

Scaling up ART in Rwanda: the financial and economic costs

Dissertation Submitted to the Health Economics Unit, School of Public Health and Family Medicine in Partial Fulfilment of Requirements for the Award of a Masters of Public Health specialising in Health Economics by the University of Cape Town.

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August 2007

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Dedication:

To all those who dare to dream of free and universal access to ART

Acknowledgements:

I wish to extend my sincere thanks to the World Health Organisation –Africa Regional Office for having granted me a full fellowship to pursue a fulltime master's programme at the University of Cape Town. This research was undertaken during this fellowship.

Through the Health Economics Unit, I wish to thank the Alliance for Health Policy and Systems Research for the younger researcher grant that supported me during the field work phase of this research.

I acknowledge the invaluable debt of gratitude to my supervisor Ms Susan Cleary for the tireless effort, vision and belief in shaping my research skills. Thank you so much for the wonderful person you are.

I wish to sincerely thank all the respondents for their valuable time and information without which a major part of this study would not have been possible. Staff at the CHUK, TRAC, Ruhengeri Hospital, CAMERWA and MSH deserve special mention for volunteering their limited time to assist me collect various data. I would like to specifically thank Esther Rebero, JMV Musonera, Felix Kayigamba and Bony Banyanga for always being there for me. Special mention also goes to Dr. Abel Kagame, Senior Physician: CHUK and Mr. Lugira Charles, Manager Property Portfolio, *Société Nouvelle d'Assurance du Rwanda* for providing expert opinion and technical support in their areas of specialisation.

Lastly I would like to thank my family: Alex, Toni, Ortega and Ganza for support, patience and sacrifice during my tenure at UCT.

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Abbreviations and acronyms

3TC	Lamivudine
ABC	Abacavir
ADB	African Development Bank
AIDS	Acquired Immune Deficiency Syndrome
ART	Anti-retroviral Therapy
ARVs	Anti-retroviral (drugs)
ATC	AIDSTREATCOST
AZT	Zidovudine
CAMERWA	Rwandan Central Drug Procurement and Distribution Agency
CD4	CD4 lymphocyte cells
CHUK	Kigali Central University Teaching Hospital
CPV	Cost Per Visit
CT	Cape Town
D4T	Stavudine
ddi	Didanosine
EDPRS	Economic Development and Poverty Reduction Strategy
EFZ	Efavirenz
FDA	Federal Drug Administration
FL	First-line (ARV regimen)
Frw	Rwandan Francs
FY	Fiscal/Financial Year
GF	Global Fund
GFATM	Global Fund to fight AIDS, Tuberculosis and Malaria
GoR	Government of Rwanda
HAART	Highly Active Antiretroviral Therapy
HIPC	Highly Indebted Poor Countries
HIV	Human Immuno-Deficiency Virus
ICAP	International Center for AIDS Care and Treatment Programs
IDV	Indinavir
LPV/r	Lopinavir/Ritonavir
MAP	Multi-country HIV/AIDS Program
MoH/ MINISANTE	Ministry of Health/Ministère de la Santé
MSF	Médecins sans Frontières
MSH/RPM Plus	Management Sciences for Health / Rational Pharmaceutical Management Plus
NACC/CNLS	National AIDS Control Commission/ Commission Nationale de Lutte contre le SIDA
NFV	Nelfinavir
NNRTI	Non-nucleoside reverse transcriptase inhibitor
NRTI	Nucleoside reverse transcriptase inhibitor
NVP	Nevirapine
OIs	Opportunistic Infections
OPD	Out-Patients' Department
PACFA	Protection And Care of Families Against HIV/AIDS
PEPFAR	President's Emergency Plan for HIV/AIDS Relief
PI	Protease inhibitor
PLWHA	People Living With HIV/AIDS
PMTCT	Prevention of Mother-To-Child Transmission

PRS	Poverty Reduction Strategy
RMC	Resource Management Commission
R-Value	Replacement value
SL	Second-line (ARV regimen)
TDF	Tenofovir
TRAC	Training and Research AIDS Centre
TRACnet	Information system for monitoring HIV/AIDS medical component
UK	United Kingdom
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
UNGASS	United Nations General Assembly Special Session on HIV/AIDS
US\$	US Dollars
VCT	Voluntary Counselling and Testing
WB	World Bank
WHO	World Health Organisation

Abstract

Rwanda has been rolling-out free antiretroviral treatment (ART) since 2004. This scale up could only be realised through significantly increased funding to the HIV/AIDS sub-account. Funding grew from US\$9 million in 2003 to US\$43 million in 2004 (UNAIDS, 2006b) and has continued to grow since this time given increased grants from GFATM and PEPFAR. Although international funding has been pivotal in the initiation of ART roll-out in resource poor settings, national programmes must look inwards for long term sustainability. This raises the question of whether the country will be able to sustain this level of funding once these grants cease or are significantly reduced. This question could be answered to a large extent if one knew the lifetime costs of providing ART in Rwanda and the capacity of the country to raise domestic revenue. Unfortunately the body of evidence on unit and lifetime costs for providing ART in Rwanda is nonexistent.

The study aimed to determine the economic costs of scaling up ART in Rwanda. Costing from the provider's perspective was undertaken based on data from 3,310 patients in 3 ART sites. The health care utilisation and cost data obtained, supplemented by appropriate secondary data, were used to estimate the cost per-patient period and lifetime costs. These were then used to model the costs of scaling up and to explore the financial sustainability of ART in Rwanda.

Key findings

- ✓ The modelled costs per-patient period were US\$244 for patients during the first six months on the first-line regimen and US\$306 annually thereafter. Once first-line had been failed, costs increased to US\$792 for the first six months on second-line and were US\$1,299 during each annual period thereafter. Costs were US\$680 per annum once both treatment regimens had been failed. Lifetime costs were determined to be \$4,440 discounted at 3% and US\$4,815 undiscounted. This corresponded to an annual average cost of US\$741 or US\$683 discounted at 3%.

- ✓ The 5-year cumulative costs of rolling-out ART, based on policy targets of initiating 153,014 adults on ART by 2011, were estimated to be US\$206 million, or US\$192 discounted at 3%. The cumulative total costs for scaling up was US\$187 million or US\$173 million discounted at 3%. The percentage composition of these costs was 70% ARVs, 12% clinical staff, 9% monitoring laboratory tests and 4% overheads. Over the period annual total costs increased from US\$19 million in 2007 to US\$62.5 million in 2011, an increase of 328%. Most of this increase was accounted for by increases in the costs of ARVs corresponding to 376%.
- ✓ The study established that 98.6% of ART provider costs were funded from public sources, of which 20% was domestic (central government) revenue and 80% foreign aid. *Ceteris paribus*, the ratio of domestic to foreign funding would rise to 1 to 5 or 17% to 83% by 2011. The ratio widens to about 2% to 98% when financial costs are considered. The combined commitment of US\$243.4 million from Global Fund and PEPFAR is expected to cover nearly all patient specific costs during the scaling up period.
- ✓ The total health care resource envelope allocated to the Ministry of Health from public revenue in the financial year 2006/07 was US\$73.5 million, of which 2.3% was from taxes and 97.7% from foreign aid. This is 7.8% of the total government budget (including donor funds). Total budgetary allocations to the Ministry of Health grew from US\$50.1 in 2005 to US\$73.5 million by 2007, equivalent to an increase of 46.7%. This growth was mainly accounted for by external resources, which grew by 50% while domestic resources fell by 40% during the same period. This finding does not augur well for sustainability of the ART programme in Rwanda.
- ✓ The total number of doctors in the public and the quasi-public sector is 204 and there are 465 unfilled posts (Ministry of Health 2006). The total number of full-time-equivalent (FTE) doctors (GPs) required for scale up was estimated to be 68 in 2007 rising to 164 in 2011. This would consume up to 33% of available physician time in 2007 and 80% in 2011 holding other things constant. A similar number of FTE counsellors would be required over the same period. The number

of nurses was estimated to be 204 and 491 in 2007 and 2011 respectively. Considering the human resource deficit in Rwanda and the number required to scale up ART there are serious concerns of ART crowding out other services.

- ✓ Although this cost analysis only includes ART provider costs for adult outpatients in public facilities in Rwanda, costs are projected to exceed US\$62 million by 2011 if scaling up achieves 130,000 patients in care. At this level of scale, ART funding would need to grow by a rate exceeding 50% annually. It is difficult to sustain such a level of funding from public revenue alone. Innovative health care financing mechanisms that exclude user fees need to be devised. Given that user-fees paid at the point of treatment have negative equity implications, other innovative financing approaches are needed to improve the financial sustainability of the ART programme.

Chapter 1: Introduction and background

1.1. Preamble

This dissertation aims to determine the economic costs of scaling up antiretroviral therapy, henceforth referred to as ART, in Rwanda. A cost analysis will be undertaken at the patient level combining estimates of health care resource utilisation and opportunity costs to determine the unit costs per visit to each health facility or per patient-period as appropriate. These will be combined with survival assumptions to calculate the costs of scaling-up and to gauge the financial sustainability of the ART programme in Rwanda. The introductory chapter highlights the magnitude of the HIV/AIDS disease burden and the subsequent health sector response. The chapter also presents the problem statement, the justification for the study and defines the research objectives. It concludes by defining the costs that will be considered and describes the layout of the dissertation.

1.2. Introduction

Twenty five years after its appearance on the world scene, HIV/AIDS is estimated to have killed 25 million people and infected another 38.6 million by the end of 2005 (UNAIDS, 2006a). Today, HIV/AIDS is one of the leading causes of years of life lost and has reduced life expectancy by fifty per cent in many countries. Sub-Saharan Africa (SSA) has been hardest hit by the pandemic. Although it is home to just 10% of the world's population it accounts for 60% of the world's cases. Of the total world deaths due to HIV/AIDS 77% have occurred in SSA leading to 12 million orphans. Besides being a leading cause of morbidity and mortality, its predilection for the productive age group coupled with catastrophic health expenditure has led and will continue to lead many households into poverty (UNAIDS 2005).

The emergence of Highly Active Antiretroviral Therapy (HAART) in the last decade became a beacon of hope for many people in developed countries. However, the situation remained bleak in low and middle income countries (LMIC) due to the prohibitive costs of HAART. This galvanised the international community into the first major funding initiative in 2002 when the United Nations created the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM). This was followed by

funding from the United States' President's Emergency Plan for AIDS Relief (PEPFAR) and the World Bank's Multi-Country HIV/AIDS Program (MAP) (Koeniga et al. 2004; Ravenga et al. 2004; WHO/UNAIDS, 2005).

Like many other countries in Sub-Saharan Africa, Rwanda has been a beneficiary of the WHO/UNAIDS "3-by-5" programme which aimed to treat 3 million people by 2005. Funding has been available from major donors including GFATM, MAP and PEPFAR. Bilateral donors have included the United Kingdom, Belgium, Luxemburg, France and international NGOs like the William J. Clinton Foundation (WJCF). Although international efforts to stem the pandemic are pivotal to initiating treatment, national programmes must look inwards for long term sustainability of such programmes (Ministry of Health and the Clinton Foundation, 2003; International Monetary Fund, 2007).

1.3. Rwanda's demographic and socio-economic profile

With a population of 8.2 million living on 26,338 square kilometers or 311 persons per square kilometre, Rwanda is one of the most densely populated countries in Sub-Saharan Africa (*Institut National de la Statistique du Rwanda (INSR) and ORC Macro, 2006*). Most of the population lives off subsistence farming in rural areas, 81% men and 93% women. The average fertility rate is 6.1 children for all women but is highest in rural women at 6.3 children compared to 4.9 for urban women. Such a high fertility rate combined with the 1994 war and genocide death toll means that the population is very young. It is estimated that 60% of the population is below the age of 20 years and 43.8% is below 15 years of age. Women are in the majority accounting for 52.3% of the population while men account for 47.7%. This ratio falls drastically to 65 boys for 100 girls in the 15-19 year age group. One of the social legacies of the 1994 war and genocide is a large number of vulnerable people that include orphans, adolescents heading households, widowers and widows. Female headed households account for 36%, yet these women are poorly educated and have few marketable skills. To compound the situation further, many of them were raped during the war and consequently suffer from HIV/AIDS (Ministry of Health and WJCF, 2003; *Institut National de la Statistique du Rwanda (INSR) and ORC Macro, 2006*).

Due to high population density, soil erosion and soil exhaustion, 45% of children under the age of five years are malnourished and 55% are stunted while 56% of children aged 6-59 months are anaemic. As a result of war and HIV/AIDS 3 out of 10 children are orphans, giving a total of 1,260,000 orphaned and vulnerable children {OVC} (*Présidence de la République du Rwanda: Commission Nationale de Lutte Contre le SIDA, 2005*). The country is ranked among those with the highest mortality in Sub-Saharan Africa. Life expectancy in Rwanda has fallen from 50 years in 1990 to 44 due to the HIV/AIDS epidemic (De and Dmytraczenko, 2006). Vital statistics show that the infant mortality rate (IMR) is 86 per 1,000 live births. The under-5-mortality rate (U5MR) is 152 per 1,000 and the maternal mortality rate (MMR) is 750 per 100,000 per live births. Malaria is the leading cause of morbidity and mortality, accounting for 60% of all consultations in health centres. (*Institut National de la Statistique du Rwanda (INSR) and ORC Macro, 2006; Ministère de la Santé, 2007*).

The 1994 war and genocide all but destroyed the country's economy. Although real gross domestic product (GDP) has been growing at a sustained rate of 4% per annum since 1997, it was starting from a very big trough. At the end of 2006, nominal GDP was just over US\$2.1 billion, for 8.2 million people this translates into a per capita income of just US\$256 (Ministry of Finance and Economic Planning, 2006). Agriculture is the mainstay of the economy, accounting for 43% of GDP in 2005, while services account for 37% and industry 20%.

1.4. The Rwandan health system

The Rwandan health system is built around a 3-tiered structure comprised of 5 referral hospitals, 33 district hospitals and 369 health centres including dispensaries and health posts. Of these facilities, 40% are faith based facilities (mainly Catholic and Protestant faiths) that function under quasi-public conditions including access to specific resources such as clinical staff and even funding in some cases, and are often called *agrée* institutions (Republic of Rwanda: Ministry of Health, 2006). The 369 primary level structures provide 80% of the basic medical services to the population.

The majority of these centres lack professional staff particularly doctors and laboratory technicians (Furth et al. 2006). However, the current impetus of scaling up ART services through a primary health care approach has led to a number of these facilities being refurbished and staffed. Administratively, power and authority has been decentralised to 30 health districts by an act of parliament since March 2006. However the Ministry of Health maintains the central role of strategic direction, staffing, planning and supervision.

Health care utilisation has markedly increased over the last five years, it is estimated that 60% of the population who needed health care in 2006 were able to obtain it. This has resulted from increased funding from public and private sources. Between 2002 and 2003, total health expenditure rose from US\$ 75.3 million to US\$ 116.9 million largely due to increased donor and Government contributions. This shifted total health expenditure from 4.1% of GDP in 2002 to 6.6% of the GDP in 2003, making Rwanda one of the leading contributors to health in comparison to other countries in the region (Ministry of Finance and Economic Planning, 2004). Total health expenditure as a percentage of GDP had increased to 7.5% by 2004 and Government spending on health per capita was US\$8.25. Public revenue was able to finance 56.8% of total health expenditure while private sources met the balance of 43.2%. The public resources for health care financing were composed of 62.9% local revenue and 37.1% donor contributions (World Health Organisation, 2007).

Out-of-pocket expenditure as a percentage of total expenditure on health was estimated at 43% in 2003 down from 52% in 1998 (Republic of Rwanda: Ministry of Health, 2006). Out-of-pocket expenditure as a percentage of private sources of health was 36.9% in 2004 (World Health Organisation, 2007). This is large considering the levels of poverty and the ability of households to raise money at time of treatment. However, private funding has been buoyed by the growth in community based health insurance schemes (CBHIS) which reached 74% coverage of the entire population by the close of December 2006 (*Ministère de la Santé*, 2007). The CBHIS are built around a specific provider but administered by a tripartite arrangement that includes the service provider the insured and civic interest groups (*Ministère de la Santé*, 2007).

1.4.1. Health sector response to HIV/AIDS

Rwanda's response to the HIV/AIDS epidemic has been characterised by strong leadership spearheaded by the President's Office. The President has often discussed the ravages of the epidemic in various local and international fora thus keeping the HIV/AIDS policy on the national agenda. It is said that he spearheaded Rwanda's application for funding from the Global Fund (first round and second round) and the Multi-country AIDS Program. The First Lady has been equally instrumental in championing the fight against AIDS. She founded the African First Ladies Alliance Against AIDS and PACFA, an NGO that aims to assist vulnerable families by providing a holistic family package which includes treatment, psychosocial and nutritional support and micro-finance. A Minister of State for HIV/AIDS and Large Epidemics was appointed in 2002 with a mandate to develop a comprehensive response to HIV/AIDS that includes an effective national program for treatment and care. The Minister of State is directly responsible for the Treatment and Research AIDS Centre (TRAC) and the National Reference Laboratory (NRL), the two institutions responsible for planning and delivery of HIV/AIDS care, laboratory services, training of health care professionals, and research (Ministry of Health and William Jefferson Clinton Foundation, 2003).

The National AIDS Control Commission (CNLS/NACC), under the auspices of the President's Office is responsible for multi-sector strategic vision, coordination, planning, monitoring and evaluation of the programme. It is also responsible for social mobilisation and supervision of provincial and district AIDS control programmes. Rwanda is among a few countries in Africa that have operationalised the Coordinated Procurement and Distribution Systems (CPDS) for procurement and distribution of all drugs, commodities and consumables for the ART programme. This was achieved by opening a "Common Basket Fund" which is financed by all partners and is overseen by the Resource Management Committee.

Due to acute shortage of doctors (1/50,000 of population as opposed to the World Health Organisation benchmark of 1/37,000) nurses have been trained to manage ART delivery.

1.5. Problem statement

The prevalence of HIV/AIDS in the adult population (15-49 years) in Rwanda is 3%, but prevalence is higher in women at 3.6% in comparison to men at 2.3%. The prevalence is even higher in the urban population at 7.3% compared to 2.2% in the rural population (*Institut National de la Statistique du Rwanda (INSR) and ORC Macro, 2006*). Although prevalence is low compared to most of Southern Africa, this situation could drastically change considering that 60% of the population is below 20 years and the number of orphaned and vulnerable children.

The number of adults (15 years and above) living with HIV/AIDS was estimated to be 160,000 in 2006 based on UNAIDS/WHO “3-by-5” estimates and the total death toll due to AIDS was 21,000 (UNAIDS, 2006a). The number needing ART by December 2005 was estimated to be 49,000. Out of these 67% (32,973) were targeted to receive ART between 2003 and 2005 (based on modelled estimates of patients with AIDS/newly developing AIDS in the WHO “3-by-5” Plan. By December 2005, ART scale up had reached 36% (17,781) of the target population (WHO/UNAIDS, 2005). Nonetheless 100% was achieved during the next 12 months as the total population initiated on ART had reached 34,136 (Treatment and Research AIDS Centre, 2007).

To roll-out ART government had to substantially increase funding to the health sector, specifically to the HIV/AIDS sub-account. In 2003, the sub-account spent US\$9 million, this drastically increased to US\$43 million in 2004 during the launch of the ART roll-out. The following year (2005) spending on the HIV/AIDS interventions topped US\$78 million (UNAIDS, 2006b). As a percentage of GDP, total health expenditure increased from 4.1% in 2003 to 6.6% in 2004. (*Présidence de la République du Rwanda: Commission Nationale de Lutte Contre le SIDA, 2005*).

The National Strategic Plan for HIV/AIDS care, prevention and mitigation 2005-2009, had budgeted US\$51 million for 2005. This implies that the budget was lower than expenditure by a sum of US\$27 million. This exponential growth in costs with a large variance between budget and expenditure begs a number of answers. These questions include what will it cost and can the country sustain this level of spending.

These questions could be answered to a large extent if one knew the lifetime costs of providing ART in Rwanda and the capacity of the country to raise domestic revenue from taxes. Unfortunately the body of evidence on unit and lifetime costs for providing ART in Rwanda is nonexistent. In addition, there are concerns about sustainability of donor funding for the ART programme. For instance UNAIDS (2006a) estimated the global total costs for prevention, care and mitigation of HIV/AIDS in 2007 to be US\$18.1 billions, yet only US\$10 billions had been committed by donors. UNAIDS goes on to sound the alarm that the situation is expected to worsen unless national governments and their development partners undertake specific actions to shore up sustainability of prevention, care and mitigation programmes of HIV/AIDS.

1.6. Aim and objectives

The study aims to determine the economic costs of scaling up ART in Rwanda. Unit and lifetime costs for providing ART to adults will be constructed from primary utilisation and cost data complemented by appropriate secondary data sources. These will then be used as the building blocks for determining the costs of scaling. A sub-theme of the study is to use these costs and key informant interviews to explore the long term sustainability of ART in Rwanda.

1.6.1. Specific objectives

1. To determine the cost per visit and the cost per patient-year of ART in one tertiary hospital, one district hospital and one health centre in Rwanda from the provider's perspective.
2. To use a Markov model to calculate the per-patient period costs of ART using available secondary epidemiological data and primary cost data collected in objective 1.
3. To project the cost of scaling up ART in Rwanda.
4. To determine the number of clinical staff needed for scale up.
5. To establish the extent to which the ART programme is financially sustainable.

1.7. Justification for the study

The advent of HAART has given hope to many millions of people who were originally marked for death. It has also shown that HIV/AIDS can be managed as any other chronic condition. This does not only reduce morbidity, mortality and stigma but enables the patient to return to nearly full productive capacity. This was the basis of UNAIDS/WHO “3-by-5” programme for massive scale-up of ART in developing countries.

Rwanda, like other resource poor countries, was able to tap into donor funding through the mechanism of the UNAIDS/WHO “3-by-5” programme and has been rolling-out ART in earnest since 2004. Although considerable literature has been generated on global costs for scaling up of ART programmes, these global estimates have been calculated in the absence of local data and research. Rwanda has no known studies of the economic costs of scaling up ART. According to Vassall and Comperolle (2006) there is an urgent need to carry out country specific studies to establish context specific unit costs. This is because country cost structures differ from each other (World Health Organisation, 2003; Rosen and Long, 2006). Without knowing country specific economic costs, it is difficult to generate long and medium term plans and budgets let alone a sustainability plan.

Secondly, most of the donor driven estimates cover the short and medium term, yet once patients are started on ART, it is for their entire lifetime. Longer term planning can be assisted by modelling that allows for calculation of lifetime costs. Therefore, findings from the study will be useful for making informed decisions on scaling up the ART programme in Rwanda and its long term sustainability.

1.8. Scope and limitations of the study

The study limits itself to analysing the costs of scaling up ART in Rwandan adults from the provider’s perspective. Due to methodological, time and financial constraints the study will exclude costs of hospitalisation, prophylaxis and treatment of opportunistic infections, home-based care, palliative care and prevention of mother-to-child-transmission (PMTCT). Data collection would also be limited to a maximum

of three facilities, namely one tertiary hospital, one district hospital and one health centre.

1.9. Organisation of the dissertation

Chapter 2 presents the theoretical and empirical literature on cost analysis and financial sustainability of health programmes in developing countries. It explores the theoretical foundation for different perspectives to costing and modelling in health economics. It also reviews the different ART costing models and studies as well as those on sustainability. Chapter 3 describes the costing methodology, data sources and the ART costing model used. Chapter 4 presents the cost analysis and key informant interviews. Chapter 5 is a critique of the study results in terms of agreement or disagreement with literature, plausibility of findings, generalisability and uncertainty. It also presents policy implications and recommendations.

Chapter 2: Literature Review

2.0. Introduction

This chapter reviews costing literature and methodologies relating to estimating resource needs for replicating ART programmes, focusing specifically on low and middle income countries. It also reviews the relevant literature regarding the sustainability of such programmes given the prevailing resource constraints. The first section presents the concepts of cost and cost analysis in economic evaluation of health care programmes. Definitions of types and scope of costs, costing approaches and differential timing of costs are explored. The second section dwells on the modelling approaches that can be used to calculate the lifetime costs and outcomes of providing ART and the costs of scaling up. Section three explores previous studies for scaling up ART interventions and the methods used to estimate the costs. Besides presenting quantitative studies of scaling up it also tackles the impact of disease events and scaling up on estimation of costs. The last section presents the theoretical and methodological approaches to assessing financial sustainability of health care programmes with an emphasis on ART programmes.

2.1. Cost concepts and cost analyses

2.1.1. Cost analysis and definitions of costs

Cost analyses are usually undertaken to determine the financial and/or the economic costs of a programme. Financial costs refer to the actual expenditure incurred by the programme and usually involve actual money transfers between the programme and other entities in exchange for goods and services. On the other hand economic costs are defined as the value of the resources used to produce an output. They include the notion of opportunity cost, defined as the value of the best-forgone alternative use of resources (Drummond *et al.* 2005). Whether to analyse financial or economic costs will depend on the objective of the analysis. For estimating resources needed for project replication or scaling up it is necessary to use economic costs, so as to incorporate the opportunity cost of the resources (Walker 2001). This is because one is concerned with the generalisability of costs to other settings and the sustainability of the programme. Value should also be attached to donated goods and services,

Donations of goods and services may not always be forthcoming implying that policy makers would have to find alternative funding for the programme to continue.

The concept of opportunity cost, depending on the costing perspective, seeks to value costs incurred by the service provider, the society and the patient. Besides valuing direct health care costs, it also seeks to value direct non health care costs such as patient travel costs and indirect health care costs arising for example from productivity losses due to illness (Posnett and Jan, 1996; Mooney and Jan 1997; Drummond et al. 2005). Given such a broad definition of economic costs, any cost analysis needs to draw a boundary for which costs to consider (section 2.1.2 below).

Costs can be divided into variable and fixed costs. Variable costs are those that vary with the level of output, for example the cost of drugs and other medical or non-medical consumables, laboratory tests and short term contractual staffing. On the other hand fixed costs do not vary for a certain range of output and are hard to adjust in the short run. Unlike variable costs, fixed costs are not used up in one financial year. Examples of fixed costs include costs of capital items like buildings (rent), equipments such as generators, fridges, CD4 and viral count machines, microscopes etc, the cost of permanent staff (clinical and administrative) and most overhead costs such as utilities. However, in the long run all costs are variable because input mix can be varied so as to vary the level of output. For example in the long run hospital capacity can be varied in terms of floor space, equipment, personnel and overheads (Clewer and Perkins, 1998; Kumaranayake and Watts, 2000; Drummond, et al. 2005).

We can argue therefore that the time horizon for scaling up a programme will have an important bearing on the classification of costs. If scaling up is being considered over a long time horizon it is reasonable to assume that many costs that are fixed in the short run might become variable. For example new clinics, staff and equipment can be acquired so as to increase the level of coverage (proportion of people reached and or geographical coverage). But in the short run we can only vary inputs like ARVs and supplies. Obviously the time horizon of scaling up will determine the input mix and hence the level of variable and fixed costs. It also has an important bearing on the choice of unit cost to use in the study as discussed below.

Costs can also be classified as patient-specific and non patient-specific depending on whether we can directly attribute the cost to a specific patient or activity (Clewer and Perkins, 1998). Patient-specific costs, also known as separable costs, can be directly attributed to the patient and examples include drugs, imaging and laboratory costs. Non patient-specific costs can not be directly traced to a specific patient. Examples include the cost of utilities, administration, security, laundry and so on. It should be noted that the patient-specific and non patient-specific classification is different from fixed and variable costs.

At any level of output, costs can be categorised into total costs, average costs and marginal costs. In other words all three cost statistics are a function of output. The total cost of production in the short run is equal to total fixed costs plus total variable costs. In the long run all costs are variable and hence total cost equals total variable cost. Dividing total costs by total output gives rise to the average total cost, also known as the unit cost. By the same token there are also average fixed costs and average variable costs.

A very important cost derivation is the marginal cost, which is defined as the additional cost required to produce one extra unit of output. Marginal cost relates to the rate of change in total cost as output is increased. When total cost is increasing rapidly as output is increased this leads to a high marginal cost. Alternatively a sedate increase in total cost as output is increased will yield low marginal cost. By definition, the marginal cost curve cuts the average cost curve at its lowest point. At this point (in a perfectly competitive market) marginal cost equals average total cost equals price per unit (Clewer and Perkins, 1998; Varian, 2006).

Although marginal cost is theoretically the most appropriate cost statistic to use in economic evaluations, in practice this is costly and impractical. The norm then is to use the average total cost as a proxy for marginal cost. For this to be true we must assume that unit cost (average total cost) is constant over the period under review. Unfortunately this holds true only in the long run, at the optimal scale of production which is characterised by constant returns to scale (see section 2.3.1 below). Secondly, in short run marginal cost would exclude the fixed cost component as this does not vary with output (Creese and Parker, 1994).

2.1.2. The costing perspectives

Before any costing study is undertaken, the scope of the costing (viewpoint or perspective) must be defined so as to define the boundaries of the study and which costs to consider. Different costing perspectives are recognized in the costing literature. They include societal, household and provider perspectives. The viewpoint of the provider perspective is specific to the provider in question, for example it could be the view of the central government/treasury, the ministry of health, other government ministries, donors, NGOs and so on. The household perspective considers costs incurred by patients and their households in the process of seeking and consuming health care. It will therefore value transport costs for patients to and from the health centre and the cost of time spent while accessing the service, also known as direct non-health care costs. It also places a value on productivity losses as a result of inability to work and time taken for informal care and counselling support by family and friends. The latter are referred to as indirect costs.

The provider's perspective values direct health care costs such as permanent clinical staff costs, drugs, imaging costs and the cost of laboratory monitoring tests. It also values non-patient-specific costs such as overheads and capital.

Costing from the societal perspective considers all costs incurred by anybody providing or using a service. It is the broadest form of cost analysis because it includes costs incurred by the provider and the consumer of the service. Consequently it seeks to value direct health care costs, direct non-health care costs and indirect costs.

Which costs to consider or perspective to take will depend on the objective of the cost analysis. This is because a cost from one perspective may not be a cost from another perspective. One could argue that though productivity losses are important to the household and the society (absenteeism from work), it is not a cost to the Ministry of Health (Drummond *et al.* 2005). It has also been argued that if a study values outcomes solely in terms of health, then only the opportunity cost of health care resources should be valued (Mooney and Jan 1997). This is because the opportunity costs associated with indirect and non-health care costs need to be traded-off against

wider societal outcomes than narrow health gains. In light of these arguments, and considering that this dissertation seeks to inform policy, only health care resources will be analysed from the perspective of the provider (Ministry of Health and her partners).

