Financial Cost Implications of an Expanded Free Antiretroviral Therapy Programme in Uganda and its Financial Sustainability

BY

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Declaration

This thesis in its original form is entirely mine and has never been submitted to this University or any other institution of higher learning for any award. It is a product of my original study done in Uganda between December 2003 and January 2004. All other sources are fully acknowledged.

Signed by candidate

Lennie. SB. Kyomuhangi

Date: 2 November 2004

This thesis has been submitted for examination to the University of Cape Town with my full permission.

Ms Susan Cleary
SUPERVISOR

Date: 2 November 2004

Dedication:

This Thesis is dedicated firstly to my Lord and Saviour Jesus Christ. I also dedicate this thesis to my late daughter Samantha Sematimba whose memory has been my constant inspiration during this course, and to my late brother Polly Bazira Tibifumira, who made sure that I went to the best school in Uganda and paid all my tuition fees. You are both dearly missed and always loved.

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Abbreviations

AIDS:	Acquired Immuno Deficiency Syndrome.
ARVs:	Antiretroviral drugs.
ART:	Antiretroviral Therapy.
ATC:	AIDSTREATCOST
AZT:	Zidovudine
3TC:	Lamivudine
CD4:	CD4 lymphocyte cells
CT:	Cape Town
D4T/3TC/NVP:	Triomune
D4T:	Stavudine
ddi:	Didanosine
EFZ:	Efavirenz
FL:	First line Antiretroviral regimen
HAART:	Highly Active Antiretroviral Therapy
HIV:	Human Immunosuppressive Virus
LFT:	Liver Function Test
MAP:	Multi country HIV/AIDS programme
MSF:	Médecins sans Frontières
NGO:	Non-governmental organisation
NVP:	Nevirapine
OIs:	Opportunistic Infections
PHRplus:	Partners for Health Reform plus Project
PLWHA:	People Living With HIV/AIDS
PMTCT:	Prevention of Mother–To -Child Transmission
SL:	Second line Antiretroviral regimen
TB:	Tuberculosis
UGS:	Uganda Shillings

UNAIDS:	The Joint United Nations Programme on HIV/AIDS
US$;	US Dollars
VCT:	Voluntary Counselling and Testing
VL:	Viral load (HIV RNA) test
WB:	World Bank
WHO:	World Health Organisation

Terms of reference

The study aimed to achieve the following objectives:

1. To estimate the annual and lifetime costs of providing Antiretroviral therapy (ART) in one centre in Uganda from the perspective of the public health system.
2. Using key results from this cost analysis to determine the costs of scaling up ART in Uganda.
3. To establish the financial sustainability of the ART programme by the government of Uganda
4. To make recommendations on possible options to promote financial sustainability.

ABSTRACT

Globally there are an estimated 42 million people infected with HIV/AIDS, of whom 70 % are in Sub-Saharan African (SSA). SSA has about 4.1million people in need of Antiretroviral therapy (ART), out of whom only about 50,000 are currently receiving this treatment. Uganda has an estimated 1.1 – 1.5 million HIV positive people out of whom an estimated 100,000 are in need of ART at any one time. Currently an estimated 10,000 – 17,000 are receiving ART (Ministry of Health, 2003).

The purpose of this study has been to determine the costs of an expanded free ART programme in Uganda and its implications for financial sustainability. The annual and lifetime incremental costs of ART from one treatment centre in Uganda were analysed. The key results from this centre were used to estimate the incremental costs associated with the scaling up of ART services in Uganda from the provider's perspective. A key concern was that the financial costs involved might not be financially sustainable by the country.

Data on the costs associated with ART services were collected from one treatment centre in Uganda, the Nsambya hospital ART programme. Key informant interviews were carried out with various stakeholders to obtain information on the financial resources available for the proposed expanded free ART programme in the country, and to establish if the country has any financial sustainability plans for the programme. The results were analysed using Microsoft Excel programme and STATA statistical package. Future costs of scaling up ART were estimated using the Cape Town Antiretroviral Costing Model developed by Boulle, et al, (2004).

The key findings of the study were as follows:

- The modelled annual average ART costs per patient were found to increase with the years from US$ 1,039 in 2003 to US$ 1,141 by the end of 2008 for

the Nsambya ART programme. These costs were higher than those obtained for the national ART programme which ranged from US$ 541 per patient per year in 2004 to US$ 685 per patient per year by the end of 2008.

- The estimated lifetime costs for a patient on ART were higher for the Nsambya ART programme at US$ 6,852 per patient than for the national ART programme that were estimated at US$ 5,518 per patient. The difference in these costs was because ART costs from Nsambya reflect prices for retail prices of ARVs while those at the national level were for wholesale prices. Also patients at Nsambya were mostly on branded ARVs that were found to be more expensive than generic ARVs. From this, it can be concluded that the costs of ARVs has significant effect on the costs of the ART programme in the country. Thus, it is recommended that the Ugandan ART task force needs to look for the cheapest source of ARVs for the national ART programme. The quality of the ARVs needs to be given priority, thus, where patent versions of ARVs are cheaper than the generic ones patent ARVs should be the drugs of choice.
- Looking at the costs of scaling up ART programme in Uganda, second line (SL) regimens were found to be more expensive at US$ 884 per patient per year than first line (FL) regimens that were at US$ 437 per patient per year.
- Using survival assumptions, the proportion of patients on SL were found to increase from 9 % in 2004 to 22 % by the end of 2008. Since SL were more expensive than FL regimens the increase in the proportion of patients on SL regimens with the years led to the increase in Average ART costs with the years from US$ 541 per patient per year in 2004 to US$ 685 per patient per year by the end of 2008.
- The total costs of scaling up ART in Uganda were estimated to increase from US$ 3.18 million in 2004 to about US$ 68.3 million by the end of 2008. The available funds from the GFATM and WB (MAP) totalled US$ 74 million for

a period of about three years. Looking at the costs of ART and the available funds, the study concluded that ART services in Uganda might not be financially sustainable.

- A one-way sensitivity analysis revealed that changes in the price of ARVs and laboratory test costs have a significant effect on the ART programme costs.
- Uganda is classified as one of the least developed countries with an annual per capita income of approximately US$ 300. Health expenditure is low at US$ 13 per capita, out of which US$ 5 is funded by the government and donor funds under SWAPs. This study has estimated the per capita expenditure on ART at approximately US$ 2.8. This means that the provision of ARVs by the government would take up more than 50 % of the country's health expenditure if they were to be funded from the health budget. Thus, without donor funding specific for the provision of ARVs, the government of Uganda may not be able to finance the universal provision of ARVs. Furthermore, the government has no concrete financial sustainability plans for the ART programme apart from the continued fund flows from the GFATM.

This study has therefore concluded that given the current status quo, Uganda is not able to financially sustain the expanded free Antiretroviral therapy (ART) programme. This study recommends that the government explore other ways of raising domestic funds for the financing of its ART programme. The recommended ways are the introduction of a special levy for the ART programme, contribution from employers through the Uganda Business Coalition (UBCA) and restructuring of the current health care financing mechanisms from payment at point of consumption to prepayment funding system. This would help in the financial sustainability of the country's ART programme if donor funds were to be stopped.

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Chapter One

BACKGROUND TO THE STUDY

1.0 Overview

The study aims to analyse the financial cost implications of an expanded free Antiretroviral therapy (ART) programme in Uganda and its financial sustainability. This introductory chapter will offer background information and an overview of the study. The research problem will be defined and a description of the remaining chapters will be given.

1.1 Introduction

Global HIV/AIDS prevalence rates have continued to rise despite numerous strategies to combat this pandemic. Globally, there are an estimated 40 million people living with the Human Immunodeficiency Virus (HIV). About 95 % of these are in developing countries of whom 70 % are in Sub-Saharan Africa. Acquired Immunodeficiency Syndrome (AIDS) killed more than 3 million people in 2003 alone and there were an estimated 5 million new HIV infections (UNAIDS, 2003).

Sub-Saharan Africa (SSA) has one of the highest HIV prevalence rates. The total number of people who are HIV positive is estimated at 26.6 million. In this region alone, AIDS killed approximately 2.3 million people in 2003 and 3.2 million were newly infected with HIV, hence the current persistent high prevalence rates across the region (UNAIDS, 2003).

As a result of the growing concern for the impact of HIV/AIDS in developing countries, the World Health Organization (WHO) and the Joint United Nations programme on HIV/AIDS (UNAIDS), released a detailed and concrete plan of

providing ART to 3 million people living with HIV/AIDS in developing countries by the year 2005 (World Health Organisation, 2003). This is a vital step towards the ultimate goal of providing universal access to ART to all those who need it. Despite these efforts, the challenges posed by HIV/AIDS are still great. There is need for sustainable financing in most of SSA if this epidemic is to be contained. To do this, there is need for both political and financial commitment (Thompson, et al, 1990). Drug procurement and regulation has to be strengthened. Health workers have to be trained, infrastructure improved, communities educated, and all stakeholders mobilised for any ART programme scale up to be successful (World health Organisation, 2003).

ART helps alleviate the suffering of people living with HIV/AIDS. A study on the assessment of antiretroviral therapy in Uganda found out that ART leads to declining viral loads, improved the immune response of the patients through the elevation of CD4 counts and thus reduced episodes of opportunistic infections (Weidel, P, et al, 2000). The alleviation of OIs has been found to lead to cost savings, for example, a Brazilian study reported cost savings due to declines in annual AIDS related admissions per patient after the introduction of ART (Teixeira, et al, 2003). ART also mitigates the impact of the epidemic by providing opportunities for prevention through the raised awareness and creation of demand for testing and counselling. It also is hoped that ART will help reduce the stigma and discrimination associated with HIV/AIDS in communities (World Health Organisation, 2003). Out of the estimated 800,000 people living with HIV/AIDS who are on ART, 500,000 are from high-income countries. In SSA about 4.1 million people are in need of ART and only 50,000 (1 %) are currently accessing this treatment (World Health Organisation, 2003). However, in recent times, the provision of Highly Active Antiretroviral Therapy (HAART) has become a core component of the fight against HIV/AIDS in many of the developing countries. This has become possible because of declining

drug prices, increased donor funding to support this intervention and political will from all stakeholders (Kombe and Smith, 2003).

Most of the SSA countries including Uganda rely on donor funds for their national ART programmes. However, donor funds are affected by the politics of the countries from which they originate (Baker and Brook, 2003). The proposed expanded Uganda National ART programme is relying on funds from The Global Fund to fight AIDS, Tuberculosis (TB) and Malaria (GFATM), the World Bank (WB), and the Bush Initiative. Currently, Uganda has not budgeted for the ART programme from its local revenues (Ministry of Health, 2003).

1.2 Uganda's socio-economic indicators

Uganda is classified as one of the least developed countries. The Gross Domestic Product (GDP) was estimated at approximately Uganda Shillings (UGS) 10,567 billion {United States Dollars (US$) 7 billion} in 2002/03 (Ministry of Finance, 2003). The annual GDP growth is projected to average 6.4 % over the medium term, 2002/03 – 2006/07 and level off to 6 % over the long term. Government revenues are expected to increase to about 14 % of GDP by 2006/07 and 18.2 % by 2020/21 (IMF and IDA, 2002). The GDP per capita is estimated at US$ 300 - 330 per capita. Due to high population growth rates the per capita GDP has remained almost constant for the last five years (Ministry of Finance, 2003). The population, as per the last census, is estimated at 24.7 million people evenly split between males and females. The country has one of the highest population growth rates in the world of 3.4 % per annum. The average Ugandan woman gives birth to seven children in her life (Uganda Population and Housing Census, 2002, IN: Ministry of Health, 2003). More than 80 % of the people live in rural areas and mainly depend on subsistence agriculture for a living. The majority live below the poverty line and survive on less than a dollar per day (Ministry of Finance, 2003). Therefore, one wonders how the country would manage

to financially sustain ART to about 100,000 people per year when costs are estimated to be more than US$ 500 per person per year (Ministry of Health, 2003).

Total government spending was approximately 23.3 % of GDP in 2001/02 but is expected to decline to 21 % over the long term. This is higher than government revenues that are 14 % of GDP. The overall fiscal deficit, excluding grants, has been projected at 11 % of GDP (Ministry of Finance, 2003). Health care expenditure is low at about 3 % of GDP (Ministry of Finance, 2003). Currently government health services are funded under the Sector Wide Strategic Approach Programme (SWAPs). The current health care funding is about US$ 13 per capita per annum, of which US$ 8 is provided out of pocket, and US$ 5 by the state from both government and donor funds combined (Ministry of Health, 2003). The budget allocation to the ministry has been constant for the past three years at approximately UGS 375.06 billion (US$ 193 million) per year and was 13.1 % of the overall government expenditure in 2003/2004 (Ministry of Finance, 2003).

The country has high mortality rates. The Infant Mortality Rate (IMR) is about 97 per 1,000 live births, while the Maternal Mortality rate (MMR) is about 506 per 100,000 live births. The life expectancy has fallen from 52 years during the 1990s to about 42 years due to the HIV/AIDS epidemic. According to the MoH of Uganda (2003), physical access to basic healthcare has fallen from 45 % to 41 % within the last five years as a result of the insurgency in the Northern part of the country. Most of the health facilities have no adequate storage facilities or laboratory and clinical equipment, and are in need of physical rehabilitation. They lack both financial and human resource management capacity with no functional quality assurance systems (Ministry of Health, 2003).

The health system is decentralised to 56 districts. There are two national referral hospitals of which one is a specialised mental hospital, eleven regional hospitals, 56 district hospitals below which are health centre fours (IV). The Health Centre IVs are at the sub-district level and are the equivalent of a primary care health clinic (Ministry of Health, 2003).

1.3 Health sector response to the HIV/AIDS epidemic in Uganda

Uganda was one of the first countries to report the incidence of a recognised HIV/AIDS case in 1982, and HIV/AIDS was declared an epidemic in the country in 1986 with adult seroprevalence rates as measured from antenatal clinics (ANC), as high as 37 % (Ministry of Health, 2003). It was also one of the first African countries to respond aggressively to the HIV/AIDS epidemic (Okero, et al, 2003). The government together with international partners put in place strategic management systems, which were mainly aimed at prevention. This brought the adult seroprevalence rates to the current low values of about 6.5 % (Ministry of Health, 2003). Despite the progress made in fighting the epidemic, the country still remains vulnerable to the negative impact of HIV/AIDS like the rest of Africa (Ministry of Health, 2003). According to the Ministry of Health, Uganda has an estimated 1.1-1.5 million people living with HIV/AIDS with an infection rate of 3.4 % per annum. Although there is a decline in new infections, those already with HIV and progressing to AIDS are still many. AIDS is still a major cause of death, currently responsible for 12 % of the total annual deaths in the country and a leading cause of death among people aged 15-49 years (Ministry of Health, 2003). According to the UNAIDS "epidemiological fact sheet 2002 update", it is estimated that 230 people in Uganda die daily due to HIV/AIDS (UNAIDS, 2003). The Ministry of Health estimates that at any one time about 100,000 patients are in need of ART on clinical grounds because of advanced HIV infection. An estimated 10,000-17,000 patients are currently receiving ART (Ministry of Health, 2003).

Antiretroviral drugs (ARVs) have been in Uganda since 1998 through the Joint United Nations programme on HIV/AIDS Drug Access Initiative (UNAIDS_DAI) in collaboration with the Ministry of Health of Uganda (MoH). However, these have been confined to Non-Governmental Organisations (NGOs), and research and pilot projects, and have not been available to the wider public through the public health system (Ministry of Health, 2003). By the end of 2000, the UNAIDS_DAI initiative had resulted in about 1000 clients on ART (Ochola, et al, 2000). After this pilot phase the MoH took over the co-ordination of the ART programme in April 2000. An expansion plan to increase access to ARVs was developed with the support from WHO, which is referred to as the "National Strategic Framework for expansion of HIV/AIDS care 2001/2002 to 2005/2006". This is part of a multi-year scale up that is to be implemented within the framework of the National health policy and the HIV/AIDS health sector strategic plan (World Health Organisation, 2003).

The current focus in the fight against HIV/AIDS is to balance preventive strategies with treatment efforts for People Living With HIV/AIDS (PLWHAs). The ART roll out policy in Uganda was launched in November 2002 with the formation of the ART policy committee that has come up with guidelines for the implementation of this programme. This policy is in the process of being approved by cabinet. The government intends to offer free ARVs to the estimated 100,000 patients currently clinically eligible for ART. It will also fund related services such as laboratory monitoring tests (Ministry of Health, 2003).

The ART programme is to be phased as follows:

Phase 1: National and regional hospitals by 2004

Phase 2: District and other hospitals by 2006

Phase 3: Health centre IV's by 2010.

The services to be included as part of the ART programme include treatment with ARVs, counselling at appropriate intervals, laboratory testing at appropriate intervals, clinical diagnosis and treatment of HIV - related infections, food supplementation (if necessary) and community-based alternatives to institutional care and support.

1.4 Problem statement

The expected life expectancy of someone who is started on ARVs is 4 - 8 years (Ministry of Health, 2003). Patients on ART should have an uninterrupted drug supply for life so as to avoid developing resistant strains of the HIV virus (UNAIDS, 2002). Uganda is one of the least developed countries in the world with an annual per capita health expenditure of only US$ 13 out of which US$ 5 is funded from government and donor funds combined. The annual per patient cost of providing ARVs is estimated at between US$ 318 and & US$ 520 for first and second line regimens respectively with minimal laboratory testing (Ministry of Health, 2003). In Uganda, an estimated 100,000 patients are in need of ART at any one time (Ministry of Health, 2003).

A key concern, given the low per capita health expenditure and the high costs involved in providing ART, is how will the country be able to afford and financially sustain the ART roll out programme.

1.5 Research question

The major research question to be answered is "What are the financial cost implications of scaling up an Antiretroviral therapy programme (ART) in Uganda and what are the implications for its financial sustainability?" Considering current levels of annual per capita health care expenditure in Uganda, and the estimated annual per capita costs of providing ART, my hypothesis is that an expanded free Antiretroviral therapy programme may not be financially sustainable in Uganda.

1.6 Study objectives:

1. To estimate the annual and lifetime costs of providing ART in one treatment centre in Uganda from the perspective of the public health system.
2. Using key results from this cost analysis to determine the costs of scaling up ART in Uganda.
3. To establish the extent to which the ART programme is financially sustainable from the Uganda government funds.
4. To make recommendations on possible options to promote financial sustainability.

1.7 Justification for the study

Evaluation of ART in Uganda and other countries involved in the pilot phase of UNAIDS_DAI has demonstrated that highly active antiretroviral therapy (HAART) is effective in increasing the CD4 counts and reducing the viral load of HIV/AIDS patients leading to reduced morbidity and mortality among these people. It has been proven that rational use of ARVs is feasible in resource poor settings such as Uganda (UNAIDS 2002). However there are not many documented and comprehensive studies in Uganda on the financial cost implications and financial sustainability of free ART for all. The aim of this study was to elucidate the cost implications of a universal free ART programme for the country and its financial sustainability. Hence findings from the study will be useful for policy makers to devise a financial sustainability strategy for scaling up the ART programme in the long term. It will also inform future studies on a similar subject.

1.8 Scope and limitations of the study

The study limits itself to assessing the costs related to the provision of Antiretroviral drugs for adults. ART Costs for children were not included in this study because the

treatment centre studied did not have data on paediatric cases and time and financial resources limited this study. This study did not look at all the other costs of scaling up the management of HIV/AIDS, such as the treatment of opportunistic infections (OIs), prevention of Mother-To-Child-Transmission (PMTCT) or community based programme. This is due to the fact that the ART programme is considered to be an incremental one and their inclusion was beyond the scope of this study. However, the ART programme can also avert some of the current costs so it is not clear that it is entirely incremental. To be able to provide more comprehensive costs involved in scaling up a national ART programme, including comprehensive care for OIs and HIV related illnesses and events, would have required more time and other resources that this study did not have. Therefore, there is need for further studies in this area.

The clinical service costs used were from one treatment centre located in the district of Kampala. There may be slight differences in the clinical service costs incurred in other areas of the country. Despite this limitation, the key costs drivers of an ART programme (costs of ARVs and laboratory testing) are all in line with national treatment guidelines; therefore, these costs should be representative of the costs of scaling up. A further key driver of the costs of scaling up ART is the survival of patients on ART and the relative proportion of time spent on first line and second line regimens owing to differing regimen costs. However, it has not been an aim of this study to undertake primary survival analysis. All survival assumptions used were those incorporated in the Cape Town (CT) Antiretroviral Costing Model (Boulle, et al, 2004).

ARV drug prices are constantly declining and the costs obtained may change in years to come, thus affecting the national costs of a scaled up ART programme. This has been taken into consideration by carrying out a sensitivity analysis to find out the effect of price changes on total ART costs.

1.9 Organisation of the study

Chapter 2: Theoretical and Empirical Literature reviews. The theoretical literature review analyses the theoretical foundation of different approaches and perspectives to costing ad modelling in health economics. The empirical literature review looks at different international costing studies of Antiretroviral therapy programmes and examines different costing models used. It looks at Uganda's policy response to the HIV/AIDS epidemic and trends in ARV price reductions. The final section also looks at different literature on the theories and studies on financial sustainability of health programmes in developing countries.

Chapter 3: Methodology. This chapter describes the costing methodology, data sources and the ART costing model used.

Chapter 4: Key findings from the cost analysis and modelling are presented.

Chapter 5: Discussion of study results and projected national costs of scaling up ART programme is presented.

Chapter 6: The final chapter presents the policy implications, recommendations and conclusions.

