 1.**

1.2. GOOD MANAGEMENT OF HIV-RELATED DISEASES

1.2.1. Rationale for good management:

Good management of HIV-related diseases is integral to the delivery of ARV therapy as discussed above. The diagnosis and treatment of HIV-related diseases takes place within the arena of general health services, and as such does not require a special framework, as is the case with ARV delivery.

1.2.2. Indicators to monitor progress with HIV-disease management:

Input indicators:

- An HIV-related disease management guideline manual
- Number of staff trained and accredited in HIV-disease management in the public sector
- Number of staff trained and accredited in HIV-disease management in the private sector
- Number of facilities implementing a strengthened HIV-related disease management programme with no stock-outs of 6 key drugs: (acyclovir, ceftriaxone, ciprofloxacin, fluconazole, vincristine, morphine/codeine)
- Number of facilities implementing a CPT package with no stock-outs of cotrimoxazole

Output indicators:

- The number of patients receiving treatment for Tuberculosis (data collected from the TB registers) on a quarterly and annual basis
- The number of patients with Kaposi's Sarcoma treated with ART (data collected from the ARV Registers) on a quarterly and annual basis
- The number of patients receiving fluconazole treatment for Cryptococcal Meningitis (data collected from the Diflucan registers in the pharmacy) on a quarterly and annual basis
- The number of patients receiving fluconazole treatment for Oesophageal Candidiasis (data collected from the Diflucan registers in the pharmacy) on a quarterly and annual basis
- The number of new patients started on CPT in each quarter, following the 2005 CPT policy guidelines

The targets linked to these indicators are shown in **Annex 2.**

1.3. PRINCIPLES AROUND CONTINUED EXPANSION OF ANTIRETROVIRAL THERAPY IN MALAWI

In response to the devastating AIDS epidemic in Malawi, the Ministry of Health intends to continue expanding highly active antiretroviral therapy (HAART) so that all eligible patients in the country can access the medication and can be provided with uninterrupted drugs for as long as they remain alive. This is the principle of "Universal Access".

1.3.1.Round 1 – continued provision and expansion of ARV therapy:

There are 60 health facilities in Round 1. By the end of 2005, all these facilities will have been treating patients on ART for 6 months or more. Patients on ART will need a continuous uninterrupted supply of drugs and will need motivation from health care staff about continued adherence to treatment. As other HIV-infected persons become symptomatic, they will need to be initiated on to ART as new patients. Thus, the number of HIV-positive persons accessing ART will continue to increase exponentially. The increase in patient numbers will place a huge burden on existing health staff, and ways to reduce this burden (by simplifying ART and by decentralising therapy to health centres) will need to be found. The strategies to cope with this increasing number of patients are discussed on pages 15-16.

1.3.2. Round 2 – scale up and provision of ARV therapy:

There are 38 potential new sites earmarked for Round 2. These sites are generally rural hospitals, large health centres. MACRO-CT sites and Banja La Motsogolo (BLM) clinics, which have been selected to fill the gaps geographically as well as to serve busy cities of Lilongwe and Blantyre. During the last 6 months of 2005, the initial providers of ART in these sites will have been trained (classroom training and clinical attachments), and site assessments will have started. These will need to be continued into 2006. It is envisaged that these sites will be operational by April 2006, depending on whether they satisfactorily pass the structured site assessments

1.3.3. Round 3 and beyond – scale up and provision of ARV therapy:

New potential sites for ARV therapy will be earmarked towards the end of 2006. Exactly the same as with Round 1 and Round 2, there will be a consultative process involved in the selection, and the same scheme of training, attachments and site preparedness will be followed as before

1.3.4. Private Sector Scale up:

The Ministry of Health already started to engage with the private sector in 2004, and by June 2005, almost 200 private sector personnel were formally trained in ART. There are 30-35 private sector sites earmarked for receiving ARV drugs. A process of accrediting these sites will start in the latter half of 2005, and it is envisaged that these sites will start delivering ART by the end of 2005. In 2006 and 2007, there may be additional private clinics where staff have been trained and which can also be earmarked for ARV delivery.

1.3.5. Rationale for continued expansion of ARV therapy:

- The moral imperative. Currently, there are 170,000 HIV-positive persons in Malawi in need of ART. Every year another 85,000 HIV-positive persons join this pool of patients as HIV continues to undermine and destroy their immune systems. Without treatment about 85,000 people in Malawi die from AIDS each year, so in this scenario there is a "status quo" of 170,000 persons needing ART at any one moment in time. However, with ART scale up the scenario has changed. More people with AIDS will survive and more patients will be requiring therapy. In the ideal situation, all 900,000 HIV-positive persons currently infected will be provided with ART over the next 10 years, and, unless the number of new HIV-infections decreases, this number will also rise over time. The increase in numbers of patients needing treatment will exact a huge toll on both the health care system and on financial systems. However, HAART saves lives, both adults and children. Thus, if funding is forthcoming from international sources, then there is a moral imperative to continue treating new patients and maintaining those already on treatment.

- The equity principle. Scale up in a phased manner (Round 1,2,3 and the private sector) allows more and more people, especially from remote areas, to start accessing this life saving treatment. So far, the ARV programme is pro-poor and serves the ordinary person. This principle of equity will be encouraged and maintained. Currently, children comprise 5% of all patients on ART. From 2006 onwards, it is envisaged that increasing numbers of children will access ART so that by 2007 10% of new patients accessing ART will be children. This is reflected in the targets for the 5-year period.

- Economic and political stability. AIDS is currently killing economically productive members of society and is undermining political and economic stability. The wide-scale expansion of HAART will reduce viral load and will get sick people back to good health, and thus start to gradually reduce the huge burden of illness currently faced by the Malawi economy. Rapid country- wide scale up will cost money, but in the end this money spent within the country will save more money in the future. Getting sick people back to work and back to looking after their children will also benefit the country in economic and socio-demographic terms. So far, over 80% of patients who are alive and on ART are back to their previous work.

- Provision of better health care from health care providers. Nearly half of all staff positions in MOHP are vacant, and one of the important causes of staff shortages countrywide is attrition from HIV/AIDS. Continued expansion of ART provides all HIV-infected health care workers with potential access to HAART. The transformation of a sick staff force to a healthy staff force could be one important step in improving health care delivery in the country. In line with this principle, is the current development of a Ministry of Health policy to improve the "care of the carer".

1.4. SCALING UP ANTIRETROVIRAL THERAPY

The Goal:

Malawi's aspirational goal will be to provide "Universal Access" of ARV therapy by 2010. Fulfilment of this goal means having 170,000 patients on treatment, and each year increasing this number by the number of patients becoming eligible for ART (ie, 85,000 new patients per year). The goal of "Universal Access" is that adopted by the G8 countries in July 2005 and is the goal to be adopted by the WHO.

However, given the constraints under which the health sector works in Malawi, the goal of "Universal Access" is ambitious and extremely demanding, and in reality cannot be reached, if Malawi wishes to run an ARV Programme, which is structured, organised and well monitored. Malawi will aim to have started over 170,000 patients on ART by the end of 2010, and from the third year on will aim to place 45,000 new patients on treatment (ie, achieve 50% universal access). By the end of 2005, Malawi will have about 35,000 HIV-positive patients ever started on ART. Based on the current successful "push" system of delivering ARV drugs and quotas given to hospitals, the Table shows the estimated number of new patients starting ART per annum and the cumulative number of patients ever started on ART (and the number estimated to be alive) by the end of each year in the public and private sectors. By end of 2005, children will comprise 5% of all patients, but by 2007 it is envisaged that they will comprise 10% of new patients. The numbers in bold are those to be funded by the Global Fund against AIDS, TB and malaria for the 3 years (2006-2008)

Year	Number of new patients -adults and children- started on ART during the year	Number of patients -adults and children- ever started on ART by the end of the year (and number alive by end of year)	
2005	20,000	35,000	(30,000)
2006	**35,000**	**70,000**	**(60,000)**
2007	**40,000**	**110,000**	**(90,000)**
2008	**45,000**	**155,000**	**(130,000)**
2009	45,000	200,000	(170,000)
2010	45,000	245,000	(208,000)

The explanation for the numbers in the Table is as follows.

Round 1 ART sites (shown in **Annex 3**). In 2006, with Round 1 upgraded sites working to 100% capacity, 38,500 new patients can be started on therapy during a 12-month period. Because the upgrade starts in April 2006, and because the sites will probably at 85% capacity, it is estimated that 30,000 new patients can be started on ART during the year from these sites. In 2007 and 2008, an estimated 33,000 patients can be started on ART from these sites

Round 2 ART sites (shown in **Annex 4**). These will start in April 2006: if they all become functional and operate at 100% capacity, they can start 8,000 -10,00 new patients per year. In 2006, it is estimated that they can start 4,000 new patients on therapy. In 2007 it is estimated that this can increase to 6,000, and to 8,000 in 2008

Round 3 is an unknown quantity and the private sector will probably contribute no more than 1,000 -2,000 new patients per year. However, it is possible that together Round 3 and the private sector may contribute an additional 2,000 -3,000 new patients per year by 2010.