2.1.3. The costing process and approaches

The costing process involves the identification, measurement and valuation of the resources consumed by the intervention or programme of interest. Considering the ART outpatient programme in a hospital, one should consider both the patient-specific health care costs and the shared (non patient-specific) costs that must be traced from the central level (Drummond *et al.* 2005). The next step involves measurement of the numbers of patients treated and the quantities of resources consumed in the process (drugs, laboratory tests, utilities, staff numbers and time, capital items tied up, medical and non-medical stores). Finally a value is attached to each item.

This bottom-up and top-down approach to measuring costs is also known as the ingredients (micro-costing) method and step-down method respectively.

The step-down method uses a top-down approach to allocate costs at aggregate level, using appropriate allocation bases, to pertinent departments, units and finally to patients. This cascading process eventually allows the derivation of cost per-patient period (unit cost). For the ingredients approach valuation of costs and consequences begins at the patient utilisation level to determine unit costs which can then be multiplied by appropriate quantities (Drummond *et al.* 2005). It is therefore the most precise of all approaches to costing and should be adopted whenever costs can be directly linked to the end-user. Indeed, in a major systematic literature review by Johns and Tan-Torres (2005) most studies for scaling up ART used the micro-costing method. However, there are usually shared costs as well which have to be treated by the step-down approach.

2.1.4. Allowing for differential timing of costs and consequences

Society prefers to receive benefits (treatment) today rather than in the future and also would rather incur costs later than sooner. This is the notion of time preference for money or consumption. Society has a number of reasons to prefer to gain benefits immediately but to postpone costs. Firstly the future is uncertain and so is consumption in the future. A patient needing nutritional support today can not wait for it next year. So society takes a short term view and prefers to live for today rather than tomorrow. This is quite pertinent in Sub-Saharan Africa where HIV/AIDS has more than halved life expectancy. Secondly, a dollar earned today is worth much more than a dollar in five years time because it can be invested to earn interest (Walker and Kumaranayake, 2002). Consequently future costs and resources are worth less and must be equivalently discounted to reflect this notion.

Although health economics literature concurs on the concept of discounting costs and consequences, there is no agreement on which discount rate to use or whether costs and benefits should be discounted at different rates. However, a few countries like the United Kingdom and the United States of America advise that economic evaluations should discount costs and benefits at 5% and 3% respectively (Drummond *et al.* 2005). Otherwise in countries where such advisory rates do not exist, analysts have tended to use the real interest rate which is calculated from the rate of long term government bonds (Olsen, 1993; Cairns, 2001; Drummond *et al.* 2005). An alternative approach is to use a rate that has been widely used in previous studies of similar settings so as to enhance comparability between studies. Then sensitivity analysis was used to explore the degree of uncertainty in the results (chapter 4, section 4.3).

Annualisation (a form of discounting) is important for determining how the cost of a capital item is used up during its useful life. By definition capital items are not consumed in one financial year, it is then necessary to calculate the annual equivalent cost of such items. The procedure involves estimating the replacement value of the item and dividing it with the annuity factor. The annuity factor is computed from the useful life of the item and the real rate of return. Annuity factor tables are readily available in literature and can be used once the discount rate and useful life is known. Methodological concern again exists on the choice and calculation of the discount

rate. Lastly, one needs to decide whether services accrue at the beginning or end of each financial year as in deferred and ordinary annuities respectively (Cairns 2001; Walker and Kumaranayake, 2002; Drummond *et al.* 2005).

2.2. Modelling the costs of scaling up ART

Because HIV/AIDS is a relatively new disease and ART has only been available for approximately ten years, there is still very little data available about the long-term outcomes of a patient on ART. Models are used to track the course and costs of disease by synthesising the available primary or secondary data and extrapolating to calculate lifetime costs and outcomes. Indeed, if we knew the exact consequences of HIV/AIDS there would be no need for modelling. According to Hellinger, (2006: 632) “almost all recent models used to study the progression of HIV disease have been Markov models.” This is because they are suited to modelling stochastic and dynamic processes (Kumaranayake and Watts, 2000; Boulle *et al.* 2003; Hellinger, 2006).

2.2.1. Markov models for stochastic and dynamic processes

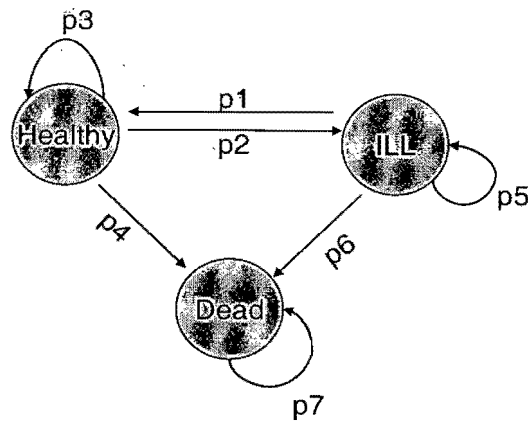
Decision making over the costs and consequences of HIV-treatment is often made under a lot of uncertainty. This is because costs are a function of disease events and the duration of treatment of each event. Unfortunately both the timing and duration of events and the timing and duration of treating each event will not be known with (certainty) for a long time. For instance to calculate the cost of second-line ARV treatment we need to know with certainty the number of patients on second-line treatment, the timing of the treatment (when patients switch from first-line) and the duration of the treatment. Analysts and even some donors have increasingly turned to mathematical models, especially the Markov process, to unravel this stochastic and dynamic process (Briggs and Sculpher, 1998; Tabas *et al.* 2001; Boulle *et al.* 2004; Cleary *et al.* 2006).

The increasing importance of the Markov model in medical decision analysis is due to its distinct advantages that allows for synthesis of data from multiple sources. In addition, the Markov model allows the analyst to peer into the future by extrapolating data taken from short term real life treatment situations. This is very important for

predicting lifetime costs and the associated outcomes. The model is also quite proficient in handling differential timing of costs and consequences. These are merely phased in at the start of the modelling process. The model then applies them to the specific treatment events along each patient's time-path until the end point. Lastly the model allows a platform for the thorough analysis of uncertainty relating to any of the input variables (Sonnenberg and Beck 1993; Briggs and Sculpher, 1998; Kuntz and Weinstein, 2001).

The model requires that patients be divided into a finite number of disease or treatment states, known as Markov states, and that these states are clinically and or economically important. The patient is only allowed to stay in one state at a time (thus states are mutually exclusive) and the time period for this state is of sufficient length to capture all important disease events or costs. This time period is known as a Markov cycle and it represents the incremental time or cost spent in the state. The model only allows a patient to move from one state to the next contingent upon the state transition probability. In other words there is no memory of previous states (Sonnenberg and Beck 1993). For the model to terminate it requires an end state that allows entry without exit, this is known as the absorbing state and can be represented by death in real life. Hence anyone entering this state has no transition probability and cannot transition to any other state. This allows for the calculation of lifetime costs and outcomes (Sonnenberg and Beck 1993; Briggs and Sculpher 1998). A detailed discussion of the Markov model and assumptions used in the analysis is available in chapter 3, sections 3.2.2.1 to 3.2.2.3.

In its simplest form the Markov model can take on three states, as shown in the diagram below, namely healthy, ill and dead. Upon entering the healthy state, one can stay healthy depending on probability 'p3'. One could fall sick and transition to the ill state depending on probability 'p2'. There is also a probability 'p4' that one could die. In the ill state one can stay ill depending on probability 'p5', get better and transition back to the healthy state given the probability 'p1'. Alternatively one could transition to the absorbing state (dead) given the probability 'p6'. Nobody can transition from the dead state to another because it is the absorbing state. P7 is the probability of staying in the dead state which is equal to 1.



A Markov-state diagram adopted from Sonnenberg and Beck (1993)

2.2.2. Overview of generic ART costing models

There are a number of models for estimating the resources required to scale up HIV/AIDS interventions, however three generic costing models easily stand out in costing literature. These include the Cape Town Antiretroviral Costing Model, henceforth referred to as the CT Model, the Resource Needs Model (RNM) and the AidsTreatCost Model (ATC). All three models were built using Microsoft Excel macros with a custom user interface. They were all designed for costing HIV/AIDS interventions but each with a slightly different emphasis. Nevertheless they all require inputs on demographic and epidemiological data, treatment protocols, actual or projected utilization rates, service and commodity costs and programme level costs (Boulle *et al.* 2003).

The Resource Needs Model, developed by the Futures Group, is a tool for estimating the total amount of resources needed for prevention, care, support and mitigation (including orphan support) for HIV/AIDS at a national level. It is thus made up of three sub-models: prevention, care and support, and mitigation. These are further subdivided into fourteen prevention programmes, six care and treatment programmes and orphan support. The model links funding and programme goals and uses local,

regional or global unit costs to compute programme costs. Its major focus is thus a comprehensive response to HIV/AIDS (Futures Group/Constella, 2005).

The AidsTreatCost model also has three sub-models, which include:

- (i) a model of the demographics in the country of interest,
- (ii) a model of the epidemiology of HIV/AIDS in the same country, and
- (iii) a model, or set of algorithms, that the ATC uses to estimate costs

This model requires detailed estimates of a country's population and how it is distributed by age, gender, and location, in addition to fertility and mortality rates by age groups. It must also be fed with the epidemiological profile of HIV/AIDS such as number of people infected, percentage with symptomatic infection, and rates of infection and disease progression (Wilwerding *et al.* 2003). The first two models were designed to handle population level cost analyses and are not flexible enough to analyse patient-level analyses of ART.

The Cape Town Antiretroviral Costing Model, as its name suggests, was specifically designed to handle costing of ART at patient, programme and national levels. The model was developed by the University of Cape Town, School of Public Health & Family Medicine in collaboration with the Provincial Administration of the Western Cape, Department of Health, South Africa. Under the auspices of the World Health Organisation the model was merged with the Resource Needs Model to estimate resource needs of HIV/AIDS interventions in Burkina Faso, Nigeria, Ghana, Mozambique, and Tanzania (University of Cape Town, Ministry of Health & Social Welfare, Kingdom of Lesotho, Médecins Sans Frontières & Scott Hospital Health Service Area, 2007).

The model allows phasing in of patient numbers overtime and the costs associated with five disease states are captured in a manner similar to a Markov model (chapter 3, section 3.2.2.1). It treats the first six months on first-line and first six months on second-line ART differently from time on ART thereafter. This allows it to predict the associated costs in the patient periods more efficiently than the other models. It also

permits patients to receive different regimens and to switch ARVs within and between regimens unlike the ATC model. It therefore allows for greater detail and precision in predicting ARV costs. The model also allows greater precision in predicting laboratory test costs as these are linked to individual ARVs. Finally, per-patient lifetime costs and outcomes are modelled and can be extrapolated to population level. We can then conclude that the CT Model is more appropriate for costing ART interventions because of the flexibility and detail that it allows in specifying ingredients and unit costs (Bouille *et al.* 2003, Wilwerding *et al.* 2003; University of Cape Town, Ministry of Health & Social Welfare, Kingdom of Lesotho, Médecins Sans Frontières & Scott Hospital Health Service Area, 2007).

2.3. Previous studies of cost of scaling up

Uvin (1995) classifies scaling up into four different typologies: quantitative, functional, political, and organizational scaling up. Quantitative scaling up is defined as reaching a greater number of people with greater health benefits. Health Economics literature is often concerned with quantitative scaling up. Kumaranayake and Watts (2000) propose a number of ways of measuring quantitative scaling up of a health intervention, but commonly the following three methods are used:

- a) level of coverage (e.g. proportion of people reached),
- b) volume of output (e.g. number of people treated, number of staff trained)
- c) and geographical coverage (e.g. number of administrative units covered)

Scaling up is therefore a process of reaching a larger proportion of the target population in a broader geographic area with sustainable health programmes. The inclusion of a broader geographical area is indeed intrinsic to scaling up because often distance plays an important role in access to health care. The caveat of sustainability is driven by the need to keep scaled up programmes operational long after the period of scaling up. This is critical in the case of scaled-up ART programmes because interruption of ART could lead to virological failure and the development of drug resistance. If a drug resistant form of the virus is transmitted, this can have implications for the treatment of future generations. Successful scaling up of ART interventions will therefore require secure funding, a conducive political atmosphere, organizational sustainability, and acceptability and ownership by the target

communities. Studies conducted to examine costs of scaling up HIV/AIDS programmes appear to fall in two broad categories:

- a) studies that deal with impact of scaling up on costs and consequences,
- b) and quantitative scaling-up studies that assess coverage and volume of output.

2.3.1. Impact of scaling up on costs and consequences

Costing studies use ingredients and step-down methods to determine unit costs, which are then multiplied by predicted future needs to estimate total costs. Unfortunately unit costs are affected by a number of factors as a programme is scaled up. These factors include the time horizon (section 2.3 above) and economies of scale and scope. This is because rapid scale up of health interventions could lead to significant changes in the cost structure and the unit costs (Over, 1986; Luce and Manning, 1998; Kumaranayake and Watts, 2000; Guinness *et al.* 2005).

Scaling up is akin to production in the long run because we are ultimately concerned with varying the scale of operation. Different operational scales are characterised by changes in the cost structure and unit costs. In the long run, the organisation learns how to use resources more efficiently. Staff become increasingly specialised, costs are spread over more units of output and discounts are obtained from bulk purchases. As a result the unit cost (long run average cost) and marginal costs are falling in this phase of production because each additional unit of output is produced at lesser cost. This phase of production is therefore characterised by economies of scale. Such advantages are exhausted after sometime and thereafter any increase in total cost will only cause the output to increase by a constant proportion. For example doubling total cost will result in output increasing exactly by 2 times. Thus this phase of production is characterised by constant returns to scale. At this point of the production phase, the unit cost (long run average cost) is constant.

As the programme (production) is scaled up [further] to remote geographical areas the communication, monitoring, transport and other adherence activities lead to increased costs of production (changing cost structure). Obviously the marginal cost and unit costs begin to gradually rise and increasing total cost will produce less and less output (Clewer and Perkins, 1998; Varian, 2006). This phase of production is therefore

characterised by decreasing returns to scale or diseconomies of scale. This situation can only be reversed by technological advances which can bring down the cost of production. Otherwise, a cost minimising firm will try and operate in the first two phases of production thereby exploiting the changing properties of the cost function. We can therefore visualise a U-shaped long run average cost (unit cost) curve joining these phases of scale together but with a shallow trough (Clewer and Perkins, 1998; Guinness *et al.* 2005)

Where scaling up exploits existing redundant capacity total output increases with low increase in input costs. Obviously this increase is up to a point where existing capacity is exhausted. If the health system is under staffed and under resourced, as is often the case in Sub-Saharan Africa, scaling up will lead to diseconomies of scale. While analysing costs of scaling up primary health care interventions in Mali, Over (1986) found that marginal costs begin to rise when coverage of the target population exceeded 30%. The changes resulted mainly from changes in cost structure such as increased transport costs to remote areas, higher supervision and capital costs. Also recruitment and training of scarce skills for rural communities increased the unit cost of labour.

Kumaranayake and Watts (2000) examined the effect of different variables on the costs of scaling up HIV/AIDS curative and preventive interventions in Sub-Saharan Africa. The authors defined the scaling up in terms of increasing the coverage to 25% of the target population and number of people reached in urban and rural setting. Their analysis showed that the population reached as a proxy for scale effects was the most consistent cost driver, closely followed by existing capacity constraints and thirdly the prevalence of sexually transmitted diseases. The analysis also showed that operating at 25% of scale corresponded to the phase of diseconomies of scale and marginal cost for treatment and care increased significantly.

In another study by Guinness *et al.* (2005) of changes in the total and unit costs as HIV/AIDS prevention interventions are scaled-up, the researchers defined scale in terms of target population (number of sex-workers reached). The analysis showed a correlation between total cost and scale effects.

Graphing cost per sex worker reached yielded a classic U-shaped average cost curve. The lowest part of the cost curve corresponded to reaching between 1000 and 1700 sex workers. The authors then caution the estimate of resource requirements based on a constant average cost concept since it may underestimate or overestimate total costs.

There is no doubt about the effect of scale on costs but the overwhelming problem is lack of reliable cost data especially in resource poor settings to inform studies estimating changes in marginal and unit costs as scale is changed. Rapid scaling up is definitely associated with inefficiencies especially in the short run because new staff have to be recruited and trained. Vertical equity considerations and decentralisation of services to reach remote areas requires motivating staff to work in rural areas hence increasing the cost of labour. Again in pursuit of vertical equity, scaling up would entail considerable increase in transport and capital costs as access for remote communities is improved. Managing the processes of scaling up is another important source of changes in economies of scale (Hanson et al. 2001). Centralisation would keep the costs of communication, monitoring and evaluation low but this would detract from the objectives of scaling up as the two have diametrically opposing objectives. In the medium and long term scaling up of ART would mean staff doing the same type of activities everyday over and over again. In such circumstances staff and even the institution become more efficient at these tasks. The downward trend in ARV costs is another source of changes in unit costs. This could be attributed to greater competition as generic manufacturers have entered the market. Economies of scope could be realised if complementary interventions to ART like PMTCT, VCT and TB were combined in one production unit (Pienaar *et al.* 2006).

To determine the costs of scaling up most studies take unit cost (average costs per recipient) and multiply them by projected future needs. But from the above it is obvious that unit costs often vary with scale as a result of economies or diseconomies of scale or scope. If there are increasing returns to scale the unit costs are decreasing and this leads to overestimation of projected total cost and vice versa for increasing returns. The reverse is worse because programme costs are underestimated as unit costs are increasing with decreasing returns to scale. This dilemma amplifies the need for research and in low and middle income countries to double efforts in cost data tracking which will enable marginal costs to be determined from time series data.

2.3.2 Quantitative costing studies of costs of scaling up HIV/AIDS interventions.

Literature on the costs of scaling up HIV/AIDS interventions reveals two distinct eras of costing paradigms. The first wave of costing studies started in the late 1990s and intensified following the United Nations' General Assembly Resolution (S-26/2) on HIV/AIDS in 2001. Urgent costing studies were conducted to estimate resource needs for scaling up HIV/AIDS interventions in low and middle income countries largely based on global, regional and cluster estimates of costs and service utilisation. Using the aggregate assumptions the estimates tended to determine financial costs in the short-run (Schwartländer *et al.* 2001; Vassall and Compemolle, 2006).

The second paradigm of costing studies focused on estimating resource needs at country and sub-national programme levels. This second group of studies comes in two distinct groups, those that were initiated by various governments to estimate resource needs for scaling up and those that are a product of routine scientific quest. The former were mainly commissioned by some countries to aid budgeting and planning and to improve the success-rate of applying for donor grants (Bertozzi *et al.* 2004; Gutierrez *et al.* 2004; Vassall and Compemolle, 2006). Examples from Sub-Saharan Africa include but are not limited to costing studies from Zambia (Kombe and Smith 2003), Ethiopia (Kombe *et al.* 2004a), Nigeria (Kombe *et al.* 2004b), and Uganda (Chandler and Musau 2005). These four studies share similar methodology because they were all modelled using the ATC model. Other countries have used either the resource needs model or the CT model alone or in combination. Burkina Faso, Nigeria, Ghana, Mozambique, and Tanzania are said to have combined the two models in their estimation resource needs for scaling up (University of Cape Town, Ministry of Health & Social Welfare, Kingdom of Lesotho, Médecins Sans Frontières & Scott Hospital Health Service Area, 2007). It is worthwhile to note that most of the studies in the former category are conducted under consultancy services, often guided by the policy makers' contextual needs rather than rigour of scientific design and are rarely subjected to external review mechanisms. Additionally most of the studies concerned themselves with financial resources and used partial costing (Kombe *et al.* 2004a; Chandler and Musau 2005).

Nevertheless, there are some full costing studies in the first category that have examined the comprehensive cost of providing ART services using health care utilisation and cost data so as to generate the costs of scaling up (National Department of Health, 2007). These closely resemble studies in the second category and have tended to use similar cost components to synthesise the full and total economic cost of providing ART (Cleary *et al.* 2005; University of Cape Town, Ministry of Health & Social Welfare, Kingdom of Lesotho, Médecins Sans Frontières & Scott Hospital Health Service Area, 2007)

The general trend shows that studies adopted the provider's perspective and used a combination of ingredients and step-down costing methodologies. These cost estimates for scaling up were largely based on the following health care utilisation and service cost data/assumptions (Schwartländer *et al.* 2001; WHO/UNAIDS, 2003; Cleary *et al.* 2005; National Department of Health, 2007; University of Cape Town, Ministry of Health & Social Welfare, Kingdom of Lesotho, Médecins Sans Frontières & Scott Hospital Health Service Area, 2007):

- (i) Expected numbers in-care each year over the scaling up period, the expected life expectancy on ART and the proportion of expected time split on first and second-line regimens,
- (ii) Expected costs and utilisation of first and second-line ARV regimens,
- (iii) Expected costs and utilisation of laboratory testing,
- (iv) Expected costs and utilisation of ART services per visit,
- (v) Expected programme-level costs e.g. infrastructure development,
- (vi) Expected costs and utilisation of related services e.g. nutrition, counselling and support by civil society.

The number of patients in care during any period is composed of patients on ART from the previous period and the in-coming cohort during each subsequent period. In Rwanda, patients are assumed to be eligible for ART if they have an AIDS defining condition at any CD4 level, or if they have a CD4 < 200 cells/ μ l at any WHO stage. This criterion for treatment initiation shows a trade-off between the two key definitions of need that are found in the literature. These are defining need as capacity to benefit or need as illness.

Mooney (2003) argues that need ought to be defined in terms of capacity to benefit. This principle prescribes that scarce health care resources be allocated on the basis of cost-effectiveness and marginal met need versus defining need as the severity of illness. Marginal met need is a concept anchored in the principle of cost-benefit analysis. It stipulates that a rational health system, operating under a budget constraint will allocate its scarce resources to those activities for which the ratios of benefit to costs are highest. It will continue to do this until all its resources are used. It will therefore want to establish a ranking of needs to be met, the ranking being based on the size of the benefit to cost ratios of different interventions under consideration. Studies have shown that starting ART early, for example at CD4 >200cells/ μ l, is more effective than starting later. In addition, as patients become particularly immune compromised their capacity to benefit from ART might become quite limited, as shown by the relatively high rate of death found in patients with CD4<50 cells/ μ l during the first 6 months on treatment (Coetzee *et al.* 2004). If these relatively sick patients are prioritised for treatment, this would imply that need were defined in terms of illness.

Because the demand for ART far outstrips supply in much of Sub-Saharan Africa the necessity to institute explicit rationing criteria could not be more urgent. Though rationing is an extremely sensitive topic, it would still help minimise the ethical and equity dilemmas that characterise demand for a public good when supply is limited (Bennett and Chanfreau, 2005). Currently most estimates are based on the premise that the cohort that needs treatment is equal to the number of patients expected to die from AIDS in the next 12 to 24 months without ART (WHO/UNAIDS, 2003; Gutierrez *et al.* 2004). However, it should be noted that these are not the patients with the highest capacity to benefit – it has been shown for example that it is more effective to initiate ART with CD4>200 cells/ μ l. Instead, this criterion incorporates a trade-off between treating the patients who are most severely ill but who still have some capacity to benefit.

The composition of an ART visit cost is diversely calculated in literature. Studies differed on inclusion of costs for treatment of opportunistic infections, capital costs, overhead (“hotel”) costs, home based care costs, palliative care costs, treatment of post-exposure prophylaxis and pre-ART care costs.

Some full costing studies (Cleary *et al.* 2005; National Department of Health, 2007) have calculated the cost of a comprehensive ART visit from the following components:

- average number of visits by ART and pre-ART patients,
- overheads (e.g. utilities, office supplies),
- non-clinical staff (e.g. data clerks, administrative staff and cleaners),
- clinical staff (doctors, nurses, counsellors, pharmacists),
- Adherence activities
- prophylactic and curative medicines,
- capital (e.g. buildings and equipment).

The determination of the total number of visits per patient period (ART, pre-ART and unscheduled visits due to side effects, psychosocial problems and opportunistic infections) is very important because it has a multiplier effect on cost per patient period. The number of visits in the Khayelitsha Cohort was estimated to be 4 for pre-ART visits, 13.1 for the first six months on first-line regimen (including 3.1 unscheduled visits) and 10.2 annually thereafter. For the first 6 months on second-line regimen, 5.3 visits were estimated and 10 visits annually there after. Failing treatment was associated with the highest number of visits, at 14.5 times annually (Cleary *et al.* 2005). In Scott Hospital Area in Lesotho, visits in the first six months on the first-line ART regimen were determined to be 9.4 and 7 annually thereafter (inclusive of 1 unscheduled visit). Additionally, pre-ART visits were estimated at 3.2. These findings are from a research setting and should be interpreted with caution in relation to public sector settings where utilisation could be lower. The cost of a comprehensive ART visit was estimated to be R160.37 (in 2003/2004 prices or US\$21.2) using the Khayelitsha cohort (Cleary *et al.* 2005). Using Scott Hospital Area data the cost of a comprehensive ART visit was estimated at 17.34 M or approximately US\$2.5 excluding capital costs and the cost of drugs for opportunistic infections and treatment of side effects.

Costs of laboratory testing have been calculated from utilisation frequencies or national guidelines and unit costs. To estimate the opportunity costs thereof most studies adopt national laboratory tariffs (Chandler and Musau 2005; Cleary *et al.* 2004; Cleary *et al.* 2006).

This is because costing laboratory equipment and staff time per test is very costly exercise. The problem with this technique is accounting for subsidised tariffs in some countries. The other approach has been to cost the tradable component and then add back on each test an average estimate for the non-tradable portion (WHO/UNAIDS, 2003). This is a less robust approach because an average estimate cost of the non-tradable component is applied across all tests. The third method is to cost both the tradable and non-tradable components from first principles and is the most precise.

Overall monitoring costs are completely dominated by the cost of viral load testing, sometimes accounting for as much as 60% of total monitoring costs (Cleary *et al.* 2004)

Programme-level costs relate to costs that go towards the management and improvement of the whole programme and can not easily be expressed per visit or per capita. These include a range of expenditure items such as infrastructure improvements, supervision, monitoring and evaluation by central organs, technical assistance, resistance monitoring, research and other central costs. Little data exist on these types of costs and many analysts assume a fixed percentage of the total cost (Cleary *et al.* 2005).

Notwithstanding the inconsistencies in the cost analyses, ARVs are the most important cost driver averaging between US\$200 and US\$500 per patient per year (Chandler and Musau, 2005; Cleary *et al.* 2006). Its share of the total cost of providing ART ranges from as low as 30% in South Africa to as high as 75% in the rest of Sub-Saharan Africa. This difference is probably accounted for by higher input prices such as labour costs in South Africa but more importantly the availability of better cost data allow for more complete estimates (Rosen and Long 2006). For studies conducted after 2003 in South Africa and Uganda, monitoring (laboratory) takes the second largest share accounting for less than 30% (Chandler and Musau, 2005; Cleary *et al.* 2005). Labour costs averaged less than 20% while capital costs accounted for less than 10%.

2.3.2.1 HIV/AIDS disease stages and their impact on costs of scaling up

We know that different disease events are associated with different costs, such as pre-ART costs, costs for first-line drugs, costs for treatment failure, and so on. In recent years, the previous shortage of articles on the cost-effectiveness of ART has been replaced by a growing number of published studies including five interesting articles in 2006 alone, these include Bachmann (2006), Badri *et al.* (2006), Cleary *et al.* (2006), Etard *et al.* (2006) and Goldie *et al.* (2006).

One of the most important variables affecting the costs of scaling up is the effectiveness of ART or number of life years gained. This is because lifetime costs are in particular influenced by the recurrent costs of ARVs which is obviously influenced by the number of life years gained. As we are yet to ascertain this period from primary data, most estimates have been guided by the World Health Organisation (2003) assumption of a mean life expectancy of 5-7 years. But recent primary outcomes data from South Africa and West Africa (Senegal) show that ART is likely to be more effective in resource poor settings (Badri *et al.* 2006; Cleary *et al.* 2006; Etard *et al.* 2006)

The South African results are based on the Cape Town (CTAC) and the Khayelitsha cohorts (Badri *et al.* 2006; Cleary *et al.* 2006). The extrapolated results after a follow-up period of 48 months in the Khayelitsha cohort were 9.5 life years and US\$9,435 lifetime costs (2003 prices; discount rate of 3%). The CTAC study (on extrapolation) yielded survival times of 18.8, 21.0 and 23.83 life years, and lifetime costs of US\$5,434, US\$5,740 and US\$6,588 for initiation of ART at <200/ μ l, 200–350/ μ l and >350/ μ l respectively (2004 prices; discount rate of 8%). The Senegalese Cohort is a 7-year follow up effectiveness study, (95% ART naïve patients out of 403) from the public sector. Results show that after 60 months on ART 74.5% of patients are still surviving. Seeing as ART might be more effective in poor resource settings than the normal assumption of 5 to 7 years, there could be a significant increase in lifetime costs with serious implications for sustainability in resource poor settings.

Whether or not assumptions about life-expectancy have an impact on costs is particularly influenced by the time period of the costing. Shorter time periods tend to

mask the full resource implications of ART. In a comparison between the CT model and a model based on the Khayelitsha cohort, it was found that there was very little difference in costs over a four-year period. Although more patients were surviving and remaining in care in the Khayelitsha model, the CT model was associated with higher costs because a higher number of patients had transitioned to the second-line regimen (National Department of Health, 2007). On the other hand, a model that projects a longer life-expectancy on ART will transition patients later to second-line ARVs thus incurring lower costs in the short-run.

The rate at which patients transition from first to second-line ARV regimen is a key cost driver in studies of costs of scaling-up ART interventions. This is because switching from the first to the second line ARV regimen results in cost increase of about 800% in Lesotho, 700% in Rwanda and 550% in South Africa (CAMERWA, 2006; University of Cape Town, Ministry of Health & Social Welfare, Kingdom of Lesotho, Médecins Sans Frontières & Scott Hospital Health Service Area, 2007). It then follows that the proportion of time spent on second-line regimen will be critical in assessing the costs of scaling up. The CT model uses a mean time split of 60% to 40% for first and second-line regimens respectively (Boulle *et al.* 2004; Cleary *et al.* 2006) over a mean life-expectancy of 6.5 years. However, primary data from the Khayelitsha cohort indicate that only 16% of the surviving cohort had switched to second-line after 4 years (Cleary *et al.* 2006). If the rate of adherence in public health care settings mirrors that of the Khayelitsha cohort, then there would be substantial savings on the cost of second-line drugs in the short run.