Chapter Two

LITERATURE REVIEW

2.1 Costing in Economic Evaluation

Economists define costs as the value of the resources used to produce something (Drummond, et al, 1987). Costing studies involve the identification, measurement and valuation of resources consumed by an intervention or activity of interest. This means identifying the need that is being addressed and the financial resources required to meet that need (Drummond, et al, 1987). Pure costing studies are different from cost-effectiveness studies, which compare the costs and outcomes of health interventions (Brouwer, et al, 2001). Drummond, et al (1987) gives two major categories of costs: the economic and financial costs. Economic costs are those that reflect opportunity costs of an input or resource. Here, opportunity cost is the value of the best-forgone alternative use of a given amount of resources. Financial costs are the actual expenditure costs incurred by individual payers such as patients or providers of care or governments (Drummond, et al, 1987).

Costs can be divided into variable and fixed costs. Variable costs are those that vary with the level of production, in this case the number of patients treated while fixed costs do not vary for a certain range of production and are hard to adjust in the short term (Drummond, et al, 1987). For example, fixed costs do not vary with the number of patients treated (Kumaranayake and Watts, 2000). For this study variable costs include ARVs, laboratory tests and ART patient visits, while fixed costs include capital items such as the purchase of new equipment and initial staff training.

Different costing perspectives are used in analysing the resources used in providing a health service, namely societal, household and provider perspectives (Brouwer, et al, 2001). The authors define societal perspective as being the broadest and here costs incurred by all the people involved in providing or using a service is counted. The

household perspective considers costs incurred by patients and/or their households in the process of seeking and consuming health care. The provider's perspective considers costs incurred by a provider of a specific service and excludes costs incurred by other groups of people who are consuming the service (Brouwer, W. et al, 2001). In this study, the provider perspective was used because it directly addresses the challenges that countries have in such a large ART programme. This is because the aim of this study is to analyse the costs of scaling up ART services that the government will have to incur and not the costs incurred by the patients or their households in seeking the service.

Frequently in estimating costs related to any services, say within a hospital, the step down allocation method is used to assign costs associated with various activities of the hospital (Barnum and Kutzin, 1993). According to the two authors, this method involves allocating all hospital expenditures to specific cost centres. They define cost centres as departments within the hospital where different services are provided. These can be broadly divided into inpatient and outpatient departments. Within each of these departments there are subdivisions into various medical disciplines such as the ART department, which is part of the general outpatient department. After identifying the cost centres, allocation criteria are used to allocate costs within a specific period to each cost centre (Barnum and Kutzin, 1993). For this study, step down allocation method has been used. Thereafter, two allocation criteria for the shared costs were used, namely the proportion of ART patient visits to total outpatient visits, and the proportion of hours spent on ART services to that of the total working hours (Barnum and Kutzin, 1993). Within the particular department, Brouwer, et al (2001) recommends the use of micro costing for analysing the individual costs of all the resources used. This is by the use of the ingredients approach to costing which involves detailed measurement of all resources used in the provision of a specific health service or intervention, for example the provision of ARVs.

2.2 Modelling in economic evaluation and scaling up of ART interventions

A model is any mathematical structure that represents health and economic outcomes of patients under different scenarios by the use of explicit assumptions (Kuntz and Weinstein, 2001). The two authors argue that where data are incomplete, modelling can help improve the decision making process by providing a tool for synthesising data and handling uncertainty. According to the two authors, models are used in health economics to inform decisions in the absence of hard data.

When looking at costs of scaling up any ART programme, models are recommended for estimating the future costs of HIV/AIDS interventions (Kumaranayake and Watts, 2000). The two argue that the paucity of data on HIV/AIDS interventions necessitates estimation of the nature of projected activities and related costs.

Various models have been developed to help project costs related to HIV/AIDS interventions at a programme or country level (Boulle, 2004). In reviewing various models developed for estimating costs for HIV/AIDS interventions, Boulle (2004) identified subtle differences between them. His recommendation is that the choice of which one to use depends on the study being undertaken and on the experience of the user. According to him, all the models are similar with respect to the inclusion of drug costs, laboratory costs and clinical care costs. The difference is in the level of detail and flexibility with which they are specified (Boulle, 2004).

Partner for Health Reform plus (PHRplus) developed the AIDSTREATCOST (ATC) model. The focus of the ATC model is on treatment interventions (Kombe and Smith, 2003). It includes short-term demographic and epidemiological estimates but does not allow for the coverage targets to be manually phased in over time. It looks at ART costs for different population groupings in a country and thus requires the user to have

detailed data on these that can be quite tedious unless one has lots of resources at their disposal (Wilwerding, et al, 2004). According to Boulle (2004), this model lacks customisability to different studies because of the uniformity of assumptions over time and lacks flexibility in the ARV regimen specification. Some of its data processing steps are not clear and the software limits its outputs (Boulle, 2004). In addition the ATC model assumes that all patients in one population grouping would be on the same ARV treatment regimen (Wilwerding et al, 2004). This is not necessarily true as some patients are on different regimens for example pregnant women cannot be put on EFZ and there are always toxic and allergic reactions necessitating patients to be switched to other regimens.

The GOALS model was developed by the Futures group to help explore the effect of different funding levels and patterns on national goals. Its intention is to support strategic planning by linking programme goals and funding levels (The Futures Group, 2001). The GOALS model links budget line items to coverage of services, behaviour change and prevention of new infections. It then uses unit costs based on local studies or international experience to calculate national programme costs (The Futures Group International, 2001). It is a comprehensive HIV response model that is broader than ARV treatment interventions and thus, is not ideal for estimating the annual costs per patient (Boulle, 2004).

The Cape Town (CT) Antiretroviral Costing Model was developed to assist planners for the introduction of ART in a province in South Africa and to inform funding proposals to the GFATM (Boulle, et al, 2004). The focus of this model is on ART interventions and it provides a comprehensive tool for estimating ART service costs, both at a unit and programme level (Boulle, 2004). Since the main focus of this study is to estimate ART service related costs, it is the best choice to use for modelling the costs of scaling up ART in Uganda. This model uses linked Excel sheets with inputs

and outputs to help project costs of scaling up ART services under different scenarios (Boulle, et al, 2004). With the CT Antiretroviral Costing Model a comprehensive analysis of all the resources used under different scenarios can be estimated. According to its developers, laboratory monitoring test frequencies for ARV drug reactions have been designed in a way that is related to the ARVs being used. The CT Antiretroviral Costing Model has an advantage over the ATC and GOALS models in that it ensures that blood tests to be performed are related to individual ARVs being used (Boulle, et al, 2004).

The GOALS model, unlike the ATC and CT Antiretroviral Costing Models, is not ideal for estimating annual per patient costs. Its assumptions on ART are less detailed than the ATC and CT Antiretroviral Costing Models (Boulle, 2004). On the other hand, the ATC model includes short-term demographic and epidemiological estimates but unlike the CT Antiretroviral Costing Model, it does not allow for the coverage targets to be manually phased in over time (Boulle, 2004). Manual phasing of patients starting ART gives greater flexibility to the user. This is why a model that allows this to be done, that is the CT Antiretroviral Costing Model, is deemed to be more appropriate for this study. The CT Antiretroviral costing Model was also developed specifically for estimating costs related to ART services (Boulle, 2004). Hence, the CT Antiretroviral Costing Model is viewed as the ideal choice of the model to use for this study.

2.3 Previous studies on the costs of scaling up national ART programme

The provision of ARVs in developing countries poses the problem of allocation of optimal resources to HIV related activities in contexts where there are very limited resources devoted to health care (Ainsworth, et al, 1998). This has called for studies to estimate the costs of scaling up ART programme in a number of SSA countries.

South Africa is one of the few SSA countries where a number of studies using different models have been carried out to explore the resource requirements for the provision of ART (Boulle, et al, 2003). In 2002, researchers from the University of Cape Town used a number of scenarios to model national ART treatment programmes over a period of five years. The individual cost-effectiveness of these scenarios was modelled and the most cost effective was used to show the potential savings of implementing ART (Boulle, et al, 2002). The researchers estimated that using the most cost-effective scenario the costs of ART in the year 2006 - 2007 would be about R 409 million with 107,000 people on treatment. After carrying out sensitivity analyses with different assumptions on the population growth rates, HIV infection rates, laboratory monitoring schedules and ARV drug prices, they found out that the highest cost drivers of providing ART were ARVs. Another study in South Africa also concluded that ARV costs contribute the largest proportion of the total ART costs taking up 50 % of the total costs while laboratory test costs took up 9.2 % of the total costs (Cleary, et al, 2003). A study carried out by Boulle, et al, (2003) estimated that the average annul costs for FL regimens at US$ 500 and those for SL regimens that were estimated at US$ 865.

The ATC model was used in 2003 in Zambia and Uganda to estimate the incremental financial costs associated with the scaling up of ART programmes. Here the authors focused exclusively on the incremental costs that are costs associated with the ART programme requirement that would not typically be included in the government health budget (Kombe and Smith, 2003). The two researchers concluded that the largest ART programme costs are those for ARV drugs taking up about 57 % of the total costs in Zambia and 63 % in Uganda. According to Kombe and Smith (2003), the ARV costs were influenced by the treatment regimens chosen. Like the South Africa study, SL regimens were found to be more expensive than first line regimens at more than US$ 1000 per patient per year. According to the studies in Zambia and Uganda,

laboratory test costs represented the second largest portion of the costs taking up 36 % to 45 % for both countries. Capital costs were found to be relatively low accounting for about 6 % of the ART costs in the two countries. Training costs on a per patient basis was found to account for about 1 % of the total ART costs. Taking all the individual costs into consideration it was estimated that the average annual incremental cost per patient for first line regimens was US$ 488 in Zambia and US$ 619 in Uganda (Kombe and Smith, 2003). According to Wilwerding et al (2004), the ATC model assumes that all patients from one population grouping chosen would be on the same ARV regimen. Thus it may not clearly bring out changes in average per patient ART costs, as patients switch to SL regimens with time and this is one of the reasons the CT model was preferred for the current study.

The ATC model was also used in Nigeria to estimate the costs of scaling up ART services from the public sector (Kombe, et al, 2004). The total incremental cost associated with the introduction of ART was estimated at US$ 742 per patient per annum. ARV costs constituted the largest proportion of the costs at US$ 368 per patient per year representing 50 % of the total costs. Laboratory monitoring costs took up about US$ 170 while labour took up US$ 161 per patient per year. Capital and training costs were relatively low taking up US$ 27 and US$ 15 per patient per year respectively (Kombe, G. et al, 2004). The results obtained in Nigeria concur with those in Zambia, Uganda and South Africa in that ARV costs are the largest cost for the ART services. However, in Nigeria the researchers looked at just one FL regimen (ZDV, 3TC, D4T) and did not consider the effect on average costs if other FL regimens and SL regimens were used. This is crucial for a comprehensive study since other regimens have to be considered as not all patients can be on the same regimen.

In Mexico, a costing study on HIV/AIDS care concluded that ARV drugs contribute the largest cost component of the ART costs by taking up 72.7 % of the total costs

(Sergio et al, 2003). The researchers also used the ATC model to estimate the costs of HAART for adults. The researchers estimated the average annual per patient costs for ARVs at between US$ 2000 and US$ 3000. These costs are much higher than those for the African studies. The difference could be attributed to the difference in prices and cost structures between the African countries and Mexico.

In Kenya, a study using the GOALS model estimated that approximately US$ 76 million would be required to assure significantly increased access to HAART (The Futures Group International, 2001). As mentioned in section 2.2, this model differs from the CT and ATC models in that it does not give the individual patient per annum specific costs (Boulle, 2004). Therefore, this study does not tell us the individual per patient costs that are important for planning to scale up ART programmes.

Researchers at Harvard University estimated that in 70 % of the patients in SSA countries, the annual drug cost per patient per year for ART would be about US$ 500. For the other 30 %, the costs were estimated to be higher at US$ 1000 (Harvard University, 2001). The researchers reached at these assumptions after taking into account that some patients develop virological resistance to FL regimens hence requiring SL regimens. The Harvard University (2001) study results put the weighted per patient annual ART costs at US$ 650 across the board. They split the costs as follows: US$ 350 for ARVs, US$ 130 for Laboratory monitoring, US$ 50 for treatment of side effects and another US$ 50 for logistics, training and other programme expenses. The Harvard study gives a broad picture of SSA countries but does not specify the costs of ART in individual countries. It is argued that not all countries are at the same level of development and they all have different cost and price structures for their health services (AXIOS International, 2002). Studies for each country are needed for estimating financial resource requirement for ART

programmes and hence help in the financial sustainability of these programmes (Ainsworth, et al, 1998).

Costing studies have also been carried out in India and the results agree with those in Africa in that ARV and laboratory test costs are the largest cost drivers for any ART programme (IAEN, 2002). In Chennai India, a cohort study of 609 patients on AIDS care (1996 - 2001), put the cost of ART at US$ 450-2,250 per person per year, and that of laboratory tests at US$ 430 per person per year (Marie, C. 2002). In Nepal a costing study estimated the costs of ART to be US$ 600 per patient per year (IAEN, 2002).

All the above-mentioned studies that used the ATC model included the costs of opportunistic infections (OIs), VCT and PMTCT. According to the MoH of Uganda, for some patients, it may not be easy to identify HIV related OIs since other immune suppressant conditions such as Cancer and Diabetes can lead to the development of similar OIs. This study chose not to include the costs of treating OIs because their inclusion was beyond the study's scope.

2.4 Progression of the HIV/AIDS disease

Information on the rate of progression through the HIV/AIDS stages in Africa is not conclusive because of the limited number of natural history studies in sub-Saharan-African settings (Gilks, et al, 1997). A study done in rural Uganda found that the median time from seroconversion to WHO stage 2 was 25.4 months and to stage 3 was 45.5 months. In the same study, 43 % of people infected with HIV–1 had signs and symptoms two years after seroconversion (Morgan, et al, 1997). Another study done in Uganda concluded that there was a 3-4 year period of being asymptomatic and 2 years of being symptomatic (Stages 2 & 3), before the onset of AIDS for HIV-1 in Uganda (Grant, et al, 1997). What this means is that people may not present with

any symptoms for a period of up to four years after counselling and testing. Even with free universal voluntary testing and counselling (VCT), not all the HIV infected people will come forward for this. This is why it is important to estimate the costs of scaling up ART under a phased formant. Of all the currently available costing models, the CT Antiretroviral Costing Model was the one that easily allows this to be done. This is why it has been used by this study.

The progression to clinical AIDS and death has been shown to slow down for patients on ART as compared to those not on ART (Weidle, et al, 2000). However, this is influenced by the stage of the disease at which patients come for treatment (Ochola, et al, 2000). During the UNAIDS pilot project in Uganda, many of the patients recruited for the ART programme were in the late stages of their disease with a median baseline CD4 cell counts of 73 cells/μL and viral load of 193,817 copies/ml (Weidle, et al, 2000). The study carried by out Weidle, et al (2000) to assess UNAIDS pilot project in Uganda gave very low survival probabilities. The probability of remaining alive and in care was estimated at 0.63 at 6 months and 0.49 at one year. These study findings are different from other studies that gave higher median survival. A study carried out in a South African township, Khayelitsha, put the average life expectancy of patients on ART at about 8 years as compared to 2 years for those not on ART (Cleary, et al, 2003). Depending on the level of care, the WHO estimates that the survival time for patients on ART is between 5 and 7 years (World Health Organisation, 2003). The CT Antiretroviral Costing Model uses a median survival time of 6 years for patients on ART (Boulle, et al, 2004).

Antiretroviral therapy is a lifetime treatment and thus the costs involved are lifetime costs (Gray, 2003). Studies done at the University of California, San Francisco, on Structured Interruption treatment found that patients whose treatment was interrupted experienced more AIDS related complications and poorer immune response than

those who took different drugs immediately after developing resistance (Altman, et al, 2003). For this reason, costs for ART will be assumed to be for life for those patients who are receiving them assuming a median survival time of 6 years (Boulle, et al, 2004).

2.5 Trends in Antiretroviral drug price reductions

The increasing demand for ARVs in developing countries and international pressures have led to dramatic ARVs price reductions in these countries, making it possible for more people to access ART (UNAIDS, 2002). ARV prices have been declining but may have reached the lowest limits for the ones that have been on the market for a number of years. This may mean that the current prices may prevail for some time (Lucchini, et al, 2003). Lucchini, et al (2003) argue that the introduction of generic versions of ARVs contributed to these price reductions by providing cheaper alternatives for developing countries, and prompted brand name drug manufacturers to lower their prices. They say that for some of the ARVs such as Didanosine (ddi) and Lamivudine (3TC) that have been on the market for more than ten years, there is a very small difference between the prices of the generic and branded drugs. The study carried out to review trends in ARV prices concluded that ARV prices tended to stabilize during the years 2001 to 2002 (Lucchini, et al, 2003). Hence in looking at different scenarios for possible drug price reductions in the future these facts have been considered.

2.6 Theoretical perspectives on financial sustainability

The perspective that has been used in defining financial sustainability is that of development economics (McPake and Kutzin, 1997). At the level of a health system, sustainability is defined as the "capacity of the system to continue its normal activities successfully in the future should foreign assistance be withdrawn" (Knowles, et al, 1997). This definition is sometimes expanded to include an additional requirement

that the system be able to expand its activities as needed to keep up with increases in demand due to economic and population growth. Knowles, et al (1997) broadly divide sustainability into institutional and financial sustainability. The authors define financial sustainability as the capacity of the health system to replace withdrawn donor funds with domestic resources, while institutional sustainability is referred to as the capacity of the health system if suitably financed, to assemble and manage the necessary non-financial resources to successfully carry out its normal activities. Institutional sustainability has a wide range of dimensions: technical, social, political, and managerial sustainability (Canadian Public health Association, 2001)). This study only looked at the financial sustainability of an expanded Antiretroviral therapy programme in Uganda.

Other authors have defined financial sustainability as the extent to which national health expenditures are funded from national resources or more flexibly, as the medium to long term stability of a mix of funding sources (McPake and Kutzin, 1997). Lafond (1995) defines financial sustainability "as the capacity of the health system to function effectively over time with minimum external input". Still other authors have looked at financial sustainability being just the continuation of activities and benefits of a programme using all resources available, whether from donors, or governments or both (Bossert, 2004). It is argued that to achieve financial sustainability, a country should not be expected to become self sufficient, at least not the most resource limited countries (The Global Alliance for Vaccines and Immunization, 2003). The Global Alliance for Vaccines and Immunization (GAVI) looks at financial sustainability as being a shared responsibility between developing countries and their donor partners. For this reason, GAVI recommends that there is need to carefully analyse the donor expenditure on government health services, and trends in the percentage of health care funding that has been coming from donors over the past years.

Knowles, et al (1997) and McPake and Kutzin (1997) put forward a number of indicators that can be used to assess the financial sustainability of health programmes. In assessing the financial sustainability of the expanded ART programme in Uganda, the researcher has assumed that these indicators will have a bearing on its financial sustainability. These indicators are as follows:

- Percentage of government health system financed by tax revenue
- Government health expenditure as percentage of total government budget
- Government health expenditure as percentage of Gross Domestic Product (GDP)
- Percentage of government health spending financed by donors
- Percentage of household expenditure for government health services
- Percentage of government health expenditure directed to the particular programme in question
- Domestic macroeconomic conditions such as the inflation rate

2.7 Previous studies on financial sustainability

Measurement of financial sustainability may be problematic because of its perceived intangibility, and multiple dimensions (Knowles et al, 1997). Some authors feel that for financial sustainability to prevail, certain factors have to be in place. These include host government policies that support programme objectives and financial resources that cover programme operational costs (Vokes, 2002). There is a need to establish policy making processes and decision making procedures that will lead to sound economic policy making on a continuing basis (Thompson, et al, 1990). Policy makers should have financial sustainability plans that are crucial for the long-term provision of adequate and reliable financial resource flows (The Global Alliance for Vaccines and Immunisation, 2003). This means understanding the current costs and

financing patterns, projection of future costs and definition of prospects for their financing (The Global Alliance for Vaccines and Immunisation, 2003).

The Australian Agency for International Development (AUSAID) developed a number of tools that can be used to address sustainability issues for immunisation programmes. Some of the tools can be applied in assessing the ART programme financial sustainability. On the issues of funding the key issue to be addressed is that any programme should look at the sources of funding during the period of donor support and beyond. It is recommended that the operational costs of the programme plus other sources of funding should be estimated if the benefits are to be sustained. The expected timeline for phasing out donor support should be described (Australian Agency for International Development, 2000). AUSAID (2002) argues that international prevailing macroeconomic conditions and the policies of the source countries influence donor fund flows.

For any programme to be financially sustainable, it should gain significant levels of funding from national sources, either budgetary or cost recovery, during the life of the programme or project (Bossert, 2004). According to Bossert (2004), the weak economic and political context of African governments has been found to inhibit sustainability. He argues that there needs to be sources of funding that need to be continued after donor funding is stopped for the benefits to be sustained. He also argues that there need to be an expected timeline for phasing out donor support.

Studies from different developing countries indicate that most health programmes are usually not financially sustainable once the external funding is withdrawn (Smith, 2001). A study done by Kombe and Smith (2003) in Zambia, estimated that if all patients who are clinically eligible for ART were to be treated, ART would costs about US$160 million for a period of five years (2003-2008). The authors concluded

that without the GFATM funds, ART services would take up over twice the country's health budget.

A meeting of African leaders, donors and technical experts in Maastricht in 1995 came up with suggestions on sustainable financing initiatives in SSA for the agriculture sector (The World Bank, 1998). Some of the recommendations can be applied to the health sector, and the ART programme in particular, in order to promote financial sustainability. The WB (1998) meeting recommended that any programme should try to mobilise resources from several sources rather than depending on one source. It recommended investment in human resources and organizational capacity building so as to improve efficiency of the public sector. The meeting agreed that there is a need for public institutions to develop basic capacities for programme management, budgeting, and accounting. It also recommended efficient management of the funds by keeping administrative costs low from the beginning. Public institutions were argued to institute financial accountability and transparency. The programme in question should be effectively monitored and evaluated. At the national level, strategic planning, good governance structures and political commitment are important determinants of financial sustainability (The World Bank, 1998).