This five-year plan incorporates a 2-year detailed operational plan (2006-2007). Each year this will be updated to a rolling 2-year detailed operational plan (ie, 2007-2008; 2008-2009) to account for numbers of patients that are in reality enrolled to ART. As a pro-poor initiative, this plan embraces the concept of free ARV drugs to HIV-infected eligible persons in the public sector. In the private sector, the ARV drugs will be subsidised, with patients paying a nominal monthly fee of MK500 (USD4).

1.4.2. Policy:

1.4.2.1. Provision of ARV therapy from Approved Sites:

The 60 sites in Round 1 that are currently providing ART in the public health system, and their classification for the March 2006 procurement order are shown in **Annex 3**. The 38 potential sites for Round 2 and their classification for the March 2006 procurement order are shown in **Annex 4.**

The regular supervision conducted to all sites in the country will determine whether a site stays in its current classification (low, medium or high burden). Sites seeing many patients, performing well and asking for upgrade status may be moved to a higher category. Equally, a site that is poorly performing may be downgraded.

For new sites, the same approach that was agreed for the first 2-year plan will be adopted for both the public and private sectors. Staff to work at the new ARV sites will have been formally trained and will have passed the formal examination. The sites will then be formally assessed by the HIV Unit for readiness to start ART. Readiness criteria (or accreditation criteria) include:- a) plans developed by the health facility for the recruitment and follow-up of patients on ART; b) hospital and health centre staff fully briefed about ART scale up; c) a functioning CT services; d) a dedicated room for the delivery of ART, which is suitably equipped and has the appropriate monitoring tools and copies of the ARV treatment Guidelines; e) suitably trained staff who have completed one of the formal training modules – eg clerk training or counsellor training; f) safe and secure storage facilities for ARV drugs.

All new ARV sites will start first with provision of first line therapy only. The reason for this approach is the greater logistic and management difficulty of providing alternative first line treatment and second line treatment to patients. However, once health facilities have proven adept at using first line therapy then they will be considered for alternative first line and second line therapy. In the meantime, if there are patients needing alternative first line or second line therapy a referral mechanism (which is already in place) can be used, whereby facilities can obtain a 6-month supply of drugs for their patients on a named-patient basis. Alternative first line and second line drugs are currently stocked by central hospitals and a number of well run and experienced district hospitals.

1.4.2.2. Assessing and reducing the burden of work in ARV clinics:

During the five-year plan, assessments will be carried out to determine the number of staff needed to run an ARV clinic related to the patient load. At present, this is an unknown variable. At the same time, ways to reduce the burden of work will be worked out and implemented in a phased manner. The current ARV delivery system is such that patients on ART are seen every 4 weeks for follow up. In each ARV clinic, the threshold for the number of patients that can be properly handled under the current system needs to be identified, and will vary from site to site depending on staff numbers. It is likely that this number will vary from 500 to 1000 patients.

There are four approaches to reducing the burden of work at the established ART clinic. First, for patients who are stable and established on ART, the follow-up visits can be reduced in frequency to every 2 months. Second, it may be possible to train lower cadres of staff to manage ART in both the hospital and health centres. Third, it may be possible to decentralise the follow-up of patients to health centres. Fourth, it may be possible to identify health centres where ART can be initiated and where registration and monitoring of patients can be done in their own right. **Annex 5** outlines the four approaches, the implications, advantages and disadvantages.

1.4.2.3. Possible constraints to large-scale expansion of ART in Malawi:

- ***Capacity of the health sector to deliver ARV drugs to people in need.*** The health sector (public sector, CHAM, the Defence Forces and Private Sector) needs to be committed to the goal of continued expansion of ART and the work required for implementation. An adequate number of staff, and a staff force that is well motivated will be critical to the success or otherwise of this initiative. If numbers of health care workers are not increased, it is likely that ARV clinics will reach a threshold of patients on ART beyond which they cannot increase. Infrastructure is also a limiting factor. The ARV clinic rooms are small, the pharmacies and their lockable cabinets are small, and if these are not increased in size, this will also limit the capacity to place more patients on therapy. If the human resource and infrastructure factors are not resolved at the peripheral level, the goal of placing 45,000 new patients on ART each year will not be met.

- ***Uninterrupted drug supplies.*** ARV drugs are currently manufactured in India (CIPLA) and are procured and distributed in Malawi by UNICEF. Uninterrupted drug supplies are crucial to the success of the programme in terms of individual outcomes and prevention of drug resistance. Manufacturing capacity has to be ensured internationally, UNICEF has to be able to procure and distribute in a timely manner, and peripheral facilities have to ensure safe and secure storage of drugs. Calculating the correct number of drugs for the country and for each facility in the public sector is the responsibility of the HIV Unit. Drug procurement for the private sector is through UNICEF, although calculations and logistics are carried out by other sources.

- ***Adequate Financial support.*** There has to be adequate financial support for an increasing number of ARV drugs. The Global Fund support may be inadequate to pay for the increasing number of ARV drugs if the principle of "Universal Access" is to be adopted. Other donors may need to provide assistance.

- ***Quarterly supervision, monitoring and evaluation of ARV therapy*.** Currently, the HIV Unit conducts quarterly supervision and monitoring to all ARV clinics in the public sector, receiving assistance for this activity from its partners such as Lighthouse, CDC, Taiwan Medical Mission and MSF-Brussels. Nevertheless, as the number of ARV clinics increases this task becomes more arduous. Approaches to ensuring quarterly visits continue include co-opting the help of mentors at central hospitals and the zonal officers.

- ***Problems with first line ARV therapy.*** There are two main problems with the current first line regimen of stavudine+lamivudine+nevirapine ("Triomune"). First there is HIV-drug resistance. However well the ARV programme is managed the development of HIV-drug resistance is inevitable at some stage. It is also possible that the use of single dose Nevirapine in the PMTCT programme may compromise the efficacy of "Triomune". Annual surveillance of drug resistance is being set up, and the degree of resistance in the community, in patients about to start ART and those who have been on ART for 12 months will be monitored. If failure to "Triomune" emerges in any significant degree, this will compromise the scale up efforts as the second line therapies are complex, expensive and difficult to manage. Second, there are side effects. Stavudine is associated with long-term toxicities of lipodystrophy and peripheral neuropathy, and this may limit the usefulness and acceptability of "Triomune" in the community.

1.4.2.4. Risks associated large-scale expansion of ARV therapy:

- Drug security issues: large-scale expansion of ARV drugs to multiple sites, especially health centres, may involve loss of control of ARV drugs. However, this risk will be minimised by:- a) UNICEF initially procuring and distributing the drugs to all end user units; b) a system of checks during M&E to compare drug consumption with drug usage (described in Malawi ARV treatment Guidelines).

- Drug adherence and risks of promoting ARV drug resistance. The ARV Treatment Guidelines suggest how to maximise drug adherence and how to monitor for drug resistance. It will be important to ensure that these activities are implemented.

- Impact on the health sector. Large expansion of ARV therapy with increasing patient numbers will inevitably involve a shift of health care staff from general duties to ARV duties, and there may therefore be an even greater deficit of staff to deal with other medical and other problems. However, over 50% of hospital in-patients have HIV/AIDS, and it is expected that the provision of ARV therapy to such patients will ultimately reduce the burden on hospitals. This might then free up staff to attend to general duties.

- Equitable access to ARV therapy: access to ARV therapy will be based on clinical eligibility criteria. So far, the routine data collected suggest that ART scale up in Malawi is pro-poor. However, at present patients in rural or remote areas are poorly served. With the expansion of sites described in Round 2 and decentralisation that may occur to health centres, ARV therapy should become more accessible to rural people.

- Attention to care of HIV at the expense of prevention. The provision of ARV therapy involves counselling and HIV testing. Explicit in the Malawi ARV Treatment Guidelines are risk reduction strategies and HIV prevention messages that accompany ART delivery. In facilities providing ART, there has been a large increase in the number of persons being counselled and tested, and it is expected that ARV therapy will assist in prevention strategies.