Another important variable in driving lifetime costs is the time for ART initiation. Currently there are two schools of thought –the “hit early and hit hard” proponents and those who insist on late initiation of ART (Wood *et al.* 2005). Currently recommendations of ART initiation are at CD4 cell count ≥ 350 cells/ μ l, between 200 and 350 cells/ μ l and at < 200 cells/ μ l (World Health Organisation, 2006a). Studies show that when treatment is started early (200 and 350 cells/ μ l or CD4 ≥ 350 cells/ μ l), patients gain more life years but at a higher cost. For example Badri *et al.* (2006) found cost-effectiveness ratios (ICERs) of US\$616 and US\$1137 for CD4 < 200 cells/ μ l versus 200-350 cells/ μ l, and CD4 count of 200-350 cells/ μ l versus > 350 cells/ μ l respectively. Patients who start ART at CD4 cell count < 50 cells/ μ l tend

to die earlier (first six months of therapy) and incur higher costs due to higher rates of side effects and increased rate of hospitalisation in particular (Egger *et al.* 2002; Badri *et al.* 2006; Cleary *et al.* 2006).

2.3.3. Summary conclusion

Although there is an apparent glut of ART cost analysis literature, it is difficult to compare within and across settings because of differences in methodological approaches. All full costing studies include the cost of ARVs, the associated monitoring lab tests and personnel. Nevertheless, differences are noted in the treatment of first and second-line ARV regimens and inclusion or intensity of CD4 and viral load testing. There are even wider differences in the treatment of the remaining components of the unit cost. Comparison of costs is also complicated by the ever changing factor prices particularly of ARV. For example between 2003 and 2005 ARV prices decreased by 53% in most resource poor settings (World Health Organisation, 2006a). Even when ARV prices are compared within a similar period, prices differ within settings due to existing bilateral and multilateral procurement agreements. For instance in 2006 the average monthly supply of efavirenz (EFV) for adults was US\$17 in Rwanda, US\$21 in Lesotho and US\$34 in South Africa. A number of studies just cost one standard first-line regimen –stavudine, lamivudine and nevirapine (3TC/D4T/NVP) which is 3 times cheaper than regimens containing EFV. Yet studies show that more than 40% of first-line regimens contain efavirenz (Cleary *et al.* 2006). As a result such estimates considerably understate the unit cost of ARVs. Most studies do not include pre-ART costs yet sustained levels of preventive efforts and a general realization by the populace of ART efficacy could see pre-ART enrolment outstripping ART enrolment. This would be at an additional cost of about US\$16 per capita par annum (University of Cape Town, Ministry of Health & Social Welfare, Kingdom of Lesotho, Médecins Sans Frontières & Scott Hospital Health Service Area, 2007)

Overall precision in estimating costs of scaling up is greatly reduced by paucity of ART effectiveness data particularly from the public sector in resource poor settings. The traditional assumption of 5-7 years of ART effectiveness could be underestimating life expectancy by more than 100%. Evidence on the split of patients

on first and second-line ARV regimens remains paltry yet second-line ARVs greatly influence the unit cost of ARVs. Country specific data on existing capacities and different cost structures is either too old or too scarce to effectively gauge the effect of scaling up on unit costs. This pernicious inconsistency in treatment and reporting of costs is not a preserve of developing countries. On reviewing 543 studies of the direct costs of HIV care from Europe and America, Levy *et al.* (2006) found only nine studies with adequate data to make meaningful statements about the costs. But even within these nine articles it was not possible to generalise as shown in the following quote:

“Valid comparisons of the estimates from the nine studies reviewed were not possible because of differences in the specific components included, the heterogeneous nature of the study populations in terms of disease stage, the sources and methods used to estimate unit costs, and the level of aggregation at which results were reported.” (Levy *et al.* 2006: 174).

2.4. Sustainability of ART programmes

2.4.1. Introduction

Sustainability is a concept that has gained a lot of attention in the last four decades and the debate about its appropriate definition is ongoing. Current definitions of sustainability of health care systems are largely based on LaFond's (1995, p.17) definition. She defines sustainability “as the capacity of the health system to function effectively with minimum external input.” In other words sustainability is the extent to which local and national resources can sustain the health system, in the medium and long term, with minimal foreign input. Importantly also the definition refers to the health system as a whole rather than a programme. This is because any health programme should not be sustainable at the expense of other services, either by diverting resources or crowding out other services. Today, most scholars still base their definition of sustainability from the view point of developmental economics albeit with some caveats. Most definitions include a caveat that the system must be able to expand and or grow at the same pace with population needs (Knowles *et al.*, 1997; McPake and Kutzin, 1997; Beattie *et al.* 1998; Olsen, 1998). Thus they define sustainability as the ability of the health system to continue functioning effectively (in

the medium to long term) after the withdrawal of foreign assistance. Implicitly, in the long run the system should be able to draw on additional resources to keep up with population growth, inflation and increased demand for health care.

Sustainability is broadly divided into two categories, namely institutional and financial sustainability. Financial sustainability refers to the capacity of the health system to replace withdrawn donor funds with domestic resources while institutional sustainability refers to the capacity to mobilise and manage corresponding non-financial resources effectively. Drawing on national resources implies that institutional sustainability affects and is affected by a wide range of sectors competing for the scarce resources.

Institutional sustainability has four dimensions, namely technical, social/cultural, political, and managerial sustainability (Knowles et al. 1997; Olsen 1998; Canadian Public Health Association, 2001). These dimensions are defined by the Canadian Public Health Association in the context of developing sustainable primary health care services, as follows:

- “Technical sustainability (development and maintenance of the necessary cadre of appropriately trained people to meet the needs at the local level);
- Social sustainability (development and maintenance of community support for the program as well as the capacity within the community to play an effective role);
- Political sustainability (development and maintenance of the political will necessary to sustain a major policy direction); and
- Managerial sustainability (development and maintenance of the capacity to direct and plan effective services responding to demonstrated needs).”

(Canadian Public Health Association, 2001: 3)

The Association defines financial sustainability in terms of provision of adequate human and material resources. Viewed from this perspective, the sustainability of a health system or programme is influenced by both demand and supply side factors. It

also becomes closely intertwined with issues affecting access to health care and eventually equity in health care (McIntyre 2006).

There are two opposing views concerning the definition of financial sustainability. One view emphasises the use of national resources and capacity (Knowles et al, 1997; McPake and Kutzin, 1997) while the other view includes all resources whether internal or external (The Global Alliance for Vaccines and Immunization, 2003; Bossert, 2004).

In the first view, financial sustainability has been defined as a program's continuing ability to deliver services or sustain benefits after the donor's technical, managerial and financial support has significantly decreased or ended. On the other hand, GAVI, the Global Alliance for Vaccines and Immunization (2003) is a strong proponent of the second view. It views financial sustainability as being a shared responsibility between low income countries and their development partners. To emphasise their viewpoint GAVI operationalises financial sustainability through the following policy definition:

“Although self-sufficiency is the ultimate goal, in the nearer term sustainable financing is the ability of a country to mobilize and efficiently use domestic and supplementary external resources on a reliable basis to achieve current and future target levels of immunization performance in terms of access, utilization, quality, safety and equity”. (GAVI, 2003: 3)

The proponents of this view hold that sustainability is a continuous process that takes time to plan for, evaluate, and build. Very few developing countries' health systems ever become completely self-supporting but instead trudge along an endless continuum of demand for health always outpacing supply (Canadian Public Health Association, 2001; GAVI, 2003; Bossert, 2004).

Considering that 60% of Rwandans live on less than a dollar a day (Ministry of Health and William Jefferson Clinton Foundation, 2003) and considering that the cost of ART is higher than a dollar a day this would be a more appealing and feasible definition of financial sustainability. However, it would be unwise to adopt this

definition in the case of ART. This is because donor funds are not always predictable. Designated funds sometimes dry up or more popular causes may sometimes emerge in donor countries. There are also often changes in the prevailing economic, political and social conditions of donor countries. Here one could cite the United States of America's PEPFAR (Presidential Emergency Plan for AIDS Relief) initiative and the current changes in United States' political climate. Will the Democrats increase, reduce or maintain the current funding levels now that they control the purse?

In view of such extenuating evidence, this analysis would rather base the definition of financial sustainability on the earlier view and define it as a programme's continuing ability to effectively deliver services after the donor's technical, managerial and financial support has significantly decreased. Although difficult to achieve, sustainability is particularly important for ART because unwarranted interruptions of treatment could lead to virus mutation and the threat of drug resistance. Virological resistance is currently one of the hotly debated topics by researchers given the current drive to significantly roll-out ART in resource poor settings (Harries *et al.* 2001; Blower *et al.* 2005; Hastings *et al.* 2006). The World Health Organisation (2006a) advises that transmission of resistance should exceed 5%.

Low income countries should be wary of their efforts to scale up ART without putting in place contingency plans to sustain scaled up programmes. If external resources were to significantly reduce without immediate and sustainable financing mechanisms in place this could result in chaos, increased resistance and death in under resourced systems. Increasing resistance would mean switching patients to second-line regimens which are very expensive. [Increasingly affected countries would have to put their populations at the mercy of patented manufacturers of drugs (read cartels and multinationals)]. Increasing resistance could also result in higher episodes of side effects and toxicities leading to low adherence (World Health Organisation, 2006b). In a nutshell scaling up and sustainability are two sides of the same coin. We need to build sustainable ART programmes, which judiciously monitor and foster patients' adherence to treatment. But we can only do so with sustainable and predictable financing mechanisms.

2.4.2. Approaches to measuring financial sustainability

As pointed out above financial sustainability is a concept with different meanings to different audiences. But we know that one of its facets relates to the ability to mobilise adequate internal resources to balance the budget. Thus analysis of a country's economic indicators, the total health care resource envelope and the health system financing functions in terms of the health system's goals can help proxy the measurement of financial sustainability. Macro-economic indicators would help gauge the ability to raise revenue [collection] and the latitude of fiscal space (Kutzin, 2001; Hensher, 2001 and Ray, 2003). One can also explore alternative means of revenue generation (other than central government and donors), also called cost-recovery mechanisms such as insurance and user fees. Secondly one could analyse the pooling of the resource envelope and the resource allocation mechanisms within the country. Based on this paradigm a number of analysts developed indicators to gauge the sustainability of health programmes (Knowles et al, 1997; McPake and Kutzin, 1997; Olsen, 1998). These are discussed in more detail in Chapter 3.

Chapter 3: Methodology and study design

3.0. Introduction

This chapter summarises the costing methodological literature, defines the terms used and sets the boundaries of the study. The chapter is divided in three large sections, namely methodology for patient-level and population-level analyses and methodology for gauging financial sustainability. The first describes the study population and setting, the study design and details the various methodological cost concepts, approaches and assumptions used. It describes the methods and assumptions used to identify, measure and value costs and outcomes of antiretroviral therapy (hereafter referred to as ART) so as to compute unit costs. The second section dwells on methods used to estimate population level costs and costs of scaling up. It describes the methodological framework for estimation of target population and need during ART scale up and for modelling costs via a Markov process. The section concludes by examining model validation and accounting for uncertainty. The third section describes the methodological approach for gauging financial sustainability of the ART programme in Rwanda.

3.1. Patient-level analyses

3.1.1. Study population and setting

The study attempted to assemble a cohort of patients that cuts across the spectrum of the Rwandan health system, which consists of a 3-tiered structure of primary, secondary and tertiary institutions. This is because these institutions are all involved in the scale-up of ART services and yet they have different cost structures. Primary costing data were collected from CHUK (*'Centre Hospitalier Universitaire de Kigali'*:- Central University Teaching Hospital of Kigali in English) which is one of the three tertiary hospitals in Rwanda. This was the first hospital to offer ART services in Rwanda. The hospital is located right in the centre of Kigali, the capital city of Rwanda. Being one of the most important tertiary hospitals in the country, it receives patients referred from all other district hospitals. Consequently a large number of patients, about 22%, receiving ART at the hospital are on second-line treatment compared to the national average of 3%. The total number of adult patients

who received ART at the hospital in 2006 was 590 (Treatment and Research AIDS Centre, 2007). The patients are seen by a physician and not a general practitioner (GP) as is the norm elsewhere. The hospital does not engage in community mobilisation, adherence visits or nutritional support.

By the end of 2006, there were twenty five (25) district hospitals offering ART services in Rwanda (Treatment and Research AIDS Centre, 2007). Out of these Ruhengeri district hospital was purposively sampled. It is located 78km from the capital city though the journey by road takes about 2 hours. The hospital acts as a referral centre for most of the Northern Province but administratively it falls under Musanze Health District with a population of 346,055 inhabitants. The hospital has a capacity of 400 beds and is responsible for eleven health centres. Under the close supervision of the hospital two health centres have already started ART services. Nearly ninety percent (90%) of the catchment population is rural (*Hôpital de Ruhengeri*, 2007) and depends on subsistence farming.

The ART Unit in Ruhengeri opened its doors in August 2004 and has a database that is nearly two year old. Data were collected on all 944 patients who received ART during 2006. The hospital runs an ART dedicated unit in which patients are attended to separately from other outpatient services but are housed together with voluntary counselling and testing (VCT), and prevention of mother-to-child-transmission (PMTCT). Each service has its own clinical staff, floor space and equipment, the exception being the ART nurse who attends to PMTCT patients. The unit's permanent clinical staff include a full time general practitioner, three nurses, and a counsellor. The lead nurse is known as the ART Nurse, and is responsible for dispensing drugs (ARVs and drugs for opportunistic infections), managing the ART database and archiving patient records. The counsellor doubles as a nutritionist and also helps out in archiving patient records. The unit staff perform a-once-weekly tracing and adherence visit to very sick, needy or difficult patients. Such patients are usually flagged by staff, particularly the counsellor during previous encounters. The hospital laboratory also serves as the central hub for the entire district. All CD4 cell counts are tested here as is the norm in other health districts.

By the close of 2006, there were 108 primary level ART sites in the country (Treatment and Research AIDS Centre, 2007). Of these TRAC Clinic, operated by TRAC within its premises in Kigali, is the busiest. The clinic was started in May 2004 as a centre for research and to pilot primary level ART roll out. The centre was purposively sampled because it is the busiest and best resourced primary level structure providing ART services in the country. But more importantly, it has the oldest and best maintained database among its peers. However, patients in pilot centres are usually assiduously treated and monitored leading to better outcomes albeit at higher costs that do not mirror real life situations. The need to deal with the generalisability of results from this centre will be discussed in the appropriate section on uncertainty. The clinic offers ART, PMTCT and VCT services, each with its own permanent clinical staff and floor space. By the end of December 2006, the number of patients on ART was 1,776, the highest in the country at any ART site (Treatment and Research AIDS Centre, 2007). The ART sub-unit has three permanent GPs, one visiting physician, a nutritionist, 12 nurses, 6 counsellors, 1 information technology manager and 2 data clerks. However, information technology staff are also part of the national TRACnet team. The sub-unit organises twice weekly community visits to enforce adherence and offer support to needy or difficult patients. Nutritional support is also offered on a selective basis targeting sickly and or indigent patients.

3.1.2. Nature of data and data types

Due to institutional arrangements responsible for ART roll-out in Rwanda, not all cost data could be obtained at the above three institutions. This is because certain services are centralised to ease planning, coordination and monitoring and evaluation. Such services include procurement and distribution of drugs, equipment and reagents, the training of personnel, maintenance certain equipment and so on. It is therefore necessary to clarify further why cost data had to be sought from other institutions.

All ARVs, laboratory test reagents and consumables for the public sector, and most of the private sector are procured by CAMERWA (*Centrale d'Achat de Médicaments Essentiels au Rwanda*: Centre for Purchase of Essential Drugs) through the Coordinated Procurement and Distribution System (CPDS). Twice a year the Quantification Committee, chaired by TRAC and made up of donors and

implementing agencies, meets to determine the necessary quantities of drugs and laboratory supplies to be purchased. In the process, they also determine the proportion of funds to be contributed by each donor/purchaser. According to the last tender of 2006, the biggest purchasers were Global Fund with a contribution of 45.94% and President's Emergency Plan for AIDS Relief (PEPFAR) with 51.46%. CAMERWA through the National Tender Board (NTB) then launches a competitive international tender process, open only to World Health Organisation approved products or Federal Drug Administration Agency (FDA) pre-qualified (PEPFAR) suppliers. Subsequently CAMERWA pools the funds from the donors, imports and distributes the products to all ART implementing sites. These sites are neither charged for the products nor are they permitted to charge the patients for either the drugs or the laboratory tests.

The system of bulk purchases also applies to capital equipment such as laboratory equipment, generators, fridges and computers. A similar system is used for maintenance of the equipment, for example Global Fund/Multi-Country HIV/AIDS Program (GF/MAP) has contracted a single supplier to maintain 113 fridges that were supplied to ART and VCT sites (including CHUK, TRAC Clinic and Ruhengeri district hospital).

Training of personnel involved in ART scale up is also centralized within specialized institutions. The National Reference Laboratory undertakes the training of laboratory technicians for all implementing partners whereas TRAC is responsible for training of doctors, nurses and counsellors involved in ART. Likewise, it is responsible for training of IT personnel and data clerks for ART sites. Management Sciences for Health (MSH) and Rational Pharmaceutical Management Plus (RPM Plus) undertakes the training of pharmacists and other personnel who dispense ARVs. They also oversee the process of strengthening pharmacies including renovation/expansion, the provision of the ART dispensing information technology tool and supervision and monitoring of pharmacies Table 1 below shows the different institutions from which data were collected:

Table 1: Types of institutions and data collected

Name of Institution	Type of Institution	Type of data
CHUK	Tertiary hospital	Direct and indirect health care costs: capital, overheads, personnel, data related to visits and drug regimens
Ruhengeri District Hospital	Secondary hospital	Direct and indirect health care costs: capital, overheads, personnel, data related to visits and drug regimens
TRAC Clinic	Primary level	Direct and indirect health care costs: capital, overheads, personnel, data related to visits and drug regimens
TRAC	Treatment HIV/AIDS and research	Training costs for doctors, nurses, and counsellors Outcomes data
CAMERWA	Autonomous body in charge of procurement of essential drugs	Procurement, handling and storage costs of ARVs and laboratory reagents/supplies
National Reference Laboratory	Autonomous body in charge of laboratory services	Training costs for laboratory technicians
MSH	NGO	Training costs for pharmacists
GF/MAP and ICAP	Project Secretariat	Capital equipment (vehicles, generators, lab equipment). Some maintenance and running costs for equipment

3.1.3. Study design

This is a full cost analysis from the provider's perspective to determine the economic costs of scaling up ART in Rwandan adults for the period 2007 to 2011. The total number of adults initiated on ART will be scaled up from 27,012 in 2006 to a cumulative total of 153,014 by 2011 (*République du Rwanda: Ministère de la Santé, 2005a*). For the purposes of this study an adult was defined as any person aged 15 years or over at the initiation of ART.

This is also a cross-sectional study in which primary and secondary data were collected through oral interviews, access to databases and interrogation of pertinent policy documents. Furthermore, given time and resource constraints the study was limited to costs associated with provision of ART to outpatients during clinic visits. Consequently, costs for hospitalisation, home-based care and palliative care were

excluded. Also excluded were costs of treatment and prophylaxis of opportunistic infections and prevention of mother-to-child-transmission (PMTCT).

Local access was sought from the Ministry of Health and Rwanda AIDS Research Ethics Council. This was subsequently used to request further access at each sampling unit and from key informants. Key informants were drawn from key personnel involved in setting the policy agenda on scaling up ART in Rwanda such as the Ministry of Health, the National AIDS Control Commission, civic society and donors. Written informed consent was obtained from each key informant using the consent form appended in Annex A. For the qualitative interviews an open-ended semi-structured questionnaire (Annex Q) was used to keep the interviews focused. All interviews were tape-recorded, with prior permission. Given ethical and confidentiality considerations, no patients were interviewed nor were any records reviewed.

The study was carried out in two phases, the first phase was the cost analysis which required collection and analysis of primary utilisation and consumption data. This allowed for the calculation of a comprehensive unit cost per clinic visit. These results were then used in a model to synthesise and calculate the per-patient period and lifetime costs and hence the total costs of scaling up. Additionally, for the model to calculate the lifetime costs it required clinical data on the risk of failing the first-line regimen (FL) and switching to the second-line regimen (SL), the risk of failing the second-line regimen and finally the risk of death.

3.1.3.1. Scope of costs

As discussed in the literature review, two major categories of costs are identified in the costing literature namely the financial and economic costs. In this study the financial costs refer to actual expenditure incurred in providing ART services while the economic costs refer to the opportunity costs (best-forgone alternative use) of the resources used to provide ART.

Accordingly, the scope of costs analysed included the following:

1. patient-specific costs,
2. overhead costs,
3. clinical staff costs,

4. capital costs
5. and other related costs.

The patient-specific costs are costs that are incurred as a result of a specific patient receiving specific treatment, such that a cost can be directly attributed to the end user. These included the costs of drugs (ARVs) and laboratory tests. On the other hand overhead costs are costs that are shared by more than one department in a hospital or clinic (Kinghorn et al. 1996, Drummond et al. 2005). For this dissertation shared costs included non-clinical staff time, utilities (water and electricity), cleaning and security services, transport, communication, and supplies such as stationary, medical and non-medical stores. The personnel costs consisted of time directly spent in the provision of ART by clinical staff. Capital costs consisted of equipment, furniture, vehicles buildings and initial staff training. Related costs included adherence visits and nutritional support. These activities increase patient retention and adherence, thus they directly improve ART health outcomes.

Nevertheless, it should be noted that the scope of costs incurred in the provision of ART services is much wider. There are costs incurred by the patients and their families for transport to and from the service points, waiting times and productivity losses during sickness. There are even further costs incurred by the wider community providing counselling and support to patients on ART. But these costs were not included in the analysis given the costing perspective of the dissertation.

3.1.3.2 Approaches to costing and unit costs

There are two major approaches to costing; the step-down method and the ingredients (micro-costing) method. In micro-costing measurement begins at the micro-level to determine ingredients and quantities which can then be multiplied by appropriate costs (Drummond, et al. 2005). The step-down method involves a top-down approach in which total costs and quantities are disaggregated to unit costs using appropriate allocation criteria. This is considered to be the less precise of the two methods and is reserved for shared costs.

Patient-specific costs were treated by the ingredients method and shared costs by the step-down approach as is discussed in sections 3.1.3.2.1 and 3.13.2.5 below.

Costs and outcomes of scaling up accrue mostly in the future. This implies that such streams of costs and benefits occurring in the future must be discounted to allow for differential timing of costs and consequences as well as recognise the opportunity cost of capital (Walker and Kumaranayake, 2002; Drummond *et al.* 2005). However, in most countries including Rwanda as well as in economic evaluation literature there is no consensus on which social discount rate to use. The study chose to use a discount rate of 3%, which has been used widely in similar modelling scenarios in developing countries (Drummond *et al.* 2005; Cleary *et al.* 2006). This would not only allow for methodological generalisability, but using a lower discount rate allows for cautious estimation (avoid understating) of future streams of costs and consequences. To circumvent this uncertainty, undiscounted costs would be presented first then discount rates of 3% and 5% investigated using sensitivity analysis.

To account for the opportunity cost of recurrent expenditure ruling prices for the base year (2007) were assumed to be as at 31st December 2006. For capital costs the standard annualisation procedure, section 3.1.3.2.4 below, was used to determine their opportunity costs (Walker and Kumaranayake, 2002). The annuity factors were calculated using a rate of 3%, the same rate for discounting costs. All expenditure was assumed to occur at the beginning of each period. To control for the instability in the exchange rate of the Rwandan Franc (Frw), all costs were translated into United States Dollars (US\$) at an average exchange rate of 1US\$ to 540.08Frw. This was the five year average exchange rate from 2002 to 2006 (Rwanda National Bank, 2006).

3.1.3.2.1. Patient-specific costs and the ingredients method

The micro-costing (ingredients) method involves identifying, measuring and valuing medical costs consumed directly by the patients. These were the costs for ARVs and monitoring laboratory tests. The actual quantities of ARVs consumed in 2006 per patient were obtained from the databases of CHUK (590 patients), Ruhengeri hospital (944 patients) and TRAC Clinic (1776 patients). Frequency of prescription and proportions of each treatment regimen were obtained by analysing the data using STATA.

Exploratory data analysis showed that patients from Ruhengeri hospital were all on first-line regimen, while those from TRAC clinic and CHUK were receiving a number

of diverse drug combination. Given the harmonisation drive of procurement and prescribing practices underway in Rwanda and recognising the need for the generalisability of results the cost analysis assumed treatment regimens recommended by the national ART guidelines.

According to the guidelines the first-line regimen is composed of two nucleoside reverse transcriptase inhibitors (2-NRTI), stavudine and lamivudine or zidovudine and one non-nucleoside reverse transcriptase inhibitor (1-NNRTI), usually Nevirapine. This may be replaced by Efavirenz in patients with Tuberculosis co-infection. Another exception involves pregnant mothers, especially in the first and second trimester that should be treated with three nucleoside reverse transcriptase inhibitors (3-NRTI): stavudine, lamivudine or zidovudine and abacavir. The second-line regimen is composed of abacavir, didanosine (2-NRTI) and lopinavir/ritonavir, a protease inhibitor (*République du Rwanda: Ministère de la Santé, 2005b*).

The split in patients on various regimens was achieved by calculating the weighted average proportion of patients on each regimen at the three sites. These proportions were then compared and aligned with national guidelines and other considerations like tuberculosis co-infection and pregnancy (see chapter 4, section 4.2.2 for more details)

The prices of ARVs, laboratory test kits and their consumables: -tradable portion (see paragraph below) were obtained from CAMERWA for the last tender of 2006. The retail prices include the import price (cost, insurance and freight:-CIF to CAMERWA) inflated by 2% handling and 5% storage charges. The September 2006 tender was chosen because its prices coincided with the ruling prices as at 31st December 2006 for the laboratory tests and ARVs.

As already discussed in chapter 2 section 2.3.2, three methods have been used in the literature to calculate the opportunity cost of monitoring laboratory tests. These include using the national laboratory tariffs in the jurisdiction of the study, measuring and valuing the tradable portion of the tests and then adding back an estimate of the non-tradable portion and costing the laboratory tests from first principles. This dissertation used a combination of the first two methods. The costs for the tradable component of each test were determined from ingredients, as accessed from the

CAMERWA database. Unfortunately the quantification committee for laboratory reagents and consumables is yet to be constituted. The norm therefore is to add a mark-up of 20% on the free-on-board price of each test at CAMERWA for the consumables. Again through the National Tender Board CAMERWA is able to procure the reagents for the laboratory monitoring tests and their consumables through an open international competitive bidding process. A fixed rate of US\$2.09 was added back for the non-tradable portion and the resultant estimate was used to compare and choose from local rates one that closely approximate the opportunity cost (detailed process included with results section 4.1.3). For ARVs the split between patients on various regimens was calculated using average utilisation weighted by number of patients and taking into consideration variables quoted in national guidelines, detailed assumptions used and the ratios are available in section 4.2.2 of results.

3.1.3.2.2. Shared costs using the step-down method

Where final consumption could not directly be linked to a specific patient, the unit costs of such resources were treated by step-down method. The majority of these costs fall into two broad categories, the overhead costs and the capital costs. Overhead costs included costs of utilities, supplies, administration, transport, communication and maintenance. Utilities included water, electricity and fuel for the generator. Administrative costs included salaries of non-clinical staff, cleaning and security services. Transport costs included transport for adherence visits, ARVs and laboratory reagents, laboratory test samples to the National Reference Laboratory, supplies and meetings. The supplies considered included stationary, indirect-medical such as stethoscopes, thermometers, etc and non-medical consumables such are linen, toiletries and so on. The capital costs considered included buildings, equipment, furniture and initial staff training.

3.1.3.2.3. Overhead costs

The step-down method for calculating overhead costs is anchored on the assumption that all outpatients utilise a similar amount of overhead cost during each clinic visit. Thus overhead unit cost is then calculated by dividing total annual overhead expenditure by total annual outpatient visits (Conteh and Walker 2004). However, in

hospitals overheads are often shared between inpatients and outpatients. The latter definitely utilise different amounts of overheads: -inpatients require more resources, such as bed and beddings, water and electricity, laundry, cleaning, security services and sometimes meals (often referred to as hotel costs).

Overheads costs for TRAC clinic could thus be directly allocated using total expenditure divided by total annual ART visits. However, this was not always possible because the clinic shares the premises with the rest of TRAC Head Office as well as VCT and PMTCT services. Therefore it was necessary to first allocate costs using appropriate bases to reach the final estimate attributable to the ART unit. All administrative costs except non-clinical staff, cost for utilities (water and electricity), generator fuel and its maintenance, cleaning, gardening and security costs were first allocated by use of floor space: -total surface area of the ART unit in divided by the total surface area of the whole facility (Conteh and Walker 2004). Overhead costs for non clinical staff, adherence field visits and transport were directly allocated, more details in chapter 4, section 4.1.4.2.

All overhead costs in CHUK and Ruhengeri hospital were allocated using the patient-day equivalent (PDE) technique. This is based on calculating the PDE factor from the average cost of outpatient visits and the average cost of inpatient days from health service utilisation data (Haile, 2000; Cleary et al. 2004). As pointed out the average cost for an inpatient day is higher than that of the outpatient visit. Thus an inpatient day can be converted to an outpatient visit by multiplying the inpatient days with the appropriate weighting factor. The total annual outpatient-day-equivalent visits are then calculated from the following formula:

$$(Annual\ inpatient\ days\ x\ weighting\ factor) + (Annual\ outpatient\ visits)$$

The most recent estimates of the average cost for an outpatient visit and an inpatient day for Rwanda are those determined by the World Health Organisation (2003). These allowed for the calculation of the PDE factor. These costs were estimated for public hospitals with a bed occupancy rate of 80% and excluded direct costs (drugs and laboratory tests). The PDE factors for outpatient visits for different hospital level in Rwanda was calculated as shown in Table 2.

Table 2: Cost per bed day and per outpatient visit by hospital level

Facility Type	Cost per bed day	Cost per outpatient visit	PDE factor
Primary Hospital	9.25	2.3	9.25/2.3= 4.02
Secondary Hospital	12.07	3.26	12.07/3.26 = 3.70
Tertiary Hospital	16.48	4.82	16.48/4.82= 3.42
Average PDE factor			3.71

For primary level hospitals an inpatient-day costs 4.02 times more than an outpatient visit. This gap shows a decreasing trend from primary to secondary to tertiary hospitals, as one moves from primary to secondary to tertiary hospitals the difference between hotel costs per-bed-day and per outpatient visit decreases.