In the lowest income countries, many attempts have been made over the last few decades to galvanise political commitment and financial support for the control of HIV/AIDS (Sachs, 2003). For most SSA countries financing is one of the key factors in trying to scale up ART programme (Chandani, et al, 2003). The authors argue that even with prices reduced to less than a dollar a day or US$ 350 per patient per year, it is equivalent to the average annual per capita income of most of these countries that is about US$ 300. When the costs of Laboratory tests are added on, it becomes unaffordable for the majority of the people who would need Antiretroviral therapy

(Chandani, et al, 2003). The financial costs involved in scaling up ART in developing countries are much higher than what these countries are currently spending on their health services, thus making the financial sustainability of such programmes a potential problem (Forsythe, 2000).

Low-income countries with a per capita income of less than US$ 755 lack sufficient resources to finance AIDS treatment by themselves, even with discounts of 90 % or more on drugs (PRoCAARE, 1999). With the current supply of domestic resources, no country in Sub-Saharan Africa can undertake widespread AIDS treatment. These countries are too poor relative to the prevalence of HIV/AIDS and the costs of ARVs (McGreevey, et al, 2000). For this reason most of them, except perhaps South Africa and Botswana, have to depend wholly on donor funding for their HIV/AIDS treatment programmes (PRoCAARE, 1999).

Uganda has considered options of financing mechanisms that would improve the financial sustainability of ART services but their implementation still remains a problem (Ministry of Health, 2003). The Ministry of Health of Uganda has come up with cost estimates under different scenarios in order to establish ways of sustaining the ART programme. A number of assumptions were made concerning levels of ART coverage and sharing of the ART costs between some of the patients and the government. The costs to government were estimated at between US$ 7 million and US$ 30 million per annum. However, the feasibility of these scenarios and the establishment of effective cost sharing mechanisms are still uncertain (Ministry of Health, 2003). The government estimates vary widely hence the need for the current study that will bring out the cost estimates of scaling up the ART services more clearly.

2.8 Conclusion

There are a number of costs and costing perspectives that can be used in health economics. The choice on which one to use is dictated by the objectives of individual studies. This study has looked at the incremental costs of scaling up ART services in Uganda from the provider's perspective which includes the private costs that would be incurred by the government in providing free ARVs from the public health sector (Drummond, et al, 1987).

A review of various cost analysis studies in SSA countries and other developing countries have revealed that the main costs drivers for scaling up ART programme are ARVs and laboratory tests. Majority of the studies used the ATC model but have varying average costs per adult patients. These differences could be explained by the difference in the prices of ARVs and costs of laboratory tests. Also these countries have different cost and price structures of their health services and hence the difference in the average ART costs. Also the proportions of costs accounted for by ARVs were not similar. This can be explained by the difference in what was involved in the cost components of ART.

The ATC model that has been used by most of the studies reviewed from SSA including that from Uganda is limited by the fact it lacks flexibility in the regimen specifications (Boulle, 2004). Also the ATC model does not allow for the coverage targets to be manually phased in over time (Boulle, 2004). For planning purposes this leaves a gap since there is need to know the costs of ART over time and under different coverage levels (Kumaranayake and Watts, 2000). This would help to ensure that the financial sustainability of ART programme is planned for.

There are various definitions of financial sustainability but only two of these definitions have been adopted for this study from the perspective of development

economics. Financial sustainability will be assumed to being the capacity of the health system to continue its normal activities successfully in the future if foreign assistance is withdrawn (Knowles, et al, 1997). Financial sustainability will also be looked at as the extent to which national expenditure is funded from national resources (McPake and Kutzin, 1997). The available literature has revealed that the majority of SSA countries have problems of financially sustaining their health programme once donor funding is withdrawn (Bossert, 2004). From the review of the costing studies in section 2.3, ART costs may be too high for most of the SSA countries. Most of these countries may not be able to afford to fully finance ART programme without external financial support (Forsythe, 2000). Therefore, the issue of financial sustainability of scaling up ART programme is important and hence the need for this study.

Chapter Three

RESEARCH METHODOLOGY

3.0 Overview

This chapter provides a description of the methodology used to collect the quantitative data, and the assumptions used to make projections of the costs associated with the expanded free ART programme in Uganda. It also describes the methodology used to obtain information on the financial sustainability of the ART programme in Uganda.

3.1 Study design

This is a cost analysis based on data from a cohort of patients (n=251) at Nsambya hospital HIV/AIDS treatment centre. Financial costs associated with Antiretroviral therapy at this clinic were collected by the treatment centre from 1998 to 2004 and stored in a patient database.

The financial costs of scaling up the ART programme in Uganda, from the provider's perspective were estimated using the Cape Town (CT) Antiretroviral Costing Model (Boulle et al, 2004). The main study outputs are annual average ART costs per patient, lifetime costs per patients and total yearly incremental costs of the ART programme. Information relating to financial sustainability of the ART programme was obtained through oral interviews carried out in December 2003 and January 2004 using semi-structured open-ended questionnaires with key informants.

3.2 Sampling and study population

Purposive sampling was used to select the ART programme at Nsambya hospital due to the limitation of time, finances and the availability of treatment centres with enough data on the costs of ART. Out of an estimated 790 HIV positive patients recorded at Nsambya HIV/AIDS treatment centre, 251 were receiving Antiretroviral

treatment. Costs for all 251 current patients as of December 2003, were reviewed since they were on different treatment regimens. This ensured that all costs involved were captured. Nsambya hospital has an HIV/AIDS treatment centre that has been operational since the inception of the Joint United Nations Programme on HIV/AIDS Drug Access Initiative (UNAIDS_DAI) in 1998. Thus it is one of the few treatment centres in Uganda with a long standing ART programme. Approximately 8.4 % of the patients studied had been on ART for more than five years, and 45.4 % had been on ART for one to two years. This helped to reflect trends in drug price reductions. Thus, costs for both first line (FL) and second line (SL) regimens have been included in the study according to 2003 prices in Uganda. These costs have been varied in a one-way sensitivity analysis in order to find out their effect on the costs of scaling up ART in Uganda.

For the oral interviews, a snowballing form of sampling was used in selecting the key people to interview. These were from different organisations in both the private and public health sectors in Uganda.

The participating organisations were as follows:

1) Ministry of Health (MoH)
2) World Bank Multi Country Action Programme against HIV/AIDS (MAP)
3) ART Policy Committee
4) Medical Access Uganda Limited
5) Nsambya Hospital
6) Joint Clinical Research Centre (JCRC)
7) Uganda AIDS Control Project (ACP)
8) DELIVER – USAID Project
9) Uganda Business Coalition against HIV/AIDS secretariat (UBCA)
10) World Health Organisation (WHO)

Written informed consent was obtained from each of the interviewees. A sample of the consent letter is given in Appendix A.

The interviews were recorded. The taped interviews were transcribed to get common themes, which were used to discuss the financial sustainability of the ART programme in Uganda.

3.3 Survey instruments and data collection

ARV drug costs were retrieved from Nsambya ART programme patient database. The database uses patient reference codes and the patient names were not accessed for purposes of confidentiality. This database was established during the pilot phase of the UNAIDS_DAI. This was for purposes of retrospective abstraction of information on patients on ARV treatment without having to review patient records. Oral interviews were carried out with the head of the Nsambya ART programme to obtain information on the laboratory test, overhead and capital costs that were not recorded on the patient charts. The overhead costs were those relating to staff salaries, administration, communication, and maintenance costs, while capital costs were for the purchase of CD4 and viral load testing machines plus the initial training of health professionals. The cost data capture sheet used is given in Appendix B.

For the qualitative part, a key informant guide with semi-structured open-ended questions was used. This is given in Appendix C. The interviews were taped after obtaining written consent from all participants.

3.4 Costing approach and assumptions

This study focuses on the incremental costs associated with scaling up access to ART that would not typically be included in the government's health budget. Therefore, certain costs have been excluded since they would be incurred whether the ART

programme exists or not. Also, capital costs associated with the construction of buildings were not included since the ART programme at Nsambya hospital, like the rest of the country's HIV/AIDS treatment centres, is run within the existing general outpatient facilities. Capital costs related to the purchase of any vehicles could not be obtained since no vehicles were purchased for the ART programme.

Some of the costs were being shared between the ART programme and the rest of the outpatient services namely personnel and administrative costs. Personnel remuneration costs were allocated to the ART programme by the use of the proportion of the working hours spent on the ART programme that was then multiplied by the total annual remuneration to get the ART personnel costs. The proportions of working hours spent on the ART programme were obtained through oral interviews with the head of the Nsambya ART programme. Overhead costs that were clearly identified as being related to the ART programme have been included namely administration, communication and maintenance costs. Where appropriate, shared overhead costs have been allocated to the ART programme using the step-down allocation method (Brouwer, et al, 2001). With this method, the cost centres (the different departments within the hospitals where resources are used) are first identified. Then the expenditures relating to the cost centres are identified which, in this case, included the ART services and the rest of the outpatient services. The total number of outpatient visits and ART outpatient visits were then obtained for the year 2003. The proportion of the ART outpatient visit to the total number of outpatient visits was obtained which was then multiplied by the total costs incurred for the year to get the ART programme overhead costs for the study period.

The quantitative data relating to ARV costs, laboratory test costs, overhead costs, capital costs and service utilisation costs obtained was entered into Excel spreadsheets. Monthly costs of ARVs per patient were recorded for both the current

regimen and the old regimen for those who have changed treatment regimens. Total annual costs were obtained for the 251 patients for both the old and current regimens. To get the frequency of each treatment regimen, the data was copied into STATA 8. Thereafter, STATA 8 was used to obtain the most frequently prescribed first and second line treatment regimens. The weighted costs for the different drug combinations were obtained by multiplying the annual costs with the proportion of patients on each combination. Average annual costs were calculated by dividing the total weighted annual costs by the total number of patients.

The current annual prices for all the drug combinations that the patients were on for the year 2003 were also obtained from records of the Nsambya ART program. More detailed information for all these combinations is given in Appendix D. Table 1 (below) gives a summary of the costs of the first and second line regimens that have been recommended by the government of Uganda. The prices given in Table 1 (below) were obtained from Nsambya ART programme.

Table 1: Summary of the annual ARVs Prices (Y2003)

Drug Regimen	Patents (US$)	Generics (US$)
ZDV/3TC/NVP [FL]	984.60	646.20
ZDV/3TC/EFZ [FL]	830.76	892.32
D4T/3TC/NVP [FL]	800.04	-
D4T/3TC/NVP - FDC (Triomune) [FL]	-	276.96
D4T/3TC/EFZ [FL]	646.20	567.36
D4T/ddi/LPV/RTV [SL]	1,261.56	958.44
ZDV/ddi/LPV/RTV [SL]	1,661.52	1,187.40
ZDV/ddi/SQV/RTV [SL]	1,753.80	1,225.92

For some of the ARVs, generic versions were more expensive than their patent counterparts. The two recommended SL regimens are ZDV/ddi/LPV/RTV and D4T/ddi/LPV/RTV. A third SL alternative regimen has been included for those patients who may develop hypersensitivity reactions to LPV/RTV. The Uganda national treatment guidelines recommend the use of fixed drug combinations (FDC) if

available for convenience and better adherence by patients. For FL regimens these include ZDV/3TC as Combivir and the generic version of D4T/3TC/NVP as Triomune. For the SL regimens the FDC available is LPV/RTV as Kaletra.

Data on laboratory monitoring tests were obtained from the head of Nsambya ART programme. Information on the frequency and costs of each test was entered into an Excel spreadsheet. Annual Laboratory tests per patient were calculated. Table 2 (below) shows these tests with their test schedules.

Table 2: Annual laboratory tests

Test	**Frequency**
CD4/CD8 Counts	4
Viral Load Test	1
Complete Blood Counts	4
Liver Function Tests	1
Renal Function Tests	1

The tests in Table 2 (above) were those that were being performed for patients on ART at Nsambya ART centre.

For personnel costs, the number of each category of personnel together with the number of their working hours spent on the ART programme and annual remuneration was entered into Excel spreadsheets. The working day was assumed to be 8 hours for all personnel. Table 3 (below) shows the raw data that has been used to calculate the personnel costs.

Table 3: Personnel cost data (US$)

Category	Annual salary (US$)	Number of Staff	Total Costs (US$)	ART programme Hours/day
Physician	9,846.15	2	19,692.31	4
Medical Officer	3,076.92	2	6,153.85	8
Nurse	2,461.54	2	4,923.08	8
Counsellor	2,461.54	2	4,923.08	8
Phlebotomist	2,461.54	1	2,461.54	8
Pharmacist	8,615.38	1	8,615.38	4
Pharmacy-technician	2,461.54	1	2,461.54	8
Accountant	6,153.85	1	6,153.85	6
Cashier	1,846.15	1	1,846.15	8
Support staff	184.62	10	1,846.15	4

The personnel overhead costs were obtained for the whole outpatient department and also include the non-clinical personnel in Table 3 (above) that is pharmacist, pharmacy-technician, accountant, cashier and support staff. The rest of the overhead costs are presented in Table 4 (below).

Table 4: Overhead costs (US$)

Item	Annual costs (US$)
Utilities	
Electricity	184.62
Water	61.54
Other utilities	184.62
Sub-Total Utilities	*430.77*
Communication	
Telephone	123.08
Fax	123.08
Email	210.26
Photocopies	184.62
Stationery	102.56
Computer Consumables	307.69
Sub-Total Communication	*1,051.28*
Maintenance	
Buildings	51.28
Vehicles	184.62
Maintenance Staff	184.62
Sub-Total maintenance	*420.51*

The total number of ART outpatient visits for the year 2003 was 9,036. The total outpatient visits for the same year was 62,847. To get the overhead costs attributed to the ART programme, the number of ART outpatient visits was divided by the total outpatient visits. The proportion obtained was multiplied by the costs to get the overhead costs attributed to the ART programme. The communication costs obtained were for the ART programme and were not shared with the rest of the outpatient services.

Capital costs are those that do not vary with the number of people treated and are not used up within a one year period (Brouwer, et al, 2001). In annualising the capital costs the discount rate used was 9 %. This was from the Bank of Uganda figures as the difference between the money market rates (14.5%) and the inflation rate (5.9 %) for the year 2002/2003. The difference of 8.6 % was rounded off to 9 % in order to be able to get the equivalent annuity factor from economic literature (Cairns, 2001). The capital costs that were incurred by the ART programme used for the study were those for the initial training of health professionals and for the purchase of equipment. A summary of the capital costs is given in Table 5 (below).

Table 5: Capital costs (US$)

Item	REPLACEMENT VALUE (US$)	Annualised costs (US$)		Total annualised costs (US$)
Initial Training			*Number trained*	
Doctors	2,000.00	514.14	2	1,028.36
Nurses	1,000.00	257.07	2	514.18
Counsellors	1,000.00	257.07	2	514.18
Equipment			*Quantity*	
CD4 Fac Machine	25,000.00	6,427.74	1	6,427.23
Viral load Machine	50,000.00	12,854.47	1	12,854.46
Computer	2,500.00	642.67	2	1,285.45
Printer	500.00	128.54	1	128.54

For the Nsambya ART programme two doctors, two nurses and two counsellors were trained. One CD4 Fac machine, one viral load machine, one printer and two computers were purchased specifically for the programme. As mentioned earlier, there were no capital costs incurred for the building of new structures or purchase of new vehicles, furniture and other equipment. The capital costs incurred for the established of the patient database and development of treatment guidelines have not been included because there were not available since they were funded by the UNAIDS_DAI programme.

Where necessary, the exchange rate that has been used to translate the Uganda Shilling (UGS) to the US dollar (US$) is that of UGS 1,950 to US$ 1. This has been the average exchange rate for the country for the last 4 years (Ministry of Finance, 2003). This was to control for any variability in the exchange rates. The exchange rate was varied in the sensitivity analysis to find out its effect on the ART costs.

3.5 Model for estimating costs of scaling up

Costs of scaling up ART in Uganda have been projected for the next five years from 2004 to 2008. This is for budgeting purposes and allows planning for the programme. HIV/AIDS disease is also an evolving paradigm and thus one cannot be sure of what will happen further ahead in the future.

The framework that was used for estimating the national costs of scaling up ART in Uganda was drawn from the Cape Town (CT) Antiretroviral Costing Model that was developed by Boulle, et al (2004). A brief description of how the model works is given in Appendix E. The information that was used to feed into the model was obtained from the results of the Nsambya ART programme and information from the key informant interviews.

The estimation of the ART costs using the CT Antiretroviral Costing Model is based on estimating the utilisation of health services by patients, the costs of these services and the average time on ART. To do this a number of assumptions are made and are divided into four main components (Boulle, et al, 2004).

These are as follows:

1: Demographics – The demographic data help define the potential users of the ART programme services, in other words the people who will be on ARV drugs at any point in time. The numbers of patients starting ART treatment per year were obtained from oral interviews with different key informants who are involved in the scaling up of ART in Uganda. These numbers are based on the estimated number of patients who are in need of ART in the country, approximately 100,000 patients. However, according to most of the key people interviewed, it's believed that not all of these would come forward for the Programme due to various problems such as lack of accessibility to health centres. Some of the patients needing ART are expected to access ART from other Non-Governmental Organisations (NGOs) such as The Uganda AIDS Support Organisation (TASO) and research institutions such as JCRC. Table 6 (below) shows the number of patients that have been assumed to be starting ART each year from the government public health sector for the projected five years.

Table 6: Numbers starting treatment

Year	Patients starting ART
2004	6,000
2005	10,000
2006	15,000
2007	20,000
2008	25,000
Total-Starting	**76,000**

From Table 6 (above) by the end of 2008 the cumulative number of patients that would have been put on ART is 76,000 patients.

2: Survival assumptions - The number of patients started on ART who would still be in care at the end of each year and at the end of the implementation were projected by the use of the median survival assumptions. The survival assumptions used are inbuilt within the model and are based on the UNAIDS and WHO estimates. The WHO three by five team has assumed a mean survival of between 5 and 7 years after starting ART depending on the level of access to care in each country (World Health Organisation, 2003). The CT Antiretroviral Costing Model uses the median survival time for patients on ART of 6 years and this is the one used for this study (Boulle, et al, 2004). In this model, patients on ART are divided into five sub groups. These are as follows:

I. Patients who started ART in the previous year and on average have been on ART for six months at the beginning of the next year.
II. Patients who started ART prior to the previous year who are still on the first line regimen.
III. Patients who started the second line regimen in the previous year and have been on this regimen for six months on average.
IV. Patients who started the second line regimen prior to the previous year.
V. Patients who have clinical progression after starting ART, who may or may not still be on second line regimens.

To get the numbers of patients in each of the above groups the model generates the probabilities of moving between these five states and the probability of dying. It is also estimated that the probability of death in the first year on ART is about 10 %. These patients are assumed to die before switching regimens. The probability of death falls thereafter. For patients who die after many years on ART they would do so after clinically progressing, that is sub-group V (above). It is also assumed that a quarter of

the patients die without clinical progression between sub groups II to IV (above). The death probabilities are combined with those of loss to follow up. It also assumes that a proportion of the patients would have clinical rebound and need to be switched to second regimens after some time on ART. Using these survival assumptions the model helps project the numbers remaining on ART, proportions on first and second line regimens and those who would be expected to have clinically progressed as a result of treatment failure despite being on ART. This then helps estimate the total costs of ART and average per patient costs at the end of each year and at the end of the projected five years.

3:Clinical protocols – These include ARV treatment regimens, laboratory test schedules and clinic visits per patient. These were obtained from key results from Nsambya ART programme and key informant interviews. The laboratory test schedules are similar to those given in Table 2 (above). The ARV treatment regimens that have been used are presented in Table 7 (below).

Table 7: Recommended ARV treatment Regimens for adults in Uganda

First Line regimens	**Abbreviations**
Stavudine/Lamivudine/Nevirapine	D4T/3TC/NVP
Zidovudine/Lamivudine/Nevirapine	ZDV/3TC/NVP
Stavudine/Lamivudine/Efavirenz	D4T/3TC/EFZ
Zidovudine/Lamivudine/Efavirenz	ZDV/3TC/EFZ
Second Line regimens	
Stavudine/Didanosine/Lopinavir/Ritonavir	D4T/ddi/Kaletra
Zidovudine/Didanosine/Lopinavir/Ritonavir	ZDV/ddi/Kaletra
Alternate Second Line	
Zidovudine/Didanosine/Saquinavir/Ritonavir	ZDV/ddi/SQV/RTV

Source: National ARV treatment and care guidelines for adults and adolescents. Draft 9 (Ministry of Health, 2003)

The treatment regimens shown in Table 7 (above) are those that have been recommended by the national treatment guidelines for the scaling up ART in Uganda (Ministry of Health, 2003).

4:Costs - These represent those for ARVs, laboratory tests, and clinic visits.
The ARV costs used are those obtained from recommended prices by the Ministry of Health of Uganda and are presented in Table 8 (below).

Table 8: Antiretroviral drug prices (Y2003)

		Drug Prices per annum (US$)	
Antiretroviral drug	**Abbreviation**	**Generic**	**Patent**
Zidovudine	ZDV	144.00	276.92
Lamivudine	3TC	148.84	148.84
Nevirapine	NVP	108.00	276.92
Stavudine	D4T	42.00	47.95
Didanosine	ddi	336.00	330.48
Efavirenz	EFV	468.00	348.00
Kaletra	LPV/ RTV	319.00	576.00
Saquinavir/Ritonavir	SQV/ RTV	847.53	847.53
Tenofovir	TDF	312.00	312.00
Zidovudine/Lamivudine	AZT/ 3TC	204.00	369.23
Stavudine/Lamivudine/Nevirapine	D4T/ 3TC/ NVP	288.00	

Source: Ministry of Health of Uganda, ART programme 2003

The costs presented in Table 8 (above) are different from those obtained from Nsambya ART programme (Table 1) in that these are prices for bulk buying by the government that have been negotiated with various pharmaceutical manufacturers. The government recommends the use of the cheapest good quality source of ARVs. Thus for those ARVs whose patent versions are cheaper than the generic versions (Efavirenz and Didanosine), the cheaper option has been assumed to be the drug of choice.