1.4.3. Institutions to deliver HAART:

Institutions to deliver HAART include:-

a) the government health sector; ie central and district hospitals, including their rural hospitals and outlying health centres, supported wherever by non-governmental organizations (NGOs) such as MSF-France, MSF-Brussels, MSF-Greece, Dignitas International

b) CHAM institutions; ie mission hospitals

c) The Malawi Defence forces and the police service

d) New non-governmental organizations (eg, Banja La Motsogolo, MACRO)

e) The Private sector: ie the private hospitals, private companies and private clinics

SECTION 2: OPERATIONAL PLAN: 2006-2007

The plan outlined below highlights the activities, which will be carried out during the two-year period [2006-2007]. The activities, process indicators, time frames, estimated budgets and sources of funding are shown in **Annex 6.**

2.1. Review / revise/ print and disseminate ARV and HIV-disease Guidelines

Revise First Edition of ARV Treatment Guidelines (October 2003):

The first edition was published in October 2003, and nearly 2,000 copies have been distributed to Health Care Workers countrywide. With increasing experience in running the ARV Programme in country, with details of monitoring and evaluation which have changed from the first edition and with a new WHO ARV Treatment Guideline manual due out by the end of 2005, it is time for Malawi to revise and publish a Second Edition. Other additions to consider are an expanded section on paediatric ART and the management of anti-TB drugs and ARV drugs. The meetings to undertake this will be held in the first and second quarter of 2006, with a finished product ready by June 30th 2006.

Possible Revision of HIV-Disease Guidelines (April 2004):

The first edition was published in April 2004, and with the delay in printing the published version only came out in August 2005. However, over 1000 copies of the first edition were photocopied and distributed to Health care workers countrywide. Management of HIV-related disease changes less frequently than ARV treatment, and there may not be need to revise the first edition. However, in mid-2007 a meeting will be held with national experts to decide whether and how a second edition may be needed.

Print and disseminate ARV Guidelines and HIV-disease Guidelines:

Whether new guidelines are produced or not, there is a continuing need to print and disseminate ARV Guidelines and HIV-disease Guidelines to health workers in the field, those attending the in-service training courses and the students at the Colleges of Higher Education (Medical school, Nursing schools and College of health sciences) One thousand copies of each will be printed and disseminated each year.

Print and disseminate the District ARV Training Module:

In 2005, a district based hard copy ARV Training Module was developed so that ARV teams can brief and train hospital and health centre staff in their districts. Up to twenty thousand copies will be printed and distributed in 2006, and depending on demand another 2,000 to 3,000 copies the following year.

2.2. Build capacity for ARV and HIV-related disease Management

Revise the ARV/HIV Training Module

New additions to the ART training module include a) management of ART in children, b) management of anti-TB drugs and ARV therapy, c) updated WHO staging categories, and d) revised monitoring tools. A 2-3 day consultative meeting will need to be held to revise this module. This will take place in the first six months of 2006

Conduct classroom training for ARV / HIV-disease management in Public Sector

Every quarter two classroom training sessions (of 5 days each) will be held:- one in Lilongwe for the Central and Northern Regions and one in Blantyre for the Southern Region. There will therefore be 8 training sessions per year. These will be coordinated and run by the HIV Unit, working with its partners. The target audience will be clinicians and nurses, and will either be directed towards building capacity in Round 1 and Round 2 sites or directed towards training new staff at new sites for Round 3. An average of 100 staff will be trained in each quarter. The key materials used will be ARV Treatment Guidelines and HIV-disease Guidelines. There will be a formal examination at the end of each training course, which all participants will be expected to pass (pass mark 70%).

Conduct classroom training for ARV / HIV-disease management in Private Sector

Every quarter one classroom training session (of 2 days at the weekend) will be held:- one in Lilongwe for the Central and Northern Regions in one quarter and one in Blantyre for the Southern Region in the next quarter. There will therefore be 4 training sessions per year. A press release will appear every 6 months informing the community about the timing of these training sessions. These will be coordinated and run by the HIV Unit. The target audience will be clinicians and nurses who work in the private sector, although other personnel working in the public sector will also be accepted. An average of 25 staff will be trained in each quarter. The key materials used will be ARV Treatment Guidelines and HIV-disease Guidelines. As in the public sector, there will be a formal examination at the end of each training course, which all participants will be expected to pass (pass mark 70%).

Clinical attachments in the Public Sector

A formal clinical and nursing attachment of two weeks is undertaken for the clinician and nurse who are going to set up a new ARV clinic. These attachments are carried out at one of the experienced ARV delivery sites in the country (Lighthouse, Queen Elizabeth Central Hospital, Zomba Central Hospital, Thyolo District Hospital). In 2006, staff will be attached for the first 3-6 months as a result of Round 2 classroom trainings. In 2007, it is envisaged that more staff will be attached after Round 3 classroom trainings.

Conduct classroom refresher courses / knowledge dissemination in the Public Sector

Every year there will be an ART classroom refresher training course (1 day) followed concurrently by knowledge dissemination and best practices (1 day) for staff running ART clinics. It will be particularly important to update in-service staff on new developments. These courses will be organised at regional or zonal level.

Pre-service training on ART and HIV-related diseases

In 2005, a pre-service training course was held for tutors at the Colleges of Health Sciences and Colleges of Nursing, with a view to getting the tutors certified in ARV therapy and starting the process of getting ARV therapy integrated into the pre-service curriculum. The training officer at the Lighthouse was co-opted to work with the HIV Unit to take charge of getting equipment (computers and LCD projectors) and training materials (ARV Guidelines, HIV-disease Guidelines, flip charts) to the sites, and helping the sites get ready for implementation. Altogether there are 15 pre-service institutions shown in the Table:

Training Facility	**Name of Training Institution**
Medical School	College of Medicine, Blantyre
College of Health Sciences	Lilongwe Campus Blantyre Campus Zomba Campus
Nursing Colleges	Kamuzu College of Nursing, Lilongwe Kamuzu College of Nursing, Blantyre Nkhoma Mission Hospital, Lilongwe St Johns Mission Hospital, Mzuzu Ekwendeni Mission Hospital, Mzuzu St Josephs Mission Hospital, Chiradzulu Malamulo Mission Hospital, Thyolo St Lukes Mission Hospital, Zomba Holy Family Mission Hospital, Phalombe Trinity Mission Hospital, Nsanje Mulanje Mission Hospital, Mulanje

It is hoped that most institutions will incorporate the pre-service ART module into the curriculum this year, for students graduating this year, with the ultimate aim of incorporating the module into Year 2. This will be monitored on an annual basis.

Maintain a Data Base of Personnel formally trained in ART

A data base is already set up for tracking the number of persons trained in the public and private sector, their names and affiliations and their examination marks. Whenever a course is completed, the data base is updated and the names are passed to the Malawi Medical Council and the Malawi Nursing Council, that all maintain a data-base about who is certified in ART.

District Modular training

With support from WHO-AFRO-Canadian Funds, a district training module (prepared as a hard copy) was developed in 2005 in order that ARV teams could do one-day briefings for a) hospital staff and b) health centre staff. It is expected that Round 1 sites will conduct this training of staff and this will be monitored on an annual basis.

HIV Clinical Unit staff to attend International meetings

It is important that the HIV Unit staff attend meetings in the region and in other international sites in order to learn what other countries are doing with regard to ART scale up and to disseminate the knowledge gained in Malawi from scaling up in country. It is expected that each staff member will attend one conference per year.

Increased human resources

This plan cannot (and should not) incorporate a separate human resource plan, which has already been developed by the MOH and its partners. However, ARV scale up is going to need increased human resources, and all partners need to advocate and push for increased graduate and diploma outputs from all the Colleges (and thus increased resources for the Colleges), retention of staff, and regular assessments of the human resource needs in the field. Lighthouse has estimated that there needs to be 20 FT nurses and 5 FT clinical officers to manage 10,000 ART patients: these sort of calculations are very valuable, and need to be discussed and further elaborated.

2.3. Procure drugs to treat HIV and HIV-related diseases

2.3.1 ARV Drug Procurement:

Categorisation of facilities and numbers of new patients accessing ART:

The hospitals to deliver HAART have been categorised into Low Burden, Medium Burden, High Burden and Very High Burden ARV Units. Low Burden units will provide HAART cumulatively to 25 new patients per month, Medium Burden units to 50 new patients per month. High Burden Units to 150 new patients per month and Very High Burden units to 250 new patients per month. The categorisation of hospitals in Round 1 and Round 2 is shown in **Annex 3 and 4.** This categorisation enables the Ministry of Health to calculate how many new patients will come on therapy in each quarter. It should be realised that these categories are not fixed in stone and may change during the year as sites improve their performance or find they cannot cope with the increasing numbers. This is already happening.