The study opted to use a weighting factor of four for primary hospitals because ART services are being decentralised to health centres and district hospitals. The pertinent overhead expenditure was then allocated to outpatient visit using the following formula:

$$\frac{\text{annual} \cdot \text{overhead} \cdot \text{expenditure}}{(\text{inpatient} \cdot \text{days} \times 4.0) + (\text{annual} \cdot \text{outpatient} \cdot \text{visits})}$$

3.1.3.2.4. Capital costs

Capital items used in ART service delivery were identified from each centre and their replacement value established. They included initial staff training costs, furniture, vehicles, generators, fridges, electronic equipment such as computers, medical equipment such as trolleys and buildings. The initial staff training costs were collected from the various institutions detailed in section 3.1.2 above. The replacement value for buildings was determined per square metre by enlisting the services of an insurance property market expert Mr. Lugira Charles, Manager Property Portfolio, *Société Nationale d'Assurance du Rwanda* (SONARWA). Measurements of floor space used by ART patients at each site were taken. Total floor space attributable to ART was then multiplied by the cost per square metre. To estimate the useful life of each item the national guidelines for depreciating capital costs was consulted. Using the useful life of each item and an annualisation rate of 3%, the annual equivalent cost (AEC) for each item was calculated (Walker and Kumaranayake 2002). The cost per

visit was then calculated by dividing the annual equivalent cost with total annual ART visits.

For shared capital items, appropriate allocation criteria were devised to determine the cost directly attributed to ART services per period, see more details in chapter 4, section 4.1.4.1.

3.1.3.2.5. Clinical staff costs

These consisted of cost of time spent by clinical staff directly ministering to ART patients and time spent on administrative chores that directly accrue from service delivery thereof. To illustrate the point, the ART nurses in TRAC and Ruhengeri hospital were responsible for patient records (retrieval and archiving, dispensing and capturing the movement of stock of ARVs). Additionally, staff from both centres performed tracing and adherence home visits to 'difficult' patients (chapter 3, section 3.1.1). These activities were construed as part of ART service delivery and therefore included in clinical staff costs. Clinical staff included doctors, nurses, counsellors, phlebotomists and nutritionists. The rest of the staff that included data clerks and administrative staff such as hospital directors, administrators, heads of departments that provide services to ART units such as head pharmacists in CHUK and Ruhengeri, cashiers, and so on were treated in overheads.

Interviews were conducted with programme managers and where necessary the actual staff concerned to determine the proportion of time with ART patients per day. Clinical staff costs were then allocated to ART services by the proportion of working hours spent on ART multiplied by total annual remuneration. A cost per visit was calculated by dividing these amounts by the total number of visits in a year.

Beginning January 2007, Rwanda implemented a new salary scale for medical personnel in a bid to attract and retaining scarce skills. Prior to this, public service medical personnel were earning up to 6 times less than those in the private and quasi-public institutions such as CHUK and TRAC (Ministry of Health, 2006). Given the need to estimate the opportunity costs and the need for generalisability of costs of scaling up the new public health sector salary scale was adopted for all three institutions.

3.2. Population-level costs

3.2.1. Estimating need and target population

The study aimed to determine the economic costs of scaling up ART in Rwandan adults for the period 2007 to 2011. For purposes of this dissertation scale was conceptualised in terms of number of patients initiated on ART by 2011 (Kumaranayake and Watts, 2000). Since the major objective of this study is to inform ART policy in Rwanda, the projected target population and numbers in need were used as is in the Government policy documents. A more detailed discussion of these numbers is available in chapter 4, section 4.2.1.

3.2.2. Modelling the costs via a Markov process

Decision making over the future course of events is often under uncertainty, this is more so while dealing with new and evolving treatments or chronic diseases when primary outcomes data are unavailable. ART is such an example where this data, particularly in low and middle income countries, will be unavailable for some time to come. To generate data of such calibre will entail undertaking large and collaborative clinical trials over a long period of time (at least 5 to 10 years). It is therefore necessary to use models to estimate survival time and lifetime costs through extrapolation of available short term data supplemented by secondary data sources.

The modelling used was based on a Markov process. The model uses currently available short term data and extrapolates it onto a long term horizon. The model assumes that a disease consists of a number of states known as Markov States. It can then allow a patient to stay in one state for a period of time that is sufficiently long to capture all disease effects for that state. This period is known as a Markov cycle. The model can only allow the patient to switch to the next state contingent upon the state's transition probability.

Two conditions must hold true for orderly and systematic transition through the model and these are:

- (i). The Markov states are mutually exclusive,
- (ii). And collectively exhaustive.

Additionally the model does not take into account the patient's history, so that prognosis is determined by the current state's transition probability only. This is known as the Markovian assumption. This is an anomaly because a patient's current and future prognosis is influenced by past history. This drawback is overcome by creating tunnel states. These are temporary states with different transition probabilities reflecting the patient's history (Sonnenberg and Beck, 1993; Briggs and Sculpher, 1998; Kuntz and Weinstein, 2001).

For the model to terminate an end state that allows entry without exit is required. This is known as the absorbing state and can be represented by death in real life. Hence any one entering this state has no transition probability and cannot transit to any other state (Sonnenberg and Beck 1993).

3.2.2.1. Defining the Markov states and their cycle lengths

The Markov states have been variously defined in the literature but all definitions are based on criteria that predict HIV/AIDS prognosis. These criteria include the CD4 cell count, which is inversely related to the state of disease progression, viral load count which is positively correlated to disease progression and WHO HIV/AIDS staging. Most prior studies have used CD4 cell count as method of choice for defining Markov states. Overall researchers have not agreed on the best predictor of risk of disease progression and death (Coetzee et al. 2004). For this dissertation the Markov states were defined according to the time spent on each ART regimen following the CT Antiretroviral Costing Model (Boulle et al, 2004). Patients on ART were divided into six Markov states as follows:

- I. Patients on first-line regimen for ≤ 6 months
- II. Patients on first-line regimen after the first 6 months
- III. Patients on second-line regimen for ≤ 6 months
- IV. Patients on second-line regimen after the first 6 months

V. Patients who have clinically progressed and may or may not be on treatment

VI. Dead

It is known that the risk of death is often higher during the first 12 months of starting treatment. Failing treatment and death is more likely to occur if treatment is initiated late (i.e. at lower CD4 levels such as $CD4 < 50$ cells/ml). The risk of failing treatment and switching to second-line regimen is low in the first 6 months and increases over time as a result of side effects and or virological failure (Egger et al. 2002; Chan et al. 2002; Coetzee et al. 2004; Mayanja-Kizza et al. 2006).

Patients in each of the above states incur different costs, for instance a patient in state (I) would incur costs of first-line ARVs and higher costs of laboratory monitoring. Patients in Markov state (I) need more monitoring because of the higher risk of side effects and death. Those in State (II) would incur lower costs of laboratory monitoring but cumulatively more costs of first-line ARVs and also switching drugs within the first-line regimens. The situation for those in states (III) and (IV) is similar to the first two scenarios but the patients would incur even higher costs because more monitoring is needed combined with even higher costs of second-line ARVs.

The failed-treatment state (V) is associated with palliative care costs which are not included in this study. But in reality and especially in resource poor settings virological monitoring is still rudimentary and therefore patients remain on second-line ARVs unless they have severe side effects. Therefore a cautious approach was to assume that these patients remain on treatment until they transition to the dead state. Patients entering the absorbing state (dead) are associated with zero costs from the provider's perspective. In real practice there is a seventh group of patients who abandon treatment and are lost to follow-up. Loss to follow up is usually associated with clinical rebound leading to quick disease progression and death. For purposes of this study; it is assumed that the provider will incur no further ART costs for such patients and they would be modelled in state (VI).

The Markov cycle represents the incremental time or cost spent in a particular health state. The length of this cycle is contingent upon the natural history of the disease or

events being modelled. If one were to model costs of say cholera, an acute illness lasting only a few days, then the length would be in hours or even in minutes. But a chronic condition like AIDS requires a longer period (usually months) to capture all disease effects, including but not limited to response to treatment, development of side effects and failing current treatment. Previous studies have used cycle lengths ranging from 1 to 12 months (Freedberg, Losina et al. 2001; Tebas et al. 2001; Cleary et al. 2003; Badri et al. 2006). For this dissertation the cycle length is defined according to the CT model in which Markov state I and III are 6 months each and the other states are 12 months each. The choice of these periods is guided by the course of treatment events and the associated treatment monitoring milestones (*République du Rwanda: Ministère de la Santé, 2005a*; World Health Organisations, 2006a).

3.2.2.2. Transition probabilities

For patients to switch from one state to the next (or to remain in the same state) the model must have transition probabilities for each possible pathway. Thus for patients in state (I) transition probabilities required were:

- ◆ Probability of dying directly and heading to state (VI), includes patients lost to follow-up.
- ◆ Probability of failing first-line and switching to second-line state (III)
- ◆ Probability of failing treatment directly and transitioning to state (V)
- ◆ Probability of responding to treatment and remaining in state (I)

Likewise it is possible to die directly from state II, III, IV and V, fail treatment or remain in treatment. Only state VI has no transition probabilities. To determine probabilities that reflect the true population estimates requires large clinical trials spanning a long time horizon. Patient level data from ART sites could also be used if it covers a sufficiently long time horizon. But the data collected from Rwanda span on average a period of roughly two years and exploratory analysis revealed important anomalies that precluded the use of these data as a source of transition probabilities. For instance the percentage of patients who have switched to second-line regimens over 24 months is 1% for the whole country (Treatment and Research AIDS Centre, 2007). Yet in the Khayelitsha cohort this percentage was 4.66% over the same period (Cleary *et al.* 2006). Additionally no transition probabilities are available beyond 24

months from the Rwanda data. Therefore the transition probabilities were taken from the CT model (Boulle *et al.* 2004).

3.2.2.3. Model validation and accounting for uncertainty

Model validity can be likened to the exploratory data analysis in research setting. The process involves four sequential steps namely technical validity, predictive validity, face validity and modelling process validity (Sendi *et al.* 1999).

Technical validity refers to correcting programming and typing errors, removing redundant variables or dealing with unexpected model behaviour. Technical validity can be explored by varying one or more variable(s) over its entire range and cross-checking for anomalies. Predictive and modelling process validity was cross-checked by comparing model outcomes against real life situation data and from published studies that addressed similar questions. Face validity was cross-checked by ascertaining that the cohort behaved as expected during transition, such as more people dying from states I and V than II and III during transition (Sendi *et al.* 1999).

According to Drummond *et al.* (2005, pp.39) “every valuation will contain some degree of uncertainty, imprecision, or methodological controversy,” and Briggs (1995) characterises four sources of uncertainty in economic evaluations. These are data requirements of the study, generalisability of results, data extrapolation and choice of analytic method. Uncertainty in the results of this dissertation could also arise from the use of a constant unit cost over the period of scaling up instead of incorporating economies or diseconomies of scale and scope or learning by doing. The assumption that unit costs derived from one tertiary hospital, one secondary hospital and a pilot clinic are representative of the units costs of various facilities in Rwanda is another source of uncertainty. The quality of cost data in low and middle income countries is another important source of uncertainty.

To minimise the degree of uncertainty, unit costs from patient-level analyses were compared with secondary data sources. Additionally, locally established norms and guidelines (*République du Rwanda: Ministère de la Santé*, 2005a and 2005b) were used to compare and align utilisation data for the derivation of unit costs. Finally

results from the study were compared with other published studies. Utilisation data were compared to Chandler and Musau (2005), Cleary *et al.* (2005), University of Cape Town, Ministry of Health & Social Welfare, Kingdom of Lesotho, Médecins Sans Frontières & Scott Hospital Health Service Area (2007) and National Department of health (2007). Likewise cost data including lifetime costs were compared to Badri *et al.* (2006), Cleary *et al.* (2006) and most of the studies named above. Uncertainty due to analytic methods included the choice of the discounting rate used in the analysis. This was accounted for by presenting results of undiscounted costs (0%) and discounted costs at 3% and 5% (Drummond *et al.* 2005). Additionally sensitivity analysis was used to explore important variations identified in the results (chapter 4, section 4.3).

3.3. Financial sustainability

This dissertation aimed to gauge the financial sustainability of the ART programme in Rwanda. Sustainability is broadly divided into institutional and financial sustainability. Financial sustainability refers to the capacity of the health system to replace withdrawn donor funds with domestic resources while institutional sustainability refers to the capacity to mobilise corresponding non-financial resources (Knowles *et al.* 1997; Olson 1998; Canadian Public Health Association, 2001). In other words, sustainability requires sufficient inputs into the health system, the effective and efficient use of these resources, and the delivery of services on a continuous basis. From this definition there is a fine line between financial and institutional sustainability. For instance the cost for ART service delivery is composed of shared costs (capital, overheads and clinical staff) and patient specific costs (ARVs, drugs for OIs and labs). This analysis therefore included some elements of institutional sustainability by determining the number of clinical staff required for scaling up. The analysis focused on current total resource envelope for ART programme in Rwanda in relation to total expenditure on health and the ability to mobilise sufficient resources in the future once donor support is reduced or withdrawn.

The analysis of total resource requirements for ART in relation to total expenditure on health and financing sources allowed the candidate to draw conclusions on the

importance of each source of funding and resource allocation across the health sector. This was necessary because sustainability of ART should not be at the expense of other health services. The ability to continuously mobilise sufficient internal resources by any country is influenced by the macro-economic conditions and the health care financing system in place. It was therefore necessary to examine Rwanda's ability to generate both public and private revenue for health care given the macro-economic conditions.

Finally raising sufficient funds is not an end in itself; sustainability requires that there are sufficient clinical staff in the health system to prevent the effects of crowding out. This would result if the funding for ART drained clinical staff from other health interventions. By predicting the number of clinical staff required for scaling up ART and comparing it to existing human resource gaps/capacities in the health system the dissertation sought to draw a clearer picture of ART sustainability in Rwanda.

The ratio of domestic resources to foreign aid was determined using financial and economic costs. The financing mix of public expenditure was used for analysing financing sources to Ministry of Health, HIV/AIDS and ART. For economic costs data were collected on financing sources from CAMERWA and at the ART sites. The ratios were then determined as described in chapter 4, sections 4.4.1 and 4.4.2. Using the results of the cost analysis the number of clinical staff required to scale up ART between 2007 and 2011 was determined from clinical staff costs as described in chapter 4, section 4.4.3.

Key informants interviews were conducted using an open-ended, semi-structured questionnaire (Annex Q) to explore the above indicators. The interviews targeted key informants involved in the design, funding and implementation of the programme. For all consenting interviewees the sessions were tape-recorded and later transcribed. The list of interviewees and their responsibilities is appended to this report in Annex K. These were augmented through desktop research to complete the data gaps.

Chapter 4: Results

4.0. Introduction

This chapter presents the results of the analysis including underlying assumptions and calculations whenever necessary. Section one presents results from cost analysis using cost and health care utilisation data at patient level. The results include the derivation of unit costs for patient specific costs (labs and ARVs) and the shared costs (capital, clinical staff and overheads). These unit costs are then fed into the CT Model in section two to estimate the population level costs and the costs of scaling up. Section three details the use of sensitivity analysis to explore key uncertainties in important cost parameters. Section four presents the findings used to gauge financial sustainability of ART in Rwanda, including prediction of the domestic to foreign aid ratio and the number of clinical staff required for ART scale up.

4.1. Estimation of unit costs from patient-level analysis

4.1.1. Data sources and sample description

The number of adult patients in this cost analysis, as obtained from the databases of CHUK, Ruhengeri District Hospital and TRAC Clinic, is 3,310. This is the total number of adults enrolled on ART and still in-care as of December 31st 2006. The breakdown of the sample by institution is shown in Table 3 below:

Table 3: Number of patients by type of institution

Name of institution	Type of institution	Number of adults on ART
Kigali Central Hospital (CHUK)	Tertiary hospital	590
Ruhengeri District Hospital	District hospital	* 944
TRAC Clinic	Pilot clinic	1,776
Total		3,310

4.1.2. Cost estimate for ARVs

The cost of ARVs was estimated from quantities consumed in 2006 by each patient in the above sample. Prevailing treatment regimens and the frequency of their prescription by institution was obtained by analysing the said data using STATA, the output is shown in Table 3 below.

Table 4: Frequencies of prescribed regimens by institution

ARV Regimen		Institution			Weighted average
		CHUK	TRAC	Ruhe ngeri	
First-line regimens (FL)					
Lamivudine/stavudine/nevirapine	(3TC/D4T/NVP)	24.19%	51.06%	44.38%	43.51%
Lamivudine/zidovudine/nevirapine	(3TC/AZT/NVP)	16.20%	16.25%	10.33%	15.62%
Alternative regimens FL					
Lamivudine/stavudine/efavirenz	3TC/D4T/EFV	3.72%	7.12%	7.23%	6.55%
Lamivudine/zidovudine/efavirenz	3TC/AZT/EFV	44.30%	22.35%	35.98%	30.15%
Lamivudine/efavirenz/abacavir	3TC/EFV/ABC	1.40%	0.39%	0.05%	0.10%
Lamivudine/zidovudine/abacavir	3TC/AZT/ABC	3.80%	0.37%	1.24%	1.19%
Lamivudine/stavudine/abacavir	3TC/D4T/ABC	6.40%	2.46%	0.81%	2.62%
Total (FL regimens)		100%	100%	100%	100%
Second-line regimens (SL)					
Didanosine/abacavir/lopinavir/ritonavir	ddi/ABC/ LPV/r	28.80%	48.66%		38.73%
Lamivudine/abacavir/lopinavir/ritonavir	3TC/ABC/LPV/r	37.58%	26.33%		31.96%
Abacavir/tenofovir/lopinavir/ritonavir	ABC/LPV/r/TFD	10.40%	6.38%		8.39%
Lamivudine/stavudine/lopinavir/ritonavir	3TC/D4T/LPV/r	5.16%	0.08%		2.62%
Lamivudine/zidovudine/lopinavir/Ritonavir	3TC/AZT/LPV/r	10.40%	11.97%		11.19%
Lamivudine/zidovudine/indinavir	3TC/AZT/IDV	6.55%	5.78%		6.17%
Stavudine/didanosine/nelfinavir	D4T/ddi/NFV	1.11%	0.80%		0.96%
Total (SL)		100%	100%		100%

Data analysis showed that all patients in Ruhengeri hospital were on first-line ART regimens compared to 78.5% in CHUK and 95% in TRAC. The majority of patients in TRAC and Ruhengeri (51% and 44% respectively) were receiving the traditional first-line ART regimen of lamivudine, stavudine and nevirapine while 44% of patients in CHUK were receiving the alternative first-line regimen of lamivudine, zidovudine

and efavirenz. In general CHUK seems to be offering a different standard of care from the other two facilities. It was also noted that the CHUK cohort was twice as old as the other two and therefore had more time to switch drugs and also change regimens.

The costs of ARVs obtained from CAMERWA included costs of importation, storage and handling charges (chapter 3, section 3.1.3.2.1). But there is an additional cost of transport for reagents and drugs from CAMERWA to the ART sites. The sites collect supplies once every three months and the associated cost of transport is therefore small but also includes other supplies not specific to ART. It was deemed necessary to treat these in overhead costs. To calculate the mean patient-specific unit costs, physical units of resources consumed were multiplied with their market values from CAMERWA. Table 5 below shows the monthly cost of adult ARVs in Rwanda in December 2006.

Table 5: Annual cost of adult ARVs in Rwanda (US\$ FY06)

Product name and specification	Supplier	Monthly Dose	Annual dose
WHO pre-qualified			
Lamivudine/stavudine (3TC+d4T); 150/40mg, 60 tablets	RANBAXY	5.58	66.96
Lamivudine/stavudine (3TC+d4T); 150/30mg, 60 tablets	RANBAXY	5.52	66.24
Lamivudine/stavudine/nevirapine (3TC+d4T+NVP); 150/40/200mg, 60 tablets	HETERO	8.12	97.44
Lamivudine/stavudine/nevirapine (3TC+d4T+NVP); 150/30/200mg, 60 tablets	HETERO	7.69	92.28
Lamivudine/zidovudine/nevirapine (3TC+AZP+NVP); 150/30/200mg, 60 tablets	HETERO	15.9	190.80
Didanosine (ddI); 200mg, 60tabs	BMS	27.31	327.72
Didanosine (ddI); 50mg, 60tabs	BMS	10.17	122.04
Indinavir (IDV) 440mg, 180caps	MSD	53.55	642.60
Nevirapine (NVP); 200mg, 60tabs	AURO	3.88	46.56
Lopinavir/ritonavir (Kaletra); 200/50mg, 120tabs	ABBOT	47.12	565.44
Ritonavir (RTV); 100mg, 60tabs	ABBOT	85.68	1028.16
Nelfinavir (NFV); 50mg powder	AUROBND0	33.5	402.00
FDA pre-qualified			
Lamivudine/zidovudine (3TC+AZT); 150/300mg, 60tabs	CIPLA	11.25	135.00
Abacavir (ABC); 300mg, 30tabs	CIPLA	40.7	488.40
Efavirenz (EFZ); 600mg, 30tabs	CIPLA	17.14	205.68
Nelfinavir (NFV); 250mg, 270tabs	AUROBND0	83.81	1005.72
Tenofovir (TDF); 300mg, 30tabs	GILEAD	18.21	218.52

Source: CAMERWA database; December 2006

As discussed in chapter 3, section 3.1.3.2.1 the cost of monitoring laboratory tests is composed of a tradable (reagents/consumables) and non-tradable portion (equipment and laboratory technician's time). Table 7 below presents the cost per test for the tradable portion for calculating tariff B, see details below.

Table 7: Cost of laboratory tests reagents and consumables (US\$ FY06)

Kit	# of tests per kit	Cost per kit CAMERWA	Add back 20% consumables	Cost per test CAMERWA
Viral load	48	856.00	1027.2	21.40
CD4 (FACcount)	50	246.10	295.32	5.91
CD4 (FACScaliber)	50	217.21	260.652	5.21
Haematology	100	166.05	199.26	1.99
Urea	180	192.60	231.12	1.28
Creatinine	160	47.08	56.496	0.35
Glucose	302	323.14	387.77	0.97
ALAT (GPT)	73	78.11	93.732	0.47

Source: CAMERWA

As discussed in the methodology, this dissertation assumed that the cost charged to private patients in tertiary hospitals would be an appropriate proxy for the opportunity cost of laboratory tests. The appropriateness of this assumption is now tested using four different scenarios or rates (Table 8). Tariff A is the Ministry of Health mandated rate for insured patients in public and private facilities (available <http://www.moh.gov.rw/publication.html>). Tariff B is based on the actual costs of the tradable portion together with an assumed cost of US\$2.09 for the non-tradable portion for each test (WHO/UNAIDS, 2003). Tariff C is the tariff charged to private patients (not insured) at tertiary hospitals (CHUK) and tariff D is charged to private patients (not insured) by private-for-profit providers. Viral load and CD4 cell count tests are neither paid for by insurance nor are these tests performed by private-for-profit providers. Since rate B includes the actual opportunity cost for the tradable portion and approximates the non-tradable component one could assume that it must be closer to the true cost. This is assumed to be the baseline scenario against which other rates are compared using a percentage change. For CD4 and viral load only rate C can be compared to the baseline.

Tariff A appears to underestimate the monitoring test costs for glucose, alanine aminotransferase (ALT) and creatinine. The difference is large for glucose, at 21.2% and small for ALT (5.9%) and creatinine (1.2%). Tariff C understates the glucose cost by 8.5% but exceeds the baseline for ALT and creatinine by 9.4% and 14.8% respectively. Rate D, which includes a profit mark up exceeds the baseline by 53.5% for both tests and 61.8% for glucose. Tariff A is therefore rejected for being less than the baseline and D for being the furthest from the baseline. We also know that it includes a profit mark-up for the private-for-profit facilities. Although Tariff C exceeds the baseline, it is considered to be a better estimate than Tariffs A or D of the opportunity cost of monitoring laboratory tests in Rwanda.

Table 8: Composite cost per lab test comparison (US\$ FY06)

TEST	MoH mandated Insurance rate (A)	Percentage change from rate (B) $((B-A)/B)*100$	Tradable portion plus US\$2.09 (B)	Private patients: Tertiary facility (C)	Percentage change from rate (B) $((B-C)/B)*100$	Private For-profit (D)	Percentage change from rate (B) $((B-D)/B)*100$
Viral load	-	100%	23.49	25.8	-9.8%	-	100%
CD4	-	100%	8.00	12.6	-57.5%	-	100%
QBC (WBC & D)	6.5	-59.3%	4.08	6.7	-64.2%	10.2	-57.4%
Glucose	2.41	21.2%	3.06	2.8	8.5%	3.9	-61.8%
ALT/GPT	2.41	5.9%	2.56	2.8	-9.4%	3.7	-53.5%
Creatinine	2.41	1.2%	2.44	2.8	-14.8%	3.7	-53.5%

To test the uncertainty in the results, sensitivity analysis will be used to explore monitoring costs using Tariff B.

4.1.4. Results for shared costs

Shared costs were categorised into three groups, namely capital costs (buildings, equipment, vehicles and initial staff training), overhead costs (utilities, communication, non-clinical staff, supplies, transport, maintenance, etc) and clinical staff costs. Unit costs were calculated in each category from the total number of visits and total quantities as detailed in subsequent sections and Annex C. The total number of ART visits in each institution is displayed in Table 9 below:

Table 9: Number of ART visits by institution: 2006

Institution	ART visits	Total Internal Medicine visits	Ratio
CHUK	1,831	5,640	0.32
Institution	ART visits	Total Unit visits (ART, OI and PMTCT)	Ratio
TRAC	6,799	11,612	0.059
Ruhengeri	3,857	7,491	0.51

TRAC and Ruhengeri have dedicated ART clinics, which provide ART, PMTCT and VCT services but each has its own clinical staff and floor space. However, ART and PMTCT patients in both institutions share administrative, pharmacy and laboratory staff. They also share certain common spaces like general reception areas and amenities such as toilets and in case of TRAC a TV. On the other hand ART services in CHUK are delivered within a general outpatient setting that provides other services in the specialities of paediatrics, internal medicine (including ART), surgery and obstetrics & gynaecology. Therefore multiple allocations bases were required before a final cost per visit was calculated. The total annual visits in the different sub-units of CHUK OPD Clinique in 2006 are shown below:

Table 10: Annual OPD visits at CHUK-Clinique: 2006

Speciality	Internal Medicine (+ART)	Surgery	Obstetrics & Gynaecology	Paediatrics	Total
# of visits	5,640	1,189	4940	1498	13,267

In CHUK and Ruhengeri overhead costs (utilities, cleaning, security, supplies etc) were shared across the entire hospital. Unit costs were calculated by dividing the total cost by the patient-day-equivalent [$PDE_{outpatients}$] visits as discussed in section 4.1.4.2 below.

4.1.4.1. Capital costs

For ease of calculation and allocation, capital costs were analysed in three different categories:

1. buildings;
2. furniture and equipment, and
3. initial staff training.

Information collected to allow for calculation of capital costs of buildings included the cost per square metre, useful life of each building, floor space at each site and the total surface area of the facility. Using appropriate allocation bases, as described below, and an annualisation rate of 3% per annum the annual equivalent costs were calculated for each building and facility, Table 11 below.

Table 11: Cost of buildings by ART site (US\$ FY06)

	Floor space	Item				
		Size (m ²)	Proportion (ART use)	Replacement value	Useful life r=3%	Annual equivalent cost (US\$)
CHUK	Administration office (sister-in-charge)	20.5	0.14	943	30	48.11
	Dispensing room	20.5	0.60	4,099	30	209.15
	Reception	41.2	0.14	1,895	30	96.69
	Consultation room	20.5	0.32	1,440	30	73.49
	Counselling room	20.5	0.90	6,149	30	313.72
	General ODP Store	20.5	0.14	943	30	48.11
	MF5 store	9.45	0.30	945	30	48.21
	Phlebotomy room	19.56	0.14	900	30	45.91
	Corridor	34.06	0.14	1,567	30	79.93
	Toilet	16.08	0.14	740	30	37.73
	Total	222.9		19,621		1,001.03
Cost per visit: 1001.03/1831 = 0.55						
Ruhengeri	ART Room	14.10	0.51	3,261	30	166.36
	Consultation room	14.10	1.00	3,261	30	166.36
	Counselling room	14.10	0.60	1,956	30	99.82
	Shade (general waiting area: prefab)	69.00	0.27	555	10	65.12
	Stock (pharmacy)	15.77	0.71	3,647	30	186.04
	Total	127.7		12,680		683.71
	Cost per visit: 683.71/3857 = 0.18					
TRAC	Admin Office (sister in charge)	6.49	0.59	984.73	30	85.81
	Pharmacy (Stock)	11.33	0.59	1720.20	30	149.89
	Reception (MF5 store)	14.04	0.59	2130.96	30	185.68
	ART Rooms (3)	16.36	1.00	2482.93	30	216.35
	Phlebotomy room	5.45	0.59	827.64	30	72.12
	Doctor's rooms (4)	23.32	1.00	3539.46	30	308.41
	IT (computer) room	9.80	0.59	1487.42	30	129.61
	Corridor	40.14	0.59	6092.51	30	530.88
	Toilet	2.89	0.59	438.58	30	38.22
	Shade (general waiting area: prefabricated)	94.77	0.22	7191.99	10	1439.96
	Total	224.6		26,896		3156.93
Cost per visit: 3156.93/6799 = 0.46						

In CHUK OPD '*Clinique*', the administration room for the sister-in-charge, reception, cashier's room, toilets, phlebotomy room, general OPD store and the general reception area (corridor) were allocated using the ratio of ART visits to total OPD '*Clinique*' visits, that is 1,831 out of 13,267 or 0.14 (Table 9 and Table 10). The consultation room was allocated using the ratio of ART visits to Internal Medicine visits (1831/5640). The dispensing room was allocated on the basis of physical space allocated to adult ARVs, paediatric ARVs and drugs for opportunistic infections. The counselling rooms at the three institutions were allocated by the time spent on ART to non-ART counselling visits. In Ruhengeri the ART room was allocated by the ratio of ART visits to total visits: 3,857 out of 7,491 or 0.51 (Table 9). Ruhengeri has a stock pharmacy, as an annex to the main pharmacy specifically constructed to house ART and PMTCT drugs. Allocation of floor space to ART was based on physical space occupied by adult ARVs, paediatric ARVs and drugs for opportunistic infections. Likewise allocation of floor space in TRAC was based on similar principles.

Total floor space in TRAC and CHUK is almost equal yet the number of patients in TRAC is three times higher than at CHUK. Ruhengeri has the least amount of floor space, pointing to resource constraints. Likewise replacement values for buildings show similar trends. Thus the cost per visit for buildings in Ruhengeri is lower, approximately 3 times cheaper than at TRAC and CHUK. Additionally the buildings are made of less permanent materials (burned bricks and mortar) compared to CHUK and TRAC where buildings are made of block cement. The cost of land and labour is also cheaper in Ruhengeri (rural setting) than in Kigali City.