Annual ARV costs and laboratory monitoring test costs are calculated as per patient costs. The costs per visits used are those obtained from the Nsambya ART programme and include personnel, overhead and capital costs

3.5.1 Antiretroviral drugs

Information on proportions of patients on each ARV and treatment regimens for first line, second line and failing treatment was obtained from the key informant interviews. The only drugs considered were those that have been recommended by the Uganda National Treatment ART guidelines. It has been assumed that 60 % of all the patients accessing ARVs from the public sector will be on Triomune for first line (FL) regimens (Ministry of Health, 2003). Table 9 (below) shows the drug regimens fed into the model with the proportions of expected use in the respective periods.

Table 9: Antiretroviral Treatment regimens

	Percentage of people on each regimen				
	First Line		Second Line		
Regimen	Initial 6 months	Annually thereafter	Initial 6 months	Annually thereafter	Failing treatment
Triomune	60%	50%			
ZDV/3TC/NVP	20%	15%			
ZDV/3TC/EFZ	10%	15%			
D4T/3TC/EFZ	10%	15%			
TDF/3TC/EFZ	0%	5%			
ZDV/ddi/Kaletra			65%	60%	50%
D4T/ddi/Kaletra			35%	20%	20%
ZDV/ddi/SQV/RTV			0%	20%	10%
Total	**100%**	**100%**	**100%**	**100%**	**80%**

From Table 9 (above) treatment regimens are specified for the first six months and annually thereafter for both first and second line regimens. This is based on the assumption that most changes due to toxicity will occur by six months on treatment (Boulle, et al, 2004). From Table 9 (above), 50 % of the patients on first line (FL)

regimens have been assumed to remain on Triomune after the initial six months. A third combination using Tenofovir (TDF) has been included at a small proportion of 5% to cater for the few patients who may develop hypersensitivity reactions to both Stavudine (D4T) and Zidovudine (ZDV). Since 70 % of the patients would have D4T in their first line regimen, the proportion using this ARV would be lower when patients are switched to second line regimens at 30 %. It has been assumed that 80 % of the patients failing treatment on second line (SL) regimens would be maintained on treatment whereas 20 % would be put off treatment (Boulle, et al, 2004).

3.5.2 Laboratory monitoring costs

The costs used to feed into the model were those obtained from the treatment centre at Nsambya HIV/AIDS ART programme. The laboratory testing schedules were assumed to be similar to those for the rest of the country and have been given in Table 2 (above). The model also helps calculate the blood monitoring tests required depending on the ARVs being used.

3.5.3 Clinic visit costs

Close monitoring is essential to assess adherence to the prescribed regimen, tolerance and side effects of the medication plus efficacy of the therapy (Ministry of Health, 2003). On average, eight visits are recommended during the first six months. Thereafter the patients are seen about 8 times in a year. This is for the doctor and nurse visits. For the regional and referral hospitals with physicians, these are recommended to see the patients about four times in a year. Table 10 (below) shows a summary of the clinic visits recommended by the Ministry of Health of Uganda.

Table 10: Clinic visits per patient

Consultations	Initial 6 months	Annually thereafter
Physician	2	2
Doctor	3	4
Nurse	3	4
Counsellor	6	8
Phlebotomist	2	2

The clinical personnel visit costs were calculated for each category of clinical consultation, and to this was added the overhead and capital visit costs to get the total visit costs. The counsellor's visits are concurrent with those for doctor and nurse visits. This is for purposes of attending to any psychological, emotional or social issues that could affect patient's adherence to treatment. This means that counsellor's visits are about 8 per year. The phlebotomist sees the patients when they need laboratory testing that is about twice for the initial six months and twice annually thereafter. The phlebotomist visits are also concurrent with the doctor and nurse visits in that the patients see them during the same time depending on the need for any laboratory tests. This means that the patient does not have separate visits to see the counsellor or phlebotomists but does so when they come to see the doctor or nurse. However, since time is spent on these concurrent visits they have been counted as separate visits for allocation purposes. The visit costs for the administration personnel who do not come into direct contact with the patients have been considered together with the overhead visit costs.

3.6 Key informant interviews

Key informant interviews formed the qualitative part of the study. These were people that have been instrumental in the designing and implementation of the Uganda expanded ART programme. This was for purposes of getting information on policy

and financial sustainability issues. The interviews were tape-recorded and were later transcribed to abstract common themes on issues of financial sustainability.
The key guiding questions that were used to discuss these issues are as follows:

- Anticipated financial sources for the ART programme
- Percentage of government health expenditure that has been directed to the ART programme
- Proposed usage of the ART funds
- Current health expenditure on health services
- Percentage of government expenditure on health services
- Percentage of government health expenditure that is financed by donors
- Government's financial sustainability plans for the ART programme

The answers to the above questions have been used to discuss the issue of financial sustainability for the ART programme in Uganda. A more detailed list of the guiding questions used for the key informant interviews is given in Appendix C.

Chapter Four

RESEARCH RESULTS

4.0 Introduction

This chapter presents the findings of the study. Quantitative results for the cost of the ART programme from Nsambya HIV/AIDS centre will be presented. The financial costs of an expanded ART programme for Uganda obtained using the Cape Town (CT) Antiretroviral Costing Model will be presented. Then the key informant interviews that form the qualitative part of the study will be presented and financial sustainability of the ART programme discussed.

4.1 Highly Active Antiretroviral Therapy

The costs of HAART in this section comprise of ARV drugs, laboratory monitoring tests, capital costs, personnel costs and overhead costs (administration, maintenance and communication costs). These will be discussed using data obtained from the Nsambya HIV/AIDS treatment centre for a cohort of 251 patients who were on ART.

4.1.1 Antiretroviral drug (ARV) costs

The records obtained from Nsambya HIV/AIDS database showed a total of 52 ARV drug combinations that are being used. The annual per patient costs varied widely depending on the ARV drug regimen and whether patent or generic ARVs were used. The highest proportions (27 %) of the patients were on Combivir/Efavirenz (ZDV/3TC/EFZ). Table 11 (below) shows the proportion of regimens that the patients were being treated with.

Table 11: Drug combination distribution

ARV Drug combination	Percentage (%)
D4T/3TC/EFZ	20.72
D4T/3TC/NVP	5.58
ZDV/3TC/EFZ	26.69
ZDV/3TC/NVP	3.59
Triomune	0.8
D4T/ddi/LPV/RTV	1.2
ZDV/ddi/LPV/RTV	1.99
Other	39.43
Total	**100**

About 3.2 % of patients were clearly on second line regimens and 57.4 % on first line regimens. The category "other" includes all the other combinations that are not similar to those recommended by the national ART treatment guidelines. A comprehensive list of all the ARV regimens that were in use is given in Appendix D. The multiplicity of treatment regimens is due to the fact that patients currently pay for their ARVs and are put on various regimens depending on what they can afford. Market price fluctuations have prompted doctors to keep switching regimens depending on which drug prices have been reduced. Therefore, the regimen changes are not due to treatment failures as is expected to normally happen. The high proportion of the patients being on drug regimens that may not be clearly defined as first or second line regimen calls for standardised national treatment guidelines at all ART centres, for both public and private patients. This is of great importance in case the free universal provision of ARVs is not financially sustainable. If proper nationally recommended treatment regimens are not followed there may be development of resistant strains of HIV that may further complicate the HIV/AIDS situation in the country.

The average weighted per patient annual ARV costs was calculated and Table 12 (below) shows a summary of these costs for the regimens that will be considered for the national ART programme.

Table 12: Annual costs per patient

	Annual costs (US$)	
ARV Drug regimen	**Patents**	**Generics**
FL regimens		
D4T/3TC/EFZ	646.15	584.62
D4T/3TC/NVP	800.00	-
ZDV/3TC/EFZ	830.77	769.23
ZDV/3TC/NVP	984.62	553.85
Triomune	-	369.23
SL regimens		
D4T/ddi/LPV/RTV	1,046.15	958.39
ZDV/ddi/LPV/RTV	1,323.08	1,187.32
ZDV/ddi/SQV/RTV	1,753.85	1,454.93

From Table 12 (above), SL regimens on average are more expensive than FL regimens. The generic versions were on average cheaper than their patent counterparts for all the regimens. The cheapest regimen was the generic fixed drug combination of D4T/3TC/NVP (Triomune) at annual per patient cost of US$ 369.23. Fewer patients were using it, only 0.8 %. The most commonly used first line regimen was the patent version of ZDV/3TC/EFZ (26.69 %) but was also the most expensive FL regimen at US$ 830.77. These costs represent ARV retail drug prices for the year 2003.

4.1.2 Laboratory monitoring tests

The number of times each test should be administered is still being debated internationally. The testing schedules presented in Table 13 (below) reflect the current practice in Uganda. These are the recommended test schedules for Uganda (Ministry of health, 2003).

Table 13: Summary of the laboratory monitoring tests results

		COSTS (US $)	
Test	Frequency	Unit Cost	Per Patient Costs (Year 1)
CD4/CD8 Counts	4	33.33	133.32
Viral Load Test	1	76.92	76.92
Complete Blood Counts	4	6.15	24.6
Liver Function Tests	1	3.59	3.59
Renal Function Tests	1	3.59	3.59
Total			**242.02**

The above testing schedules may not represent WHO recommended guidelines for patients on ART. This is due to the fact that patients were paying for the laboratory tests and thus a minimum number had to be performed in order to minimise the costs. Viral load tests were only performed at baseline before starting the patients on ART. This was because of the high costs associated with viral load tests (Personal communication with the head of Nsambya ART programme, 2003). The total per patient laboratory test cost for the first year was US$ 242.05. The annual laboratory test costs thereafter are expected to be lower since viral load test is only performed at baseline. The most expensive test is the viral load test with a unit cost of US$ 76.92. However CD4/CD8 testing takes up the highest proportion (55 %) of the total laboratory costs because it was performed more frequently.

4.2 Patient visit costs

The patient visit costs were calculated for clinical personnel, overhead (administration, maintenance, communication) and capital costs.

4.2.1 Overhead visit costs

These comprise of costs for the administrative staff, communication and maintenance services. The annual costs attributed to ART services were multiplied by the proportion of the ART outpatient visits for the year 2003 (9,036) to the total outpatient visits (62,847) for the same year to get the cost per patient visit for each of

these individual costs. A summary of these overhead visit costs is given in Table 14 (below).

Table 14: Overhead visit costs (US$)

	Visit Costs (US$)	
Category	**Annual ART visit costs**	**Cost Per patient visit**
Pharmacist	4,307.69	0.48
Pharmacy technician	2,461.54	0.27
Accountant	4,615.38	0.51
Data entry clerk/Cashier	1,846.15	0.20
Support staff	923.08	0.10
Communication	1,051.28	0.12
Maintenance	60.46	0.01
Electricity	26.54	0.01
Water	8.85	0.005
Other Utilities	26.54	0.01
Total Overheads	**61.94**	**1.73**

The non-clinical staffs were considered as part of the overhead visit costs since they do not see the patients per se but their costs contribute to the visit costs. It was assumed that the overhead costs were shared equally among the clinical personnel on a per visit basis and were added onto the clinical personnel visit costs.

4.2.2 Capital visit costs

These comprised of initial training of health professionals and purchase of equipment for the ART programme. Table 15 (below) shows a breakdown of the annualised capital per patient visit costs.

Table 15: Capital visit costs (US$)

	Costs (US$)	
Capital Item	**Annualised costs**	**Cost Per Visit**
Initial Training		
Doctors	1,028.36	0.11
Nurses	514.18	0.06
Counsellors	514.18	0.06
Sub-Total Initial Training	*2,056.71*	*0.23*
Equipment		
CD4 Fac Machine	6,427.23	0.71
Viral load Machine	12,854.46	1.42
Computer	1,285.45	0.14
Printer	128.54	0.01
Sub-Total Equipment	*20,695.68*	*2.29*
Total Capital	**22,752.40**	**2.52**

The only capital costs incurred for this particular programme were for the initial training of the clinical personnel and the purchase of laboratory monitoring equipment as shown in Table 14 (above). This training was necessary since provision of ARVs is a relatively new field and thus these personnel were not equipped with this knowledge during their routine training. This is expected to apply countrywide with the scaling up of ART services. Capital visit costs were also shared equally among all the clinical personnel visit costs.

4.2.3 Clinical personnel visit costs

These were looked at in terms of the annual remuneration and the proportion of time spent on ART programme by each health professional for the year 2003. The clinical personnel visit costs are presented in Table 16 (below).

Table 16: Clinical personnel visit costs (US$)

Category of Personnel	Annual cost of personnel	Total visits (2003)	Cost Per Visit
Physicians	9,846.15	1,004	9.81
Medical Officers	6,153.85	2,008	3.06
Nurse	4,923.08	2,008	2.45
Counselors	4,923.08	3,012	1.63
Phlebotomist	2,461.54	1,004	2.45

The numbers of visits are different for the different categories of health professionals. This is due to the fact that patients do not have to see them all each time they visit. Physician visit costs were the most expensive at US$ 9.81 per visit. However, it should be noted that most of the treatment centres may not have a physician and thus the costs will be lower for some of the lower levels of care. The ART centre studied is at a level of a regional hospital where physicians are expected to review some of the patients on ART.

4.2.4 Overall costs per visit

To each of the clinical personnel visit costs were added the overhead and capital visit costs to get the total costs per visit as shown in Table 17 (below).

Table 17: Total costs per visit (US$)

Clinical personnel	Clinical personnel per visit costs	Overhead per visit costs	Capital per visit costs	Total cost per visit
Physicians	9.81	1.73	2.52	14.06
Medical Officers	3.06	1.73	2.52	7.31
Nurse	2.45	1.73	2.52	6.70
Counsellors	1.63	1.73	2.52	5.88
Phlebotomist	2.45	1.73	2.52	6.70

From Table 17 (above), physician visit costs were the most expensive at US$ 14.06 per patient. The doctor visit costs are approximately half of the physician visit costs.

Since most of the national ART centres may not have physicians, the visit costs may be lower than what this study has estimated.

4.3 Incremental costs for Nsambya ART programme

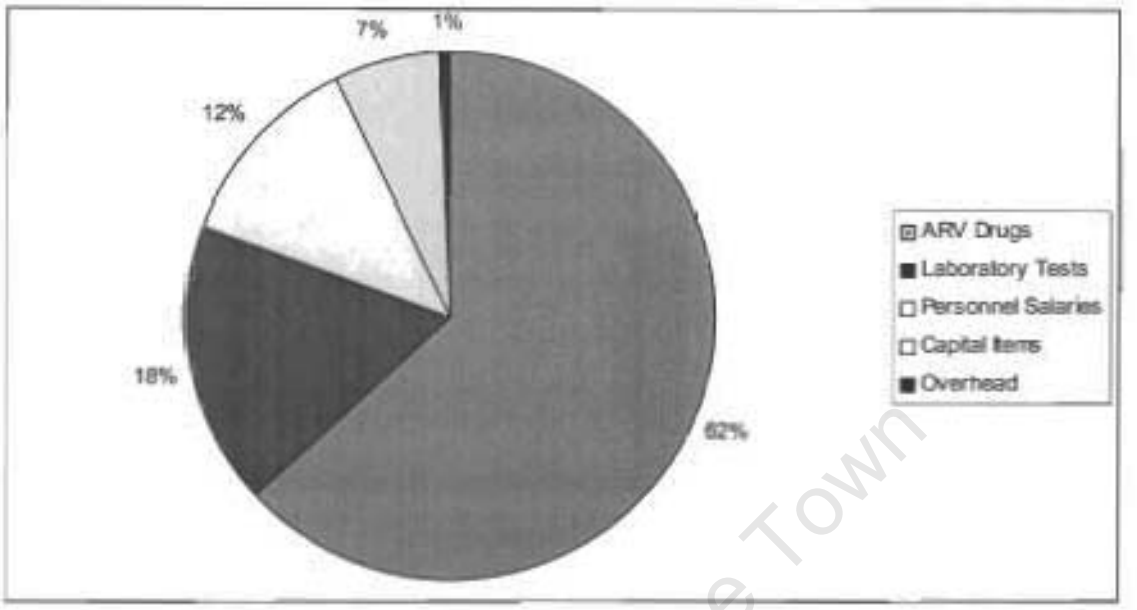
These are the costs that were incurred as a result of the introduction of ART services at Nsambya hospital. The total incremental ART programme costs were obtained by summing up the annual ARV and laboratory test costs for the 251 patients on ART, plus the personnel remuneration and overhead costs for the year 2003. To these were added the costs for the capital items. The total programme costs for the cohort of 251 patients in the year 2003 were US$ 346,246.61 (UGS 675,179,845.91). A summary of the costs incurred and how they were distributed is given in Table 18 (below).

Table 18: Nsambya ART programme costs for the year 2003 (US$)

Item	Costs (US$))	Percentage (%)
ARV Drug costs	218,861.54	63.21
Laboratory Monitoring	60,996.92	17.62
Personnel Remuneration	42,461.54	12.26
Capital	22,752.40	6.57
Communication	1,051.28	0.60
Maintenance	60.46	0.02
Utilities	61.94	0.02
Total	**346,246.07**	**100.00**

ARV drug costs contributed the largest proportion of the ART programme costs constituting 63.21 % of the total ART programme costs and 67.66 % of the recurrent costs. The second largest costs were attributed to laboratory monitoring tests. These results are in agreement with previous costing studies that also concluded that ARV costs and laboratory test costs are the largest cost drivers (Kombe and Smith, 2003). Figure 1 (below) shows a diagrammatic of the distribution of the ART programme costs.

Figure 1 - ART costs distribution



The total personnel remuneration costs constituted 12.26 % of the total ART programme costs and 13.13 % of the recurrent costs. Capital costs contribute a small percentage of 6.57 % since ART services were integrated into the existing hospital outpatient services. This meant that new capital development projects did not have to be undertaken. Overhead costs accounted for the least of the total ART programme costs at approximately 1 % of the total costs.

4.4 Lifetime costs for ART patients at Nsambya hospital

Using median estimates of time spent on FL regimens, SL regimens and failing of treatment, lifetime costs per patient on ART were estimated. These costs are divided into the initial six months (0.5) for FL and SL regimens, and annual costs thereafter. Patients have also been assumed to stay on ART for about one year after failing to respond to ART anymore. The time spent on FL has been assumed to be about 2.8

years, SL 2.2 years and I.0 year after failing treatment. The distribution of these lifetime costs is presented in Table 19 (below).

Table 19: Lifetime Costs for Nsambya ART patients in US$

	First line		Second line		Failing treatment	Total=6 years
Time (Years)	0.5	2.3	0.5	1.7	1.0	
Costs (US$)	618.33	893.94	783.84	1,331.19	1,130.92	
Lifetime costs (US$)	618.33	2,056.07	783.84	2,263.02	1,130.92	**6,852.18**

It has been assumed that patients spend longer on FL regimens than they do on SL regimens (Boulle, et al, 2004). From Table 19 (above) the lifetime costs for a patient on ART is estimated at US$ 6,852.18. The lifetime costs have not been discounted for ease of interpretation by policymakers.

4.5 Model Results for scaling up national Antiretroviral therapy

4.5.0 Overview

Using key results from Nsambya ART programme, plus a number of different assumptions, national ART costs were projected using the CT Antiretroviral Costing Model. This section presents costs of scaling up ART in Uganda from the public sector. The results show projected ART costs for a period of five years starting in the year 2004.

4.5.1 Survival estimates

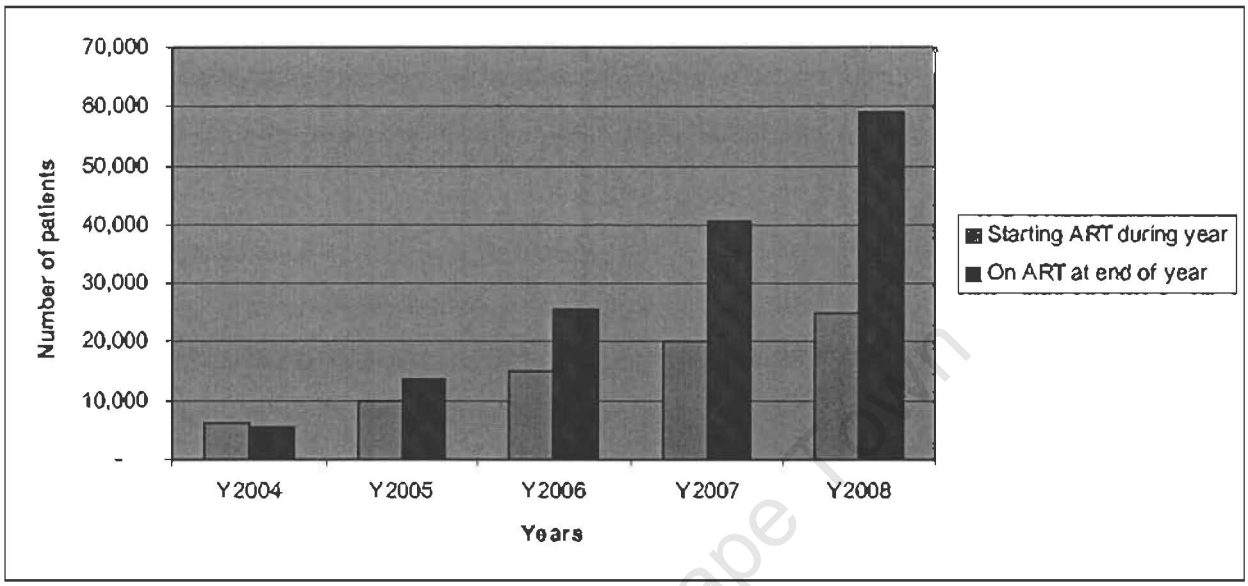
Using the previously mentioned survival assumptions, the total number of patients on ART at the end of each year is shown in Table 20 (below).