Malawi's different ARV regimens:

The ARV drugs for the different regimens are shown in the Table

Drug Regimen	**Drugs in the regimen**
First Line Regimen:	Stavudine+Lamivudine+Nevirapine D4T+3TC+NVP "Triomiune"
Alternative First Line Regimens: Substitution for Neuropathy Substitution for Hepatitis/Skin	 Zidovudine+Lamivudine+Nevirapine AZT+3TC+NVP Stavudine+Lamivudine+Efavirenz D4T+3TC+EFV
Second Line Regimen:	Zidovudine+Lamivudine+Tenofovir+"Kaletra" AZT+3TC+TDF+LpV/RtV

Procurement of Drugs:

First line therapy: Drug procurement for first Line regimen works through an established system of "Starter Packs" and "Continuation Packs". Stavudine has to be provided at a dose of 30mg twice a day for patients weighing 59KG or less, and a dose of 40mg twice a day for patients weighing 60KG or more. Both packs provide for formulations that are 80% stavudine-30mg and 20% stavudine-40 mg. Starter packs provide 2 weeks treatment for 25 new patients per month for 3 months (there are special needs for the first 2 weeks because Nevirapine has to be provided at half dose). Continuation packs complement this by providing continuation therapy of Triomune for 75 patients for 3 months. The packs provide the treatment in tins, and tins are given to patients rather than individual tablets, thus minimising chances of error and theft. If Pedimune becomes available for children, orders for this drug will need to be factored in to the procurement orders.

Alternative first line therapy: Experience has shown that about 10% of patients on first line therapy experience side effects. However, not every patient needs to substitute to an alternative regimen. It is estimated that about 4% of patients substitute for peripheral neuropathy and 1% because of skin/hepatitis.

Second line therapy: Calculating the needs for second line therapy is difficult, but in the experienced sites running for 2 or more years up to 1% of patients need second line therapy.

Drug ordering: The initial scale up of ART in Round 1 sites was done in phases. However, these phases are now synchronised, and drug orders will now be made twice a year in March and in October. The process is now established and is as follows. The HIV Unit calculates the number of patients to be put or kept on treatment, works out the number of Starter packs and Continuation packs and other drugs required for the country on a 6-month basis, and works out the distribution list. This is then forwarded to UNICEF who prepares the cost-estimates. Cost-estimates are sent back to the Ministry of Health, for approval, and the drug orders can then be placed. Because of the high quantities of drugs involved, drug ordering is done at least 6 months in advance, requiring estimates to be made of the number of patients to be started on treatment and the number already on treatment.

The drugs ordered for October 2005 (already paid for in the first phase of GF funding) are for patients from January to June 2006. Thus, the first order in the next tranche of funding will be made in March 2006 for patients starting therapy between June and December 2006. Six orders will therefore be placed with Global Fund moneys during the period 2006 to 2008 which should provide treatment for patients up till June 2009.

Drug quantities and costs: estimated for January 2006 to December 2008:

Predicting numbers for ARV therapy is not an easy exercise. Facilities may not work to full capacity, patients are lost to follow-up, die or stop treatment, and there is also a need to build in a buffer system for ARV drug stocks.

For drug procurement calculations it is estimated that at the end of every year, 85% of patients will be alive and on ART. Thus, of the 35,000 patients ever started on ART by December 2005, it is estimated that 30,000 will be alive and on ART at the beginning of 2006. Of the 70,000 patients ever started on ART by the end of 2006, it is estimated that 60,000 will be alive and on ART at the beginning of 2007. Of the 110,000 ever started on ART by the end of 2007, it is estimated that 95,000 will be alive and on ART at the beginning of 2008. Of the 155,000 ever started on ART by the end of 2008, it is estimated that 130,000 will be alive and on ART at the beginning of 2009. **Annex 6** shows the estimated number of starter packs and continuation packs needed over the three-year period, as well as the number of patients placed on alternative first line therapy, second line therapy and post-exposure prophylaxis. Every 6 months these will be reviewed based on drug stocks at the end-user site and the number of patients on treatment and planned for treatment over the next 6 months.

Total Drug Budget for the 3 years of Global Funding and the 2-year plan:

3-years Global Funding: The total ARV drug bill over the remaining 3-year period of Global Funding is USD$57,083,000. To this must be added an in-country distribution charge of 12%= $6.8 Million. Thus, the total estimated budget = USD$63,932,000.

2-years Operational Plan: For the two year operational plan, the ARV drug bill is USD$31,359,600. To this must be added an in-country distribution charge of 12% -= $3,763,152. Thus, the estimated budget for the 2 year operational plan = USD$35,122,752.

2.3.2. Procure Drugs for HIV-related diseases

Drugs for HIV-related diseases will be ordered every 6 months. There is a lot of uncertainty surrounding the specification and quantification of these orders. However, there are some general principles:- a) key drugs for treating serious HIV-related diseases [ceftriaxone, ciprofloxacin, morphine, codeine, vincristine, ganciclovir, acyclovir] will be the priority for orders; b) nutritional supplements [F100, F75 and plumpy nut] with quantities to be determined by the Nutrition Unit; and c) cotrimoxazole for prophylaxis.

2.4. Implement ARV therapy in the public sector

General implementation

ARV therapy will be delivered at certified ART sites in accordance with the ARV National guidelines. Attempts will be made to conduct routine HIV testing of hospitalised patients to increase case finding for eligibility for ART

Laboratory support for ART scale up

The need for laboratory support (e.g., CD4 machines) will be determined as ART scale up proceeds, and the HIV Unit and its partners will work with the Department of Health Technical Services and CHSU in this regard. Currently, there are 15 facilities able to do CD4-lymphocyte counts, but there are many logistic problems with regard to test reagents and reagents for the machines. Several facilities have had to stop CD4 measurements in the last 6 months of 2005 because of stock-outs. In the first six months of 2006, there will be an external consultation to assist Malawi to:- a) review current use of CD4 machines in country and recommend a suitable policy for use of CD4-lymphocyte counts; b) review current system of procurement of reagents for tests and for running the machines; c) review maintenance contracts; d) provide advice about quality assurance; e) assess the need for other laboratory support, for example Haemoglobin, LFTs; and f) assess the laboratory support for ART scale up in the context of the Essential Medical Laboratory Services project.

Adherence to ART and compliance with follow-up visits

Adherence to therapy is crucial to the success of this ART scale up plan. ARV clinics will need to work with community-based organizations (CBO) to assist patients in adhering to therapy. Links will also need to be made with these CBOs and health centres to trace patients who fail to report for follow-up, and encourage them back to treatment. Monitoring tools too assist this process need to be developed.

Special Groups

Within the general scale up of ART, there are groups that will warrant special attention. These include:- a) children; b) patients with TB and patients who develop TB while on ARV therapy; c) HIV-positive pregnant women who are found eligible for ART as a result of staging or CD4 lymphocyte counts; d) patients who fail the first line regimen and who need second line therapy. Ad hoc meetings will be held during the 2-year period to review the needs of these special groups.

HIV-positive children:
At present, only 5% of all patients accessing ART are children (aged 12 years or less), yet it is estimated that this should be 10-15%. There is an established Malawi Paediatric ART Group, which will meet regularly to determine how to increase access of children to treatment. Nutritional rehabilitation units will be particularly targeted to increase counselling and HIV testing of young children to increase their access to ART. Guidance in other areas will be sought from experienced sites (QECH, Lighthouse, Thyolo, Chiradzulu, Mzuzu central Hospital) as well as the newly established Baylor College in Lilongwe.

There will be an expanded paediatric section in the new ARV Guidelines and in the revised ARV Training Module, and ways to teach paediatric ART management to already practising staff will be worked out. Further work will be carried out on split dose Triomune and research studies will start to evaluate the paediatric formulations of Triomune called "Pedimune".

HIV-positive patients with TB:

The HIV Unit will work with the national TB Programme (NTP) and partners over this period to resolve the issues surrounding ART in HIV-positive TB patients, given that the NTP will move to a rifampicin-throughout regimen. The issues include:

a) maximising access for HIV testing for TB patients
b) when to start ART
c) use of nevirapine or efavirenz with rifampicin
d) how to manage patients who develop TB when on ART
e) continuation of cotrimoxazole
f) the need for isoniazid at end of TB treatment to reduce risk of recurrent TB

A first meeting took place in CHSU in October 2005 between NTP and HIV Unit where a decision was made to continue NVP-ART in patients developing TB while on Triomune, and to conduct operational research at district level to build the evidence base for use of NVP or EFV with rifampicin in the continuation phase. Further meetings will take place every 6 months to coincide with visits of external consultants.

HIV-positive pregnant women:

The HIV Unit will work with the Reproductive Unit in determining that better links be formed between pregnant mothers enrolled in PMTCT and access to ART. Currently, very few pregnant mothers are enrolled to ART, and targeting CD4-lymphocyte count testing at this priority group may increase their access. ART for pregnant women would provide better prevention of mother to child transmission, both at labour and during breast-feeding.