The comprehensive list of equipment and furniture and allocation bases is detailed in Annex C. However, a summary of these costs by facility type is presented in Table 12. In this table, the final allocation to ART use is US\$11,981 for CHUK, US\$19,907 for Ruhengeri and US\$40,847 for TRAC.

Table 12: Cost of equipment and furniture by site (US\$ FY2006)

Institution	All equipment and furniture				
	Total replacement value (US\$ FY06)	Final allocation to ART use	Annual equivalent cost; r=3%	Number of visits	Cost per visit
CHUK	123,851	11,981	2,424	1,831	1.32
Ruhengeri	55,421	19,907	3,040	3,857	0.79
TRAC	71,748	40,849	11,392	6,799	1.68

CHUK has the highest replacement value for equipment as expected because it is a tertiary hospital. The pilot (TRAC) also has more equipment than Ruhengeri, the district hospital. For instance the ART unit has eleven computers for adults and a photocopier at a combined value of US\$25,788 compared to two computers at CHUK and one in Ruhengeri for ART and PMTCT. Most of the furniture at TRAC and CHUK are either imported or factory made unlike those at Ruhengeri that are locally made by local craftsmen. The most expensive asset at Ruhengeri (ART unit not the entire hospital) is a car, which is shared by the whole hospital, and used to transfer patients to CHUK and collect drugs and laboratory supplies from CAMERWA. It is also used for adherence visits and transport of blood samples to the National Reference Laboratory for quality control and resistance monitoring. CHUK and TRAC have no cars, with the implication that they have to contract out transport services. Overall the visit cost for equipment in Ruhengeri is 2 times cheaper compared to the other two sites.

Initial staff training costs per trained member of staff are standardised throughout the country as explained in chapter 3, section 3.1.1. To calculate the annual equivalent cost, the useful life was assumed to be three years. The rationale for this assumption is that ART is a rapidly evolving intervention with newer approaches to adherence and resistance monitoring plus changes in national guidelines in response to newer or cheaper drugs. The costs were annualised at a rate of 3% and are detailed in Table 13.

Table 13: Initial staff training costs by facility type (US\$ FY2006)

Item	ART site		
	CHUK	Ruhengeri	TRAC
Doctors; @ US\$393.5	2	1	3
Nurses ; @ US\$393.5	5	3	5
Counsellor; @ US\$393.5	1	1	1
Pharmacist/Dispenser; @ US\$240.9	1	2	3
Lab technicians ; @ US\$810.5	3	3	
Total number trained	12	10	12
Replacement Value	5820.1	4880.5	4568.9
Useful life; r=3%	3	3	3
Annual equivalent cost	2057.7	1725.5	1615.3
Unit cost	1.12	0.45	0.24

It is relatively expensive to train laboratory technicians in Rwanda because actual reagents are used during training including viral load and CD4 testing reagents. The training also takes three weeks compared to the other professionals who are trained for one week. This is because one week each is allotted to chemistry, haematology and HIV/AIDS testing. Otherwise any difference in unit costs across facilities is solely due to the number of staff trained in each facility versus the total number of patients/visits. Since TRAC is close enough to use the National Reference Laboratory for laboratory testing it incurs no training costs for laboratory technicians.

In summary, visit capital costs were US\$2.99 for CHUK, US\$1.41 for Ruhengeri and US\$2.38 for TRAC clinic.

4.1.4.2. Overhead costs

All overheads in TRAC except those for non-clinical staff, transport and per diems were first allocated by floor space. This is because the costs are shared by the National Treatment and Research AIDS Centre (TRAC) and TRAC Clinic. The combined surface area of TRAC and TRAC clinic is 768m² out of which the Clinic accounts for 208.86m². This gives an allocation base of 0.272. Non-clinical staff costs were allocated according to the estimated time that they spent on work related to the clinic. This was necessary because the non-clinical staff also work on the national ART programme especially as part of the TRACnet team and supervision of all ART sites in the country.

Transport and per diem costs were available in a format that allowed for direct allocation to the TRAC Clinic. All overhead costs were then finally allocated to visits using the total annual clinic visit of 11,612. Allocation of overheads in CHUK and Ruhengeri was based on the patient-day-equivalent technique described in the methodology. Using the information in Table 15 an outpatient-day-equivalent factor was calculated as shown below.

Table 14: Additional utilisation data for the hospitals, (FY2006)

Item	Average hospital stay (days)	Total # of outpatients	Total # of inpatients	PDE factor ¹
CHUK	13	100,126	11,990	4
Ruhengeri	5.4	74,017	14,830	4

The annual number of inpatient days was calculated from data on average length of stay and total number of inpatients as follows:

$$\text{Average hospital stay (days)} \times \text{Total number of inpatients}$$

$$\text{For CHUK} \Rightarrow 13 \times 11,990 = 155,870$$

$$\text{For Ruhengeri} \Rightarrow 14,830 \times 5.4 = 80,082$$

The outpatients' patient-day-equivalent visits were then calculated as follows:

$$\text{PDE}_{\text{outpatients}} = (\text{annual inpatient days} \times \text{PDE}_{\text{outpatients}} \text{ factor}) + (\text{annual outpatient visits})$$

$$\text{PDE}_{\text{outpatients}} \text{ for CHUK} = (155,870 \times 4) + 100,126 = 723,606$$

$$\text{PDE}_{\text{outpatients}} \text{ for Ruhengeri hospital} = (80,082 \times 4) + 74,017 = 394,345$$

An overview of the overhead costs in all three facilities is provided below but detailed costs and quantities are available in Annex C. The annual overhead expenditure for CHUK and Ruhengeri was US\$840,427 and US\$252,381 respectively. The final allocation of overheads to the ART unit at TRAC is US\$11,612.

Table 15: Overhead costs by institution

Item	ART site		
	CHUK	Ruhengeri	TRAC
Total annual overhead expenditure	840,427	252,381	129,051
First allocation	N/A	N/A	39,885
PDE _{outpatients} visits	723,606	394,345	11,612
Cost per visit	1.32	0.64	3.43

¹ See methodology section 2.2.2.2

The overhead cost per visit is calculated by dividing the annual overhead expenditure by the equivalent visits. However, in CHUK there was one exception to this general rule. ART patients in CHUK pay for the lab tests and also contribute US\$18 per month per family towards the cost of ARVs. This means they use the services of a cashier. One cashier is permanently available in OPD *Clinique* and her costs could not be spread over the entire hospital like other overheads. This cost was allocated by the total number of annual visits to OPD *Clinique*, totalling 13,267 (Table 9).

Ruhengeri has the lowest overhead cost per visit - 2 times cheaper than CHUK and 5 times cheaper than TRAC. These differences are not fully justified by differences in patient numbers. It is mostly due to differences in access to resources. CHUK is a teaching hospital and therefore has access to more resources than a district hospital (Hansen et al. 2000; Adam et al. 2003). TRAC being a research centre has also more resources per patient. For instance we saw above that they have 11 computers and a photocopier compared to one at Ruhengeri. The servicing of this equipment also contributes to the running costs of each facility.

4.1.4.3. Clinical staff costs:

As explained in methodology, section 4.1.4.5 the new salary scale for the public health sector was adopted for calculating clinical staff costs. The unit costs for clinical staff by institution, calculated on the basis of proportion of time spent on ART services are shown in Table 16 below:

Table 16: Clinical staff costs by institution

Item	ART site		
	CHUK	Ruhengeri	TRAC
Physician; @ US\$12,737 per annum	1	1	1
General doctor; @ US\$9,689 per annum	0	1	3
Nurse (A0); @ US\$6,745 per annum	0	0	0
Nurse (A1); @ US \$5,330 per annum	2	0	6
Nurse (A2); @ US \$2,190 per annum	4	3	4
Counsellor (A1); @ US\$5,330 per annum	0	0	1
Counsellor (A2); @ US\$2,190 per annum	1	1	3
Nutritionist (A0); @ US\$6,129 per annum	0	0	1
Nutritionist (A1); @ US\$5,330 per annum	0	0	0
Phlebotomist (Nurse A2); @ US\$2,190 per annum	1	0	2
Total number of staff	9	6	21
Total annual salary	34,306	33,256	104,952
Total cost attributed to ART	13,070	12,631	46,168
Number of ART visits	1,831	3,857	6,799
Unit cost	7.14	3.27	6.79

Scale (A0) is equivalent to a university graduate, Scale (A1) is a post-matriculation diploma such as registered nurse and scale (A2) is a pre-matriculation diploma such as an enrolled nurse. TRAC Clinic has more graduates than any other site: 5 compared to 2 for Ruhengeri and 1 for CHUK. But CHUK has 2 specialist physicians who work in OPD Internal Medicine on an alternate basis and are therefore counted as one (even though the full training costs for both of these specialists have been included). Although it is not possible from this analysis to assume that any clinic has an ideal mix of staff for their ART service, it is likely that staff at Ruhengeri are overworked considering the workload and staffing profile at each unit. As a result, they spend much less time with patients resulting in clinical staff cost that is nearly 2 times cheaper. By the same token staff at the other two sites spend more time with their patients leading to higher clinical staff costs. These differences again are attributable to differential access to resources; the teaching hospital and the research centre are

able to garner adequate resources per capita compared to the district hospital which is under funded.

4.1.4.4. The comprehensive average cost per clinic visit

The comprehensive average cost per clinic visit is made up of non-patient specific costs, namely capital, overheads and clinical staff costs. It is calculated from the health care utilisation data and costs of a tertiary hospital, a district hospital and an ART pilot/research clinic. It has been calculated by summing up the unit costs from each facility and then dividing by three as shown below.

Table 17: Comprehensive average cost per-clinic visit (US\$ FY06)

Item	CHUK	%	Ruhengeri Hospital	%	TRAC Clinic	%	Average unit cost	%
Capital cost	2.99	26%	1.41	27%	2.38	19%	2.26	23%
Overheads	1.32	12%	0.64	12%	3.43	27%	1.80	18%
Clinical staff	7.14	62%	3.27	61%	6.79	54%	5.73	59%
Total	11.45	100%	5.32	100%	12.6	100%	9.79	100%

The comprehensive average cost per clinic visit was calculated to be about US\$9.8 per visit. It is not weighted for facility type nor does it take into consideration the differences in risk profiles of the three cohorts of patients. Lastly it does not take into consideration the policy directions of scaling up ART in Rwanda.

The estimate of US\$9.8 is large compared to an earlier estimate for Rwanda by World Health Organisation (2003) using 2000 United States Dollars (Table 2). Notwithstanding the general growth in inflation, this difference is expected as a result of the large jump in clinical staff costs. Before the end of 2006 a doctor in the public service was earning a basic salary of about US\$75 per month and another US\$200 in benefits (Ministry of Health, 2006) but with the new salary scale the basic pay is now around US\$180 per month with an additional US\$780 per month payable on a performance contract basis.

In comparison to other studies, the figure is still lower than the Rand 146 (in 2006 prices), equivalent to US\$21, found in South Africa and much higher than 17.34 Maloti (2006) equivalent to US\$2.6 for a rural district hospital in Lesotho (National

Department of Health, 2007; University of Cape Town, Ministry of Health & Social Welfare, Kingdom of Lesotho, Médecins Sans Frontières & Scott Hospital Health Service Area, 2007). But again differences in cost structure and the level of detail of costs considered limit meaningful comparison. Sensitivity analysis is used to explore uncertainties associated with this parameter in section 4.3 below.

4.2. Population level analyses

In the preceding sections of this chapter cost analysis of health service utilisation data allowed for the calculation of a comprehensive cost per visit and cost per-patient year for ARVs and laboratory monitoring. The results obtained in the preceding section are then used to model the costs of scaling up and lifetime costs. Population level costs are estimated using the CT model from the product of unit costs, survival assumptions, coverage population and the projected period for scaling up. The number of adults initiated on ART from 2007 to 2011 is projected to be 153,014, see Table 19. Survival assumptions were taken from the CT model (Boulle *et al.* 2004) because data collected from Rwanda span a short period and patients had not made sufficient transitions between each Markov state (chapter 3, section 3.2.2.2). Table 18 shows the transition probabilities used in the model.

Table 18: Transition probabilities

Regimen	Months	Transition probability				
		Death	Lost to follow up (LTF)	Death plus LTF	Fail treatment	Switch to SL
FL	≤ 6 for six-month period	0.08	0.03	0.11	0.03	0.08
	>6 for annual period	0.02	0.02	0.04	0.01	0.10
SL	≤ 6 for six-month period	0.01	0.01	0.02	0.13	
	>6 for annual period	0.02	0.02	0.04	0.25	

Adopted from CT Antiretroviral Costing Model Version 1

Life expectancy was assumed to be 6.5 years with 60% and 40% of the time on ART split between first and second-line regimens respectively. This split has been validated from primary data (Cleary *et al.* 2006). For patients who have clinically progressed, 80% were assumed to remain on second-line treatment. This is because even after virological failure, patients kept on treatment have better prognosis than those stopping it altogether.

Lack of routine viral load testing in resource poor settings also means that patients who are failing the second-line cannot necessarily be identified, the exception being those who develop drug intolerance.

4.2.1. Numbers initiating ART during scale up

Table 19 below shows the estimated number of HIV positive adults in Rwanda from 2006 through 2011 and the estimated target population for ART scale up (*République du Rwanda: Ministère de la Santé, 2005a*).

Table 19: Estimated adult population initiating ART during scale up

Year	HIV Positive adults 15-45 years	Ministry of Health defined ART new need	Ministry of Health defined ART new target
2006	135,907	10,114	
2007	140,922	10,477	27,012
2008	145,328	10,855	28,902
2009	149,551	11,207	30,649
2010	154,027	11,549	32,341
2011	158,557 ²	11,884	34,110
Total	748,385	55,972	153,014

In Rwanda, patients are clinically eligible for ART if they have an AIDS defining condition at any CD4 level, or if they have a CD4 cell count less than 200 cells/ μ l at any WHO stage. Therefore, only a fraction of the total adult population living with HIV/AIDS would need to be initiated on ART. Estimated adult population living with HIV/AIDS in 2006 was 135,907 and new need was estimated at 10,114 adults, however the actual number initiated on treatment was 13,424 (*République du Rwanda: Ministère de la Santé, 2005a; Treatment and Research AIDS Centre, 2007*). These figures would seem to suggest that coverage of new need was 133%, which does not make sense unless there was untreated old need. Alternatively, projections could be lower than the actual number living with HIV/AIDS, for instance UNAIDS (2006a) quotes a revised figure of 160,000 for 2006. The revised figure includes all adults aged 15 years and above as opposed to the Ministry of Health estimate defining adults to be aged between 15-45 years.

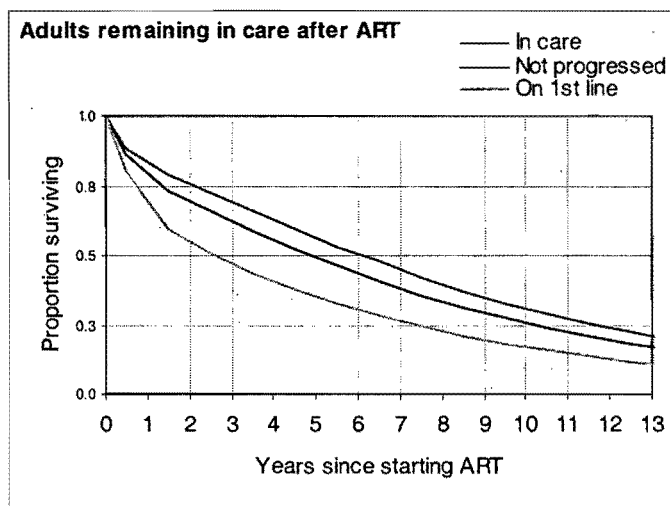
² Figure calculated from average annual increase between 2007-2011 plus figure for 2010

Although the estimated target for scaling up is higher than estimated new need, it was still used because the objective is to cost the ART scale up policy. No adjustments were made for treatment via the private sector because the numbers treated via the private sector were less than 0.5% of total population on ART during 2006.

From Table 20, the projected number of adults entering ART each year will increase from 27,012 in 2007 to 34,110 by 2011. The incoming cohort in 2007 will be augmenting the 2006 surviving cohort composed of 30,991 or 98.8% adults on first-line regimens and 388 or 1.2% on second-line regimens. By the end of 2011 the total number of adults initiated on ART will be 153,014.

Figure 1 illustrates the estimated survival of patients in the CT model. These survival and patient need/uptake assumptions combine to yield the output in Figure 2.

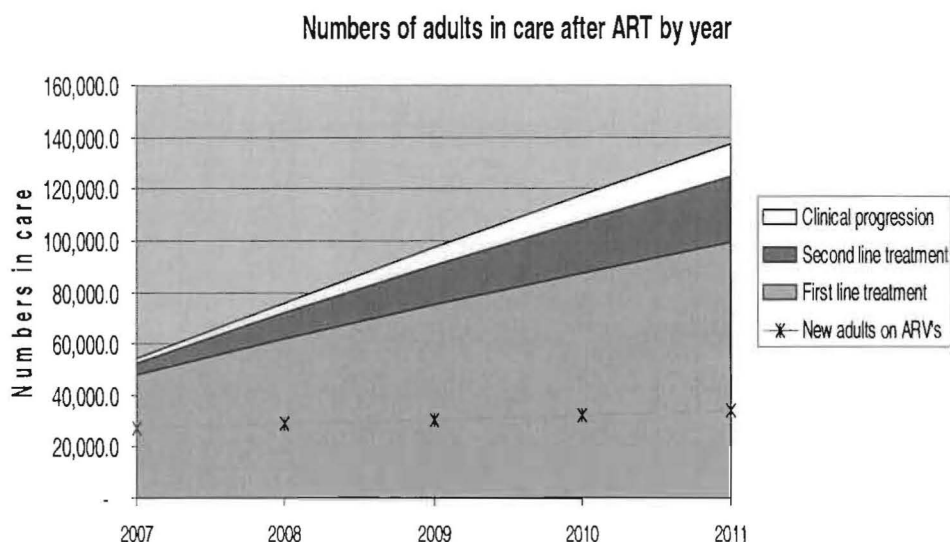
Figure 1: Survival ART cohort



In figure 1, the lowest curve shows the assumptions regarding the overall time spent on the first-line regimen. The middle curve summarizes the time spent on first and second-line regimens together. The highest curve shows the overall survival both on and off treatment. The lowest curve has the steepest gradient and therefore the highest rate of change in proportion of patients on first-line regimen. This change is sharpest in the first 12 months and slows down from 24 months onwards. The other two curves have slower rates of change and are influenced by the lowest curve.

After 6 months of initiating ART care, the graph shows that the proportion of patients remaining in care will be 88.5%, of which 80.1% will still be on first-line, while 6% will have switched to second-line and 2.1% will have failed treatment (Markov state V). The remaining 11.5% are either lost to follow-up or will have died. After 36 months 72.4% are still surviving and remaining in care, out of which 65.4% are on ART. Of those on ART, 50.7% are on first-line and 15.1% are on second-line regimens. After 6.5 years, the respective proportions are 47.5% in care, of which 28.1% are on first-line and 12.6% on second-line. Implicitly 6.7% have clinically progressed while 52.5% are either dead or lost to follow-up. After 10 years about 30% are still in care of whom only 4.8% are clinically progressed. Figure 2 shows the actual numbers remaining on treatment over the scale up period.

Figure 2: Number of adults in ART care each year



Year	2007	2008	2009	2010	2011	Total
First-line treatment	48,164	61,966	75,083	87,532	99,527	372,272
Second-line treatment	4,559	9,914	15,094	20,081	24,878	74,526
Clinical progression	1,358	4,029	6,909	9,903	12,872	35,071
Total in care	54,082	75,910	97,087	117,516	137,278	481,873
New adults on ARVs	27,012	28,902	30,649	32,341	34,110	153,014

From figure 2, the total number in care increases from 54,082 in the base year to 137,278 by 2011. The corresponding figures for first-line, second-line and clinically progressed are 48,164, 4,559 and 1,358 respectively during 2007 but will have grown to 99,527, 24,878 and 12,872 respectively by 2011.

The percentage changes in these numbers over the scale up period are 277% for first-line, 546% for second-line and 948% for clinically progressed.

4.2.2 Health care utilisation and cost assumptions

Given the multiplicity of ARV regimens at the three institutions and the need for generalisability of results, the national recommended regimens were assumed. Average frequencies weighted by the number of patients on each regimen were calculated using data in Table 4. From this calculation 59% of all patients on first-line regimen were receiving nevirapine, 37% were receiving efavirenz and 4% were on 3-NRTIs that included abacavir or tenofovir. This split was adjusted to 65% nevirapine, 30% efavirenz and 5% abacavir/tenofovir respectively based on a number of assumptions. The national guidelines advise that patients with co-infection with tuberculosis be treated with efavirenz as the NNRTI of choice. For pregnant mothers, especially in the 1st and 2nd trimester, the guidelines advise to avoid the NNRTIs.

The incidence of proven tuberculosis in patients with HIV/AIDS was 32% in 2006 (*Ministère de la Santé, 2007*). The remaining 5% was evenly split between abacavir and tenofovir for pregnant mothers (early pregnancy and patient who might develop intolerance to nevirapine/efavirenz containing regimens). After the first 6 months on treatment more patients would be expected to develop side effects and hypersensitivity to nevirapine and efavirenz necessitating additional switches to abacavir or tenofovir containing regimens. Thus regimens containing these two drugs would increase from 5% to 15%. Of this 15%, it was assumed that 10% would be placed on tenofovir because it is associated with fewer side effects compared to other ARVs and is cheaper. It was also assumed that 2.5% patients would be switched from stavudine to zidovudine after the first 6 months on treatment due to side effects.

For the second-line regimen, national guidelines recommend that all patients be treated with didanosine, abacavir and lopinavir/ritonavir. However, it was assumed that 10% of patients would switch from didanosine and abacavir to lamivudine/zidovudine and lopinavir/ritonavir during the first 6 months. This proportion was assumed to increase to 30% after the initial 6 months (Markov state

IV). Table 20 details the recommended regimens and the assumed percentage utilisation of each regimen during scale up.

Table 20 : Adjusted frequencies of ARV regimens

Regimen		Frequency on each regimen			
		FL		SL	
		First 6 months	Annually thereafter	First 6 months	Annually thereafter
Lamivudine/stavudine/nevirapine	3TC/D4T/NVP	50%	45%		
Lamivudine/zidovudine/nevirapine	3TC/AZT/NVP	15%	20%		
Lamivudine/zidovudine/efavirenz	3TC/AZT/EFZ	30%	20%		
Lamivudine/stavudine/abacavir	3TC/D4T/ABC	2.5%	5%		
Lamivudine/zidovudine/tenofovir	3TC/AZT/TDF	2.5%	10%		
Didanosine/abacavir/lopinavir/ Ritonavir	ddi/ABC/ LPV/r			90%	70%
Lamivudine/stavudine/lopinavir /ritonavir	3TC/AZT/ LPV/r			10%	30%

Inputting these assumptions into the CT model yields an input/output synthesis of annualised costs of ARV regimens as shown below. Note that the regimens are assumed to be non-fixed dose combinations although most of the first-line regimens are fixed. This is due to model requirements.

Figure 3: Model synthesis of cost of ARV regimens (US\$ FY06)

ARV Regimens									
non-FDC									
First line				Second line				Failing	
First 6 months		Annually thereafter		First 6 months		Annually thereafter			
Individual ARVs									
30%	EFV	20%	EFV					80%	ddl
3%	TDF	10%	TDF	90%	ddl	70%	ddl	80%	ABC
		0%	0	100%	LPV/ r	100%	LPV/ r		
3%	ABC	5%	ABC	90%	ABC	70%	ABC	80%	LPV/ r
Regimens									
33%	AZT/ 3TC	30%	AZT/ 3TC	10%	AZT/ 3TC	30%	AZT/ 3TC		
50%	d4T/ 3TC/ NVP	45%	d4T/ 3TC/ NVP						
3%	d4T/ 3TC	5%	d4T/ 3TC						
15%	3TC/AZT/NVP	20%	3TC/AZT/NVP						
Cost (annualised) including procurement & distribution									
201		212		1,313		1,177		560	

The regimens predominantly used in the first 6 months of second-line are the most expensive, at annualised cost of US\$1,313.

This is because the first choice second-line regimen of didanosine, abacavir and lopinavir/ritonavir is the most expensive second-line regimen, yet it accounts for 90% of prescriptions in this period. Thereafter, 30% of the cohort on this regimen is allowed to switch to lamivudine, stavudine and lopinavir/ritonavir which is cheaper. This results in a lower annualised period specific cost of US\$1,177. Sensitivity analysis will be used to explore potential costs savings using cheaper regimens in this period. The other annualised costs for Markov states I, II and V are behaving as expected and are noted as US\$201, US\$212 and US\$560 respectively.

Laboratory schedules used are discussed in section 4.1.3 above, however for patients on second-line ART it was assumed that they would have at least one viral load test once a year because of the increased need for pharmacovigilance and resistance monitoring. The expected utilisation of visits for ART and pre-ART during scale up are outlined in Table 21.

Table 21: Utilisation visits

Period	Timing	# of visits
Pre-treatment (pre-ART)		3
First-line (FL) first six months	begin FL treatment	1
	Week 1	1
	Week 2	1
	Week 4	1
	Month 2	0.8
	Month 3	0.9
	Month 4	0.3
	Month 5	0.5
	Month 6	1
Total FL first six months visits (including Pre-ART)		10.0
Total # of visits annually thereafter		7.0
Second-line (SL) first six months	begin SL treatment	2.0
	Week 1	1.0
	Week 2	1.0
	Week 4	1.0
	Month 3	1.0
	Month 4	0.6
	Month 5	0.4
	Month 6	1.0
Total # of visits SL first six months		8.0
Total # of SL visits annually thereafter		7.5
Fail treatment (estimate)		7.5

The cohort failing treatment was assumed to have the same number of visits as the cohort on second-line. The detailed model input/output assumptions and synthesis of per-patient periods costs are shown below:

Table 22: Per-patient period summary costs and assumptions (US\$ FY06)

Item		First line initial 6 months	First line annually thereafter	Second line initial 6 months	Second line annually thereafter	Failing treatment
ARV's	Annual cost	Percentage of people on each ARV				
ddl	328	-	-	90%	70%	80%
NVP	47	-	-	-	-	-
EFV	206	30%	20%	-	-	-
TDF	218	3%	10%	-	-	-
LPV/r	565	-	-	100%	100%	80%
ABC	488	3%	5%	90%	70%	-
AZT/ 3TC	135	33%	30%	10%	30%	80%
d4T/ 3TC/ NVP	95	50%	45%	-	-	-
d4T/ 3TC	66	3%	5%	-	-	-
3TC/AZT/NVP	191	15%	20%	-	-	-
Per period cost		100	212	657	1,177	560
Laboratory tests	Unit cost	Average tests in period per person on treatment				
FBC	4.20	1.0	1.0	0.2	1.6	2.4
Diff	2.50	1.8	0.7	1.1	2.0	1.6
Creatinine	2.80	1.3	0.7	1.0	2.0	0.8
ALT	2.80	1.3	1.3	-	1.0	0.8
Glucose	2.80	1.6	0.7	-	1.0	0.8
CD4	12.60	2.0	1.0	2.0	2.0	2.0
Viral load	25.80	-	-	1.0	-	-
Per period cost		45	26	57	48	46
Consultations	Unit cost	Number of visits in period				
ART visit	9.79	10	7	8	8	8
Per period cost		98	69	78	73	73
Grand total cost		244	306	792	1,299	680

The per-period costs for the Markov states (I) through (V) are 45, 26, 57, 48 and 46 United States Dollars respectively for monitoring laboratory tests. Their magnitudes are behaving according to the degree of intensity of monitoring associated with particular states. The costs for clinic visits are also behaving accordingly, they are highest in the first 6 months which also include 3 pre-treatment visits and are least in Markov state (II). The grand total includes the per-period costs of ARVs already explored in Figure 3 above.

4.2.3. Patient specific costs

The total annual costs by year for ARVs and the associated laboratory monitoring test costs generated from the model are presented in Table 23. Assuming that the costs for 2007 have already been secured/incurred, the cumulative cost of scaling up is calculated by subtracting total costs in the base year from the cumulative total over the scaling up period.

Table 23: Total cost for ARVs and labs (US\$ FY06)

Category	Year					Grand Total	Costs of scaling up
	2007	2008	2009	2010	2011		
ARVs	12,122,462	22,665,893	28,754,995	37,309,588	45,591,081	146,444,018	134,321,556
Lab test	2,143,939	3,020,364	3,851,076	4,658,717	5,445,230	19,119,327	16,975,388
Total	14,266,401	25,686,257	32,606,071	41,968,305	51,036,311	165,563,345	151,296,944

The cost of ARVs is about US\$12 million during the base year but increases sharply to exceed US\$45 million by 2011. The total cost for ARVs over the scaling up period is US\$134 million. The total cost for laboratory monitoring tests increases from about US\$2 million in 2007 to US\$5.4 million by 2011. Overall, the additional patient specific costs for scaling up will exceed US\$151 million over the five years. The 5-year cumulative patient specific costs increase from a modest sum of US\$14 million to roughly US\$165 million.

4.2.4. Shared costs

The projected costs over the scaling up period for overheads, capital and clinical staff costs are set out in Table 24.

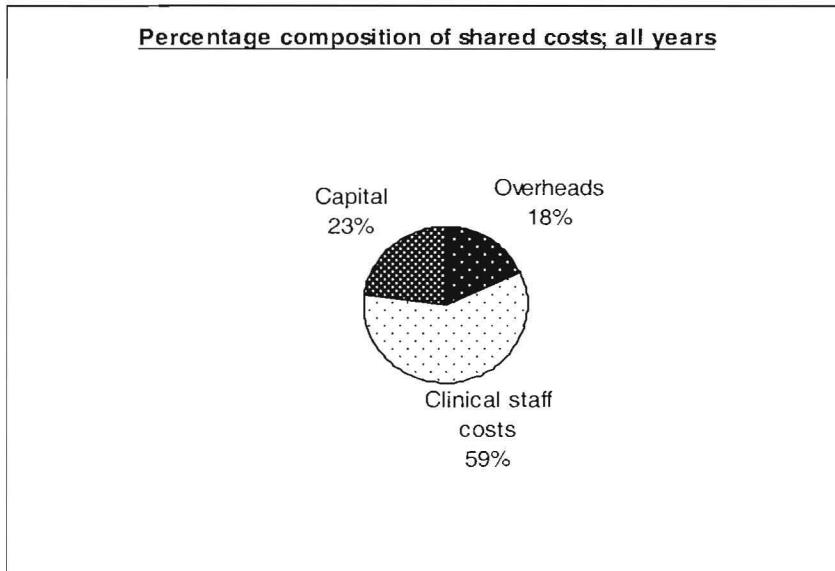
Table 24: Shared costs by category mix (US\$ FY06)

Category	Year					Grand Total	Costs of scaling up
	2007	2008	2009	2010	2011		
Overheads	859,593	1,183,794	1,486,669	1,779,713	2,064,310	7,374,078	6,514,485
Clinical staff	2,817,554	3,880,214	4,872,970	5,833,502	6,766,349	24,170,590	21,353,036
Capital	1,098,368	1,512,626	1,899,632	2,274,077	2,637,729	9,422,433	8,324,065
Total	4,775,515	6,576,634	8,259,272	9,887,292	11,468,389	40,967,101	36,191,586

Overhead costs in the base year are roughly US\$0.9 million and will have increased to US\$2 million by 2011. Clinical staff costs are US\$2.8 and US\$6.8 million in the corresponding periods, whereas capital costs increase from about US\$1 million in 2007 to US\$2.6 million by 2011.