Table 20: Summary of patients on ART

	2004	2005	2006	2007	2008
Numbers starting ART during year	6,000	10,000	15,000	20,000	25,000
Cumulative numbers starting ART	6,000	16,000	31,000	51,000	76,000
Cumulative Numbers on ART at end of year	5,308.28	13,591.92	25,520.17	40,734.67	58,916.12

From Table 20 (above) at the end of each year a proportion of the patients starting ART are projected to die despite being on treatment. Thus the numbers on ART are less than those starting ART every year. By the end of the projected five years 77.5 % of the patients started on ART would still be alive and in care. From Figure 2 (below), 76,000 patients would have gone onto ART by the end of 2008, but less than 60,000 would still be alive and on treatment.

Figure 2 - Patients on ART per year



From Figure 2 (above), approximately 22.5 % out of the cumulative number of patients started on ART would have died by the year 2008 despite being on treatment.

4.5.2 Antiretroviral drugs

Using the ARV regimens and costs given in Tables 8 and 9 (above), costs of ART were estimated for each of the periods as presented in Table 21 (below).

Table 21: Summary of projected ARV use and costs (US$)

	Percentage of people on each ARV				
	First Line		Second Line		
Regimen	Initial 6 months	Annually thereafter	Initial 6 months	Annually thereafter	Failing treatment
D4T/ 3TC/ NVP	0.6	0.5	0	0	0
ZDV/3TC/NVP	0.2	0.15	0	0	0
ZDV/3TC/EFZ	0.1	0.15	0	0	0
D4T/3TC/EFZ	0.1	0.15	0	0	0
TDF/3TC/EFZ	0	0.05	0	0	0
ZDV/ddi/LPV/ RTV	0	0	0.7	0.6	0.5
D4T/ddi/LPV/RTV	0	0	0.3	0.2	0.2
ZDV/ddi/SQV/ RTV	0	0	0	0.2	0.1
Costs (US$)	**184.14**	**436.87**	**381.65**	**884.31**	**671.65**

From Table 21 (above), the average costs for FL regimen for the initial six months is less than the annual costs thereafter. The increase in the FL costs after the initial six months can be explained by the fact that the proportion of patients on D4T/3TC/NVP (Triomune) reduces from 60 % to 50 %. This implies that more expensive regimens are used in higher proportions thus driving the average per patient costs upwards. Likewise the average per patient costs for the initial six months on SL regimens are lower than their annual costs thereafter because a more expensive drug SQV/RTV is introduced thus driving the costs higher. The costs given in Table 21 (above) are for generic ARVs since the government plans to use these for patients who will be accessing ART from the public sector. Other scenarios that could prevail if branded ARV drugs were used will be presented in the sensitivity analysis section.

Annual SL regimens are more expensive than the FL regimens. This is of importance because as the patient's duration on ART increases more patients will be on SL regimens due to treatment failure on the FL regimens. Table 22 (below) shows the difference in the average annual per patient costs for FL and SL regimens. It also shows that as the proportion of patients on SL increases with the years, there is an increase in the average per patient ART costs.

Table 22: Comparison of FL and SL regimen costs (US$)

Year	2004	2005	2006	2007	2008
Annual FL regimen costs	436.87	436.87	436.87	436.87	436.87
Annual SL regimen costs	884.31	884.31	884.31	884.31	884.31
Proportion on SL regimens	0.09	0.15	0.18	0.20	0.22
Average adult ART cost	541.08	621.67	653.71	673.67	685.46

From Table 22 (above), the annual FL regimens are US$ 436.87 as compared to US$ 884.31 for SL regimens. The proportion on SL regimens also increases from 9 % in 2004 to 22 % by 2008. This is accompanied by an increase in the average per patient per year ART costs from US$ 541.08 in 2004 to US$ 685.46 in 2008. This has implications for the costs of scaling up ART because with time the financial requirements for ART services will increase as more of the patients on ART are switched to SL regimens, unless there are price reductions in SL regimens. Thus, if ART is to be adequately funded and financially sustained, there should be plans to make sure that this increase in the costs is budgeted for.

4.5.3 Laboratory monitoring test costs

The laboratory testing schedules related to safety is based on the recommended testing schedule for each individual ARV (Boulle, et al, 2004). The CD4 and viral load schedules are specified according to the ART guidelines for Uganda and are independent of which drugs are used since they are used to monitor the patient response to ART. Table 23 (below) presents the laboratory test schedules and estimated associated costs

Table 23: Laboratory monitoring tests

		Average tests in period per person on treatment				
		First Line		Second Line		
Laboratory tests	Unit cost	Initial 6 months	Annually thereafter	Initial 6 months	Annually thereafter	Failing treatment
FBC	6.15	1.5	0.6	3.25	1.6	1.2
Diff	6.15	1.5	0.6	3.25	1.6	1.2
Creatinine	3.59	0	0.1	0	0	0
ALT	3.59	4.8	1.3	0	0	0
Cholesterol&TG	3.59	0	0	2	2	1.6
Glucose	1.54	0	0	2	2	1.6
CD4	33.33	2	2	2	1	1
Viral load	76.92	1	0	0	0	0
Total Lab costs (US$)		**179.28**	**79.08**	**116.92**	**63.28**	**56.31**

The laboratory test costs are higher for the initial six months for both FL and SL regimens. This is due to the fact that patients need closer monitoring when they first start each regimen so as to gauge their response to the treatment. As shown in Table 23 (above), the laboratory test costs for the initial six months are almost two times higher than the annual costs thereafter. The laboratory test costs sharply fall for patients failing treatment because the frequency of laboratory monitoring tests reduces and also the proportion of patients on ART reduces to 80 %.

4.5.4 Clinical service costs

The clinic visit costs used are those obtained from Nsambya ART programme as presented in Table 17 (above). These clinic visit costs have a component of overhead and capital costs. Table 24 (below) shows the visit costs using the scheduled visits for each health professional as recommended by the Uganda national ART treatment guidelines.

Table 24: Visit costs (US$)

		Number of visits in period				
		First Line		Second Line		
Consultations	Visit cost (US$)	Initial 6 months	Annually thereafter	Initial 6 months	Annually thereafter	Failing treatment
Physician	14.06	2	1	3	2	2
Doctor	7.31	5	5	4	5	4
Nurse	6.7	5	5	4	5	5
Counsellor	5.88	8	9	7	9	7
Phlebotomist	6.7	2	2	2	2	0
Total visit costs (US$)		***164.49***	***150.43***	***159.48***	***164.49***	***132.02***
Average ART costs (US$)		**527.91**	**666.37**	**658.05**	**1,112.08**	**859.98**

The patient visit costs are higher in the initial six months of starting ART and switching to SL regimens because they have to be monitored more closely to assess their response to ARV treatment. From Table 24 (above) the total per patient visit costs for both FL regimens are about 1.5 times higher in the first six months than the subsequent annual visit costs, while for SL regimens they are 1.2 times higher. An extra visit has been included to cater for any unexpected complications necessitating patients to be seen more frequently than the recommended number of visits for each period. The last row in Table 24 (above) represents Average per patient costs for ARVs, laboratory tests and consultations.

4.5.5 Summary cost estimates for the Public ART model

Using the above numbers for the patients on ART and various costs, the total and per patient expected costs for the ART programme are given in Table 25 (below). The costs presented are for adults only using generic versions of ARVs or patent versions if these are cheaper as obtained from MoH of Uganda. It has been assumed that prices for ARVs and laboratory tests, the highest cost drivers for the ART services, would remain constant during the projected five years.

Table 25: Summary of costs and numbers on ART by year

	2004	2005	2006	2007	2008
Patients starting during year (1000)	6	10	15	20	25
Patients on ART at end of year (1000)	5.31	13.59	25.52	40.73	58.92
Annual first line regimen cost (US$)	436.87	436.87	436.87	436.87	436.87
Annual second-line regimen cost (US$)	884.31	884.31	884.31	884.31	884.31
Average adult ART cost (US$)	541.08	621.67	653.71	673.67	687.98
Total costs for year (US$ Million)	3.18	12.22	26.04	44.87	68.30

The model used generated the above costs. Assuming that the estimations of the ART policy committee still hold that say that at any one time 100,000 people living with HIV/AIDS would be in need of ART. Using median survival assumptions, by the end of the projected five-year period, the ART programme would be meeting 58.92 % of the expected need. The total costs for this period is projected to be US$ 68 million.

The costs for FL and SL regimens in Table 25 (above) are lower than those obtained for the Nsambya ART programme presented in Table19 (above). This can be explained by the fact that the Nsambya ART programme costs reflect retail prices for ARVs being paid by private patients. The majority of Nsambya patients were also on branded drugs because the treatment centre purchases most of the ARVs from Medical Access Uganda Limited, a private company that was established by the UNAIDS_DAI and currently procures and distributes mostly patented drugs that are more expensive than the generic versions. This is of importance since the type of ARVs used will have implications for the costs of any ART programme.

4.5.6 Lifetime costs for patients on ART

Lifetime costs for patients using Nsambya ART programme costs were compared with those obtained for the scaling up of ART programme from the public sector in

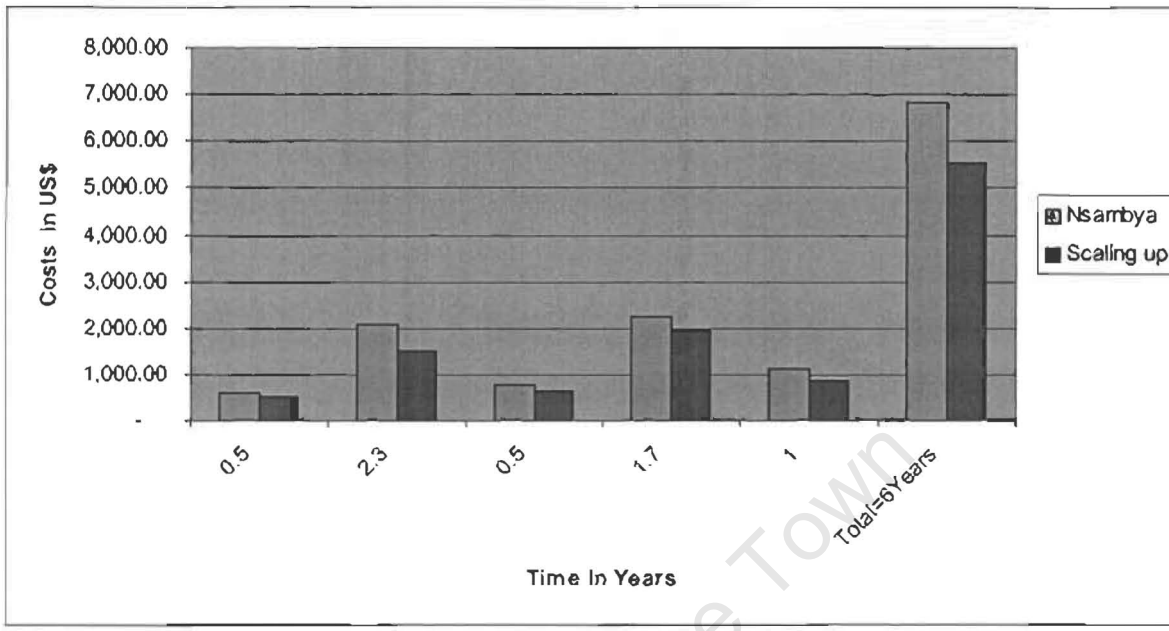
Uganda. The lifetime costs for the two programmes are presented for comparison in Table 26 (below).

Table 26: Lifetime costs in US$

	First line		Second line		Failing treatment	Total (6Years)
Time (Years)	0.5	2.3	0.5	1.7	1.0	
Nsambya	618.33	2,056.07	783.84	2,263.02	1,130.92	**6,852.18**
Scaling up	527.91	1,532.66	658.05	1,925.82	874.04	**5,518.49**

From Table 26 (above), ART costs from Nsambya ART programme are higher than those for the national ART programme for all the periods. A diagrammatic representation of the lifetime costs is presented in Figure 3 (below).

Figure 3 - Comparison of lifetime costs



From Figure 3 (above), lifetime costs per patient for Nsambya were higher at US$ 6,852.18 than for the national ART programme, which was estimated at US$ 5,518.49. This difference is due to the difference in the prices of ARVs used for the two programmes.

Looking at the distribution of the lifetime costs, ARVs were found to account for the largest proportion of the costs. From Table 27 (below), during the initial six months of starting ART the lifetime costs are almost equally distributed between ARVs, laboratory tests and consultations. But thereafter ARV costs take up more of the costs.

Table 27: Distribution of per patient ART costs

	Percentage of the Total Costs (%)				
	First line		**Second line**		
Category	**Initial 6 months**	**Annually thereafter**	**Initial 6 months**	**Annually thereafter**	**Failing treatment**
Antiretroviral drugs	34.88	65.56	58.00	58.00	76.84
Laboratory test	33.96	11.87	17.77	17.77	6.44
Consultations	31.16	22.57	24.24	24.24	16.71
Total	**100.00**	**100.00**	**100.00**	**100.00**	**100.00**

From Table 27 (above) the ARV cost contributions increase as the patient's duration on ART increase and are lowest for the initial six months for patients on ART. This is due to the fact that more monitoring tests have to be done and there are more visits during the initial six months of starting ART.

In estimating the costs of scaling up it was assumed that only one viral load at baseline would be done. For this reason the laboratory monitoring cost contribution is higher than for consultation for the initial six months but thereafter the proportion of laboratory monitoring is lower than for consultation as seen from Table 27 (above). This is because the most expensive viral load test is not performed on an annual basis. For this reason, laboratory test costs decline after the initial six months leading to the lower contribution of laboratory test costs after the first six months.

4.6 Sensitivity analysis

The results from Nsambya ART programme and those obtained by estimating the costs of scaling up ART in Uganda led to the conclusion that ARVs and laboratory monitoring tests were the highest cost drivers. For the national programme it was assumed that 60 % of the patients on FL regimen would be on Triomune. It was also assumed that there would be no price changes for ARVs and laboratory tests. This has been taken as the baseline scenario for the public model ART programme. The public

model ART costs relating to these were varied using different scenarios to find out their effects on the total programme and average per patient costs.

The following scenarios were considered:

1. Public Model using patented ARVs for both first and second line regimens as these have higher prices than their generic counterparts.
2. Using current retail ARVs prices as obtained from Nsambya ART programme so as to compare these with prices for bulk purchases.
3. Public model using the lowest exchange rate for the last five years of UGS 1800 to US$ 1
4. Public model using the highest currency exchange rate in the past five years of UGS 2000 to US$ 1
5. Public Model using Médecins sans Frontières (MSF) best ARV price offers. These are prices for both generic and patent ARVs that have been offered for developing countries by different pharmaceutical companies (Médecins Sans Frontières, 2003) to assess their effect on the ART costs if Uganda were to access these reference prices.
6. 15 % reduction on prices of FL regimens and 30 % reduction on SL regimens in 2005 and maintaining these prices throughout the rest of the years
7. 3.75 % reduction on first line ARVs and 7.5 % price reduction on second line ARVs every year
8. 10 % reduction on costs of CD4/CD8 test and 20 % reduction on costs of viral load test in 2005
9. No viral load before starting ART
10. No CD4/CD8 counts
11. No CD4/CD8 counts and no viral load test

The rationale for scenarios 6 to 8 is to establish the effect of anticipated price reductions on both ARVs and laboratory tests on the ART costs. Scenarios 9 to 10

will help bring out the advantage of using cheaper alternate test for monitoring the immune response of patients rather than the use of CD4 and viral load tests.

A one-way sensitivity analysis was carried out whereby one item was varied at a time in order to assess its impact on the total and average ART programme costs. The proportion of patients on the drug regimens was maintained at 60 % of the patients being on D4T/3TC/NVP as FL during the initial six months for all the scenarios. The main changes were observed in the average per patient annual costs and on the total costs. The changes in the average per patient costs are given in Table 28 (below).

Table 28: Average per patient cost variations

	Average per patient costs (US $)				
SCENARIO	2004	2005	2006	2007	2008
Baseline	541.08	621.67	653.71	673.67	687.98
Public Model using Patent ARVs	635.93	741.45	784.22	810.98	830.27
Nsambya ARVs prices as of 2003	1,039.13	1,099.24	1,117.81	1,131.71	1,140.79
Using exchange rate of UGS 1800 to I US $	569.20	645.42	676.34	695.65	709.55
Using exchange rate of UGS 2000 t0 1 US $	532.64	614.54	646.93	667.08	681.51
15% off FL and 30% off SL in 2005	541.08	561.14	582.09	594.97	604.07
3.75 % off FL and 7.5 % off SL per year	541.08	606.53	618.84	617.76	610.71
10 % off CD4/CD8 and 20 % off VL in 2005	541.08	608.13	642.13	663.23	678.28
No Viral Load tests	470.40	586.47	627.69	652.94	670.60
No CD4/CD8 counts	474.82	556.72	589.98	610.76	625.73
No CD4/CD8 counts and Viral Load tests	404.13	521.53	563.95	590.02	608.34
MSF best price offers-Generics	530.65	602.38	634.67	655.21	670.32
MSF best price offers-Patents	678.61	806.70	857.32	888.82	911.38

The main changes in the total costs at the end of each year and after the projected five years are presented in Table 29 (below).

Table 29: Total costs variations

	Total costs (US$)				
SCENARIO	**2004**	**2005**	**2006**	**2007**	**2008**
Baseline	3,181,963.95	12,237,745.29	26,103,301.84	45,012,942.84	68,547,345.96
Public Model using Patent ARVs	3,739,802.98	14,595,887.59	31,314,720.49	54,187,889.04	82,724,659.62
Using exchange rate of UGS 1800 to I US$	3,347,315.20	12,705,258.95	27,006,714.84	46,481,451.02	70,696,401.50
Using exchange rate of UGS 2000 to I US$	3,132,358.58	12,097,491.20	25,832,277.94	44,572,390.38	67,902,629.30
15% off FL and 30% off SL in 2005	3,181,963.95	11,046,183.04	23,243,153.77	39,754,028.40	60,185,866.71
3.75 % off FL and 7.5 % off SL per year	3,181,963.95	11,939,854.73	24,710,744.12	41,277,092.44	60,847,591.48
10 % off CD4 and 20 % off VL	3,181,963.95	11,971,328.80	25,640,951.55	44,315,438.83	67,580,618.05
No Viral Load	2,766,278.36	11,544,935.97	25,064,087.85	43,627,324.18	66,815,322.64
No CD4 counts	2,792,268.36	10,959,198.96	23,558,226.93	40,809,140.08	62,344,113.52
No CD4/CD8 counts and No Viral load tests	2,376,582.77	10,266,389.63	22,519,012.94	39,423,521.42	60,612,090.20
MSF best price offers-Generics	3,120,601.37	11,858,136.98	25,342,920.28	43,779,211.05	66,787,325.23
MSF best price offers-PATENTS	3,990,750.65	15,880,371.26	34,233,757.33	59,388,945.16	90,806,084.73

From the sensitivity analysis results presented in Tables 28 and 29 (above), the following conclusions can be made:

- Current retail ARV prices in Uganda as obtained from Nsambya ART programme gave the highest costs due to the fact that patients were on branded drugs and did not have the advantage of wholesale prices. MSF best price offers for generic ARVs leads to lower average per patient ART costs and total ART costs than the prices that are available in Uganda.
- The use of patented ARVs significantly increases both the average per patient ART costs and total ART costs.
- The level of the Ugandan currency has a significant effect on both the average and total ART costs. This is because Uganda has to import all its ARVs and laboratory test reagents and these affect the costs of ART.
- Even if at baseline one viral load test was done, not doing any at all still impacts on the ART costs by lowering the average per patient costs by about US$ 71 in 2004 as shown in Table 28 (above). It also lowers the total costs by more than US$ 1 million at the end of the projected five years.
- If both CD4/CD8 and viral load tests are not done there is a larger reduction on the average ART costs of about US$ 137 in 2004, and reduces the total ART costs by approximately US$ 8 million by the end of the projected five years.

Some clinicians in Uganda have argued that patients on ART can be safely monitored clinically and by the use of lymphocyte cell counts in order to lower the costs of ART (Ministry of Health, 2003). The current results have shown the option of not performing viral load and CD4/CD8 tests lowers the ART costs. Therefore, the option of using other means of monitoring the immunological response of patients on ART should be explored.

The prices of ARVs significantly affect the ART programme costs. Therefore, the ART task force should endeavour to negotiate for the best price offers available on the international market.

4.7 Results from the key informant oral interviews

These results were obtained from oral interviews with ten key informants who are involved in the scaling up of the expanded national ART programme in the country. A list of all the key people interviewed is given in Appendix F. The interviews were carried out between December 2003 and January 2004. Each interview lasted between 30 and 45 minutes. This section presents the results from the oral key informant interviews. It brings out issues that relate to the financial sustainability of an expanded ART programme in Uganda.

4.7.1: Sources of funds for the national ART programme

The two main sources of funds for the patients who will be accessing ART from the public sector are:

1) The World Bank (WB) under the Multi country HIV/AIDS programme (MAP)
2) The Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM)

Uganda qualified for the World Bank's Multi country HIV/AIDS Programme (MAP) funding. This fund is for a number of developing countries as a grant at US$ 47.5 million for a period of five years (2001 – 2006). Uganda has already received its share of US$ 3 million.