Failure of first line regimen:

Malawi changed its second line regimen in 2005 from what was decided in the ARV Treatment Guidelines to a more powerful regimen for adults (zidovudine/ lamivudine/ tenofovir/ lopinavir- ritonavir- AZT+3TC+TDF+Kaletra). An appropriate second line regimen for children will need to be agreed on by paediatricians and MOH, as tenofovir is unsuitable for children. The HIV Unit will work with its partners to assess the efficacy of these new regimens.

Human resource needs

Discussions to determine the optimal number of clinicians, nurses and other cadres to run ART clinics (based on Lighthhouse estimates) need to be conducted early in 2006.

Equity in ARV delivery

A policy paper on equity has been completed, and attempts will be made to ensure that equity is promoted, monitored and reported upon.

2.5. Implement Cotrimoxazole Preventive therapy (CPT)

In June 2005, the Ministry of Health endorsed a new CPT policy. The new recommendations are shown in the Table.

Adults	CTX should be offered to the following HIV+e adults (13 yrs +):- • All persons with symptomatic disease • All persons with CD4 count of 500/mm3 or less • Pregnant women after the first trimester with symptomatic disease or CD4 count < 500/mm3
Children	CTX should be offered to children in the following circumstances:- • Any child born to an HIV-positive woman irrespective of whether the woman has received ARV therapy in pregnancy • Any child who is HIV-positive regardless of symptoms

Although this policy has been circulated to all health facilities, there is little sign to date of implementation being carried out. During 2006, implementation must be started according to policy operational guidelines. Drugs must be procured for CPT and are likely to arrive in Malawi in the first half of 2006. CPT will be given to patients starting ART, as this may reduce the early deaths seen in sick patients starting ART. A record will be made of this intervention in the ART register. A CPT register must also be developed for the facility pharmacy to record the total number of persons starting CPT and number continuing to remain on CPT. Several hospitals will be selected to test the practice of CPT. The health staff must be briefed about the policy, and pharmacy technicians trained in how to use the CPT register. If the piloting is successful, then the policy implementation will be rolled out countrywide.

2.6. Increase health worker / public education of ARV drugs and HIV-diseases

The responsibility for health education for patients, guardians and the general public falls under the Health Education Unit (HEU) of the Ministry of Health. With the support of the key communication partners, the HEU has developed a national ARV communication plan, key messages, and begun packaging materials for all media channels. All materials produced are pre-tested in the three regions of Malawi for both Chichewa and Tumbuka audiences.

The HEU established a SRH and HIV Communication Group comprised of key communications and technical experts, which meets quarterly to review specific HEU outputs and plans for next steps. Through the group, other partners' communications efforts and activities are coordinated to ensure that messages are harmonised, and introduced in a way that supports the scale up of services.

Health service providers

With regard to health service providers, the HEU is providing and will continue to provide ARV Flip Charts and ARV calendar booklets. The aim of these materials is to support client understanding about treatment, the importance of adherence and positive home care. The booklet also reminds both the provider and client of key messages and questions to ask each month. These materials have already been printed and distributed to all facilities delivering ART, but stocks will need to be replenished at regular intervals. The HIV Unit will liaise with the HEU on this matter.

General public

With regard to the general public, key methods of education are the dissemination of print materials, production and airing of radio spots and programmes, drama group performances and outdoor advertising through minibuses. To date, drama trainings have taken place within all the districts (2 drama groups per district) and districts are submitting proposals for performances. HEU has produced posters, and outreach materials. The Unit has also initiated production of 3 radio spots and a radio drama, minibus advertisement, and educational videos which will be used for viewing at district hospitals, in communities through mobile video units, and edited down for television broadcasting. Communication materials developed also support access to HIV counselling and testing as the entry point for treatment and promote links between services for referral.

The HEU will need to target future strategies and materials to support access by vulnerable groups identified in the ARV Equity Policy while also addressing the need for widespread treatment literacy. There will be a need to continue to develop materials related to the targeted promotion of services for vulnerable groups, and to replenish stocks at regular intervals. Radio will also be an important channel to further develop with regular programmes addressing treatment literacy and community support issues. The IEC materials that have been produced in Chichewa and Tumbuka are shown in the Table below.

ARV Flipchart	What to Expect from VCT Booklet
ARV Calendar Booklet	VCT for Couples Booklet
PMTCT Referral Poster	VCT Provider Poster
OI Referral Poster	VCT for Young Couples Promotion Poster
ARV Adherence Poster	VCT for Older Couple Promotion Poster
Misconceptions about ARVs Poster	VCT Promotion Poster for Young People
	VCT for Couples as Entry for Treatment Poster
	VCT for Couples as Prevention Poster

2.7. Enhanced monitoring and evaluation for ART and HIV-related disease

Printing and distribution of Monitoring and evaluation tools

The HIV Unit has produced and disseminated a variety of ARV monitoring tools, which are systematically being used in ARV delivery sites. These are shown in the Table below.

ARV Patient Register
ARV Drug Register
ARV Patient Master Card
ARV Patient Identity Card
ARV Patient Identity Stamp for Health Passport
ARV Quarterly Cohort Analysis forms
ARV Cumulative Cohort Analysis Forms
ARV/CT Monitoring Forms for NTP
ARV site assessment forms for ART readiness

The HIV Unit will re-assess these tools in early 2006 and decide which ones need to be revised to compliment changes in ART Guidelines. The HIV Unit will also make central orders for printing of these tools. During the quarterly supervision, sites will be assessed about the need for replenishing of these tools and at the same time sites can be replenished during the visits. Other tools will need to be produced during the two year period: a) the Post-exposure Prophylaxis Register to be kept in the pharmacy; b) the Cotrimoxazole Preventive therapy Register to be kept in the pharmacy.

Countrywide situational analysis of HIV-AIDS services in Malawi

Every year for the last three years, a countrywide situational analysis has been conducted. This has been jointly planned between the HIV Unit and the National TB Programme (NTP), and carried out by the TB-HIV team in the NTP. The analysis normally takes place in the first quarter of each year. A report is produced and widely circulated. This will take place in 2006 and 2007.

Quarterly monitoring and evaluation site visits for ART and HIV-related disease

The site visits for Monitoring and Evaluation are combined with supervision and mentorship (see below). These are and will continue to be carried out on a quarterly basis by the HIV Unit and its partners from Lighthouse, CDC, Taiwan Mission, and MSF-Brussels. A system has been set up where the schedule for visits is prepared in advance and circulated to all ARV delivery sites. Using a structured proforma, sites are visited and data collected on case finding and treatment outcomes of patients who have a) started ART in the previous 3 months (quarterly analysis) and b) ever started on ART (cumulative analysis). Additional data is collected on ARV drug stocks, use of a CD4 machine, key CT data and number of new HIV-related diseases treated quarterly (TB, Kaposi's sarcoma, cryptococcal meningitis, and oesophageal candidiasis). This data is entered into an EXCEL data base for regional and national collation of information.

Quarterly ARV and HIV-related disease reports

Once the sites have been visited, the HIV Unit collates the regional and national data and a quarterly report is produced. From 2006 onwards the Unit will work with Lighthouse and CDC to develop a better way of collating district site data, to take some of the pressure off the limited staff numbers at MOH headquarter. Once reports have been completed, they should be circulated to all stakeholders before the end of the quarter. Hard copies of the report will also be taken to the peripheral units during the next supervision.

Supporting M&E at the peripheral site level (including computerised systems)

During the two-year period, a pilot will be carried out to introduce computers and an electronic database to ARV clinics. A touch screen system that mirrors the register and master cards has already been developed, but needs to be refined and then tested. This system will run parallel to the manual system, and is designed to help clinics prepare their own quarterly and cumulative cohort analysis.

Annual surveillance of HIV-drug resistance

A plan has been developed to conduct annual surveillance of HIV-drug resistance. There are two main components to the plan. First, a monitoring survey to assess HIV viral suppression and HIV drug resistance in patients recruited to ARV therapy in 4 sites around the country. Within this monitoring survey, there will be both prospective and retrospective surveys. Second, a threshold surveillance study to determine the degree and pattern of drug resistance in persons recently infected with HIV in Malawi, focusing on HIV-positive (primigravida) pregnant women below the age of 25 years. Surveillance will start at the end of 2005, and become a regular annual activity.

2.8. Assess new ARV sites and supervise established ARV sites

Site Assessments for Readiness to start ART

The structured assessment tool and the mechanisms to assess new ARV facilities have already been developed and used in the field. ARV sites in Round 2 will need to be assessed by the end of the first quarter of 2006. Other sites, which start ART at a later time (Round 3 and beyond), will also need to be assessed.

Site supervision and mentorship

These visits will be conducted on a quarterly basis, and will be combined with the monitoring and evaluation visits (see above). At the same time, efforts will be made to work with the newly established zonal offices and the mentors who are being recruited to central hospitals to assist with ART scale up.