The 5-year cumulative total cost will exceed US\$40 million by 2011 and the total costs required for scale up is US\$36 million. The percentage contribution to the 5-year cumulative total cost by each category mix is 59% clinical staff costs, 23% capital costs and 18% overhead costs as depicted in figure 4.

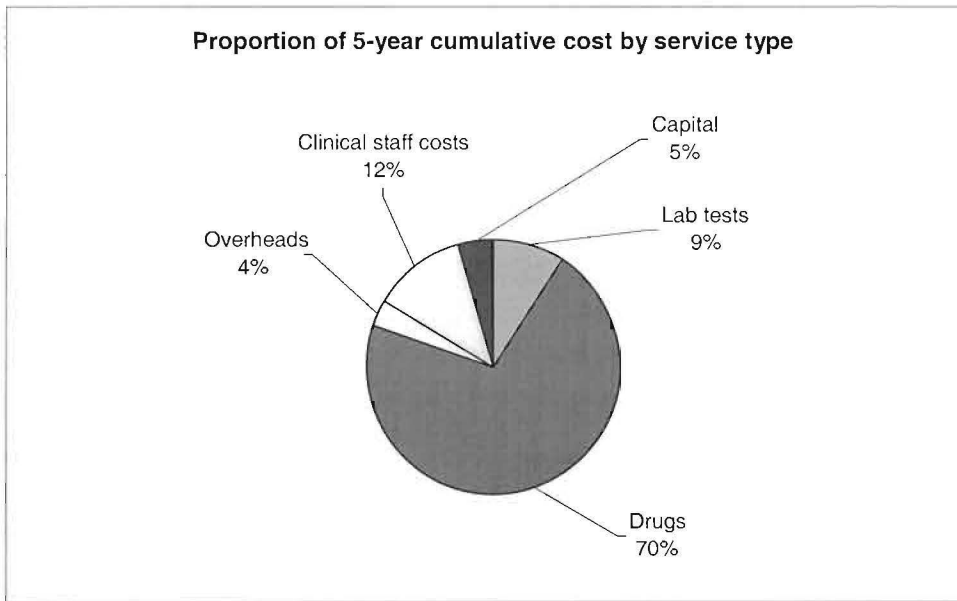
Figure 4: Composition of shared costs



4.2.5. Costs of scaling up

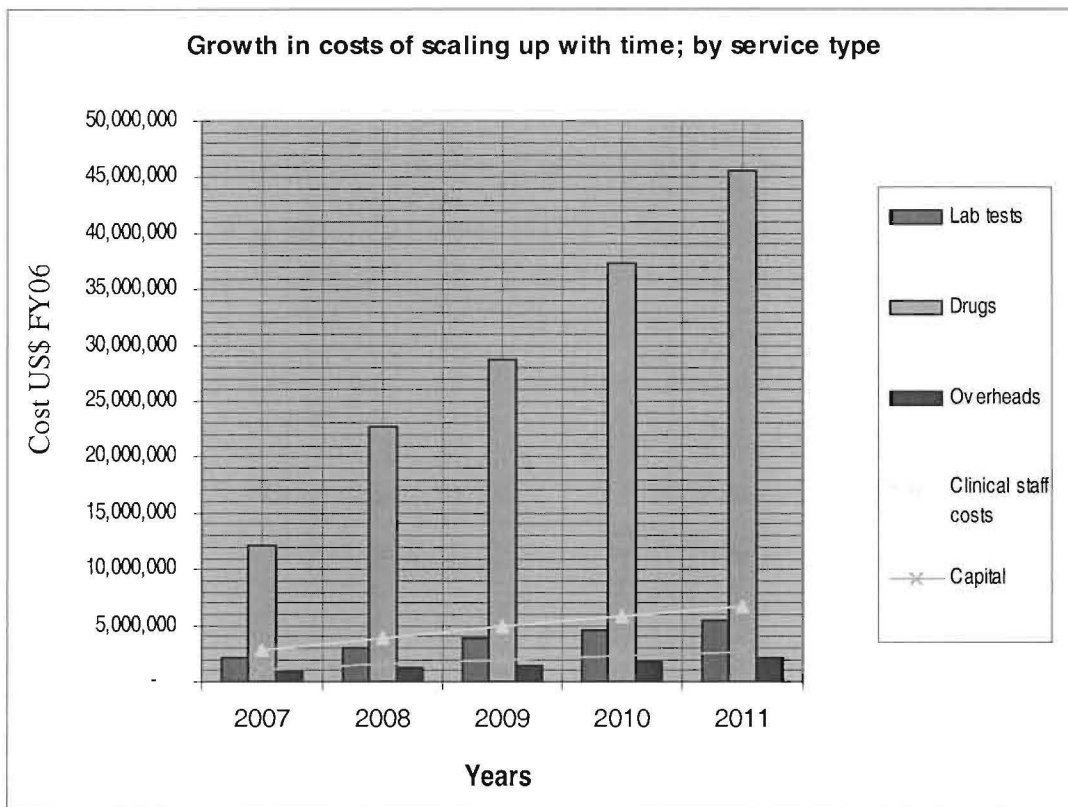
Keeping other things constant, the total undiscounted costs for scaling up ART in Rwanda is US\$187 million, if current coverage of 54,082 adults in 2007 is to be increased to 137,278 adults on ART by 2011. In the process a combined total of 152,014 adults will have been initiated on ART. The percentage contribution of ARVs, labs, capital, overheads and clinical staff costs to the cumulative total cost is depicted in figure 5 below. ARVs dominate all other costs, contributing 70% to the cost of scaling up. This is followed by clinical staff costs, at 12%, monitoring laboratory tests at 9% and lastly overheads contributing 4%. The growth in category mix costs over the scale up period is highlighted in Figure 6.

Figure 5: Percentage contribution to the 5-year cumulative cost by category



The growth in costs of scaling is captured in Figure 6 below:

Figure 6: Growth in costs of scaling up by category mix



There is an explosive growth in the costs of ARVs, dwarfing all other costs over the scale up period. The other three costs grow more sedately, led by clinical staff costs, followed by laboratory monitoring costs, capital costs and lastly overhead costs.

4.2.6. Lifetime costs

The lifetime cost is defined as the total cost of providing ART to a patient from pre-ART visits and labs until death or loss to follow-up. Therefore it is the summation of the different Markov states costs, within the boundaries of life expectancy that give rise to lifetime costs. From the above results we predict the lifetime costs by splitting the 6.5 years on treatment between first and second-line regimens by a ratio of 0.6 to 0.4. This translates into 47 months on first-line regimens and 31 months on second-line regimens. Then the time in years spent on first-line annually thereafter is calculated as follows:

$$(47-6)/12= 3.42 \text{ years}$$

It is also assumed that of the 31 months, 6 will be spent in the “fail” treatment state, hence the time in years on second-line treatment annually thereafter equals:

$$(31-12)/12= 1.58 \text{ years}$$

From the output in Table 22 above different period specific costs are used to calculate the lifetime costs shown in Table 25

Table 25: Lifetime costs (US\$ FY06)

Item	Per-period or Markov state costs					Lifetime Costs
	First-line		Second-line		Failing treatment	
	First 6 months	Annually thereafter	First 6 months	Annually thereafter		
period cost	244	1047	792	2052	680	4815

Following the computation the undiscounted lifetime cost of providing ART to an adult in Rwanda is US\$4,815. This implies an annual average undiscounted cost of US\$741, which compares well to similar estimates from the region that range from US\$396 to US\$2,761 (Rosen and Long, 2006). The annual average and lifetime cost is low because it excludes a number of costs as discussed in the methodology, especially hospitalisation and treatment of opportunistic infections.

4.3. Sensitivity Analysis

The results presented so far are not discounted to allow for differential timing of costs, thus two discount rates of 3% and 5% will be presented in sensitivity analysis. Likewise there is a need to explore uncertainties in the results. These could have come from the need for generalisability of results during scale up, the choice of analytic methods and data requirements of the study all of which imposed certain key uncertainties.

The results presented so far are based on a comprehensive average unit cost per clinic visit, which assumes that the three sampled facilities and their cost structures can be generalised to other facilities during the scale up. However, the unit cost per outpatient visit increases as one moves from primary to secondary to tertiary level structures (Hansen et al. 2000; Adam et al. 2003). There are a number of reasons that may explain these differences. These may include differences in funding, for instance teaching hospitals have access to more resources than non-teaching hospitals. Tertiary hospitals also tend to deal with more complex and severe illnesses compared to secondary and primary structures thus employing more resources. Since this is an important source of uncertainty, although not a key cost driver, it is necessary to explore the alternative use of a weighted average comprehensive unit cost per clinic visit. This is calculated from the assumption that 90% of ART patients will be treated at primary and secondary levels and the remainder at the tertiary level. This is also in line with the national policy of scaling up which assumes that delivery would be executed by primary and secondary level health facilities (Treatment and Research AIDS Centre, 2007).

The split of 9 to 1 is derived from the number of patients who received ART in 2006. As shown in Table 26 below, the percentage that received treatment at primary and secondary levels was 91.7% compared to 8.3% at tertiary levels. The unit costs of the pilot were found to mirror those of CHUK, a tertiary institution, and are therefore treated as such. However uncertainty is again introduced by having to weight the pilot clinic as a tertiary institution and equating the costs of the district hospitals to those of health centres. Nevertheless, the degree of uncertainty relating to the unit cost of a pilot is diluted by the small weight given to tertiary level institutions.

Table 26: Total number of ART patients by level of health system

Type of institution	Total number of patients served	Percentage
Tertiary	2,599	8.3%
Secondary and primary	28,780	91.7%
Total number of ART patients	31,379	

Source TRACnet Report January 2007

A weighted average comprehensive cost per clinic visit is then calculated from the results in

Table 17 and the results are presented below.

Table 27: Weighted average cost per clinic visit (US\$ FY06)

Item	Institution			W
	CHUK	Ruhengeri	TRAC	
Capital cost	0.15	1.27	0.12	1.54 (25.7%)
Overheads	0.07	0.58	0.17	0.81 (13.6%)
Personnel	0.36	2.94	0.34	3.64 (60.8%)
Total	0.57	4.79	0.63	5.99

The computation yields a weighted average unit cost of nearly US\$6 per clinic visit which is 40% lower than the average unit cost. This result will now be used in sensitivity analysis to gauge sensitivity in results.

ARVs dominate all the other costs, and small changes in their prices could lead to wide swings in the costs of scaling up. The baseline scenario has assumed a once off price reduction of 25% on second-line ARVs in 2009. This relates to the recent breakthrough announced by the Clinton Foundation regarding second-line ARV prices. Considering that the prices of ARVs have shown a downward trend in the last 5 years, exploration of further price reductions is necessary. However, going by recent history no sensitivity analysis for price hikes is warranted. Sensitivity analysis is used to explore variations in total cost if prices of first-line and second-line ARVs were to drop by 5% year-on-year or every year from 2007 to 2011. This is equivalent to an overall reduction of 18.5% in the prices of ARVs in 2011. Also included is a 10% year-on-year reduction in the prices of ARVs as it is within a realistic range.

The first choice second-line regimen used in Rwanda of didanosine, abacavir and lopinavir/ritonavir is expensive compared to what other countries are using in the region. Use of a cheaper first choice second-line regimen could have important implications on total costs. Use of cheaper second-line regimens such as lamivudine, zidovudine and lopinavir/ritonavir (3TC/AZT/LPV/r) lamivudine, tenofovir and lopinavir/ritonavir (3TC/TDF/LPV/r) or didanosine, tenofovir and lopinavir/ritonavir (ddi/TDF/LPV/r) will be explored. Since Rwanda achieved a 7% reduction in consecutive tender prices of ARVs, a 5% year-on-year price reduction is a realistic assumption. Combining this with judicious choice of second-line ARVs in a 2-way sensitivity analysis could have important economic implications.

The choice of tariff C (the rate for private patients in a tertiary institution) to proxy the opportunity cost of laboratory monitoring tests which is greater than the mandated insurance rate (tariff A) could be associated with a degree of uncertainty. The degree of change in total costs will be investigated using one way sensitivity analysis and tariff B (which consisted of the cost of the tradable portion of these tests together with an assumed cost for the non-tradable component). Tariff A can not be used because it does not have rates for CD4 and viral load. Lastly, currency crises could also impact the estimated costs of scaling up. Sensitivity analysis will be used to investigate changes in costs at lowest and highest exchange rates of US\$1 to 405Frw and 576Frw respectively (Rwanda National Bank, 2006). The results of sensitivity analysis are displayed below.

Table 28: Results of sensitivity analysis (US\$ FY06)

Scenario	Changes in costs			
	Cumulative total cost A	Lifetime costs B	Difference A-Ai	% change from baseline $((A-A_i)/A) \times 100$
Baseline (A)	206,530,446	4,815	0	0
(A) discounted at 3% (A1)	191,874,449	4,440	14,694,732	7.6%
(A) discounted at 5% (A2)	183,052,135	4,221	23,517,047	12.8%
Weighted average cost (A3)	190,591,419	4,581	15,939,027	8.4%
Tariff B, using US\$2 for non-tradable portion for lab costs	201,533,622	4,700	4,996,824	2.4%
Lowest exchange rate of US\$1 to 405Frw	154,874,890	3,839	51,655,556	25.0%
Highest exchange rate of US\$1 to 576Frw	220,987,577	5,152	-14,457,131	-6.8%
5% reduction in FL & SL ARV prices year-on-year (A5)	181,535,545	4,232	24,994,901	13.8%
10% reduction in FL & SL ARVs year-on-year (A6)	160,295,159	3,737	46,235,287	28.8%
Cheaper SL regimen (3TC/AZT/LPV/r) (A7)	188,694,994	4,399	17,835,452	9.5%
Cheaper SL regimen (ddi/TDF/LPV/r) (A8)	196,126,561	4,572	10,403,885	5.3%
Cheaper SL regimen (3TC/TDF/LPV/r) (A9)	183,475,680	4,278	23,054,766	12.6%
5% reduction in ARVs year-on-year and cheaper SL (3TC/TDF/LPV/r) (A10)	172,047,769	4,011	34,482,677	20.0%
5% reduction in year-on-year and cheaper SL regimen (3TC/AZT/LPV/r) (A11)	177,267,083	4,133	29,263,363	16.5%
Weighted average cost AND Cheaper SL regimen (3TC/TDF/LPV/r) (A12)	161,328,056	3,761	45,202,390	28.0%

The 5-year discounted costs are roughly US\$191 and US\$183 million at rates of 3% and 5% respectively. This is equivalent to a cost reduction of 7.6% and 12.8% respectively. The corresponding discounted lifetime costs are US\$4,440 and US\$4,221. Using a weighted average cost instead of an average cost per clinic visit results in an important cost reduction of 8.4%. However, adopting tariff B to proxy opportunity costs of laboratory tests is not associated with significant variation in total cost, just a 2.4% reduction in overall cost.

Significant swings in exchange rate can cause the costs of scaling up to change significantly. Using the lowest exchange rate of 405Frw to the dollar resulted in a significant decrease in total costs. Total costs drop from US\$206 million to US\$155

million or 25%. However, it is unlikely for the dollar to weaken considerably against the Rwandan franc. On the other hand a weakening of the Rwandan Franc against the dollar from 540.08 to 576Frw results in a 6.8% increase in total costs or an extra US\$14.4 million. This is a real threat to the validity of the estimated costs because the Franc has been weakening against the dollar over the last 5 years.

Overall, the sensitivity analysis shows that the total cost is most sensitive to changes in prices of ARVs. A 5% year-on-year reduction in the cost of ARVs will result in 13.8% reduction in total cost, or US\$25 million over 5 years. If the prices were to drop by 10%, then total cost would tumble by 28.8%, yielding a cost saving of nearly US\$46 million over the same period. Sensitivity analysis shows that use of cheaper second-line regimens could reduce the total cost by as much as 12.6%, if Rwanda were to use say lamivudine, tenofovir and lopinavir/ritonavir (3TC/TDF/LPV/r). Varying two variables at the same time while keeping others constant, such as using a cheaper second-line regimen and a 5% reduction in cost of ARVs, yields even more significant cost savings.

4.4. Financial sustainability findings

Financial sustainability findings are based on the results of the cost analysis, key informant interviews and examination of key policy documents. Between December 2006 and February 2007, eleven key informants (Annex K) were interviewed using an open ended questionnaire (Annex Q) to gauge the financial sustainability of the ART programme in Rwanda. The findings from key informant interviews, desktop research and the results of cost analysis are integrated in the subsequent sections analysing the financial sustainability of the ART programme in Rwanda.

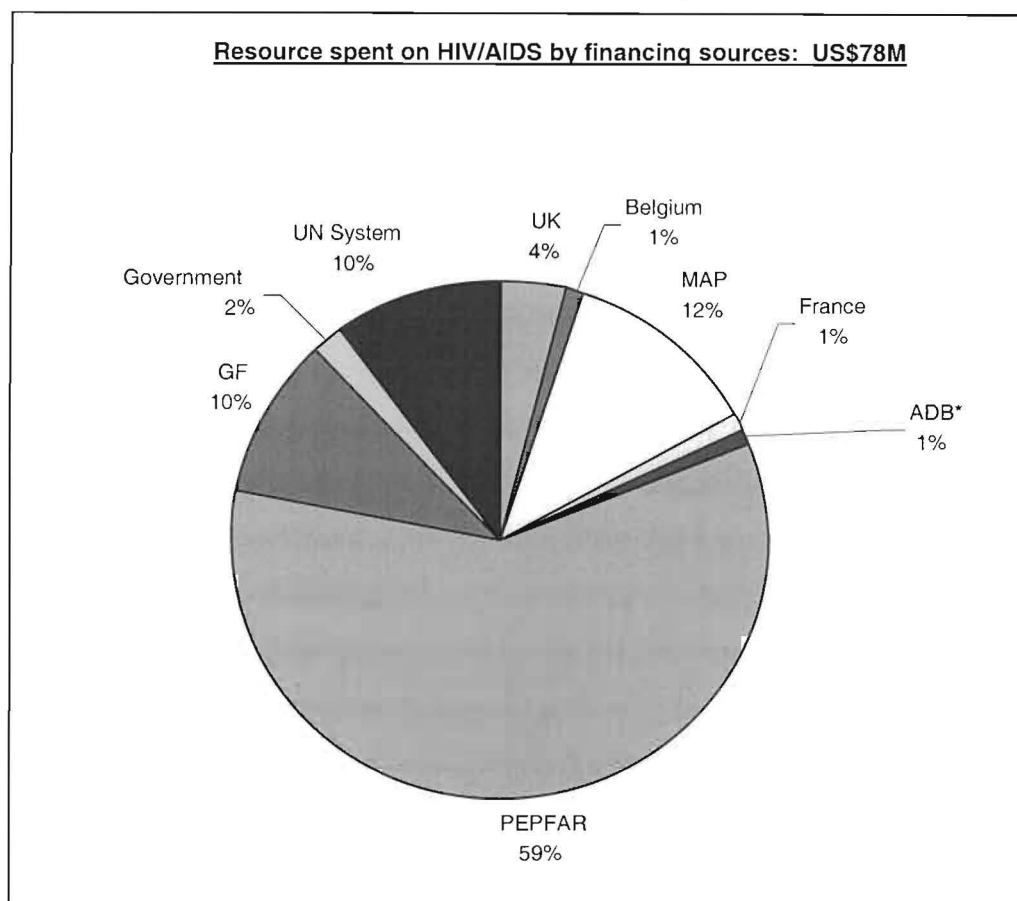
4.4.1. Sources of funds for ART in Rwanda

Findings show that all costs for ARVs and the tradable portion of laboratory tests are paid for by donor funds. Also funded is certain laboratory and pharmacy equipment required to upgrade capacity at primary and secondary level health facilities to deliver ART services. Examples include the provision of CD4, haematology and chemistry machines for laboratory monitoring, and generators and fridges to ensure that ARVs

and laboratory reagents are kept at optimal temperatures. Transport of blood samples from health centres to district hospitals and to the national reference laboratory is another niche for foreign funds. This cost is covered either in cash or in kind through provision of motorcycles. Another important use of foreign funds is the provision of technical assistance particularly in design and operationalisation of structures and systems and monitoring and evaluation. The domestic funds then cover most of the running costs for health facilities, personnel and capital costs.

For the most recent estimate of HIV/AIDS expenditure by source of funds, the candidate was referred to the UNGASS report (UNAIDS, 2006b). According to the report, in 2005 a total of US\$78 million were spent on HIV/AIDS from public sources. Ninety seven point four percent (97.4%) were donor funds and only 2.6% were domestic funds. However, the report hastens to add that this figure did not capture running costs for health facilities. The methodology of reporting expenditure was not uniform also because PEPFAR funds included “long” and “short” term technical assistance and out-of-country costs. Figure 7 shows the percentage contribution of each funding source in 2005.

Figure 7: Rwanda: HIV/AIDS financing sources 2005



**ADB: -African Development Bank*

The pie chart shows that PEPFAR was the largest contributor (59%) to the public funds for HIV/AIDS prevention, treatment and mitigation in 2005. The Multi-country AIDS Program (MAP) was second largest with 12%, followed by the Global Fund (GF) and UN-System with 10% each. The United Kingdom was the largest bilateral donor at 4% of the total budget.

Nearly all key informants agreed that the major source of funds for scaling up ART in Rwanda from 2007 to 2010 will come from two major donors and to a lesser extent from domestic revenue. The two major donors were said to be grants committed by PEPFAR and the Global Fund. According to Ms Hakizinka Ida, the Permanent Secretary for the Country Coordinating Mechanism, the Global Fund (Table 29) had committed an extra US\$58.9 million in 2007 during GF round 6. This was in addition to the ongoing commitment of US\$90.5 million from round 3. Another major consignment of funds for ART during scale up was said to come from the ongoing

commitment of US\$94 million from PEPFAR. The Multi-country AIDS Program of the World Bank is another important source of funds that go directly to ART services. The Bank provided a new commitment of US\$10 million in 2007 for HIV/AIDS, of which 36% will purchase ARVs and lab tests for 5,000 patients.

These findings are validated by data from CAMERWA which is responsible for purchase, storage and supply of all ARVs, and laboratory tests and their consumables. During the September 2006 tender, PEPFAR was the largest contributor with 51.46% followed by GF/MAP with 45.94% followed by Médecins sans Frontières (MSF) with 1.2% and the balance of 1.4% mainly by private employers. This arrangement is largely based on the number of patients under each donor's jurisdiction and increases according to the level of uptake in that jurisdiction. The PMTCT services are largely funded by the Clinton Foundation and are thus treated differently from ART.

Table 29: Major commitment of funds from donors

Source	Commitment (US\$: million)	Status (comments & balance on disbursement)
MAP	10	New commitment from 2007, \$3.6M earmarked for care and treatment
Global Fund (Round 6)	58.9	New commitment signed April 2007, GF round 6. phase 1 disbursement totals \$31.6M for 2007/08
PEPFAR	94	Ongoing commitment, prevention care and mitigation
Global Fund (Round 2)	90.5	Ongoing commitment since 2005, includes US\$33.6 million for capacity building

The Central Government budget for the period 2005 to 2007 was also consulted to further unravel sources of funds and resources allocated to health. Below are the 3 year budgetary allocations for the financial years 2004/5, 2005/6 and 2006/7.

Table 30: Budgetary allocation to Ministry of Health by source; US\$ FY06

Indicator	Year		
	2005	2006	2007
Total government budget	681,906,190	733,581,039	938,277,894
Budgetary allocation to MoH	50,818,695	55,808,876	73,490,864
Budgetary allocation from central government revenue	2,876,426	1,583,189	1,709,006
Budgetary allocation from foreign revenue (grants)	47,942,269	54,225,687	71,781,858
Total allocation to MoH as percentage of total government budget	7.5%	7.6%	7.8%
External resources for health as percentage of total health budget	94.3%	97.2%	97.7%
Central government revenue as a percentage of health budget	5.7%	2.8%	2.3%

Source: Ministry of Finance and Economic Planning Budget Unit

These data include funds allocated to the Ministry of Health from the public budget and are comprised of central government revenue and foreign aid either in the form of grants or loans. Naturally they do not include outlays from private sources such as insurance/social security and out-of-pocket expenditure by households and employers. The foreign resources cited here are only grants and do not include loans because government treats such outlays as part of domestic resources.

These data show that budgetary allocations to Ministry of Health grew from 7.5% in the financial year 2004/5 to 7.8% by 2006/7. This growth is mainly accounted for by the growth in donor funds, because central budgetary allocation actually fell by 40% over the same period, whereas foreign funds grew by 50%. As a result the percentage budgetary share of Ministry of Health budget met by donor funds grew from 94% in 2004/5 financial year to 97.7% by 2006/7. This finding does not augur well for sustainability of the ART programme in Rwanda. This is because sustainability implies that local funds should grow at a commensurate rate to foreign funds, with a long term view of substantially replacing them.

4.4.2 Estimating the foreign to domestic resources ratio using economic costs

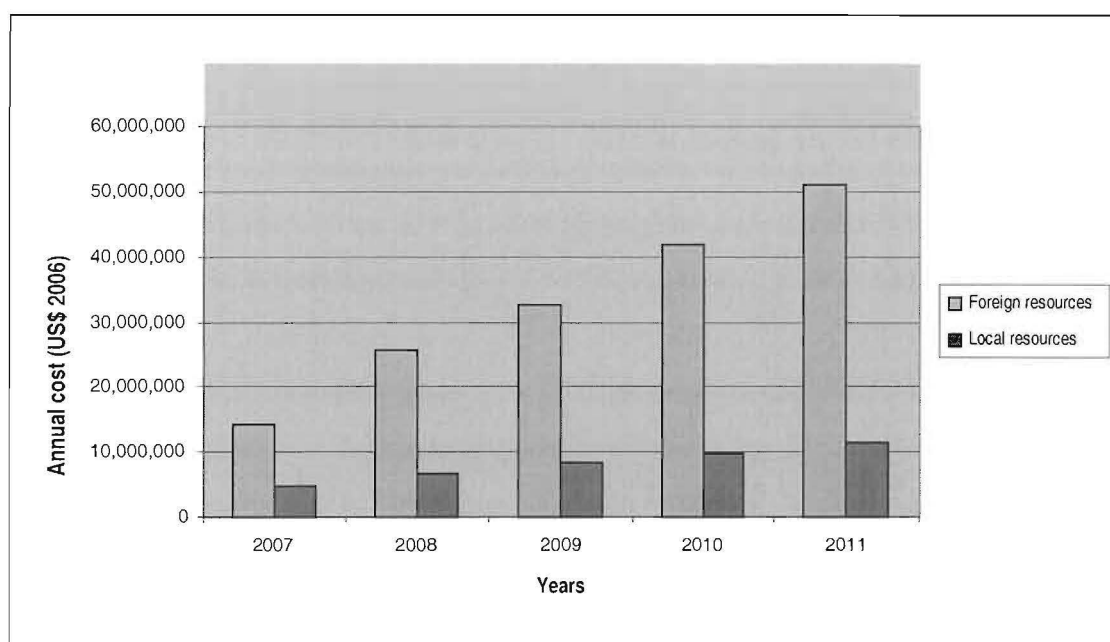
Previous estimates of the foreign aid to domestic resource ratio for HIV/AIDS resources have been based on financial costs and more often than not partial financial

costs (De and Dmytraczenko, 2006; UNAIDS, 2006b). Based on the results of this study the ratio of foreign aid to domestic resources for the ART programme is estimated using the following assumptions:

1. All patient specific costs (ARVs and labs) are 100% paid for by donor funds 100%, (ignoring 1.4% local funds for ease of calculation).
2. Local funds meet all shared costs (overheads, capital and clinical staff costs).
3. The non-tradable portion of laboratory tests from local funds off-sets foreign funds that pay for some capital and operational costs.
4. No significant outlays from private financing sources (households, private employers and insurance) on ART services. Only CHUK and King Faycal Hospital charge patients a subsidised user-fee of US\$18 per family per month (section 4.1.4.2 above) for ARVs and a full amount for laboratory tests. Public funds pay for 98.6% of total cost towards purchase of ARVs, and commodities and consumables for labs.

Using the results of the baseline scenario, the undiscounted patient specific costs in 2007 would amount to US\$19 million out of which US\$4.8 million would be shared costs. This translates into a domestic to foreign aid ratio of 1 to 4 or 20% to 80%. By 2011 this ratio will have grown to 1 to 5 assuming current trend continues. This means that one local dollar will be complemented by 5 foreign United States Dollars. Figure 8 shows the projected growth in ART funding from foreign and domestic resources over the scaling up period

Figure 8: Projected growth in ART costs by source



4.4.3 Estimating the number of clinical staff for ART scale up

Using the results of the cost analysis the number of clinical staff required for scaling up ART in Rwanda was estimated using the following assumptions:

1. For every one doctor three nurses and one counsellor would be required for an ART unit. The counsellor would earn the same salary as a nurse.
2. All doctors would be non-specialists (GPs) and earn a similar salary.
3. The annual salary for a GP is US\$9,690, nurse or counsellor at scale A1 is US\$5,331. It is also assumed that there will be no salary increase in real terms over the period of scale up.
4. An allocation ratio or annual salary split between the doctors, nurses/counsellor is estimated as follows: total annual salary = $(9690 + 5,331 \times 4) = \text{US}\$31,013$. Proportion of total salary that is paid to a doctor = $9690/31,013 = 0.31$. Proportion of total salary that is paid to 3 nurses and 1 counsellor = $21,324/31,013 = 0.69$.
5. Finally, it is assumed that clinical staff will spend 6 hours in direct contact with ART patients and the remaining 2 hours on other duties like

administration and training. This allows for calculation of full-time-equivalent (FTE) staffing for ART.

From these assumptions the total number of clinical staff required to scale up ART is calculated as shown in Table 31.