The GFATM funds are to be released in three phases for a period of three years. The first round of funds to Uganda is US$ 56 million for a period of one year. Of this money, US$ 9 million will be for the procurement of ARV drugs, while the rest is for other GFATM supported programme such as the control and treatment of TB and

Malaria and other HIV/AIDS interventions. The second round of GFTAM funds to Uganda is US$ 112 million for a period of two years. Out of this, US$ 62 million has been earmarked for ART and the rest is for the other interventions for HIV/AIDS, TB and Malaria.

President Bush has pledged about US$ 15 billion to 14 countries in Sub-Saharan African and the Caribbean to help with diagnosis, treatment and prevention of AIDS within five years. However, the information regarding the amount and when it will be availed to the Ugandan ART programme is not clear. Most of the people interviewed were of the view that this money may not go directly to the government public health sector but may be channelled through other NGOs involved in the care of HIV/AIDS patients.

There are no expected funds directly from the government budget nor has the government worked out any financial sustainability plans for the ART programme. Most of the key people interviewed were of the view that the time frame for which the country is assured of financial resources for the ART programme is that of three years, from the two main donors, that is the WB and GFATM.

4.7.2: Proposed fund usage

It is estimated that out of the 1 – 1.5 million HIV infected people in Uganda at any one time 100,000 would be in need of ART. However, not all of these will be able to be recruited into the public sector ART programme. Some of the patients are expected to be catered for by other NGOs, or continue accessing ART from the private sector. Some of the patients qualifying for ART services may not be able to access this treatment due to problems of lack of accessibility to ART centres. The numbers starting ART are to be phased over a number of years as the country builds enough capacity within public sector facilities. By the end of the projected five years, a total

of about 76,000 patients would have been started on ART within public sector facilities.

The ART programme hopes to treat about 6,000 adults and 300 children with ARV drugs using the WB bank funds of US$ 3 million for the year 2004. From the results obtained, the costs of treating this number of patients has been estimated at approximately US$ 3 million (Table 25). This is only for adults without taking into account children. This means that if the government does not get additional funds to start the ART programme, the WB money alone is not sufficient to meet the financial resource requirements in 2004. Furthermore, these are costs just relating to ART services without taking into account other programme administration costs.

With the GFTAM first round of US$ 9 million earmarked for ART, 10,000 patients will be started on ART in 2005. With the additional GFTAM second round funds of US$ 62 million for the ART programme of which $ 36 million is for ARVs, it is anticipated that a total of 76,000 patients will be accessing ART from the public sector by 2008. Taking into account the survival assumptions mentioned in chapter 3, by the end of 2008 approximately 58,916 patients would still be alive and on ART (Table 20 and Figure 2). The total costs for this cumulative number of patients has been estimated at US$ 68 million (Table 25). The total funds available for this period from both the WB and GFATM are US$ 74 million. Looking at the financial requirements and the available funds, ART related services alone would take up about 92 % of the available funds. This would mean that the country would have to look for additional funds to finance the ART programme's administration costs such as monitoring and evaluation costs. However, most of the people interviewed implied that at the moment there are no additional funds for the proposed scaling up of ART programme. From this situation analysis it looks like the ART programme may not be

adequately funded using the currently available funds, unless the number of patients starting ART is scaled down to include fewer patients.

There is need to train health professionals who will be involved in the administration of ART to patients. Most of the training is funded separately by a number of donors through the specialised training centres in the country. These include Academic Alliance funded by Pfizer, and the Joint Clinical research Centre (JCRC) who receive funds from the Centre for Disease Control (CDC). However, it is expected that some of the ART funds may have to go towards personnel training. From the cost estimations, training takes up a small proportion of the total ART costs of 0.37 %. Therefore, training costs would not significantly affect the available ART funds.

There are no major capital development projects specific to the ART programme. All the capital developments to be undertaken are part of the Health Sector Strategic Plan (HSSP) to upgrade most of the hospitals and health centre IVs (primary health care clinics) accredited to the Ministry of Health. The only capital costs that will be incurred by the ART programme will be for the purchase of Laboratory equipment for regional hospitals. These will include CD4 and Viral Load testing machines. These have been incorporated into the ART clinical visit costs and take up about 6.57 % of the ART funds. However, if any capital development projects were to be required, the available resources at the moment may not be able to cater for them.

4.7.3 Discussions on financial sustainability issues

Uganda has an annual population growth rate of 3.4 % and a high fertility rate of seven births per average woman. The economic growth rate is at 6.4 % per annum. This implies that even if the economy is growing, the rapid increases in the population size have led to an almost stagnant per capita gross domestic product (GDP) at US$ 300 – 320. Most of the interviewees felt that there is no expected growth in the

budget. Thus government funding of such an expensive programme of universal free access to ART remains uncertain.

In the event that donor funding for the ART programme stops, the government will have to review its budgetary statements to attempt to sustain it. However, this may not be possible given the current budgetary constraints. A principal planner in the Ministry of Health commented that currently the government is only able to fund a third of its drug needs, at only US$ 3.5 per person per year and cannot adequately provide free antimalarials to its nationals.

The health resource envelope, including both government and donor funds under the sector wide approaches (SWAPs), was at UGS 375.06 billion (~US$192 million) for the year 2003/2004. The principal planner in the Ministry of Health said that the WB and International Monetary Fund (IMF) have imposed budgetary sector ceilings to start in 2004/2005. These are for purposes of macroeconomic stabilisation by controlling government expenditure. With the budgetary sector ceilings, any new donor monies absorbed into a government sector must be accompanied by a similar reduction within the sector in order to keep the expenditure limit (Ministry of Finance, 2003). If these WB and IMF conditions were not addressed, it would mean that if Uganda accepts money from the GFATM, the Ministry of Finance might reduce its contribution to the health budget so that it remains the same with or without the GFATM monies, a condition that may not be acceptable to the GFATM (Principal planner for Ministry of Health, 2003). Therefore, there is need to address this situation so that the flow of GFATM funds to Uganda is not affected in the future.

It is assumed that the GFATM is a long-term programme for about 20-30 years, and is committed to the fight of the three diseases (AIDS, TB and Malaria). This might mean that the ART programme in Uganda will be able to run for the next 30 years. On the

other hand there is no guarantee that donor countries and organisations will keep sending money to the GFATM fund. International political and macroeconomic conditions affect the contributions of these countries and hence the financial sustainability of any programme wholly dependant on these donations (Personal communication with Okounzi, 2003).

Some of the interviewees were of the view that if the definition of financial sustainability were extended to mean the using of all resources available then the Ugandan government would be able to sustain its ART programme. This would be so if there were mixed funding and full commitment by all the involved parties. The other proposed sources of funds would be from employers through the Uganda Business Coalition against HIV/AIDS (UBCA). UBCA is currently providing ARVs to about 10,000 patients at subsidized prices and hopes to increase the number to 25,000 patients by 2005 (Personal communication with the chairman of UBCA, 2003). Some of the interviewees suggested that a special tax or levy for ART should be introduced. Other options that were suggested for the financing the ART programme included a restructuring of the health care financing mechanism within the country. They suggested the introduction of health insurance or other prepayment schemes or cost sharing of ART costs by some of the patients with the means to do so. If such initiatives are supported and coordinated by the government, it may go a long way in helping the financial sustainability of the ART programme in the country.

Discussions with various people on the Uganda ART task force revealed that currently there is duplication of services aimed at HIV/AIDS interventions. This is as a result of a multiplicity of funding sources from various international donors that are channelled through different NGOs. These funds are currently not under the control of the Ministry of Health. These include funds to the Uganda AIDS Support Organisation (TASO), JCRC among others. It was felt that if these funds were

properly coordinated, it would help in the proper management of the ART funds. This could help in the future financial sustainability of the ART programme.

The majority of the interviewees felt that one should consider treating and saving lives for at least three years rather than letting people die just because one cannot guarantee drugs for life. They argued that for now the government should go ahead and start treating the few patients with the available donor funds.

Comprehensive discussions with all the people interviewed revealed no comprehensive financial sustainability plans for the ART programme. At the moment the ART task force seems to be relying on the fact there will be continued fund flows from the GFATM.

Chapter Five

DISCUSSION OF RESULTS

5.0 Overview

Antiretroviral therapy has changed the way issues related to HIV/AIDS are looked at and given people living with the disease a new lease on life. This study set out to analyse the financial cost implications of an expanded free Antiretroviral therapy programme in Uganda. Results from Chapter four have shown that Antiretroviral drugs are the largest cost drivers of the ART programme from one treatment centre and for the modelled national ART programme. This study also looked at the extent to which the ART programme is financially sustainable by Uganda.

5.1 Study design

This study solely focused on the incremental costs associated with the introduction of ART within existing health services. Lifetime costs of patients on ART were analysed using a median survival of six years. Previous studies in the country did not look at lifetime costs and yet these are important for purposes of establishing the financial sustainability of the ART programme.

The cost analysis of ART services was done for one treatment centre. However, laboratory testing schedules and costs of ARV regimens are all derived from the national protocol. Thus the results obtained will apply to the rest of the country. The CT Antiretroviral Costing Model was used to estimate the costs of scaling up the ART programme.

5.2 Average ART costs per patient per year

The major categories of the incremental costs that were identified as being attributed to the ART programme was for ARVs, Laboratory monitoring tests, clinical personnel, overhead and capital costs. ARV and laboratory monitoring test costs were looked at as costs per patient per year, whereas the personnel, overhead and capital costs were considered in terms of visit costs. Using the CT Antiretroviral Costing Model, and assuming that ARVs and laboratory test costs remain constant the average per patient costs were found to increase with the years from US$ 541 in 2004 to about US$ 685 in 2008.

5.2.1 Antiretroviral drug costs

The provision of ARV drugs is the main concern of the ART programme in Uganda. From the cost analysis ARVs contributed the largest proportion of costs accounting for 63.2 % of the total. This is consistent with results from other studies done in the recent past. Previous studies done in SSA, using the ATC model, found that ARVs contributed 63 % of the total costs in Uganda and 50 % of the costs in Zambia (Kombe and Smith, 2003). In the Mexican study ARV costs took up more than 75 % of the total treatment costs (Sergio, et al, 2003). In Nigeria, ARV costs contributed 50 % of the ART costs (Kombe, et al, 2004). However, with this study, when the ART costs were divided into various periods, there were changes in the proportion of costs taken up by ARVs as shown in Table 27 (above). This study has shown that during the initial six months, ART costs are almost equally distributed between ARVs, laboratory tests and consultation. This is due to the fact that during the initial six months, patients have to be monitored more frequently and thus the costs of laboratory tests and consultations are higher. After this, ARVs take up more of the costs ranging from 58 % to 77 %, as shown in Table 27 (above).

The cheapest annual costs for the first line (FL) regimen (D4T/3TC/NVP) was at US$369.23 for Nsambya ART centre and US$ 288 for the national programme. The difference in the costs was because ART costs for Nsambya reflect retail market prices for ARVs, while those for the national programme reflect wholesale prices. The Nsambya ART programme also gets its ARVs from an intermediary distributor, Medical Access Uganda Limited. This is significant in that if the government buys its ARVs in bulk directly from pharmaceutical manufacturers, there will be a reduction in the ART costs. In Zambia the cheapest FL regimen (D4T/3TC/NVP) was estimated at US$ 233.24 (Kombe and Smith, 2003). The difference in the costs of this drug between the two countries could be attributed to the different sources for the ARV drugs. The difference could also be attributed to difference in the cost and price structures within the two countries.

SL regimens were on average more expensive than FL regimens. The average SL regimen cost was estimated at US$ 884 per patient per year as compared to US$ 437 per patient per year for FL regimens. These are not significantly different from those obtained in a study in South Africa by Boulle, et al (2003), where the annual per patient costs of SL were estimated at US$ 865 and FL at US$ 500. Since SL regimens are more expensive than FL, in this study as the proportion of patients on SL regimens increases from 9 % in 2004 to 22 % in 2008 it will lead to an increase in the average annual per patient ART costs with the years from US$ 541 in 2004 to US$ 685 in 2008. This has cost implications in that as the number of patients on SL regimens increases the ART costs are bound to go up unless there are price reductions in SL regimens. Previous studies in SSA have all concluded that SL regimens drive of ART costs upwards (Kombe and Smith, 2003). Kombe and Smith (2003) suggested the exclusion of SL regimen treatment for patients accessing ART services from public health facilities. However, this may not benefit HIV/AIDS patients who require to be put on SL regimens as a result of treatment failure on FL regimens. If patients are

maintained on FL despite treatment failure it may lead to the development of HIV resistant strains (Lawrence, et al, 2003). Thus, SL regimens, despite being expensive, need to be budgeted for by the national ART programme.

Prices for ARVs have been dropping and in Uganda this has been quite dramatic. The cost of first line triple therapy for an adult per year has dropped from about UGS 8.4 million [US$ 4,200] to between UGS 432,000 and UGS 840,00 (US$ 216 – 420) (Ministry of Health, 2003). It is hoped that ARV manufacturers will reduce ARV prices for developing countries in the future (Lucchini, et al, 2003). It has been assumed that prices for FL regimens may not change much since they may have reached their lowest levels, while those of SL regimens are expected to reduce a little more (Lucchini, et al, 2003). Taking this into consideration in varying ARVs prices, higher percentage price reductions were considered for SL than for FL regimens. When this was done, there were reductions in both the annual average per patient and total ART costs.

From this study results, major increases in the average per patient costs were observed if patent versions of the ARVs were used for both current price offers in Uganda and if MSF best price offers were used. Therefore, it is recommended that the option of using generic ARVs should be considered where these have been certified to be of acceptable quality.

5.2.2 Laboratory monitoring tests

Laboratory monitoring test costs contribute the second largest costs accounting for 17.6 % of the total costs at Nsambya ART centre. When estimating the costs of scaling up ART in Uganda, this study assumed that only one viral load test would be performed at baseline as has been recommended by the national treatment guidelines. From this study results, laboratory tests accounted for 34 % of the total costs during

the initial six months. However, this proportion declined from 34 % to 12 % -18 % in the subsequent periods since no more viral load tests were done. Looking at the sensitivity analysis results, if no viral load test were performed there would be a reduction in the average ART costs of US$ 71. If both viral load and CD4/CD8 tests were not performed, there would be a reduction of US$ 137 in 2004 and US$ 80 in 2008 (Table 28). Kombe and Smith (2003), found a reduction in the laboratory tests of about US$ 80 if more basic laboratory tests were used for monitoring patients on ART instead of using viral load and CD4/CD8 tests. From these results, the type of tests used to monitor the immune response of patients on ART will affect ART costs. The study, thus recommends that the performance of one viral load test before starting ART should be stopped.

5.2.3 Visit costs

Antiretroviral drug costs and laboratory test costs are easily attributed to individual patients. The costs of clinical personnel, overhead and capital costs that are not easily attributed to individual patients were looked at in terms of the visit costs.

5.2.3.1 Clinical personnel visit costs

Personnel remunerations accounted for 12 % of the total ART costs at Nsambya ART centre. Looking at the costs of scaling up ART in Uganda, clinical personnel visit costs contributed the largest proportion of the visit costs accounting for about 71 % of the total visit costs. Of these, physician visits were the most expensive at US$ 9.81 per visit. This is in agreement with a study in South Africa where human resources were also found to be the largest contributors of the visit costs taking up about 76 % of the visit costs (Cleary, et al, 2003).

5.2.3.2 Capital visit costs

Capital costs were relatively low contributing only 7 % of the total ART programme costs, and 11 % of the visit costs. This is due to the fact that ART services are to be integrated into the existing health services, and thus no major capital development projects are to be undertaken. Most of the capital costs were for the purchase of equipment for laboratory monitoring and initial training of health professionals. The purchase of the CD4/CD8 and viral load testing machines took up 84.7 % of the total capital costs and 10 % of the visit costs. Initial training of health professional was approximately 1 % of the total ART visit costs. In the Zambian study by Kombe and Smith (2003), training costs took up less than 1 % of the total national ART programme costs. This is due to the fact that one trained health professional can treat many patients. Thus, the relatively low cost of training coupled with its importance for ART programme success suggests it deserves a strong investment (Kombe and Smith, 2003). Health professionals have also been affected by the HIV/AIDS epidemic and therefore some will die. There is also loss of health professionals as a result of emigration from poor countries like Uganda to developed countries with more attractive remuneration and working conditions. Thus training should be accompanied by better remuneration and working conditions so as to retain these health professionals and further minimise the training costs.

5.2.3.3 Overhead visit costs

Overhead costs are the least accounting for less than 1 % of the total costs and 7 % of the ART visit costs. This is due to the fact these costs are shared with other general outpatient departments and are generally cheap in Uganda.

5.2.4 Lifetime costs of patients on ART

Lifetime costs are crucial for purposes of planning for the financial sustainability of the ART programme. This study estimates lifetime costs for a patient on ART at US$

6,852 for the Nsambya ART programme and US$ 5,518 for the national programme, assuming a median survival time of 6 years. This difference is because lifetime costs at Nsambya reflect retail prices for ARVs while those for the national ART programme had the advantage of wholesale prices. Although, Nsambya is a non-profit making hospital, all the patients were paying for their ARVs. Since ARVs accounted for the largest costs of ART, the difference in ARV prices led to the variations in the lifetime costs for the two programmes within the same country. Previous studies in Uganda have not looked at these costs and yet lifetime costs for purposes of sustaining the ART programme. Knowing the lifetime costs helps in the planning of lifetime care for patients on ART.

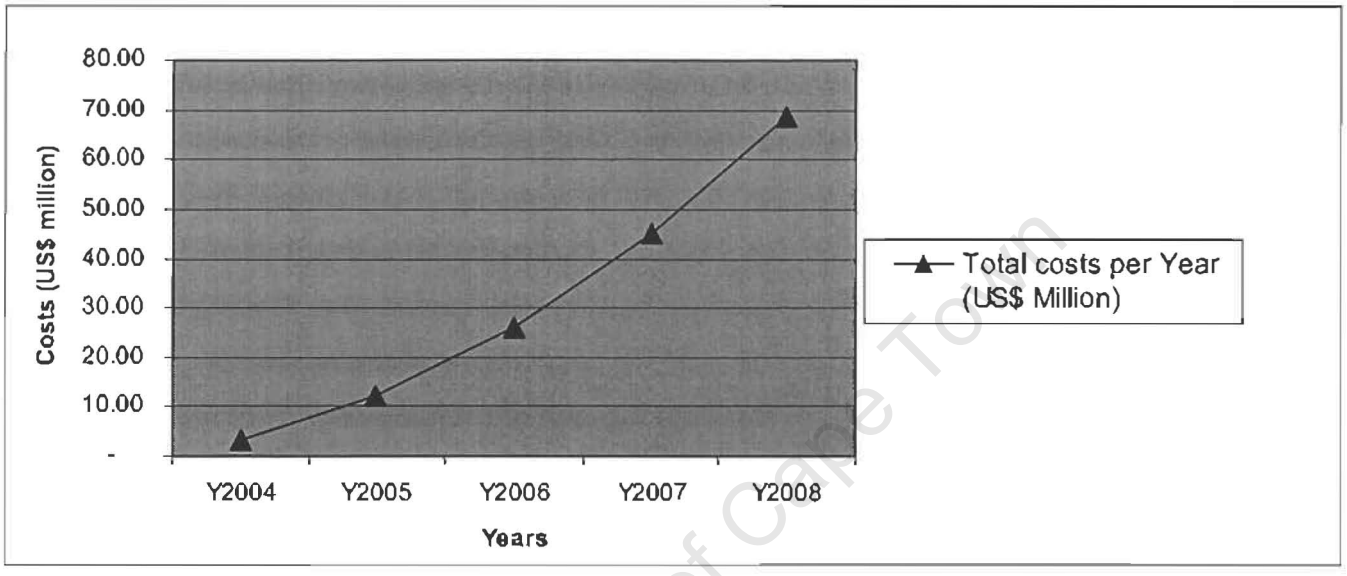
The only other study that calculated the lifetime costs for ART patients was in South Africa by Cleary, et al (2003). In the South African study, the lifetime costs for ART patients were estimated at US$11,071, using the exchange rate of R8.4 to US$ 1 (Cleary, et al, 2003). These are higher than for this study because the average life expectancy for South Africa was estimated at 8 years as compared to the 6 years used in this study. There also are differences in purchasing power parity between South Africa and Uganda. Costs of ARVs, laboratory tests and visit costs also differ between the two countries. This could also be due to the inclusion of inpatient costs by the South African study that have not been considered by this study.

5.2.5 Trends in total costs of scaling up ART programme

Costs for ART are projected to increase on an annual basis as coverage increases. This is because patients on ART live longer (UNAIDS, 2002). The HIV infection rate in Uganda is estimated at 3.4 % per year, which means that more people will need ART in the future (Ministry of Health, 2003). Thus, as more people are brought into the ART programme, the costs of ART would grow accordingly. Figure 4 (below)

shows the projected total ART costs for Uganda for the next five years (2004 to 2008).

Figure 4 - Trends in total costs



From Figure 4 (above), the total ART costs are projected to increase from about US$ 3 million in 2004 to US$ 68 million by the end of 2008. These costs have been estimated by this study using the numbers of patients starting ART shown in Table 20 (above). The available funds during the same period of US$ 74 million from the WB and GFATM could cover the costs of ART services if there are no other ART programme service costs to be met.

5.3 Financial sustainability of an expanded ART programme in Uganda

For any programme to be financially sustainable by a country there should be plans for ensuring the continuity of funds once the donor funds are stopped (Vokes, 2003). Various indicators have been used to analyse the financial sustainability of ART services in Uganda (Knowles, et al, 1997) and (McPake and Kutzin, 1997).