There are two aspects to site supervision. First, and already established, is the supervision to check that registers, master cards, cohort analyses, etc are being properly completed. Second, and not yet well established, is the supervision to check that clinical staging is accurate, side effects are well managed, drugs properly adhered to, etc. Given the human resource constraints experienced everywhere, these two aspects need to be combined with one member of the supervision team looking at the registration aspects and the other looking at the more clinical aspects.

2.9. Conduct ARV Operational Research

ARV Operational Research Group Meetings

Depending on the interest and time available, it is envisaged that ARV Group meetings with interested stakeholders to discuss operational research are held quarterly, with the venue alternating between Lilongwe and Blantyre.

HIV and ARV Knowledge Centres

Knowledge centres should be established, where a significant core of expertise is concentrated for the country and for the regions. The College of Medicine is ideally placed to be the dominant HIV/ARV knowledge centre for the country and specifically for the South. For this to work efficiently, there will be a need to place two consultants, specialised in HIV and ART, within this institution. Lighthouse and the Baylor College (for children) are ideally placed for the Central Region, and Mzuzu Central Hospital and Taiwan Mission for the Northern Region.

ARV Operational Research

In late 2004 a national ARV Research agenda was developed and agreed by stakeholders. The key thematic areas are listed in the Table.

- To determine appropriateness of clinical eligibility criteria for ART
- To determine the efficacy and safety of Malawi's standardised regimens
- To assess access to ARV therapy
- To assess the efficacy and safety of Pedimune versus split dose Triomune
- To assess the use of health surveillance assistants to follow up ART
- To assess use of computers at ART sites for M&E
- To assess the best ways to monitor and report on treatment outcomes
- To assess factors influencing drug adherence
- To determine the effect of ART scale up on health service delivery
- To study the wider impact of ART

Through WHO-AFRO-Canadian Funds, some operational research has already been supported and funded, and this will continue into 2006 and beyond. These projects include:- a) use of Triomune in TB patients; b) use of Triomune in patients with chronic Hepatitis B; c) ART in children; d) efficiency of ARV service delivery at a district level; e) patient losses during the process of patient recruitment to ART; f) storage of drugs in the home. One of the aims of this activity is to produce 5 papers a year on ARV operational research, which have been submitted to journals.

Subscription to key journals

It is important that the Unit keeps up to date with new developments in the field of HIV care and support, and this will assist in the thoughts about new operational research. Four key journals will be subscribed to:- Lancet, BMJ, New England Journal of Medicine, AIDS.

2.10. Manage ARV therapy and HIV-disease at Headquarters

Strengthened HIV/AIDS Unit

The HIV/AIDS Unit is small and under-resourced. There is a Head of Unit, supported by one ARV officer and one technical assistant in HIV care and support for ARV scale up and HIV-disease management. The HIV-Coordinator assists where possible, but his role is not that of implementation of the programmes. There is an urgent need for another ARV officer. There is also need to consider maintaining the technical assistant in post for a further three years, after January 2007, as the ARV scale up programme will begin to feel the effects of large numbers of sites offering treatment and large numbers of patients on ART.

HIV Management Group Meetings

The HIV Unit holds 6-weekly management group meetings to discuss progress with the ARV and CT scale up plans. The core membership is the HIV Unit staff with others co-opted from Central Medical Stores, Health Technical Services, National AIDS Commission, Health Education, Lighthouse, National WHO, CDC and also PMTCT. These meetings will continue to be held 6-weekly, with minutes circulated.

Other Management and Knowledge Dissemination meetings

There is an HIV Implementation Group, which meets every 3 months. The membership is the HIV Unit, Reproductive Health Unit, Health Technical services, and home based care. The purpose is to share information between other departments in the Ministry of Health.

There is a Health Sector HIV/AIDS Forum, which meets on a monthly basis. Membership is wide and includes Ministry of Health, National AIDS Commission, NGOs and any other interested stakeholders. The purpose is to share information about HIV-AIDS activities in the country.

Office support

The HIV Unit will need ongoing office support for a) office equipment and consumables, such as stationary, toner; b) transport, fuel and maintenance of vehicles, c) communication equipment

2.11. ARV therapy in the Private Sector

ARV therapy will be provided in the private sector for patients at a subsidised rate. It has been agreed that patients can attend private ARV clinics and pay MK500 per month for their drugs. Part of this money will be retained by the private sector to compensate for costs of dispensing and part will be returned in order to provide a sustainable system of monitoring and supervision.

The private sector has already agreed to follow national systems. Nearly 200 service providers have been trained and passed the formal examination from over 70 facilities in the country. Two meetings have been held to discuss implementation and about 35 facilities have been earmarked for providing support. The facilities have been provided with standardised monitoring tools.

Progress is being made. Funds for supporting private sector ARV scale up have been found from WHO-AFRO-Canada. The Malawi Business Coalition (MBCA) has taken an active interest in managing the process. An officer has been appointed to take charge of assessing sites and conducting supervision, monitoring and evaluation in the private sector, and will be employed under the MBCA. During 2006-2007, private sector sites will start delivering first line ART, mainly in Lilongwe and Blantyre.

The HIV Unit will maintain an active interest in private sector scale up, will receive and collate ART data into its public sector reporting and will continue to train private sector staff. However, the day to day running (including drug procurement) will not be the HIV Unit's responsibility, but will be that of the MBCA.

2.12. Linkages to other scale up plans for CT, PMTCT and Laboratory support

This plan will be linked to the other 5-year scale up plans being put together for counselling and HIV testing, Prevention of Mother to Child transmission and Laboratory support. These linkages will be made by the HIV coordinator, MOH, once the other scale up plans have been finalised

2.13. Budget for the 2-year period

The budget breakdown is shown in **Annex 7.** The total budget for the 2-year period is USD$47,273,500.

Annex 1: Targets for ARV scale up

Strategy Indicator	Baseline (End 2005)	2006	2007	2008	2009	2010
Input Indicators:						
Up to date ART Manual Which is in circulation	Yes	Yes	Yes	Yes	Yes	Yes
Number of districts providing ART (cumulative)	28	30	30	30	30	30
Number of public health facilities providing ART (cum)	60	90	90	110	120	120
Number of private health facilities providing ART (cum)	30	40	50	60	70	80
Number of public HCW trained and accredited in ART (cum)	1000	1400	1800	2200	2600	3000
Number of private HCW trained and accredited in ART (cum)	200	300	400	450	500	550
Number of facilities with stock-outs of ARV drugs	0	0	0	0	0	0
Output Indicators:						
Number of new patients started on ART each year	20,000	35,000	40,000	45,000	45,000	45,000
Number of new children started on ART each year	1,000 (5%)	2,625 (7.5%)	4,000 (10%)	4,500 (10%)	4,500 (10%)	4,500 (10%)
Number of patients ever started on ART by end of year (cum)	35,000	70,000	110,000	155,000	200,000	245,000
Number of children ever started on ART by end of year (cum)	1,750 (5%)	4,375 (6.25%)	8,375 (7.6%)	12,875 (8.3%)	17,375 (8.7%)	21,875 (8.9%)
Number who are alive and on ART at end of each year (cum)	30,000	60,000	90,000	130,000	170,000	208,000
Proportion of those ever started who have died (cum)	8%	12%	12%	17%	17%	17%
Proportion of those ever started who are lost to follow-up (cum)	8%	10%	10%	10%	10%	10%
Proportion of patients alive who are ambulatory (cum	85%	85%	85%	85%	85%	85%
Proportion of patients alive who are at work (cum)	80%	80%	80%	80%	80%	80%
Proportion of patients alive with 95% drug adherence (cum)	90%	90%	90%	90%	90%	90%

Annex 2: Targets for Management of HIV-related disease

Strategy Indicator	Baseline (End 2005)	2006	2007	2008	2009	2010
Input Indicators:						
Up to date HIV-Management Manual in circulation	Yes	Yes	Yes	Yes	Yes	Yes
Number of public HCW trained and accredited in HIV-disease management (cum)	1000	1400	1800	2200	2600	3000
Number of private HCW trained and accredited in HIV disease management (cum)	200	300	400	450	500	550
Number of facilities implementing a strengthened HIV-disease programme with no stock-outs of HIV-drugs	Unknown	20	40	50	50	50
Number of facilities implementing CPT package with no stock-outs of CTX	0	10	20	40	50	50
Output Indicators:						
Number of new patients treated for tuberculosis each year	25,000	25,000	25,000	25,000	25,000	25,000
Number of new patients with Kaposi's Sarcoma treated with ART each year	800	800	800	800	800	800
Number of new patients treated for Cryptococcal Meningitis with fluconazole each year	1,000	1,000	1,000	1,000	1,000	1,000
Number of new patients treated for Oesophageal Candidiasis with fluconazole each year	2,500	2,500	2,500	2,500	2,500	2,500
Number of new patients started on CPT each year using the new 2005 policy guidelines	0	10,000	15,000	20,000	25,000	25,000