Table 31: Projected number of clinical staff for ART scale up

Item	Year				
	2007	2008	2009	2010	2011
Annual salary per GP (X)	9,690	9,690	9,690	9,690	9,690
Annual salary per nurse or counsellor: scale A1 (Y)	5,331	5,331	5,331	5,331	5,331
Total clinical staff costs	2,817,554	3,880,214	4,872,970	5,833,502	6,766,349
Allocation base for doctors	0.31	0.31	0.31	0.31	0.31
Total salary allocated to doctors (P)	880,379	1,212,421	1,522,620	1,822,750	2,114,229
Allocation base for nurses and counsellors	0.69	0.69	0.69	0.69	0.69
Total salary allocated to nurses & counsellors (Q)	1,937,174	2,667,793	3,350,351	4,010,753	4,652,120
Number of FTE doctors: $(P \div X) \times 0.75$	68	94	118	141	164
Number of FTE nurses; scale A1: $((Q \div Y) \times 0.75) \times 0.75$	68	94	118	141	164
Number of FTE counsellors scale A1: $((Q \div Y) \times 0.75) \times 0.25$	204	282	354	423	491

Keeping other things constant, the required number of FTE doctors in 2007 is 68 and would have increased to 164 by 2011. The number for counsellors is similar to that of doctors. For nurses the respective numbers are 204 in 2007 and 491 in 2011. Currently the total number of doctors in public and quasi-public institutions is 204, leaving 465 posts unfilled or 70% (Ministry of Health, 2006). If the number of doctors in Rwanda were to remain unchanged, ART scale up would consume up to 80% of all consultation time by 2011.

Furth *et al.* (2006) estimated that 126 full-time-equivalent GPs would be required for scaling up ART in Rwanda to 100,000 patients, which is equivalent to 794 patients per doctor. This estimate was arrived at by assuming that total annual ART visits per patient is 6. ART outpatient consultation time was determined to be 14 minutes by timing consultations at 20 ART locations. This is lower than 18.53 minutes in South Africa (Cleary *et al.* 2004) because level of monitoring is higher as shown already.

Since the numbers of patients are different these results can be better compared using the workload or number of patients per doctor as shown below:

Table 32: Number of ART patients per doctor by year

Item	Year				
	2007	2008	2009	2010	2011
Total number of patients in care (X)	54,082	75,910	97,087	117,516	137,278
Total number of doctors (Y)	68	94	118	141	164
Number of patients per doctor (X/Y)	795	808	823	833	837

With fewer patients these results are similar but as the number of patients increase they differ because of a multiplier effect. The multiplier effect is the estimated number of annual ART visits per patient, which was estimated to be 8 in this study and 6 in Furth et al. When results are calculated using the consultation time method and assuming 6 visits per patient per year they are identical. Secondly, as time on ART increases more patients transition to Markov states III to V thus requiring more visits/costs.

Whichever scenario is used to predict the total number of doctors required for ART scale up, the results show that there are serious implications for the health system as a whole because other services could be crowded out. Firstly, even the 204 doctors are mal-distributed, 97% are located in hospitals, but worse still 50% are in the 5 tertiary hospitals (including 1 neuropsychiatry hospital). Since it takes up to 7 years to fully train a doctor, domestic supply is unlikely to keep up with the increasing demand of scaling up. Government recognised the acute shortage of human resources for health particularly doctors, 1/50,000, pharmacists, 1/125,000 and laboratory technicians 1/40,000 per inhabitants (Furth *et al.* 2006). Consequently, nurses have been and continue to be trained to administer ART services in various health centres that have no doctors. They are also being trained to offer counselling and dispensing of ARVs. To attract and retain clinical staff and redress the current mal-distribution Government has revised salaries for medical personnel to reduce the gap between private and public sector scales.

All interviewees agreed that in the short and medium term ART is not sustainable in Rwanda but pointed out that a number of strategies are being pursued. Though specific policy documents are still on the drawing board, most key informants pointed to the following objectives. Government is committed to increase the share of health from 7.5% to 12% of GDP by 2009 and to 15% by 2015 so as to meet the millennium development goals (MDGs), the Abuja Accord and the Lusaka Declaration. This figure was 3.7% in 2002, way below the Sub-Saharan Africa average of 6%. Government is also committed to increase the money spent on each person per year from \$8.25 (average dollar rate) to \$16 by 2009. As a way of redressing regressivity in health care financing and inequalities in access to health care, Government is committed to operationalise a risk equalisation fund, by 2007. This will be capitalised by a vote from the central budget, social health insurance, military medical insurance and community based health insurance. Re-allocations from the fund to insurers/facilities will be guided by a prescribed minimum package, membership and risk profiles of each insured population. Community based health insurance will be grown from 12% to 50% of the entire population by 2009. This way Government will reduce the impact of out-of-pocket expenditure on households at the time of seeking medical care.

Government hopes to finance these objectives through the following mechanisms:

1. Creation of a national health insurance, explained above
2. Cost cutting: Government has implement a number of cost cutting measures that have included reducing the size of public service, selling off all government owned cars and government owned business and reduced spending on many other non-essential services like the military. These savings are said to be redirect to social sectors. No exact figures of how much has been redirected to health, especially ART could be obtained from the interviews who espoused these ideas.
3. Direct savings from HIPIC initiative, totalling US\$32 million annually to social sectors (education, health, water and income generating activities for poor households)
4. Ask development partners to translate short term aid into long term aid to reduce impact of volatility in aid and to enhance planning and budgeting.

Through sector wide approaches (SWAps) finance gaps in social sectors and infrastructure development.

5. Maximise the impact of aid by channelling it through EDPRS: –Economic Development and Poverty Reduction Strategy instead of parallel projects. EDPRS is Rwanda's PRS phase III.

When interviewees were asked about short falls in financing ART, particularly if a major donor absconded in the short or medium term, the following answers were provided:

1. Insurance schemes have been asked to build reserves to meet sudden short falls in financing,
2. Development partners have been asked to be prepared for such eventualities,
3. Be optimistic and hope otherwise.

4.4.4. Summary of key findings

The cost of providing ART to over 137,000 adults in Rwanda by 2011 will exceed \$62 million per annum not counting the cost of other ART interventions and HIV/AIDS prevention and mitigation. This is higher than the total budgetary allocation to the Ministry of Health in 2005/2006 which amounted to US\$55.8 million. In terms of human resources, 164 FTE doctors will be required, equivalent to 80% of the current workforce. Although the overall budgetary allocation to health has been increasing, especially for the HIV/AIDS sub-account, it is unlikely to keep up with the pace of increase in total resource requirements for maintaining the scaled up ART programme. Secondly, while foreign aid increased by 50% between 2005 and 2007, domestic inflows to health plummeted by 40%. This widening of the foreign aid to domestic resources gap means that health care financing is less sustainable today than it was in 2005.

Given current levels of poverty and human resource constraints the ability to substantially increase the total resource envelope for health from local sources is very limited. There is a real risk of ART crowding out other services unless careful planning is given to human resources. For the foreseeable future sustainability of ART

in Rwanda will only be possible if partners continue to hoist the mantra of matching financial resources with the increasing costs of ART.

Chapter 5: Discussion

5.0. Introduction

This chapter discusses the key findings of the study in light of existing literature, limitations and key uncertainties. It examines whether the results are in agreement or disagreement with similar studies, the plausibility of the findings in terms of empirical evidence and the generalisability of the findings to other settings. Section one presents an overview of the methodology used. Section two reviews the key findings at patient and facility level, and section three examines the findings at population level. Section four discusses the findings on financial sustainability and section five explores overall limitations and key uncertainties. Lastly, section six details policy implications and recommendations given the findings of the study.

5.1. Design and scope of cost analysis

A full cost analysis from the provider's perspective was conducted to determine the economic costs of scaling up ART in Rwanda for the period 2007 to 2011. Scaling up was defined in terms of the number of adults initiated on ART during the period. It was assumed that patients would be phased in annually, starting with 27,012 in 2007 to reach a cumulative total of 153,014 patients by 2011. Given time and resource constraints the study limited itself to the costs associated with provision of ART to adult outpatients during clinic visits. Therefore costs for hospitalisation, treatment and prophylaxis of opportunistic infections, home-based care, and palliative care, ART for children, post exposure prophylaxis and PMTCT were excluded. Given the provider's perspective, the study excluded direct non-health care costs such as household costs arising from transport to and from the health facilities and indirect costs such as productivity losses.

Patient specific costs (ARVs and laboratory monitoring tests) were assessed as a cost per patient period while shared costs (overheads, clinical staff capital) were calculated in terms of a cost per visit.

These unit costs were fed into the CT model to project the costs of scaling up. Output from the model was combined with key informant interviews and desktop research to explore the financial sustainability of ART in Rwanda.

5.2. Key findings at patient-level

5.2.1. Unit costs for patient specific costs

The cost of ARVs for Markov state I was estimated to be US\$100, which corresponded to the first 6 months of treatment with first-line regimen. Thereafter the weighted average annual cost increased to US\$212, as patients switched single ARVs within the first-line regimen due to side effects. This period corresponded to Markov state II. When the patient made transitions to Markov state III, which corresponded to the first six months on the second-line regimen, the cost increased to US\$657. This increase was expected given the cost of second-line regimens. Annual cost for Markov state IV averaged US\$1,177. This 10% drop in cost per-patient period (compared to the cost of the first six months on second-line) is explained by the first choice of second-line ARV regimen in Rwanda. The national guidelines recommend didanosine, abacavir and lopinavir/ritonavir as the first choice second-line regimen and then a switch to lamivudine, zidovudine and lopinavir/ritonavir or lamivudine, tenofovir and lopinavir/ritonavir in case of toxicity to didanosine/stavudine. The cost of ARVs in Markov state V (the failing state) was US\$560 per annum, in this state only 80% of the patients were assumed to be maintained on their failing regimens.

The costs of ARVs increased over the scaling-up period, as would be expected from theoretical and empirical evidence. It is known that first-line regimens are much less expensive than second line regimens (World Health Organisation, 2006c; *Médecins sans Frontières*, 2006). It is also known that the longer the duration of treatment the higher the chances of developing side effects, consequently patients switch ARVs within regimens (Cleary *et al.* 2006). The switch is more often associated with being put on a more expensive drug. With time toxicities or resistance to first line ARVs develop and patients are allowed to transition to the second-line regimen. The earlier cycle is again repeated of switching drugs leading to changes in unit costs. Finally

virological failure sets in and patients transition to Markov state V which again is associated with a different cost structure.

These findings were comparable to collated costs and prices of ARV regimens quoted for different pharmaceutical companies by Médecins sans Frontières (2006) and World Health Organisation (2006c) from different countries. They were also comparable to findings by Cleary et al. (2005) and National Department of Health (2007), not in terms of magnitude but in terms of behaviour of costs over time. Given the current practice of coordinated procurement and distribution system, the results are generalisable to all facilities in Rwanda during the scale up. To increase this degree of generalisability during scale up national treatment guidelines were adopted and the split between regimens was weighted and adapted to the guidelines but also compared to secondary data.

The degree of generalisability to other settings in the region is affected by a number of factors. Chief among these include existing patent protection agreements pertaining to TRIPS (Trade-Related Aspects of Intellectual Property Rights), bilateral pricing arrangements that particular countries have with different pharmaceutical companies and the degree of competitiveness of generic manufacturers in a given country. For instance Médecins sans Frontières (2006) quotes a figure of US\$144 as the average weighted price in low income countries for a fixed-dose-combination of lamivudine/stavudine/nevirapine in 2005 prices. But this price can not be applied to Kenya, Malawi, Uganda, Zambia, Zimbabwe and most of Francophone Africa because nevirapine is still under patent in these countries (Médecins sans Frontières, 2006). World Health Organisation (2006c) quotes the same price from data as of June 2006 at US\$142. Differences also arise from import duties, handling, storage and distribution charges. For instance in Rwanda the price quoted for the regimen (September 2006 prices) was US\$91. When markup for handling, storage and distribution charges was added the cost increased to US\$97.42.

Another source of variation in per-period unit costs arises from the proportion of patients on alternative first and second line regimens. These alternative regimens have different costs again. For instance the annual price of a fixed-dose-combination of lamivudine/zidovudine/nevirapine is quoted at US\$380 from data as of June 2006 by

World Health Organisation (2006c). In Rwanda, the annualised cost for the regimen in 2006 prices is US\$178 or US\$191 (including mark up for handling, transport and storage). Data from the three sites in Table 4 has shown that 15.6% of all patients were receiving this regimen (combined total for Markov states I and II). Considering that it costs 2 times more than the cost of the traditional first line regimen, then the higher the proportion of patients receiving it the higher the unit cost for Markov states I and II. Likewise patients with co-infection with tuberculosis are switched to efavirenz instead of nevirapine which is also more expensive (US\$330). Therefore generalisability to different settings of the unit costs will again be dictated by the proportion of patients on alternative regimens. In Rwanda the nevirapine efavirenz split is 7 to 3, while stavudine to zidovudine split is 9 to 1 in the first 6 months. In Cleary *et al.* (2005) these splits were 6 to 4 and 19 to 1 respectively. These proportions change with time as side effects and toxic reactions set in. They are also influenced by disease stage at initiation of ART.

Monitoring laboratory tests were also determined per-patient period, compared to and aligned with national guidelines to allow for generalisability to all facilities that will be scaling up ART in Rwanda. From Table 22 the unit cost for the first 6 months is US\$45, or US\$90 per annum, then it decreases by 71% to US\$26 per annum. Biological and virological monitoring is highest in the first 6 months (Markov state I) as a patient is initiated on treatment. This intensity reduces as the patient becomes adherent to treatment during the next Markov state. There is another upsurge in unit costs as patients fail the first-line regimen and transition to the second-line. The unit cost increases to US\$57 per 6 months or US\$114 per year in Markov state III (the first six months on second-line) and then evens out at US\$48 per annum in Markov states IV and V. These findings concur with inherent assumptions which are based on known and modelled treatment outcomes of ART. For example it was assumed that patients who have clinically progressed (Markov state V) would continue to be monitored at the same rate as those in Markov state IV. Also assumed was once a year viral load testing for patients on second-line treatment (Markov state III-V). This was necessary because of increased need for pharmacovigilance as patients are maintained on treatment over the long term.

The findings for Markov state I and II are similar to findings by Kyomuhangi (2004) and Cleary *et al.* (2005), not in magnitude but at least in behaviour of costs. But they differ from each other in the Markov states III to V. This is partly explained by exclusion of routine viral load testing in Rwanda. Nevertheless this dissertation included one test for patients on second-line regimen. This is different from the other two studies where viral load test is done at the beginning and more than once. In both studies viral load testing was done at initiation of ART and twice in Markov state II in the South African cohort. Because the cost of viral load testing completely dominates the cost of other lab tests (even their combined sum) this reversal and decrease in number of tests performed explains the observed differences. Also in both studies more tests (number and frequency) were done, for example cholesterol and triglycerides were not routinely tested in the Rwandan cohort unlike in the South African and Ugandan studies.

Other considerations include changes in prices of input factors such as the cost of viral load testing reagents and differences in cost of labour. For instance in Cleary *et al.* (2005), set in South Africa, the cost of a single viral load test was quoted at US\$40 in 2003/2004 prices and in Kyomuhangi (2004), Uganda, it was US\$76.92 in 2003 prices. This cost in Rwanda was found to be much lower, at US\$25.8 per test in 2006 prices. This difference is too big to be explained by differences in the cost of the non-tradable component alone but also falling prices for the tradable component.

In conclusion the unit costs for monitoring laboratory tests can be readily generalised to other settings in Rwanda but in other settings consideration should be given to extenuating circumstances.

5.2.2. Shared costs

Shared costs include the cost of capital, overheads and clinical staff. They were determined from health care utilisation and cost of quantities consumed at the three ART sites. Unlike patient specific costs these were determined per clinic visit and combined into a comprehensive unit cost per clinic visit. In other words how much capital, overheads or clinical staff time is consumed during each ART visit?

Capital costs per visit were calculated to be US\$2.99 for CHUK, US\$1.41 for Ruhengeri hospital and US\$2.38 for TRAC Clinic. As explained in chapter 4, section 4.1.4 the differences were mainly due to differential access to resources. This was expected given the cost structure of a teaching and national reference hospital, a district hospital and pilot/research centre. The average capital cost per clinic visit was calculated to be US\$2.26 for the three sites. This accounted for 23% of the comprehensive unit cost per clinic visit.

The overhead costs per clinic visit were calculated to be US\$1.32 for CHUK, US\$0.64 for Ruhengeri hospital and US\$3.43 for TRAC Clinic. Again Ruhengeri had the lowest overhead cost per visit, being 2 times cheaper than CHUK and 5 times cheaper than TRAC. The unit cost per visit at TRAC was unexpectedly high - even when compared to CHUK it was 2.6 times higher. A re-examination of cost structures showed that the ART unit at TRAC is better resourced than the other two sites. For instance the site has a total of 11 computers compared to only 2 computers for CHUK Clinique and one for Ruhengeri. TRAC clinic also had a photocopier whereas none of the other two sites had one. Although these are capital equipment, the need for upkeep and maintenance also has implications for running costs. TRAC clinic also runs 2 adherence home visits per week compared to none for CHUK and one for Ruhengeri again incurring more overhead costs per patient in terms of transport and per-diems or field visit allowances. The average overhead cost per clinic visit was calculated to be US\$1.80 for the three sites. This accounted for 18% of the comprehensive unit cost per clinic visit.

Clinical staff costs included the cost of time spent directly with patients by doctors, nurses, counsellors and phlebotomists. Other staff, such as pharmacists, administrators, data clerks, accountants/cashiers, etc, were included in overhead costs. The amount of time spent directly with patients by each cadre was determined through interviews. The clinical staff cost per clinic visit was calculated to be US\$7.14 for CHUK, US\$3.27 for Ruhengeri hospital and US\$6.79 for TRAC Clinic. Again Ruhengeri had the lowest clinic staff cost per visit, being 2 times cheaper than CHUK and TRAC. Findings (Table 16) show that Ruhengeri has 6 staff, CHUK 9 and TRAC 21. Considering the work load at each site in terms of number of patients per clinical staff (157 for Ruhengeri, 66 for CHUK, and 85 for TRAC) it can be adduced that

Ruhengeri is under resourced compared to the other 2 sites. As such staff spent less time per patient hence a lower cost per clinic visit. Additionally, clinical staff costs are higher at CHUK because only specialist doctors (physicians) see patients. TRAC had nursing staff with higher qualifications compared to the other sites (Table 16).

These differences again are attributable to differential roles and access to resources by each site. The teaching hospital and the research centre are able to garner adequate resources per capita compared to the district hospital which is less capable than the other two and hence it is relatively under funded. The average clinical staff cost per visit was calculated to be US\$5.73 for the three sites. This accounted for 59% of the comprehensive cost per clinic visit.

5.2.2.1. The comprehensive cost per clinic visit

Overall the comprehensive cost per clinic visit at the three sites (Table 17) was found to be US\$11.45 at CHUK, US\$5.32 at Ruhengeri and US\$12.6 at TRAC clinic. As expected the cost at the teaching hospital is higher than at the district hospital. The cost per visit at the pilot/research centre was also expected to be high and was found to be even marginally higher than that of the teaching hospital.

The comprehensive average cost per clinic visit was calculated to be about US\$9.79 per visit. It is not weighted for facility type nor does it take into consideration the differences in risk profiles of the three cohorts of patients. As already discussed in section 4.1.4.4 of chapter 4, it is comparable to the estimates of World Health Organisation (2003) using 2000 United States Dollars after adjusting for increased input factor prices.

In comparison to other studies, the figure was lower than the Rand 146 (in 2006 prices), equivalent to US\$21, found in South Africa and much higher than 17.34 Maloti (2006) equivalent to US\$2.6 for a rural district hospital in Lesotho (National Department of Health, 2007; University of Cape Town, Ministry of Health & Social Welfare, Kingdom of Lesotho, Médecins Sans Frontières & Scott Hospital Health Service Area, 2007). However, differences in cost structure, purchasing power parity

and level of detail in costs considered could all account for this variation other than threats from internal validity or imprecision in the estimate for Rwanda.

The composition of the comprehensive average cost per ART clinic visit was found to be made of 59% clinical staff costs, 23% capital costs and 18% overhead costs. These proportions are similar to those found in Uganda (Kyomuhangi, 2004) which showed that clinical staff costs contributed 48%, capital 31% and overhead costs 21%.

The comprehensive cost per clinic visit was combined with the number of visits per Markov period to calculate the cost per Markov state. This necessitated determining the number of visit per patient per Markov period/state. These were found to be 10 during Markov state I and 7 for Markov state II. This is again expected given the intensity of patient monitoring in those states. The number for Markov state III (first 6 months of second-line regimen) again increased to 8 visits per period. The visits were assumed to stabilise at 8 visits per annum in the remaining Markov states.

The number of visits per period was lower than that determined by Cleary et al. (2005) in South Africa - 17.1 for Markov state (I), 10.6 for Markov state (II), 5.3 for Markov state (III), 10.6 for Markov state IV and 14.5 for Markov state V. These variations can be attributed to the difference in levels of monitoring and care that is already sited above in regard to laboratory testing. There were also a significant number of visits attributable to the nutritional programme which is still infantile in Rwanda. Per period consultation costs were calculated to be US\$98 during the first 6 months on first-line ART, US\$69 annually thereafter, US\$78 during the first 6 months of second-line ART, US\$73 annually thereafter and US\$73 during Markov state V. This structure of costs has already been explained above.

5.3. Key findings at population-level

5.3.1. Target population

Because the objective of the study was to cost the ART scale up plan/policy, the number of adults entering ART care in each year of scale up was taken from targets in policy documents. The number of people entering ART care is projected to increase

from 27,012 in the base year to 34,110 by 2011, giving a cumulative total of 153,014. After accounting for death and loss to follow-up, the total number of patients remaining in care by 2011 was estimated to be 137,278. Given the age of the study cohort of roughly 24 months on ART, it was necessary to use survival assumptions from secondary data sources. Life expectancy on ART, transition probabilities and time spent on first and second-line regimens by patients were taken from the CT model (Boulle *et al.* 2004) and Cleary *et al.* (2006).

The model assumes that the proportion of patients remaining in care was 88.5% after 6 months, 72.4% after 36 months and 47.5% after 78 months. The proportion that had switched to the second-line regimen was 6%, 15.1% and 12.6%. The proportion that would have been lost to follow-up or died at the end of 6.5 years was 52.5%. In absolute numbers the figures for first-line, second-line and clinically progressed were 48,164, 4,559 and 1,358 respectively during 2007, increasing to 99,527, 24,878 and 12,872 respectively by 2011. The percentage changes in these numbers over the scale up period were 277% for first-line, 546% for second-line and 948% for clinically progressed.

The sharp increase in the proportion of patients on second-line regimen and clinically progressed is related to the proportion of patients starting ART with CD4<50 cells/ μ l, the level of adherence and the overall assumed survival on ART of 6.5 years (chapter 2, section 2.3.2.1). If survival is higher than the 6.5 years, as a number of studies seem to suggest (Badri *et al.* 2006; Cleary *et al.* 2006; Etard *et al.* 2006), then the cost of scaling up could be over-estimated during the period under consideration in this study, although ultimately costs would be underestimated over longer time frames. It has been shown (National Department of Health, 2007) that the CT Model calculates a cost of scaling-up that is 6% higher than a model with an assumed life expectancy of approximately 10 years if one considers costs over a five-year time frame in the South African National Strategic Plan for HIV and AIDS. The reason for this is that if life-expectancy is shorter, patients would be switched to the second-line regimen more quickly. This over estimate of costs is of course only in the short run because in the long run patients will still switch to the second-line regimen and incur higher costs as they continue to survive in commensurate proportions. Until the question of

effectiveness of ART in resource poor settings is resolved this will remain an area of uncertainty in studies on the costs of scaling up.

5.3.2. Patient specific costs

Undiscounted total cost of ARVs was estimated at about US\$12 million in 2007 and increased sharply thereafter to top US\$45.5 million by 2011. The proportional annual increase in costs over 2007 is 187%, 237%, 308% and 376% from 2008 to 2011 respectively. This rapid acceleration in costs is related to survival assumptions discussed above. Holding other things constant, the 5-year cumulative cost of ARVs was estimated at US\$146.4 million while the corresponding cost towards scaling up was US\$134.3 million (the cost from 2008-2011). The undiscounted total cost of associated laboratory monitoring tests was estimated at roughly US\$2 million in 2007 and would have increased to US\$5.4 million by 2011. The undiscounted patient specific costs were found to increase from a modest sum of US\$14 million in 2007 to roughly US\$165 million over the five-year period. The corresponding amount for scaling up was estimated to exceed US\$151 million between 2008 and 2011.

5.3.3. Shared costs

The undiscounted overhead costs were roughly US\$0.9 million in 2007 and increased to US\$2 million by 2011. The projected costs over the scaling up period for overheads, capital and clinical staff costs are highlighted in Table 24. Undiscounted clinical staff costs increased from US\$2.8 to US\$6.8 million, whereas capital costs grew from US\$1.1 to US\$2.6 million during the same period. Holding other things constant, the undiscounted 5-year cumulative cost of capital, overheads and clinical staff was estimated at US\$41 million while the corresponding cost towards scaling up was US\$36 million.

5.3.4. Costs of scaling up

If the number of adults on ART in Rwanda is to increase from 54,082 in 2007 to 137,278 by 2011, the estimated undiscounted cost will be US\$206 million. When discounted at 3%, the cost reduces to US\$192 million and US\$183 million when discounted at 5%.

Assuming that costs in the base year are already covered, the total undiscounted costs for scaling up are US\$187 million, while the corresponding discounted costs are US\$173 and US\$164 million respectively. The percentage composition of these costs is 70% ARVs, 12% clinical staff, 9% monitoring laboratory tests and 4% overheads. It is not possible to compare the magnitude of these costs to other studies because that depends on the number of people being treated. However, comparison is possible at unit cost level, which has been done in the preceding section.

It is also possible to compare the percentage contribution by category mix to the total costs. These should be correlated within a reasonable margin. The percentage composition of the total cost is similar to that in per-period patient costs, which have been discussed above. Most studies agree that ARVs take the largest share ranging from 33% to 77% (Rosen and Long 2006). This wide range is accounted for by methodological differences and level of detail of cost included in each study. Though studies done before 2005 show that laboratory monitoring tests contributed the second largest share of total costs, this trend is changing in later studies because the cost of and number of viral load tests has significantly reduced in resource poor settings. Thus personnel costs are the next largest contributor to total cost, except when costing the entire HIV/AIDS programme this may be eclipsed by overheads (Cleary *et al.* 2006).

5.3.5. Lifetime costs

The undiscounted lifetime costs of providing ART to an adult in Rwanda was determined to be US\$4,815. At an average of 6.5 years of life expectancy, this implied that the annual undiscounted cost of providing ART to an adult outpatient is US\$741. This estimate was found to fall within the range of previous estimates at between US\$396 and US\$2,761 (Rosen and Long, 2006). The reason this estimate is in the lower range is due to exclusion of costs of hospitalisation and treatment of opportunistic infections. It also excludes home based and palliative care. Discounted lifetime costs were determined to be US\$4,440 and US\$4,221 at discount rates of 3% and 5% respectively.

5.4. Financial sustainability

There are two opposing views concerning the definition of financial sustainability. One view emphasises the use of national resources and capacity (Knowles et al, 1997; McPake and Kutzin, 1997) while the other view considers all resources whether internal or external (The Global Alliance for Vaccines and Immunization, 2003; Bossert, 2004). However, both schools hold that sustainability is a continuous process that takes time to plan for, evaluate, and build. Very few developing countries' health systems ever become completely self-supporting but instead trudge along an endless continuum of supply of health care chasing the ever growing demand and/or need for health care. Nevertheless, even if financial sustainability is difficult to achieve given the magnitude of HIV/AIDS and resource constraints faced by low income countries like Rwanda, this dissertation holds that financial sustainability is critical for delivering free and universal access to ART. This is because foreign aid is usually too volatile to allow for sufficient planning and budgeting. Besides donor fatigue, there are often changes in the prevailing economic, political and social conditions of donor countries. As already said, one could cite the example of the President's Emergency Plan for AIDS Relief (PEPFAR), no one can say for sure what the future funding levels will be given the recent political changes in the American Senate.

Unless Rwanda has contingency plans to immediately compensate for any fluctuations in foreign aid or even replace it with local resources, interruptions in capacity to deliver ART could result. This interruption in treatment or lack of capacity to judiciously monitor and foster patient adherence would fuel resistance and escalate costs as patients are quickly switched to second-line regimens. Escalating costs would then further reduce access to treatment and sustainability. Therefore, financial sustainability was viewed as a programme's continuing ability to effectively deliver services after the donor's technical, managerial and financial support has significantly decreased. In other words once donor resources have significantly reduced, ART delivery will depend on the continued ability to locally raise sufficient financial and human resources. Human resources are included here because sustainability of ART programmes should be viewed in the broader light of a health system. This is because when viewed as a stand alone programme ART might look financially sustainable

while crowding out other health interventions, in particular by using up the available human resources.

To gauge the financial sustainability of the ART programme in Rwanda, the analysis examined the ability of the country to raise resources (revenue and clinical staff) and the allocation of those resources to the Ministry of Health, the HIV/AIDS programme and finally to ART. The domestic revenue to foreign aid ratio was determined using financial and economic costs. The results of the analysis were also used to predict the number of clinical staff required for scale up.

Considering Rwanda's macroeconomic indicators explored in chapter 1, the country's ability to raise local revenue especially from taxes is seriously constrained. In 2006 the nominal gross domestic product (GDP) was US\$2.1 billions; spread over a total population of 8.2 million people translates into a GDP per capita of \$256. Government revenue from taxes amounted to 15% of GDP (Ministry of Finance and Economic Planning, 2007). Income inequalities mean that the tax base is even narrower as 83% of the population is living on less than 2 dollars per day (UNAIDS, 2006a). This means that the majority of households cannot afford the current annual cost of US\$741 for ART even if this cost were to be reduced to US\$1 a day. This finding is in agreement with previous studies (Bossert, 2004).

With total annual ART costs growing from US\$19 million in 2007 to US\$62.5 million by 2011, this is equivalent to an annual growth in cost of 57% or 35% year-on-year (compounded) growth rate. Such a large growth in costs could not be financed by the growth in GDP alone. It will therefore require devising innovative health care financing mechanisms to make ART scale up sustainable.