A key factor that affects the financial sustainability of health programme is the percentage of the health system that is financed by tax revenues (Knowles, et al, 1997). The percentage of the Ugandan government health system that is financed by tax revenue stands at about 52 %. Various international donors finance the other 48 % (Ministry of Health, 2003). Furthermore, out of the US$ 13 per capita health expenditure, only US$ 5 is funded by the government and donor SWAPs. The remaining US$ 8 is mainly out of pocket payments by individual patients (Ministry of Health, 2003). From this study estimates, total ART costs will range from US$ 3.18 million in 2004 to about US$ 68 million in 2008 as shown in Figure 4 (above). Using the current estimated population of about 24.7 million (Uganda Population and Housing census 2002, IN: Ministry of Health, 2003), the per capita ART costs would be about US$ 0.13 in 2004. The current population growth rate is estimated at 3.4 % per year, which means that the total population by 2008 would be about 28 million. The per capita ART expenditure would then be approximately US$ 2.8. This means that given the current per capita government health expenditure, per capita ART expenditure would take up approximately 56 % of the total government per capita health expenditure of US$ 5 by the end of 2008.

Government's health expenditure as a percentage of the total government budget and as a percentage of GDP, also affects financial sustainability of health programme (Knowles, et al, 1997). The health budget accounted for 13.1 % of the total government budget for the year 2003/2004 (Ministry of Finance, 2003). A principal

planner in the Ministry of Health said that there is no expected increase in this budget in the next few years. The health budget has been estimated to be approximately 3 % of the GDP (Ministry of Finance, 2003). According to the Ministry of Finance, Uganda's GDP, at factor cost measured in current prices, was approximately UGS 10,567 billion (US$ 7 billion) in 2002/2003. The annual real GDP growth for 2002/2003 was estimated at 4.9 % and has remained below 7 % for the past four years (Ministry of Finance, 2003). This implies that the total health budget may not increase much more in the future to meet the costs of scaling up ART services if donor funds were to be stopped. Furthermore, sector budget ceilings imposed by the WB and IMF are to start in 2004/2005 for both government budget and externally funded projects. These sector ceilings will have implications for the predominantly externally funded ART programme because even if the money was available the amount to be spent may have to be within the government expenditure ceiling for the health sector (Personal communication with the principal planner for Ministry of Health, 2003).

The percentage of government health expenditure directed to the particular programme in question is also crucial for its financial sustainability. From discussions with various key informants, the Ugandan government has made no provisions for the ART programme in its current budget except for the continued funding for the treatment of opportunistic infections. However, even the treatment of HIV/AIDS related opportunistic infections is not being adequately funded considering that currently the government is meeting its drug funding by only a third at US$ 3.5 per capita per year. Since the government has not budgeted for ART services, if donor funds were to be stopped the programme may not be financially sustainable through the country's own current budgetary allocations to the Ministry of Health.

The percentage of health services funded by individual households also influences the financial sustainability of any programme. Of the total annual health care expenditure

of US$ 13 per capita, US$ 8 is out of pocket payments by individual households (Ministry of Health, 2003). This means that households contribute about 62 % of the total health care expenditure. However, given the current per capita income of about US$ 300 – 330, and the average per patient costs of ART at US$ 541 - 688, patients may not be able to privately pay for these services if donor funding were to stop. If patients were to privately finance the ART costs, it would take up about 35 % of the US$ 8 per capita health expenditure by households. Furthermore, this money is currently not being used efficiently due to the fact that patients pay for health services at the point of consumption. This out of pocket payments could assist in the financing of ART services if other systems of health care financing were introduced in the country. These could include social health insurance and prepayment schemes. Furthermore, from the results of the Nsambya ART programme, patients were on various treatment regimens due to fluctuations in prices of the ARVs. Thus if households were to pay for the ARVs, there would be a need for proper treatment guidelines to avoid the situations where doctors prescribe wrong drugs depending on each patient's financial ability.

The percentage of a country's health budget that is funded by donors also influences the financial sustainability of health programmes. Various international donors finance 48 % of the Ugandan government health budget. Donor funding contributes 34 % of the recurrent health expenditure and 82 % of the development health budget (Ministry of Finance, 2003). Since a big percentage of the health system is externally funded this means that the financial sustainability of ART from local revenues may not be possible.

The financial sustainability definition can be extended to include the use of all available financial resources for the programme in question. Since the ART programme is relying on external donor funds, the trends of the donor fund flows

have to be considered (Australian Agency for International Development, 2002). The GFATM was created in 2002 in response to growing international concern about the global impact of three diseases (HIV/AIDS, TB and Malaria). It is a new financial instrument that gets funds from different countries without limits and conditions imposed by individual governments (Poore, 2003). According to Poore (2003), in theory the GFATM can disburse these funds indefinitely provided it could continue to attract them thus, becoming the first initiative that is truly "financially sustainable". On the other hand, there is a strong feeling that GFATM funds have to rely on the goodwill of the United States of America (USA) and European countries and that there has been some reluctance by these countries to continue to contribute to this fund (Brook and Baker, 2003). The two argue that President Bush has urged congress to restrict the USA grant to the fund to only US$ 200 million a year. They say that the European Union countries have yet to meet their targets of US$ 1 billion for the year 2004, agreed at the Paris GFATM meeting of June 2003. Thus the financial sustainability of ART in Uganda, which depends on the goodwill of the US and the European Union, remains questionable.

The GFATM funds are not solely for HIV/AIDS but also for TB and Malaria programme (The Global Fund, 2003). The principle of the GFATM is to disburse these funds in phases depending on the GFATM board's approval of each country's proposal in a given period. This means that Uganda's future fund releases depends on whether the proposal made meets with the GFATM board's approval (Poore, 2003). Thus the financial sustainability of ART services will depend on the country's ability to come up with proposals that satisfy the requirements of the GFATM board members. Of the US$ 56 million disbursed for Uganda from the first phase only US$ 9 million has been earmarked for ART. From the second phase of US$ 112 million for Uganda, US$ 62 million will be for ART. This means that at the moment the ART programme is assured of about US$ 71 million from the GFATM. When the WB

money of US$ 3 million through MAP is added on it brings the funds available for this programme to US$ 74 million. The question is whether these funds are enough to sustain the ART programme and for how long. From the key informant interviews, it is assumed that with the WB money of US$ 3 million at least 6000 adult patients would be started on ART. This is the figure that was used as the starting number for patients on ART in 2004. From the above results at the end of 2004, the ART costs have been estimated at US$ 3,18 million, which is more than the WB money. This does not take into account the programme administration costs. Thus with the status quo, the ART programme may not be able to take off as planned unless the number of patients starting ART is scaled down.

From this study results, at the end of 2008 the total annual ART costs were estimated at US$ 68 million. The GFATM money that has been guaranteed for this period is US$ 71 million. This would mean that patient related services would take up more than 90 % of the GFATM funds. This means that there would be a need for additional funds for the programme administration costs or the number of patients accessing ART would have to be much fewer than what this study has assumed.

Some authors have argued that programme financial sustainability should be taken to include the use of all available financial resources from both local and international sources (Bossert, 2004). If this definition was to be considered then the ART programme may be financially sustainable. One of the recommended ways for funding ART services would be from employers under the Uganda Business Coalition against HIV/AIDS (UBCA). Given that out of pocket expenditure on health is substantial, if restructured it could be another source of funding ART services.

5.4 Conclusion

This study has assumed modest estimates on the number of patients starting ART every year. By the end of the projected five years a total of 76,000 patients would have been started on ART out of whom 58,916 patients would still be alive and on ART. The average adult ART costs have been estimated to be in the ranges of US$ 541 to US$ 685 per person per year. This translates into the per capita ART costs of about US$ 2.8 per year. These costs are much higher than the current per capita annual health expenditure of only US$ 13. If the estimated ART costs were to be financed by the government, they would take up more than 56 % of the government's per capita health expenditure. Thus, it can be safely concluded that without donor funds and given the current economic situation in Uganda the scaling up of ART programme services may not be financially sustainable unless other ways of raising funds from domestic sources were explored, implemented and properly coordinated.

Chapter Six

POLICY IMPLICATIONS, RECOMMENDATIONS AND CONCLUSION

6.0 Introduction

From this study results various policy issues have been identified that need to be addressed if the expanded national ART programme is to be financially sustainable. This chapter discusses the policy implications of scaling up the ART programme in Uganda and gives some recommendations on possible options on how best to sustain the programme.

6.1 Policy implications and recommendations

The Uganda ART programme should aim at controlling the costs of ARVs, the largest cost contributor of scaling up the provision of ART. Proper national treatment guidelines should be adhered to in order to ensure that there is uniformity of treatment throughout the country.

Intermediary wholesalers between manufacturers and buyers have been observed to lead to higher ARV prices (Lucchini, et al, 2003). The government, therefore, is advised to directly buy from the manufacturers and avoid intermediary wholesalers.

The use of protease inhibitors for first line regimens drive costs higher, thus NNRTIs such as Nevirapine and Efavirenz should be the drugs of first line choice for public sector patients.

From the sensitivity analysis results, ARV prices are of great importance as regards the costs of the ART programme in Uganda. The national ART task force should endeavour to negotiate better ARV price offers by the various pharmaceutical manufacturers. This may be possible, since Uganda, being one of the least developed

countries, does not have to implement the Trade Related Intellectual Property Rights (TRIPS) patent protection for pharmaceuticals till 2016 (Shaffer, 2003). The sensitivity analysis also showed that there is a greater reduction on the average per patient costs if there are bigger price cuts for both FL and SL regimens in 2005 than if the price cuts are spread out over the years. Therefore, it is recommended that the ART task force try to negotiate for bigger price cuts at the beginning of the scaling up of ART services.

The number of viral load and CD4 tests performed should be kept at the minimal safest levels or completely stopped so as to reduce the costs of laboratory monitoring tests. The use of other laboratory tests, such as lymphocyte counts, is recommended in order to reduce on the costs of ART in Uganda.

Training of health professionals has been found to take up a small proportion of the ART costs. However, Uganda like the rest of SSA still faces the problems of losing its health professionals who migrate to more developed countries with better working conditions (Kombe and Smith, 2003). Therefore, it is recommendation that the Ugandan government tries to improve the remunerations and working conditions of its health professionals in order to attract and retain them. A number of health workers will also continue to die of AIDS, thus, in scaling up ART, priority should be given to health workers (Ministry of Health, 2003). This will help to keep the training costs down.

If HIV/AIDS patients are to benefit from the ART programme, they need to be supplied with ARVs without interruptions in the treatment for the rest of their lives (Lawrence, et al, 2003). The lifetime costs of ART are quite high, ranging from US$ 5000 to more than US$ 6000 for a period of six years. Thus, in planning for ART costs, the government needs to look further than the yearly costs and consider these

lifetime costs. Plans need to be put in place for continuous fund flows to the ART programme. This calls for financial sustainability plans to be instituted.
The objective of the government should be to raise money for the ART programme and also create a climate that allows spending it where it is most needed (Brook and Baker, 2003). The two authors recommend that measures need to be put in place to avoid situations where health budgets are capped and global fund money would only replace national contributions or contributions by other donors and thus not be able to create new services. They argue that the GFATM should be accompanied by a right-based approach to social services that legitimise public budgets that are in accordance with real needs and not limited to percentages of GDP if it is to benefit poor countries that really need the funds. They argue the GFATM to issue a formal statement on "additionality" to challenge the IMF and WB sector ceilings. This is in order to prevent the GFATM funds from being used to supplement health budgets and to allow governments to use them as special funds (Baker and Brook, 2003).

This study agrees with the WB (1998) recommendations for the government to ensure that there is efficient management of the ART funds. There should be proper accounting and budgeting practices, accountability and transparency in the way these funds are used. There should be continued political commitment to the ART programme.

Uganda is also faced with the problem of the multiplicity of parallel programme for HIV/AIDS interventions. These are funded by various donors and are run by different NGOs. This study recommends that there should be a multi-sectoral approach to mobilising funds for the ART programme. There is need for proper coordination of all these funds in order to avoid duplication of services. This will help in ensuring that the country financially sustains its ART programme.

Currently out of pocket payments account for about 62 % of the per capita annual health expenditure at US$ 8 out of the total per annum per capita health expenditure of US$ 13. However, this money is not being used efficiently due to the system of payment for health services at point of consumption (Ministry of Health, 203). This study therefore, recommends a change in the way health services are funded in Uganda in order to move away from payment at point consumption to a prepayment system.

This study also recommends that ways could be explored of introducing a cost sharing system for some of the patients with the means to do so, or the introduction of a special tax or levy for the ART programme (Economic Commission for Africa, 2004). This could help the government raise domestic funds for financing its ART programme if donor funds were to stop.

6.2 Conclusion

The financial sustainability of the expanded ART programme in Uganda is still questionable given the prevailing economic situation in the country. Uganda's domestic revenues that are predominantly tax revenues are about 12.7 % of the GDP. Donors fund 48 % of its health budget. The country has a very small formal sector and thus a small tax base. The revenue collection system is still inefficient, with high levels of corruption within the public sector (Ssengooba and McPake, 2000). With the current economic situation in Uganda, the financial sustainability of ART services in the country may not be possible without external international donor funding.

For a programme to be financially sustainable, there is a need for both political and financial commitment. Uganda has the political commitment to fight HIV/AIDS for as long as the current president is in power. However, it is questionable as to whether the next leadership will have the same commitment to fight this epidemic (Gorik, 2003).

For this reason, it is the recommendation of this study that the government puts in place plans for ensuring the financial sustainability of its ART programme. This study recommends that the provision of free ART services be passed as an act of parliament of the government of Uganda.

6.3 Directions for further studies

Programme administration costs, such as monitoring and evaluation, were not analysed. If these were to be included, they may lead to an increase in the total ART costs. Therefore, a more comprehensive study is recommended to analyse all the costs of comprehensive care for OIs and HIV/AIDS related illnesses and events plus the analysis of programme administration costs.

Programme sustainability is a broad topic with multiple dimensions that include financial and institutional (technical, social, political and managerial) sustainability (Canadian Public Health Association, 2001). Thus more studies should be carried out to look at the institutional sustainability of an expanded ART programme in Uganda.

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APPENDIX A: Letter of Consent for Key Informants

I _____ agree to participate in the research of financial implications and sustainability of the Antiretroviral treatment (ART) roll out Programme in Uganda. I understand that my participation is entirely voluntary. The procedures used to ensure my confidentiality have been explained to me and I fully understand them. My participation in this research can be terminated at any time if I so wish. I also give/not give permission for this interview to be taped by the interviewer.

Signed _____

Date _____

APPENDIX B: Quantitative Data capture sheet

B.1: Patient Information:

A): Patient Reference Code	
B): Date of Treatment commencement	
C): Treatment Regimen: A) First Line, B) Second Line, C) Alternative regimens	
d) Duration of Antiretroviral treatment	

B.2: Price of drugs:

Antiretroviral drug	**Annual costs (US$) [Patent]**	**Annual costs (US$) [Generic]**
Nucleoside Reverse Transcriptase Inhibitors (NRTIs)		
Zidovudine (ZDV)		
Lamivudine (3TC)		
Stavudine (D4T)		
Didanosine (ddi)		
Non-Nucleotide Reverse Transcriptase Inhibitors (NtRTIs)		
Tenofovir (TDF)		
Non-Nucleoside Reverse Transcriptase Inhibitors (Antis)		
Nevirapine (NVP)		
Efavirenz (EFZ)		
Protease Inhibitors (PIs)		
Lopinavir (LPV)		
Ritonavir (RTV)		
Lopinavir/Ritonavir		

(LPV/r)		
Kaletra		
Saquinavir (SQV)		
Neflinavir (NFV)		

B.3. Antiretroviral drug combinations:

Drug Combination	Monthly costs per patient (US$)	Annual costs per patient (US$)	Number of patients	Total costs (US$)
First Line Regimen				
ZDV/3TC / EFZ or NVP				
TDF/3TC/EFZ				
D4T/3TC/EFZ or NVP				
Second Line Regimen				
D4T/ddi/ LPV/r				
ZDV/ddi/LPV/r				
Alternative Regimens				
ZDV/ddi/SQV/RTV				
ZDV/ddi/NFV				
Total drug costs				

B.4: Diagnostic tests costs:

Laboratory Test	Monthly cost per test per patient (US$)	Annual cost per test per patient (US$)	Total number of patients	Total laboratory costs (US$)
CD4/CD8 cell counts				
Viral Load				
Complete Blood counts				
Liver Function Test				
Renal Function Tests				
Other Tests				
Total Lab costs				

B.5: Clinical Personnel:

Category of personnel	Number	Annual Remuneration	Time spent on ART programme	Cost incurred by ART programme
Doctors				
Nurses				
Counsellors				
Phlebotomist				
Total personnel costs				

B.6: Overhead costs:

Item	Cost (US$)	Total outpatient visits (2003)	ART patient visits (2003)	Proportion of ART patient visits (2003)	ART programme costs (US$)
Electricity					
Water					
Utilities					
Communication: - Telephone - Fax - Email					
Stationery: - Photocopying - Other					
Computer consumables					
Support staff					
Transport/Vehicle running costs					
Maintenance: - Buildings - Vehicles - Maintenance staff					
Total overhead costs (US$)					
Other related ART service costs (US$)					
Total recurrent costs (US$)					

B.7: Capital costs:

Item	Replacement value (US$)	Discount factor	Annuity factor	Annualised costs (US$)
Initial staff training				
Laboratory equipment				
Buildings				
Vehicles				
Total capital costs				
Grand total (US$)				

APPENDIX C: GUIDING QUESTIONS FOR KEY INFORMANT INTERVIEWS:

Question and Probes:	**Responses**
What is your name?	
What organization do you currently work for? • Are you on the ART policy committee? • If yes, what are your responsibilities on this committee?	
What is you current position in your organization?	
How long have you been in this position?	
What are the main sources of finances for ART programme in Uganda? • Who are the main donors for this Programme? • For how long has their funding been guaranteed?	
What proportion of the funding is from the	

government of Uganda? {That is from public budget expenditure}	
What is time frame for which the government has secured financial resources for the ART programme?	
Do you think free universal ART is sustainable in Uganda? ❖ What plan does the government have in case the GFTAM withdraws its financial support? ❖ How would the government fund the provision of free ART if this happened?	
Which pharmaceutical companies are supplying ARVs to Uganda for the ART programme? ❖ Is the Programme using generic or patented drugs or a mix Of the two?	
Is the ART programme getting discounted price for ARVs? ❖ Please elaborate on this.	

How is the Procurement done? ❖ Is the ART programme using UNAIDS_DAI for this? ❖ Is the Programme getting any donated drugs from any international agencies? If yes, which ones?	
Do you think there are adequate Health workers for the ART programme?	
Is the government going to recruit any more health professionals for the ART programme? ❖ Please explain the mechanism for the way it will be done.	
What measures have been put in place for training of health professionals? • Is there a special Programme for the training? • Who is sponsoring the training?	
Are there any capital development projects for	

ART? {For example, build new health centres, buy vehicles or new medical equipment} • Does the Programme have adequate resources for these developments?	