Annex 3: Round 1 [60 ART Sites currently providing ARV therapy]

Health facility	Region	ART status as of March 31 2006
Chitipa District Hospital	North	Low Burden – 25 new patients per month
Karonga District Hospital	North	Medium Burden – 50 new patients per month
Nkhata Bay District Hospital	North	Medium Burden – 50 new patients per month
Rumphi District Hospital	North	Medium Burden – 50 new patients per month
Livingstonia Mission Hospital	North	Low Burden – 25 new patients per month
Mzuzu Central Hospital	North	High Burden – 150 new patients per month
Mzuzu Moyale Barracks Hospital	North	Low Burden – 25 new patients per month
Mzimba District Hospital	North	Medium Burden – 50 new patients per month
St Johns Mission Hospital	North	Low Burden – 25 new patients per month
Ekwendeni Mission Hospital	North	Medium Burden – 50 new patients per month
Embangweni Mission Hospital	North	Low Burden – 25 new patients per month
Mchinji District Hospital	Central	Medium Burden – 50 new patients per month
Kapiri Mission Hospital	Central	Medium Burden – 50 new patients per month
Ntcheu District Hospital	Central	Medium Burden – 50 new patients per month
St Theresa Hosp, Mikoke, Ntcheu	Central	Low Burden – 25 new patients per month
Dedza District Hospital	Central	Medium Burden – 50 new patients per month
Mua Mission Hospital	Central	Low Burden – 25 new patients per month
Kasungu District Hospital	Central	Medium Burden – 50 new patients per month
Dowa District Hospital	Central	Medium Burden – 50 new patients per month
Madisi Mission Hospital	Central	Low Burden – 25 new patients per month
Mtengawatenga Mission Hospital	Central	Medium Burden – 50 new patients per month
Ntchisi District Hospital	Central	Low Burden – 25 new patients per month
Salima District Hospital	Central	Medium Burden – 50 new patients per month
Nkhotakhota District Hospital	Central	Medium Burden – 50 new patients per month
St Anne's Mission Hospital	Central	Low Burden – 25 new patients per month
Dwangwa Matiti Clinic	Central	Low Burden – 25 new patients per month
Lilongwe CH –Lighthouse	Central	Very High Burden – 250 new patients per month
Lilongwe CH – OPD1	Central	Medium Burden – 50 new patients per month
Lilongwe CH-Paediatric Clinic	Central	Low Burden – 25 new patients per month
Lilongwe SOS	Central	Low Burden – 25 new patients per month
Kawale Health Centre, Lilongwe	Central	Low Burden – 25 new patients per month
Mlale Rural Mission Hospital	Central	Low Burden – 25 new patients per month
Nkhoma Mission Hospital	Central	Low Burden – 25 new patients per month
Likuni Mission Hospital	Central	Medium Burden – 50 new patients per month
St Gabriels Mission Hospital	Central	Medium Burden – 50 new patients per month
LLW Kamuzu Barracks Hospital	Central	Medium Burden – 50 new patients per month
Nsanje District Hospital	South	Medium Burden – 50 new patients per month
Trinity Mission Hospital	South	Medium Burden – 50 new patients per month
Chikwawa District Hospital	South	Medium Burden – 50 new patients per month
Montfort Mission Hospital	South	Low Burden – 25 new patients per month
Sucoma Clinic, Chikwawa	South	Low Burden – 25 new patients per month
Mangochi District Hospital	South	Medium /High Burden –100 new patients per month
Machinga District Hospital	South	Medium Burden – 50 new patients per month
Balaka District Hospital	South	Medium Burden – 50 new patients per month
Adiamu Comfort Clinic, Balaka	South	Low Burden – 25 new patients per month
Thyolo District Hospital	South	High Burden – 150 new patients per month
Malamulo Mission Hospital	South	Medium Burden – 50 new patients per month
Mulanje District Hospital	South	Medium Burden – 50 new patients per month
Mulanje Mission Hospital	South	Medium Burden – 50 new patients per month
Phalombe Mission Hospital	South	Low Burden – 25 new patients per month
Mwanza District Hospital	South	Medium Burden – 50 new patients per month
Chiradzulu District Hospital	South	High Burden – 150 new patients per month
St Joseph's Mission Hospital	South	Medium Burden – 50 new patients per month
Zomba Central Hospital	South	Medium/ High Burden – 100 new patients per month
Zomba Cobbe Barracks Hospital	South	Low Burden – 25 new patients per month
Zomba Police Hospital	South	Low Burden – 25 new patients per month
St Lukes Mission Hospital	South	Low Burden – 25 new patients per month
QECH in Blantyre	South	High Burden – 150 new patients per month
Ndirande health center	South	Medium Burden – 50 new patients per month
Mlambe Mission Hospital	South	Medium Burden – 50 new patients per month

Annex 4: Round 2 [38 Potential new ART sites to start in April 2006]

Health Facility	District	Type of Unit
Northern Region:		**11 Units**
Kaseye Mission Hospital	Chitipa	Low Burden
Chilumba Rural Hospital	Karonga	Low Burden
BLM- Rumphi	Rumphi	Low Burden
Bolero Rural Hospital	Rumphi	Low Burden
Chinteche Rural Hospital	Nkhata Bay	Low Burden
BLM-Nkhata Bay	Nkhata Bay	Low Burden
Katete Mission Hospital	Mzimba	Low Burden
BLM-Mzimba	Mzimba	Low Burden
St Peters Mission Hospital	Likoma Island	Low Burden
Mzuzu – MACRO	Mzuzu	Low Burden
Mzuzu University Clinic	Mzuzu	Low Burden
Central Region:		**13 Units**
Lilongwe Bottom Hospital	Lilongwe	Medium Burden
Mitundu Rural Hospital	Lilongwe	Low Burden
Kabadula Rural Hospital	Lilongwe	Low Burden
Partners in Hope (PIH)	Lilongwe	Medium Burden
Area 18 Health Centre	Lilongwe	Low Burden
Area 30 Police Hospital	Lilongwe	Low Burden
Lilongwe- MACRO	Lilongwe	Low Burden
Lilongwe City Assembly Clinic	Lilongwe	Low Burden
Nkhamenya Rural Hospital	Kasungu	Low Burden
Mponela Rural Hospital	Dowa	Low Burden
Sharpe Valley Rural Hospital	Ntcheu	Low Burden
MAFCO, Salima	Salima	Low Burden
Life-Line Clinic	Salima	Low Burden
Southern Region:		**14 Units**
Chilomoni Health Centre	Blantyre	Low Burden
Limbe Health Centre	Blantyre	Low Burden
Bangwe Health Centre	Blantyre	Low Burden
Blantyre-MACRO	Blantyre	Low Burden
BLM-Lunzu	Blantyre	Low Burden
Blantyre City Assembly Clinic	Blantyre	Low Burden
Malawi Polytechnic Clinic	Blantyre	Low Burden
St Martins Mission Hospital	Mangochi	Low Burden
Mulibwanji Rural Hospital	Mangochi	Low Burden
Monkey Bay Community Hospital	Mangochi	Low Burden
Chipini Health Centre	Zomba	Low Burden
BLM- Zomba	Zomba	Low Burden
Chancellor College Clinic	Zomba	Low Burden
Neno Rural Hospital	Neno	Low Burden

Annex 5: Approaches to reducing burden of work in established ART sites

Approach	Implications	Advantages	Disadvantages
Follow-up of patients every two to three months	None	Will reduce the follow-up load in the clinic by 50% or more	Patient adherence to treatment may be compromised Side effects may be identified too late
Lower cadre of staff to run ART	Need to identify what is the lower level of staff and commence training	Will increase the number of staff able to man ART clinics	Poor ART management
Follow-up of patients decentralised to health centres	Staff at health centres need to be trained Special training module needs to be developed for health centre staff Monitoring tools needs to be placed at health centres (eg duplicate master cards, special registers) ARV drugs need to be stored at health centres Hospital ARV clinic team needs to provide regular supervision and M&E	Reduces the burden of work at the established clinic Easier and less costly monthly access to ART follow-up for patients living close to the health centre	Extra work for central unit staff to prepare a training module and conduct training Duplicate monitoring tools to be developed Risk of ARV drug abuse unless the drug consumption is closely monitored
Patients initiate ART at the health centres	Staff at health centres need to be formally trained (classroom and attachments) Health centre sites need to be formally assessed Registration and monitoring tools placed at health centres ARV drugs need to be stored at health centres Central Unit needs to provide regular supervision and M&E	Better access for patients in remote areas who need to start ART Better and cheaper follow-up access	Central Unit staff need to train the health centre staff and conduct site assessments Risk of ARV drug abuse unless drug consumption is closely monitored Number of ARV sites to be monitored and supervised increases

Annex 6. Drug procurement needs and costs for the three years of Global Funding: 2006 – 2009

ARV Item	Unit Cost USD$ - includes CIF	Numbers of Items / or patients on treatment and estimated cost per 6 month period – includes CIF up to the port of entry						Total number of items	Total cost (USD$)
		Jul-Dec 06 (Order in March 06)	Jan-Jun 07 (Order in Oct 06)	Jul – Dec 07 (Order in March 07)	Jan–Jun 08 (Order in Oct 07)	Jul–Dec 08 (Order in March 08)	Jan – Jun 09 (Order in Oct 08)		
Starter Packs	550	240 $132,000	270 $150,000	270 $150,000	300 $165,000	300 $165,000	300 $165,000	1,680 Starter packs	$924,000
Continuation Packs	3000	1560 $4,680,000	2000 $6,000,000	2600 $7,800,000	2850 $8,550,000	3500 $10,500,000	3830 $11,490,000	16,340 Cont. packs	$49,020,000
Alt 1st Line PN	22 / month	1800 x6 $240,000	2400 x6 $315,000	3000 x6 $400,000	3600 x6 $475,000	4200 x6 $550,000	4800 x6 $634,000	1,190,000 courses	$2,614,000
Alt 1st Line HP/SK	42 / month	450 x6 $113,000	600 x6 $150,000	750 x6 $190,000	900 x6 $226,800	1200 x6 $302,400	1500 x6 $378,000	325,000 courses	$1,360,000
2nd Line Treatment	95 / month	450 x6 $256,000	600 x6 $342,000	800 x6 $456,000	950 x6 $542,000	1200 x6 $684,000	1500 x6 $855,000	33,000 courses	$3,135,000
Post-exp Prophylaxis	15 / month		1000 $15,000		1000 $15,000			2,00 courses	$30,000

Annex 7: Activities of the 2006 and 2007 ARV and HIV-disease Scale up Plan: Process Indicators, Time frame and Budget

Activities for ARV and HIV-disease Management Scale up	Activities for 2006				Activities for 2007				Cost (USD) for 2 years	Source of Funds
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4		
2.1 ARV and HIV-disease Management Guidelines:									**84,500**	
Revise 1st edition of ARV Treatment Guidelines Indicator: Edition revised	X	X							5,000	NAC
Possible revision of HIV-disease Guidelines Indicator: Edition revised					X	X			3,500	NAC
Print and disseminate ARV and HIV Guidelines: Indicator: copies of ARV Guidelines Indicator: copies of HIV-Disease Guidelines			2000 1000				2000 1000		30,000 30,000	NAC NAC
Print and disseminate District ARV Training Module Indicator: copies of Training Module	5000				3000				16,000	WHO

Annex 7: Activities of the 2006 and 2007 ARV and HIV-disease Scale up Plan (continued)

Activities for ARV and HIV-disease Management Scale up	Activities for 2006				Activities for 2007				Cost (USD) for 2 years	Source of Funds
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4		
2.2. Build capacity for ART/HIV management:									**1,200,000**	
Revise ARV/HIV Training Module Indicator: Revised Module on CD-ROM	X	X							20,000	NAC
Classroom trainings in Public sector Indicator: Number of trainings	2	2	2	2	2	2	2	2	900,000	NAC
Classroom trainings in Private sector Indicator: Number of trainings	1	1	1	1	1	1	1	1	20,000	NAC
Clinical attachments in Public sector: Indicator: attachments in the quarter	X	X			X	X			85,000	NAC
Classroom refresher and dissemination meetings Indicator: meetings held each year in each region				1				1	100,000	NAC
Pre-service training on ART and HIV disease Indicator: trainings in the quarter			X	X			X	X	40,000	NAC
Maintain data-base on personnel trained Indicator: data base entries in the quarter	X	X	X	X	X	X	X	X		
District Modular training Indicator: trainings in the quarter	X	X	X	X	X	X	X	X		
HIV Unit attend International meetings: Indicator: three in the course of one year		1	1	1		1	1	1	35,000	NAC
Increased human resources: Indicator: human resources match the stated need										

Annex 7: Activities of the 2006 and 2007 ARV and HIV-disease Scale up Plan (continued)

Activities for ARV and HIV-disease Management Scale up	Activities for 2006				Activities for 2007				Cost (USD) for 2 years	Source of Funds
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4		
2.3 Procure ARV drugs and HIV drugs:									**45,122,000**	
Procure and distribute ARV drugs Indicator: Procurement undertaken	X		X		X		X		35,122,000	NAC
Procure HIV-disease management drugs Indicator: Procurement undertaken	X		X		X		X		10,000,000	NAC
2.4. Implement ARV therapy in public sector:										
General implementation: Indicator: ongoing service delivery	X	X	X	X	X	X	X	X		
Laboratory support for ART scale up: Indicator: Report of a consultative visit Indicator: Implementation of the report	X	X X	X	X	X	X	X	X		Other sources of funds
Adherence to ART and compliance with Follow-up: Indicator: Pill count and default rates	X	X	X	X	X	X	X	X		
Special Groups: Children; TB patients; PMTCT; Patients who have failed first line regimen Indicator: Reports on Progress with implementation	X	X	X	X	X	X	X	X		
Equity in ART: Indicator: on-going service and monitoring	X	X	X	X	X	X	X	X		
Human resource needs for ART: Indicator: HR resources match stated needs	X	X	X	X	X	X	X	X		
2.5. Implement CPT:										
Implementation of CPT activities Indicator: Number of sites implementing CPT policy	O	0	6	6	10	25	35	45	See 2.3	See 2.3

Annex 7: Activities of the 2006 and 2007 ARV and HIV-disease Scale up Plan (continued)

Activities for ARV and HIV-disease Management Scale up	Activities for 2006				Activities for 2007				Cost (USD) for 2 years	Source of Funds
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4		
2.6. Increase health education on ART and HIV:									**28,000**	
Implementation of health education Indicators: reported on by HEU	X	X	X	X	X	X	X	X	28,000	NAC
2.7. Monitoring and Evaluation of ART and HIV:									**329,000**	
Printing and distribution of monitoring tools Indicator: Monitoring tools printed and distributed	X	X			X	X			30,000	NAC
Country-wide situational analysis Indicator: Situational analysis completed	X	X			X	X			24,000	NAC
Quarterly M&E visits Indicator: Visits undertaken to all ART sites	X	X	X	X	X	X	X	X	40,000	NAC
Quarterly ARV and HIV-disease reports Indicator: copies of Reports circulated	X	X	X	X	X	X	X	X		
Supporting electronic M&E at pilot sites Indicator: number of computers at sites (cumulative)	0	0	4	4	6	6	8	8	35,000	NAC
Annual surveillance of HIV-drug resistance Indicator: Survey undertaken	X			X	X			X	200,000	WHO CDC
2.8. Assess new ART sites and supervise old sites									**5,000**	
Assess new ART sites Indicator: sites assessed in each quarter	X	X			X	X			5,000	NAC
Quarterly Supervision of established ART sites Indicator: visits undertaken to all ART sites	X	X	X	X	X	X	X	X		

Annex 7: Activities of the 2006 and 2007 ARV and HIV-disease Scale up Plan (continued)

Activities for ARV and HIV-disease Management Scale up	Activities for 2006				Activities for 2007				Cost (USD) for 2 years	Source of Funds
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4		
2.9. Conduct ARV and HIV Operational Research:									**350,000**	
Quarterly meetings of ARV research group Indicator: Meetings held	1	1	1	1	1	1	1	1	24,000	WHO
HIV and ARV Knowledge Centres Indicator: Resource centres established	X	X	X	X	X	X	X	X	24,000	NAC
Operational research studies undertaken Indicator: 5 papers written per year				5				5	300,000	NAC WHO
Subscription to key journals Indicator: Journals received by HIV Unit	X	X	X	X	X	X	X	X	2,000	NAC
2.10 Manage ART and HIV at Headquarters:									**75,000**	
Strengthened HIV Unit Indicator: Additional ARV officer appointed			X	X	X	X	X	X		
HIV Management Group Meetings 6-weekly Indicator: Meetings held with minutes	X	X	X	X	X	X	X	X		
Other Management Meetings (eg Implem. Group) Indicator: Meetings held with minutes	X	X	X	X	X	X	X	X		
Office support Indicator: No stock outs of office materials	X	X	X	X	X	X	X	X	75,000	NAC SWAPS
2.11. ARV in the Private sector:									**80,000**	
Progress made with private sector Indicator: quarterly reports from MBCA	X	X	X	X	X	X	X	X	80,000	WHO
2.12. Linkages with other scale up plans:										
Other scale up plans finalised and linked with ART Plan Indicator: Explicit linkages with ART scale up	X	X								