APPENDIX D: ARV drug regimens and prices from Nsambya ART programme (2003)

Patient reference code	Date of starting ART	Current ARV regimen (2003)	Current monthly ART costs (US$)	Old ARV regimen	Old monthly ART costs (US$)
2	Aug-98	D4T/ddi/IDV/RTV	105.13	ZDV/3CT	246.15
3	Aug-98	CBV/Kaletra	89.74	ZDV/3TC	246.15
8	Aug-98	D4T/3TC/EFZ	53.85	3CT/ZDV/CXN	512.82
11	Aug-98	CBV/SQV/RTV	146.15	D4T/ddi/Hydrea	200.00
12	Aug-98	CBV/EFZ	69.23	D4T/3CT/CXN	451.28
13	Aug-98	D4T/ddi/Kaletra	89.74	ZDV/Hivid/SQV	461.54
14	Aug-98	ABC/CXN/ddi	194.87	ZDV/3CT	246.15
20	Aug-98	D4T/3TC/EFZ	53.85	D4T/3CT/CXN	451.28
23	Aug-98	3TC/ddi/TDF	94.87	ZDV/3TC/CXN	512.82
28	Sep-98	D4T/ddi/EFZ	66.67	CBV	179.49
31	Sep-98	CBV/EFZ	69.23	D4T/ddi/Hydrea	169.23
37	Sep-98	CBV/EFZ	69.23	D4T/ddi/CXN	523.08
53	Oct-98	D4T/RTV/SQV/TDF	166.67	D4T/ddi/CXN	512.82
56	Oct-98	CBV/EFZ	69.23	ddi/Hu	184.62
60	Nov-98	ABC/3TC/Kaletra	176.92	CBV/EFZ	123.08
62	Nov-98	D4T/ddi/EFZ	82.05	ZDV/3CT/CXN	512.82
64	Nov-98	ZDV/EFZ/Kaletra	117.95	ZDV/3TC	246.15
84	Dec-98	D4T/ddi/EFZ	66.67	D4T/ddi/HU	269.23
89	Dec-98	CBV/EFZ	69.23	CBV/NFV	374.36
90	Dec-98	D4T/ddi/NVP	79.49	ddi/HU	192.31
91	Dec-98	D4T/3TC/NVP	66.67	ZDV/3TC/SQV	343.59
94	Jan-99	D4T/3TC/EFZ	53.85	ZDV/3TC/SQV	425.64
99	Jan-99	CBV/EFZ	69.23	CBC/NFV	474.36
100	Jan-99	CBV/EFZ	69.23	D4T/ddi/CXN	512.82
102	Feb-99	CBV/EFZ	69.23	CBV	179.49
106	Feb-99	ABC/3TC/ZDV (Trizivir)	225.64	D4T/3TC/NFV	523.08
117	Mar-99	CBV/EFZ	69.23	ZDV/3TC/CXN	513.08
118	Mar-99	ABC/TDF/Kaletra	212.82	CBV/NFV	369.23
129	May-99	D4T/ddi/NFV	130.77	CBV/CXN	461.54
137	Jun-99	ZDV/3TC/NFV	138.46	ZDV/3TC/NFV	523.08
139	Jun-99	ZDV/3TC/CXN	105.13	ZDV/3TC/CXN	435.90
140	Aug-99	CBV/EFZ	69.23	CBV/NFV	466.67
141	Aug-99	D4T/ddi/EFZ	66.67	D4T/ddi/CXN	66.67
146	Aug-99	D4T/3TC/NFV	112.82	D4T/3TC	256.41
151	Aug-99	CBV/EFZ	69.23	ddi/3TC/HU	269.23
156	Aug-99	CBV/EFZ	69.23	CBV/NFV	487.18
158	Sep-99	CBV/EFZ	69.23	D4T/ddi/HU	271.79

160	Sep-99	D4T/ddi/Kaletra	87.18	CBV	179.49
162	Sep-99	D4T/ddi/CXN	92.31	CBV	179.49
166	Oct-99	CBV/NFV	128.21	CBV/CXN	451.28
168	Oct-99	TDF/3TC/EFZ	100.00	CBV/NFV	376.92
169	Oct-99	CBV/NFV	128.21	D4T/ddi/HU	269.23
173	Oct-99	CBV/NFV	128.21	CBV/NFV	476.92
181	Nov-99	ddi/RTV/CXN	100.00	ZDV/ddi/CXN	492.31
193	Jan-00	TDF/3TC/EFZ	100.00	CBV/NFV	474.36
197	Jan-00	CBV/Estiva	74.36	D4T/ddi/HU	176.92
199	Jan-00	CBV/EFZ	69.23	CBV/NFV	279.49
205	Jan-00	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	307.69
206	Feb-00	CBV/EFZ	69.23	CBV/EFZ	307.69
215	Feb-00	CBV/EFZ	69.23	CBV/NFV	374.36
216	Feb-00	CBV/EFZ	69.23	CBV/NFV	374.36
218	Feb-00	CBV/EFZ	69.23	CBV/NFV	374.36
222	Feb-00	3TC/ddi/EFZ	66.67	D4T/3TC/EFZ	320.51
225	Mar-00	D4T/3TC/CXN	79.49	D4T/3TC/CXN	297.44
237	Apr-00	CBV/EFZ	69.23	CBV/NFV	474.36
241	Apr-00	D4T/3TC/CXN	79.49	D4T/3TC/NFV	451.28
250	May-00	CBV/EFZ	69.23	CBV/CXN/RTV	466.67
251	May-00	CBV/EFZ	69.23	D4T/ddi/Kaletra	138.46
256	May-00	CBV/NFV	128.21	CBV/NFV	474.36
258	Jun-00	CBV/EFZ	69.23	CBV/EFZ	346.15
259	Jun-00	CBV/EFZ	69.23	CBV/EFZ	346.15
263	Jun-00	CBV/EFZ	69.23	CBV/NFV	425.64
264	Jun-00	CBV/EFZ	69.23	D4T/3TC/NVP	146.15
271	Jun-00	CBV/EFZ	69.23	CBV/EFZ	397.44
274	Jul-00	D4T/3TC/NVP	66.67	D4T/3TC/NVP	179.49
275	Jul-00	D4T/ddi/EFZ	66.67	CBV	176.92
277	Jul-00	CBV/EFZ	69.23	CBV/EFZ	274.36
284	Jul-00	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	256.41
292	Aug-00	D4T/3TC/EFZ	53.85	D4T/3TC/NFV	379.49
293	Aug-00	D4T/3TC/EFZ	53.85	D4T/3TC/NFV	379.49
297	Aug-00	Bivir - N	46.15	D4T/3TC/NFV	379.49
303	Aug-00	CBV/EFZ	69.23	CBV/EFZ	274.36
305	Sep-00	D4T/ddi/EFZ	66.67	D4T/3TC/NFV	425.64
309	Sep-00	D4T/3TC/EFZ	53.85	CBV/NFV	474.36
310	Sep-00	TDF/3TC/EFZ	100.00	CBV/NFV	474.36
314	Oct-00	CBV/EFZ	69.23	CBV/EFZ	274.36
315	Oct-00	CBV/EFZ	69.23	CBV/EFZ	274.36
316	Oct-00	CBV/NVP	82.05	CBV/NVP	294.87
319	Oct-00	CBV/EFZ	69.23	D4T/ddi/EFZ	225.64
321	Oct-00	CBV/EFZ	69.23	CBV/EFZ	274.36
322	Nov-00	D4T/ddi/CXN	92.31	D4T/3TC/NFV	379.49

323	Nov-00	CBV/EFZ	69.23	CBV/EFZ	274.36
327	Dec-00	D4T/ddi/NVP	79.49	CBV/EFZ	274.36
338	Jan-01	CBV/EFZ	69.23	CBV/EFZ	169.23
352	Feb-01	D4T/ddi/NVP	79.49	D4T/ddi/NVP	169.23
354	Feb-01	D4T/3TC/NVP	66.67	D4T/3TC/NVP	169.23
356	Feb-01	CBV/EFZ	69.23	CBV/EFZ	169.23
371	Apr-01	CBV/NVP	82.05	CBV/NVP	194.87
376	May-01	CBV/NFV	128.21	D4T/3TC/CXN	153.85
382	May-01	CBV/NVP	66.67	CBV/NVP	194.87
388	Jun-01	D4T/3TC/NVP	66.67	D4T/3TC/NVP	169.23
394	Jun-01	D4T/ddi/EFZ	66.67	D4T/ddi/NFV	379.49
396	Jul-01	CBV/CXN	94.87	CBV/CXN	223.08
397	Jul-01	D4T/ddi/EFZ	66.67	D4T/ddi/EFZ	174.36
406	Jul-01	D4T/ddi/EFZ	66.67	D4T/ddi/EFZ	174.36
409	Jul-01	D4T/ddi/EFZ	66.67	D4T/ddi/EFZ	174.36
411	Jul-01	D4T/ddi/EFZ	66.67	D4T/ddi/EFZ	174.36
420	Aug-01	D4T/ddi/EFZ	66.67	CBV/CXN	223.08
423	Aug-01	D4T/ddi/EFZ	66.67	D4T/ddi/EFZ	174.36
428	Aug-01	D4T/ddi/EFZ	66.67	D4T/ddi/EFZ	174.36
429	Aug-01	ddi/NVP/Kaletra	128.21	CBV/NFV	369.23
431	Aug-01	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	153.85
432	Aug-01	TDF/3TC/Kaletra	120.51	D4T/ddi/EFZ	153.85
438	Aug-01	Triomune	30.77	D4T/ddi/EFZ	153.85
441	Aug-01	Bivir/EFZ	64.10	D4T/ddi/EFZ	153.85
442	Aug-01	D4T/ddi/EFZ	66.67	D4T/ddi/EFZ	153.85
445	Sep-01	D4T/ddi/EFZ	66.67	D4T/ddi/EFZ	128.21
448	Sep-01	Bivir/EFZ	64.10	D4T/3TC/EFZ	128.21
460	Sep-01	Bivir/EFZ	64.10	D4T/3TC/EFZ	128.21
464	Sep-01	CBV/CXN	94.87	CBV/CXN	200.00
468	Oct-01	D4T/ddi/EFZ	66.67	D4T/ddi/EFZ	76.92
472	Oct-01	D4T/3TC/CXN	79.49	CBV/CXN	164.10
473	Oct-01	D4T/3TC/EFZ	66.67	D4T/3TC/EFZ	76.92
476	Oct-01	D4T/ddi/EFZ	66.67	D4T/ddi/EFZ	76.92
477	Nov-01	ddi/3TC/EFZ	66.67	D4T/3TC/EFZ	76.92
483	Nov-01	CBV/EFZ	69.23	D4T/ddi/EFZ	76.92
488	Nov-01	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	76.92
490	Nov-01	D4T/ddi/EFZ	66.67	D4T/ddi/EFZ	76.92
493	Nov-01	D4T/ddi/EFZ	66.67	D4T/ddi/EFZ	76.92
494	Nov-01	D4T/ddi/EFZ	66.67	D4T/ddi/EFZ	76.92
495	Nov-01	CBV/EFZ	69.23	D4T/ddi/EFZ	76.92
498	Nov-01	D4T/3TC/NVP	66.67	D4T/3TC/NVP	82.05
509	Dec-01	D4T/3TC/NVP	66.67	D4T/3TC/NVP	82.05
511	Dec-01	ABC/3TC/ZDV	115.38	ABC/3TC/ZDV	225.64
512	Dec-01	D4T/ddi/EFZ	66.67	D4T/ddi/EFZ	76.92

513	Dec-01	D4T/ddi/EFZ	66.67	D4T/ddi/EFZ	76.92
515	Dec-01	ddi/3TC/NVP	89.74	ddi/3TC/NVP	41.03
516	Dec-01	D4T/3TC/NVP	66.67	D4T/3TC/NVP	74.36
517	Dec-01	CBV/EFZ	69.23	CBV/EFZ	128.21
518	Jan-02	D4T/3TC/EFZ	69.23	D4T/3TC/EFZ	76.92
520	Jan-02	D4T/3TC/NVP	66.67	D4T/3TC/NVP	71.79
521	Jan-02	D4T/3TC/NVP	66.67	D4T/3TC/NVP	71.79
522	Jan-02	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	76.92
523	Jan-02	D4T/ddi/EFZ	66.67	D4T/ddi/EFZ	79.49
526	Jan-02	CBV/EFZ	69.23	CBV/EFZ	128.21
527	Jan-02	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	74.36
531	Jan-02	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	74.36
532	Jan-02	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	74.36
536	Jan-02	D4T/ddi/EFZ	66.67	D4T/ddi/EFZ	79.49
537	Jan-02	D4T/3TC/NVP	66.67	D4T/3TC/NVP	71.79
538	Jan-02	D4T/ddi/EFZ	66.67	D4T/ddi/EFZ	76.92
540	Jan-02	CBV/EFZ	69.23	D4T/3TC/EFZ	76.92
542	Feb-02	CBV/NVP	82.05	CBV/NVP	125.64
543	Feb-02	CBV/NVP	82.05	CBV/NVP	125.64
544	Feb-02	CBV/EFZ	69.23	CBV/EFZ	128.21
545	Feb-02	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	76.92
546	Feb-02	D4T/ddi/Kaletra	87.18	D4T/ddi/Kaletra	89.74
547	Feb-02	D4T/ddi/EFZ	66.67	D4T/ddi/EFZ	79.49
552	Feb-02	D4T/3TC/Mativir	30.77	D4T/3TC/EFZ	79.49
555	Feb-02	D4T/3TC/NVP	66.67	D4T/3TC/EFZ	79.49
556	Feb-02	CBV/EFZ	69.23	CBV/EFZ	128.21
560	Mar-02	D4T/ddi/NVP	79.49	D4T/ddi/NVP	79.49
561	Mar-02	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	79.49
562	Mar-02	D4T/ddi/EFZ	66.67	D4T/ddi/EFZ	82.05
563	Mar-02	CBV/EFZ	69.23	D4T/ddi/NVP	74.36
564	Mar-02	D4T/ddi/EFZ	66.67	D4T/ddi/EFZ	82.05
565	Mar-02	D4T/ddi/EFZ	66.67	D4T/ddi/EFZ	82.05
566	Mar-02	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	79.49
568	Mar-02	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	79.49
569	Mar-02	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	79.49
570	Mar-02	CBV/EFZ	69.23	CBV/EFZ	128.21
571	Mar-02	ddi/3TC/EFZ	66.67	D4T/3TC/EFZ	79.49
573	Mar-02	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	79.49
575	Mar-02	CBV/NVP	82.05	D4T/3TC/EFZ	79.49
577	Apr-02	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	79.49
578	Apr-02	CBV/EFZ	69.23	CBV/EFZ	128.21
580	Apr-02	Bivir/EFZ	64.10	D4T/3TC/EFZ	79.49
581	Apr-02	CBV/EFZ	69.23	D4T/3TC/EFZ	76.92
583	Apr-02	CBV/EFZ	69.23	CBV/EFZ	128.21

585	Apr-02	D4T/3TC/Kaletra	74.36	D4T/3TC/EFZ	79.49
588	Apr-02	CBV/EFZ	69.23	D4T/3TC/NVP	76.92
589	Apr-02	D4T/3TC/CXN	79.49	D4T/3TC/CXN	89.74
590	May-02	D4T/ddi/EFZ	66.67	D4T/ddi/EFZ	79.49
591	May-02	D4T/ddi/EFZ	66.67	D4T/ddi/EFZ	79.49
593	May-02	CBV/NVP	82.05	D4T/3TC/NVP	76.92
594	May-02	ABC/3TC/ZDV	130.77	ABC/3TC/ZDV	225.64
595	May-02	CBV/EFZ	69.23	CBV/EFZ	128.21
597	May-02	CBV/EFZ	69.23	CBV/EFZ	128.21
598	May-02	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	76.92
599	May-02	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	76.92
600	May-02	D4T/3TC/NVP	66.67	D4T/3TC/NVP	76.92
601	May-02	D4T/3TC/NVP	66.67	D4T/3TC/NVP	76.92
602	May-02	CBV/EFZ	69.23	CBV/EFZ	128.21
607	May-02	CBV/EFZ	69.23	D4T/3TC/EFZ	79.49
609	May-02	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	79.49
610	Jun-02	D4T/3TC/NVP	66.67	D4T/3TC/NVP	76.92
611	Jun-02	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	79.49
612	Jun-02	Bivir/EFZ	64.10	D4T/3TC/EFZ	79.49
613	Jun-02	Bivir/EFZ	64.10	D4T/3TC/EFZ	79.49
615	Jun-02	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	79.49
617	Jun-02	ddi/3TC/EFZ	66.67	D4T/3TC/EFZ	79.49
619	Jun-02	CBV/NVP	82.05	CBV/NVP	125.64
620	Jul-02	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	79.49
623	Jul-02	D4T/ddi/EFZ	66.67	D4T/ddi/EFZ	79.49
624	Jul-02	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	79.49
625	Jul-02	CBV/EFZ	69.23	CBV/EFZ	128.21
626	Jul-02	CBV/EFZ	69.23	CBV/EFZ	128.21
632	Jul-02	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	128.21
634	Jul-02	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	79.49
635	Jul-02	CBV	35.90	CBV	79.49
636	Aug-02	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	79.49
640	Aug-02	CBV/EFZ	69.23	CBV/EFZ	128.21
641	Aug-02	D4T/3TC/Kaletra	74.36	D4T/3TC/Kaletra	87.18
642	Aug-02	CBV/EFZ	69.23	CBV/EFZ	128.21
646	Aug-02	CBV/EFZ	69.23	CBV/EFZ	128.21
647	Aug-02	CBV/NVP	82.05	CBC/NVP	125.64
649	Aug-02	Bivir/EFZ	64.10	D4T/3TC/EFZ	79.49
650	Aug-02	Bivir/Estiva	74.36	D4T/3TC/EFZ	79.49
652	Sep-02	D4T/3TC/EFZ	53.85	D4T/3TC/Kaletra	87.18
655	Sep-02	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	79.49
656	Sep-02	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	79.49
659	Sep-02	Triomune	30.77	Triomune	35.90
661	Sep-02	CBV/EFZ	69.23	CBV/EFZ	128.21

662	Sep-02	CBV/EFZ	69.23	CBV/EFZ	112.82
665	Oct-02	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	64.10
667	Oct-02	D4T/ddi/EFZ	66.67	D4T/ddi/EFZ	82.05
669	Oct-02	CBV/EFZ	69.23	D4T/ddi/EFZ	82.05
670	Oct-02	CBV/EFZ	69.23	CBV/EFZ	128.21
671	Oct-02	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	64.10
673	Oct-02	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	64.10
675	Nov-02	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	64.10
676	Nov-02	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	64.10
677	Nov-02	D4T/ddi/EFZ	66.67	D4T/ddi/EFZ	82.05
679	Nov-02	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	64.10
681	Nov-02	CBV/EFZ	69.23	CBV/EFZ	112.82
683	Nov-02	D4T/ddi/EFZ	66.67	D4T/ddi/EFZ	66.67
684	Nov-02	Zidolam/Estiva	74.36	CBV/EFZ	112.82
686	Nov-02	D4T/3TC/NVP	66.67	D4T/3TC/NVP	76.92
689	Dec-02	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	79.49
690	Dec-02	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	79.49
691	Dec-02	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	79.49
693	Dec-02	D4T/3TC/NVP	66.67	D4T/3TC/NVP	76.92
695	Dec-02	Bivir/EFZ	64.10	D4T/ddi/EFZ	82.05
697	Jan-03	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	79.49
698	Jan-03	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	79.49
699	Jan-03	CBV/EFZ	69.23	CBV/EFZ	112.82
700	Jan-03	CBV/EFZ	69.23	CBV/EFZ	112.82
702	Jan-03	CBV/EFZ	69.23	Triomune	30.77
703	Jan-03	Bivir - N	46.15	Bivir/NVP	76.92
704	Jan-03	CBV/EFZ	69.23	CBV/EFZ	112.82
706	Jan-03	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	76.92
707	Jan-03	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	76.92
712	Feb-03	D4T/3TC/Kaletra	74.36	D4T/3TC/Kaletra	87.18
714	Feb-03	Bivir/EFZ	64.10	Bivir/EFZ	79.49
721	Mar-03	D4T/3TC/Kaletra	74.36	D4T/3TC/Kaletra	87.18
724	Mar-03	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	76.92
726	Apr-03	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	76.92
730	Apr-03	D4T/3TC/EFZ	53.85	D4T/3TC/EFZ	76.92
733	Apr-03	CBV/EFZ	69.23	CBV/EFZ	112.82
736	Apr-03	Bivir/EFZ	64.10	Bivir/EFZ	64.10

APPENDIX E: Summary of the Cape Town (CT) Antiretroviral Costing Model

The Cape Town (CT) Antiretroviral costing model was developed by a number of researchers from the University of Cape Town in 2004 (Boulle, et al, 2004). This model is intended to assist planners in estimating the potential costs of Antiretroviral therapy. It helps in the costing of ART programme by estimating the patient utilization of health services, the costs of these services and the average time on ART. This model is recommended by the GFATM for country proposal for disbursement of the Global funds.

The model consists of a range of worksheets in a Microsoft Excel workbook. The excel sheets are linked by buttons known as macros. The worksheets are divided into those requiring assumptions to be inputted and those providing outputs. The outputs are further divided into individual and group level outputs. The person using the model is required to feed the model with various information depending on the country or programme for which ART costs are being estimated.

The input information includes the following:

- **Number of patients starting treatment each year:** This data is based on planning needs and can be supply-side or demand-side based. For this study the numbers starting treatment used was derived from interviews with various key policy makers in Uganda involved in the planning of the roll out plan for ART. The figures given were based on the estimated demand needs and the resource available to meet those needs.
- **Survival assumptions:** These are based on five subgroups of patients as follows:
    I. Patients who started ART in the previous year and on average have been on ART for six months at the beginning of the next year.

II. Patients who started ART prior to the previous year who are still on the first line regimen.
III. Patients who started the second line regimen in the previous year and have been on this regimen for six months on average.
IV. Patients who started the second line regimen prior to the previous year.
V. Patients who have clinical progression after starting ART, who may or may not still be on second line regimens.

To get the numbers of patients in each of the above groups the model generates the probabilities of moving between these five states and the probability of dying. The survival assumptions used are inbuilt within the model and are based on the UNAIDS and WHO estimates. The WHO three by five team has assumed a mean survival of between 5 and 7 years after starting ART depending on the level of access to care in each country. The model uses the median survival time for patients on ART of 6 years. It is also estimated that the probability of death in the first year on ART is about 10 %. These patients are assumed to die before switching regimens. The probability of death falls thereafter. For patients who die after many years on ART they would so after clinically progressing, that is sub-group 5 above. It is also assumed that a quarter of the patients die without clinical progression between states 2 to 4. The death probabilities are combined with those of loss to follow up. It also assumed that 30 % of patients would have clinical rebound and need to be switched to second regimens after about two years. After using these assumptions the number of patients on ART at the end of each year is then estimated. However, experienced researcher can change these survival assumptions if they have their country survival estimates data.

- **Costs of Antiretroviral Therapy (ART):** The model gives a per patient summary for each of the five sub-groups for three major costs namely: The cost of Antiretroviral drugs, laboratory monitoring tests, and the costs of clinic

visits that includes staff costs, overhead and capital items. Other costs such as hospitalisation could be included depending on the level of Programme costing being considered. This study only looked at the provision of ARVs from an outpatient basis and thus such costs were not looked at.

APPENDIX F: List of Interviewees

Interviewee	Position Held
Dr Bahendeka, Silver	Head Nsambya ART programme and member of the national ART policy committee
Dr Mugyenyi, Peter	Director JCRC and Chairman national ART policy committee
Dr Namagala, Elizabeth	Coordinator MoH HIV/AIDS control programme and secretary national ART policy committee
Dr Okounzi, Sam Agatre	National council for children and Member of national ART policy committee
Dr Wilber, Steve	Logistics advisor MoH from DELIVER, USAID
Dr Mulindwa, Grace	Principal health planner for MoH
Dr Akol, Zainabu	National coordinator HIV/AIDS control programme
Dr Opul, Dickson	Chairman Uganda Business Coalition against HIV/AIDS
Mr Serutoke, Joseph	World Health Organisation - Uganda national programme officer: Essential drugs and medicines policy
Mr Tugume, Denis	Administrative secretary Medical Access Uganda Limited