The proportion of the total health care resource envelope financed by local government revenue is crucial for financial sustainability (Knowles, et al, 1997). The total health care resource envelope allocated to Ministry of Health from public revenue in the financial year 2006/2007 was approximately US\$73.5 million (Table 30). This was out of the total government budget of approximately US\$938.3 million or 7.8%. Of the total health care resource envelope, only 2.3% was to be raised locally while 97.7% was to be raised from foreign resources (Ministry of Finance and

Economic Planning, 2007). The total budgetary allocations to Ministry of Health grew from US\$50.1 in 2005 to US\$73.5 million by 2007, which is equivalent to an increase of 46.7%. Nonetheless, this growth was accounted for by growth in external resources. During the same period budgetary allocations from domestic resources actually fell by 40% while foreign funds grew by 50%. This finding does not augur well for sustainability of the ART programme in Rwanda. If domestic funds had not been withdrawn but instead maintained or better still increased to match the growth in foreign funds then the health system would be more financially sustainable today.

The most recent expenditure tracking of financing sources for HIV/AIDS in Rwanda was done in 2005 by UNAIDS (2006b). The report shows that US\$78 million was spent in 2005 on HIV/AIDS activities (Figure 7). Government contribution was estimated at 2% while the balance of 98% was donor contribution. However, the government estimate is partial because it does not include running costs for facilities. Of the donor funds PEPFAR contributed 59%, the Multi-country AIDS Program 12%, the Global Fund 10%, the United Nations' System 10% and bilateral donors 5%.

The specific financing sources for ART, according to Ms Hakizinka Ida, Permanent Secretary of the Country Coordinating Mechanism are Global Fund, PEPFAR and MAP (Table 29). The combined commitment of US\$243.4 million from Global Fund and PEPFAR is expected to cover nearly all patient specific costs of scaling up ART until 2010. These findings were corroborated by data from CAMERWA which showed that the three organisations met 97.4% of the total cost for all ARVs, laboratory tests and their consumables purchased in 2006. The respective contributions to the total costs were 51.46% by PEPFAR, 45.94% by GF/MAP, 1.2% by Médecins sans Frontières (MSF) and 1.4% by others (mainly private employers).

The results of the cost analysis were used to estimate the domestic to foreign aid ratio in terms of economic costs. It was estimated that 98.6% of ART was funded from public sources, of which domestic revenue funded the shared costs (capital, overheads and clinical staff) and foreign revenue funded the patient specific costs. From this finding it was determined that the domestic to foreign aid ratio is 1 local dollar to 4 foreign United States Dollars or 20% to 80% in 2007. If current trends were to continue then the ratio would rise to 1 to 5 or 17% to 83% by 2011. We can therefore

conclude that taxes are financing 20% of the total cost ART and 80% is financed by foreign resources. This result is much bigger than the previous ratios based on financial costs, which is expected.

The total number of doctors in the public and the quasi-public sector is 204 and there are 465 unfilled posts (Ministry of Health (2006)). The total number of full-time-equivalent (FTE) doctors (GPs) required for scale up was estimated to be 68 in 2007 rising to 164 in 2011. This would consume up to 33% of available physician time in 2007 and 80% in 2011 holding other things constant. A similar number of FTE counsellors (scale A1) was required over the same period. The number of nurses (scale A1) was estimated to be 204 and 491 in 2007 and 2011 respectively. These findings were not different from those of Furth *et al.* (2006) when the annual number of ART visits per patient was taken into consideration.

Considering the human resource deficit in Rwanda and the number required to scale up ART there are serious concerns of ART crowding out other services. Holding other thing constant, by 2011 ART alone would account for 80% of all doctors' consultation time. This would make the ART programme and the health care system unsustainable.

5.5. Limitations and Uncertainties

Given time and financial constraints the study limited itself to costs of scaling up ART in adults from the provider's perspective but excluded the costs of hospitalisation, home-based care, palliative care and treatment and prophylaxis of opportunistic infections. By definition, non-provider costs of transport, waiting times and productivity losses were also excluded. To allow for greater generalisability during scale up utilisation data of 3,310 patients collected from three facilities were compared and aligned to national guidelines. However, this had the effect of reducing the generalisability of results particularly when compared to non-public health sector settings and to studies from countries with different guidelines. Given the time span of the Rwandan cohort on ART, survival assumptions were taken from Boulle *et al.* (2004) and Cleary *et al.* (2006). Thus the study used clinical data on the risk of failing

the first-line regimen (FL) and switching to the second-line regimen (SL), the risk of failing the second-line regimen and finally the risk of death. While these data were taken from secondary sources not specific to Rwanda, this could be argued to increase the generalisability of results.

Even if patient specific costs were considered least likely to be liable to measurement error, ARV prices and costs were compared to Médecins sans Frontières, (2006) and World Health Organization (2006c). To increase the precision of laboratory test cost estimates, the tradable portion was determined from micro-costing and an estimate of the non-tradable portion was added to this total. These results were then used to benchmark the locally available tariffs to choose one that closely approximates the opportunity costs. Sensitivity analysis showed minimal variation in laboratory test costs when the chosen rate was compared to the benchmark.

The cost of ARVs is a key cost driver especially when considering the costs of scaling up ART. The cost of ARVs has been decreasing in the last 5 years. Consequently, the estimates herein have shown significant sensitivity to changes in prices of ARVs and currency crises. Sensitivity analysis showed significant variations in total cost in response to fluctuations in exchange rate and changes in the price of ARVs or choice of second-line ARV regimens.

Adherence to treatment, nutritional and emotional support and the characteristics of HIV virus is a key uncertainty. These variables will influence the length of time spent on first and second-line regimens and overall survival on treatment. To some extent this has been accounted for by adopting survival assumptions from secondary data sources which have been largely validated from primary outcomes. The overall split of patients on various regimens during scale up was arrived at by weighting, comparing and aligning the results of the 3,310 patients used in this analysis to the national guidelines.

The comprehensive average cost per clinic visit used was based on health care utilisation and cost data for a tertiary hospital, a district hospital and an ART pilot/research clinic. The calculation of the average cost assumed that the three sampled facilities and their cost structures can be representative of all facilities that

will be involved in the scale up. This assumption did not take into consideration the national policy directions of delivering ART mainly through primary and secondary level health facilities. Though this is not a key cost driver, it introduces a degree of uncertainty. As a way of accounting for this uncertainty, a weighted average cost was constructed (chapter, 4, section 4.3) to investigate the impact on costs if delivery was to be mainly through primary and secondary level structures. Indeed sensitivity analysis showed that this would be associated with a reduction in the cost of up to 8.4%. However, caution should be exercised in interpretation of this difference because results showed that the district hospital had much less resources per ART patient treated compared to the other two facilities. Ruhengeri hospital was unequivocally under resourced in terms of personnel because there were 157 patients per clinical employee compared to 66 at CHUK and 85 at TRAC. Similarly it had less capital and overhead costs per capita.

There is need to acknowledge the quality of cost and utilisation data obtained from routine public settings in resource poor countries. To minimise the degree of uncertainty, costs and quantities, utilisation data and unit costs were compared with secondary data sources, whenever possible alternative opinion from different clinical staff was sought. Locally established norms and guidelines were used to compare and align utilisation data and lastly results were compared to other studies. Overall, one can conclude that these results are in agreement with other costing studies for the categories of costs that have been included in this dissertation.

5.6. Policy implications and recommendations

The study shows that Rwanda has made important strides towards the provision of free and universal access to ART by demonstrating strong political commitment and leadership in mobilising resources. By adopting the “three ones” philosophy of one coordinating authority, one strategic plan and one monitoring and evaluation framework, the country has been able to keep costs in check while meeting the donor’s milestones (UNAIDS, 2006a). In 2006, a total of 13,424 adults were initiated on ART and 49 new ART centres were inaugurated (Treatment and Research AIDS Centre, 2007; *Ministère de la Santé*, 2007). Given current scale up efforts through a

decentralised primary health care approach and use of nurses to deliver ART, the policy will achieve the target of 100,000 patients on ART by early 2010. At this level of scale up, results show that total ART costs will have increased to US\$52 million, which is almost equal to the total budget allocated to Ministry of Health in financial year 2006/2007.

Although donor funding is guaranteed until 2009, no one can say for sure that it will continue to be available let alone grow at the same rate as the growth in ART costs. The study findings have important policy implications and recommendations.

- A specific policy document with measurable benchmarks addressing the financial sustainability of ART programme in Rwanda would be a step in right direction. This would allow for incremental progress to be reviewed after stipulated periods.
- Although resource allocation to the Ministry of Health has been growing rapidly, the growth has been mainly due to rapid increases in foreign aid. What is disturbing in terms of sustainability is the commensurate decrease in domestic outlays during the last 3 years. This could only mean that some form of capping or budgetary sector ceilings are being exercised for purposes of macroeconomic stability. Considering that the latter is an overriding goal for Government and the International Financial Institutions, ART sustainability is placed in a precarious position. There is no easy way around this dilemma, unless Government could create a cross-sector-subsidy, whereby non-essential sectors could absorb the budgetary cuts at the expense of increased funding to Ministry of Health.
- The cost of ARVs, at 70% of the total cost of delivering ART, is clearly the most important cost driver. Sensitivity analysis has shown that this cost is very responsive to small changes in price and choice of individual ARVs in a regimen. Therefore continued leadership in pursuance of access to generic medicines and rebates on bulky purchases will continue to bring down ART costs. Combined with judicious choice of second-line regimens and restricting the use of efavirenz (EFV) to co-management of tuberculosis could reduce ART costs by up to 28%.

This could only be realised if frequent meetings are held to review prescribing practices and national guidelines by policy makers and ART practitioners.

- There is a need to formulate an emergency plan that could cater for any unforeseen short term reductions in financial resources.
- Although government and her partners are committed to providing universal access to ART, the associated growth in costs will be difficult to finance from public funding alone. It is therefore necessary to innovate while operationalising the risk equalisation fund. A specific levy or tax on non-essential commodities, and social health insurance and a sliding scale user-fee could be used to capitalise the risk equalisation fund.

5.6.1. Areas for further research

- The lifetime cost estimate does not include cost of hospitalisation, prophylaxis and treatment of opportunistic infections. It is necessary to undertake a larger study to arrive at a comprehensive unit cost for ART and to determine the associated unit costs for home based care, palliative care and care for children. Studies undertaken from societal and patient perspective are even fewer, yet non-provider costs such as transport and queuing time do impact on access and adherence to treatment.
- Apart from South Africa, there are very few cost analyses in Sub-Saharan Africa to build a body of evidence on country specific costs of scaling up. The majority of the studies estimating resource needs to scale up ART are partial or based on financial costs rendering comparison of results difficult. There is a need to agree and harmonise the methods and detail of cost variables to be treated in country specific studies.
- Monitoring and evaluation instruments in ART programmes need to be harmonised across facilities and jurisdictions to improve quality of data and strengthen health systems data management.

- More outcomes data especially effectiveness of ART in a public setting of low income countries will allow for better prediction of lifetime costs.
- Efficiency studies to address changing unit costs with changes in ART scale up (economies and diseconomies of scale) and changes in unit costs in response to treatment and prophylaxis of opportunistic infections would also allow better prediction of costs of scaling up.

5.7. Conclusion

This study has estimated the cost of scaling up ART in Rwanda from a sample of 3,310 patients. If government scale-up targets are met, a total of 153,014 adults will have been initiated on ART by the end of 2011 out of whom 137,278 are estimated to be surviving and in care. The study is the first to establish the lifetime costs for providing ART in Rwanda at an undiscounted cost of US\$4,815 or US\$4,440 discounted at 3%. Lifetime costs allow for better prediction and budgetary planning of ART delivery. The annual adult cost was calculated to be \$741 (\$683 discounted at 3%). The dissertation has determined that the 5-year cumulative total cost of scaling up is US\$187 million. It has shown that the cost of providing ART to over 137,000 adults in 2011 will exceed US\$62 million, not counting the other costs of prevention, care and mitigation of HIV/AIDS. This cost exceeds the US\$55.8 million allocated to the Ministry of Health in the financial year 2005/2006. ART funding will have to grow at a rate exceeding 50% annually for the next 10 years in order to keep up with the costs of providing care and treatment for the 130,000 patients who will be surviving beyond 2011. It is very unlikely that this growth could be sustained from government taxes alone.

Given that charging user fees is argued to compromise the adherence of patients to their treatment regimens and has negative implications for equitable access, alternative innovative health care financing mechanisms need to be developed to enhance the financial sustainability of ART programmes (Whitehead *et al.* 2001; McIntyre *et al.* 2005; World Health Organisation, 2006b).

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Annexes

Annex A: Consent form for key informants

I agree to participate in the research “**Scaling up ART in Rwanda; analysis of the financial and economic costs**”.

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 do hereby give not give my permission for this interview to proceed and to be taped.

Signed

Date

Annex A2: Request for authorisation to access ART databases

The Director

Dear S/Madam,

My name is Dr. Stephen Karengera; I am a student from the University of Cape Town, Department of Public Health and Family Medicine, Health Economics Unit. I am in Rwanda to collect data for my dissertation, titled “**Scaling up ART in Rwanda; analysis of the financial and economic costs**”, from 15th November 2006 to 31st January 2007. The purpose of this research is to analyse the costs and sustainability of the ART programme. A sub-objective is to examine the fee revenue

associated with this programme and the implications for removing user fees. It is therefore hoped that the study could aid decision making for the ART programme.

Therefore, this is to request for authorisation to access the ART database for the period 2003-2006. Due to ethical reasons no patient names are required for this research but patient codes, duration of treatment, treatment protocols, tests performed, rates of attrition and costs involved would be required.

Yours sincerely,

Dr. Stephen Karengera

Signed

Date

Authorisation approved/denied

Signed

Date

The Director

Annex Q: Questionnaire for key informant interviews

Guiding Questions	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 your current position in your organization?	
How long have you been in this position?	
What are the main sources of funding for scaling up the ART programme; including major donors?	
For how long is each source guaranteed?	
What proportion of the funding is from the GoR? {That is from public budget expenditure}	
What is the time frame for which funding is secured?	
Do you think free universal ART access is sustainable in Rwanda?	

What plan does the government have in case any major donor withdraws financial support?	
How would the government fund the provision of free ART if this happened?	
Which pharmaceutical companies are supplying ARVs to Rwanda?	
Is the programme using generic or patented drugs or a mix of both?	
Is the ART programme getting discounted price for ARVs?	
How is the Procurement done?	
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?	
If no; what are the recruitment plans?	
What plans have been put in place for training staff involved in scaling up ART? Request document	

Who is sponsoring the training?	
Are there any capital development projects for scaling up ART; e.g. build new health centres, buy vehicles or new medical equipment?	
Does the programme have adequate resources for these developments?	

Annex K: List of Key Informants

S/ No	Name	Institution	Responsibility
1	Dr. Agness Binagwaho	National AIDS Control Commission (NACC; CNLS)	National Executive Secretary
2	Rev. Nathan Gasatura	Church of Rwanda; World Vision	Chairman Board of Directors NACC
3	Ms Ida Hakizinka	Country Coordinating Mechanism (CCM); GF/MP	Permanent Secretary CCM; Acting Country Coordinator
4	Dr. Anita Asimwe	TRAC	National Director TRAC
5	Mr. JM Vianney Musonera	CAMERWA	Director of Management of Programme: Bilateral and Multilateral Donors
6	Dr. Sobela Francois	World Health Organisation, Kigali Country Office	Medical Officer: “3by5” Programme
7	Dr. Jules Mugabo	TRAC	Coordinator Care and Treatment TRAC national programme
8	Dr. Claude Sekabaraga	Ministry of Health	Director of Planning and Care and Treatment
9	Dr. Maurice Bucagu	National University of Rwanda	Voting member CCM
10	Dr. Reuben Sahabo	ICAP	Country Coordinator
11	Dr. Luis Mbuguje Kitoko	GF/MP	In-Charge Care and Treatment

Annex C: Allocation of shared costs

SITE: CHUK												
Equipment/furniture												
<u>Administration room</u>	Qty	Proportion (ART use)	Unit cost (Frw FY06)	R-value (Frw FY06)	Allocation (Frw FY06)	Allocation (US\$ FY06)	Useful life (years)	Annuity Factor	AEC		Discount rate:	3.0%
Table (Office)	1.0	0.14	158,756	158,756	21910.17	40.57	3	2.8285	14.3		Exchange Rate	\$ 540
Table (wooden)	1.0	0.14	68,412	68,412	9441.65	17.48	3	2.8285	6.2			
Shelves (glass)	1.0	0.14	172,000	172,000	23738.00	43.95	3	2.8285	15.5			
Telephone (receiver)	1.0	0.14	26,000	26,000	3588.30	6.64	3	2.8285	2.3			
Computer	1.0	1.00	630,300	630,300	630,300	1167.05	3	2.8285	412.6			
UPS	1.0	1.00	147,400	147,400	147400.00	272.92	3	2.8285	96.5			
Extension cable	1.0	1.00	35,000	35,000	35000.00	64.81	3	2.8285	22.9			
Printer	1.0	1.00	245,550	245,550	245550.00	454.65	3	2.8285	160.7			
<u>OPD Reception</u>												
Table (Office)	1.0	0.14	158,756	158,756	21910.17	40.57	3	2.8285	14.3			
Table (wooden)	1.0	0.14	68,412	68,412	9441.65	17.48	3	2.8285	6.2			
Chairs (metallic cushion)	2.0	0.14	56,640	113,280	15633.95	28.95	3	2.8285	10.2			
Chairs (3 seat)	10.0	0.14	246,384	2,463,840	340038.52	629.61	3	2.8285	222.6			
Stool	1.0	0.14	23,370	23,370	3225.33	5.97	3	2.8285	2.1			
Drawer (small wooden)	1.0	0.14	21,000	21,000	2898.24	5.37	3	2.8285	1.9			
<u>Consultation room (Drs)</u>												
Drawer	1.0	0.14	120,364	120,364	16611.63	30.76	3	2.8285	10.9			

Table (Office)	1.0	0.14	158,756	158,756	21910.17	40.57	3	2.8285	14.3				
Chairs (metallic cushion)	2.0	0.14	27,000	54,000	7452.63	13.80	3	2.8285	4.9				
Chairs (3 seat)	2.0	0.14	246,384	492,768	68007.70	125.92	3	2.8285	44.5				
BP machine	1.0	0.14	28,400	28,400	3919.53	7.26	3	2.8285	2.6				
Balance (simple)	1.0	0.14	12,000	12,000	1656.14	3.07	2	1.9135	1.6				
Trolley	2.0	0.14	187,440	374,880	51737.79	95.80	3	2.8285	33.9				
Dustbin	1.0	0.14	8,000	8,000	1104.09	2.04	3	2.8285	0.7				
Examination bed	1.0	0.14	197,000	197,000	27188.29	50.34	5	4.5797	11.0				
Stethoscope	1.0	0.14	15,000	15,000	2070.17	3.83	3	2.8285	1.4				
Screen	1.0	0.14	91,000	91,000	12559.06	23.25	3	2.8285	8.2				
Wooden steps	1.0	0.14	20,500	20,500	2829.24	5.24	3	2.8285	1.9				
<u>Counselling room</u>													
Table (wooden, ord)	1.0	0.95	68,412	68,412	64991.40	120.34	3	2.8285	42.5				
Chairs (metallic cushion)	1.0	0.95	27,000	27,000	25650.00	47.49	3	2.8285	16.8				
Chairs (ord wooden)	1.0	0.95	20,000	20,000	19000.00	35.18	3	2.8285	12.4				
<u>Phlebotomy room</u>													
Table (office)	1.0	0.14	158,756	158,756	21910.17	40.57	3	2.8285	14.3				
Chairs (metallic cushion)	1.0	0.14	56,640	56,640	7816.98	14.47	3	2.8285	5.1				
Chairs (ord wooden)	1.0	0.14	20,000	20,000	2760.23	5.11	3	2.8285	1.8				
Drawer (small)	1.0	0.14	10,000	10,000	1380.12	2.56	3	2.8285	0.9				
Kidney dish	1.0	0.14	87,000	87,000	12007.01	22.23	3	2.8285	7.9				
Tambulu (drum)	1.0	0.14	70,000	70,000	9660.81	17.89	3	2.8285	6.3				
Boite	1.0	0.14	65,000	65,000	8970.75	16.61	3	2.8285	5.9				
<u>Pharmacy (ARV) room</u>													
Shelves (dispensing ARVs only)	1.0	1.00	146,881	146,881	146881.00	271.96	3	2.8285	96.2				
Table (Office)	1.0	0.14	158,756	158,756	21910.17	40.57	3	2.8285	14.3				

Maintenance generator	PDE	723,606	2,269,533	3.14	0.006										
Vehicle hire	PDE	723,606	58,697,495	81	0.15										
Fuel generator	PDE	723,606	1,060,000	1.46	0.003										
Security	PDE	723,606	51,272,004	70.86	0.131										
Cleaning & Gardening	PDE	723,606	28,416,228	39.27	0.073										
Director	PDE	723,606	8,617,980	11.91	0.022										
Admin	PDE	723,606	7,490,769	10.35	0.019										
Pharmacist	PDE	723,606	5,546,044	7.66	0.014										
Head Finance	PDE	723,606	4,261,417	5.89	0.011										
Head Tech Services	PDE	723,606	3,261,417	4.51	0.008										
Head Logistics	PDE	723,606	3,261,417	4.51	0.008										
Laundry	PDE	723,606	1,182,812	1.63	0.003										
HRM	PDE	723,606	4,261,417	5.89	0.011										
Principle Cashier	PDE	723,606	4,261,417	5.89	0.011										
Cashier	PDE	13,267	1,182,812	89.15	0.165										
Driver	PDE	723,606	1,009,800	1.40	0.003										
Data clerk (A1)	PDE	723,606	2,878,552	3.98	0.007										
			840,427		1.32										
			GRAND TOTAL (OH cost per visit)			840,427	CPV	1.32							
PUBLIC SECTOR SALARY															
Clinical staff costs	Number	ART hrs per day	Proportion	Annual salary (Frw FY07)	Annual cost (US\$ FY07)	ART cost (US\$)									
Medical Officer (specialist)	1	3.0	0.375	6,878,769	12,737	4,776									
SI Nurse A1	1	2.0	0.250	3,310,335	6,129	1,532									
Reception Nurse A2	1	2.0	0.250	1,182,812	2,190	548									

Doctor's room Nurse A2	2	4.0	0.500	1,182,812	4,380	2,190						
ART Nurse A2	1	4.0	0.500	1,241,953	2,300	1,150						
Stock Nurse A2	1	4.0	0.500	1,182,812	2,190	1,095						
Counsellor (A2)	1	4.0	0.500	1,182,812	2,190	1,095						
Phlebotomist	1	2.5	0.313	1,182,812	2,190	684						
	9				34,306	13,070						
GRAND TOTAL (Clinical Staff Costs)												
						13,070.39	CPV	7.14				

SITE: RUHENGERI HOSPITAL												
Equipment/furniture	Qty	Proportion (ART use)	Unit Cost price (Frw)	R-Value (Frw FY06)	R-Value (US\$ FY06)	Useful life (years)	Annuity factor	AEC		Discount rate:	3.0%	
Reception; Nurse's & Pharmacy											Exchange Rate	\$ 540
Table (Office)	1.0	1	40,000	40,000	74	3	2.8285	26				
Chairs	2.0	1	15,000	30,000	56	3	2.8285	20				
Shelves (glass)	3.0	1	100,000	300,000	555	5	4.5797	121				
shelves simple	2.0	1	40,000	80,000	148	3	2.8285	52				
Balance	1.0	1	10,000	10,000	19	3	2.8285	7				
Computer	1.0	1	800,000	800,000	1,481	3	2.8285	524				
UPS	1.0	1	250,000	250,000	463	3	2.8285	164				
Bench	5.0	1	10,000	50,000	93	3	2.8285	33				
Consultation room (Drs)												

Maintenance generator	1.00	394,345	610,222	1.55	0.003								
Fuel (vehicle &) generator	1.00	394,345	10,843,098	27.50	0.051								
Security	1.00	394,345	7,272,004	18.44	0.034								
Cleaning & Gardening	1.00	394,345	18,416,228	46.70	0.086								
Director	1.00	394,345	8,617,980	21.85	0.040								
Admin	1.00	394,345	7,490,769	19.00	0.035								
Pharmacist	1.00	394,345	5,546,044	14.06	0.026								
HRM	1.00	394,345	4,261,417	10.81	0.020								
Driver	2.00	394,345	2,019,600	5.12	0.009								
M&E Per diems	1.00	394,345	12,843,098	32.57	0.060								
			252,381		0.642								
GRAND TOTAL (OH cost per visit)										CPV	0.642		
Clinical Staff Costs	Number	Time worked (hrs per day)	Proportion (hrs worked)	Annual cost (Frw FY06)	Annual cost (US\$ FY06)	ART cost (US\$)							
Specialist	1	1.5	0.188	7,878,769	14,588	2,735.3							
GP	1	4.0	0.500	5,232,814	9,689	4,844.5							
ART nurse	1	6.0	0.750	1,241,953	2,300	1,724.7							
Nurses A2 Dr's room	2	4.5	0.563	1,182,812	4,380	2,463.8							
Counsellor/Nutritionist	1	3.0	0.375	1,241,953	2,300	862.3							
					33,256	12,631							
GRAND TOTAL (Clinical Staff Cost visit)										12,631	CPV	3.27	

SITE: TRAC CLINIC												
Equipment/furniture												
<i>Administration (S/I Room)</i>	Qty	Proportion (ART use)	Price (Frw)	Current cost (Frw FY06)	Current cost (US\$ FY2006)	Useful life (years)	Annuity factor	AEC			Discount rate:	3.0%
Table (Office)	2.0	0.59	85,000	99537.55	184.30	5.00	4.5797	40.2			Exchange Rate	\$ 540
Armoire metallique	1.0	0.59	254,880	149236.06	276.32	10.00	8.5302	32.4				
Photocopier	1.0	0.59	575,000	336671.12	623.37	5.00	4.5797	136.1				
Telephone (receiver)	1.0	0.59	25,000	14637.87	27.10	3.00	2.8285	9.6				
Computer	1.0	0.59	750,000	439136.24	813.09	3.00	2.8285	287.5				
UPS	1.0	0.59	300,000	175654.50	325.24	3.00	2.8285	115.0				
Printer	1.0	0.59	400,000	234205.99	433.65	3.00	2.8285	153.3				
Extension cable	1.0	0.59	5,000	2927.57	5.42	5.00	2.8285	1.9				
Chair (executive)	1.0	0.59	120,000	70261.80	130.10	5.00	4.5797	28.4				
Chairs (metallic cushion)	1.0	0.59	95,000	55623.92	102.99	5.00	4.5797	22.5				
<i>Pharmacy (Stock)</i>												
Computer	1.0	0.59	750,000	439136.24	813.09	3.00	2.8285	287.5				
Computer table	1.0	0.59	362,000	211956.42	392.45	5.00	4.5797	85.7				
UPS	1.0	0.59	300,000	175654.50	325.24	3.00	2.8285	115.0				
Fridge	1.0	0.59	702,104	411092.41	761.17	3.00	2.8285	269.1				
Stabilizer	1.0	0.59	115,000	67334.22	124.67	3.00	2.8285	44.1				
Lockable shelves	1.0	0.59	195,000	114175.42	211.40	5.00	4.5797	46.2				
Pallette	2.0	0.59	9,000	10539.27	19.51	5.00	4.5797	4.3				

Chairs (metallic cushion)	2.0	0.59	95,000	111247.85	205.98	5.00	4.5797	45.0					
<i>Dispensing room 1</i>													
Armoire metallique	2.0	0.80	254,000	406400.00	752.48	10.00	8.5302	88.2					
Table (Office)	1.0	0.80	85,000	68000.00	125.91	5.00	4.5797	27.5					
Chairs (metallic cushion)	4.0	0.80	95,000	304000.00	562.88	5.00	4.5797	122.9					
Computer	1.0	0.80	750,000	600000.00	1,110.95	3.00	2.8285	392.8					
Computer table	1.0	0.80	362,000	289600.00	536.22	5.00	4.5797	117.1					
UPS	1.0	0.80	300,000	240000.00	444.38	3.00	2.8285	157.1					
Extension cable	1.0	0.80	5,000	4000.00	7.41	3.00	2.8285	2.6					
Telephone	1.0	0.80	25,000	20000.00	37.03	3.00	2.8285	13.1					
<i>Dispensing room 2</i>													
Armoire metallique	2.0	0.80	254,000	406400.00	752.48	10.00	8.5302	88.2					
Table (Office)	1.0	0.80	85,000	68000.00	125.91	5.00	4.5797	27.5					
Chairs (metallic cushion)	4.0	0.80	95,000	304000.00	562.88	5.00	4.5797	122.9					
Computer	1.0	0.80	750,000	600000.00	1,110.95	3.00	2.8285	392.8					
Computer table	1.0	0.80	362,000	289600.00	536.22	5.00	2.8285	189.6					
UPS	1.0	0.80	300,000	240000.00	444.38	3.00	2.8285	157.1					
Printer	1.0	0.80	400,000	320000.00	592.50	3.00	2.8285	209.5					
Extension cable	1.0	0.80	5,000	4000.00	7.41	3.00	2.8285	2.6					
Telephone	1.0	0.80	25,000	20000.00	37.03	3.00	2.8285	13.1					
<i>Dispensing room 3</i>													
Armoire metallique	2.0	0.80	254,000	406400.00	752.48	10.00	8.5302	88.2					
Table (Office)	1.0	0.80	85,000	68000.00	125.91	5.00	4.5797	27.5					
Chairs (metallic cushion)	4.0	0.80	95,000	304000.00	562.88	5.00	4.5797	122.9					
Computer	1.0	0.80	750,000	600000.00	1,110.95	3.00	2.8285	392.8					
Computer table	1.0	0.80	362,000	289600.00	536.22	5.00	4.5797	117.1					

UPS	1.0	0.80	300,000	240000.00	444.38	3.00	2.8285	157.1					
Extension cable	1.0	0.80	5,000	4000.00	7.41	3.00	2.8285	2.6					
Telephone	1.0	0.80	25,000	20000.00	37.03	3.00	2.8285	13.1					
<i>Doctor's rooms 1</i>													
Armoire (wooden glass)	1.0	0.80	190,000	152000.00	281.44	5.00	4.5797	61.5					
Table (Office)	1.0	0.80	85,000	68000.00	125.91	5.00	4.5797	27.5					
Chair (executive)	1.0	0.80	120,000	96000.00	177.75	5.00	4.5797	38.8					
Chairs (metallic cushion)	2.0	0.80	95,000	152000.00	281.44	5.00	4.5797	61.5					
Computer	1.0	0.80	750,000	600000.00	1,110.95	3.00	2.8285	392.8					
Computer table	1.0	0.80	362,000	289600.00	536.22	3.00	2.8285	189.6					
UPS	1.0	0.80	300,000	240000.00	444.38	3.00	2.8285	157.1					
Extension cable	1.0	0.80	5,000	4000.00	7.41	3.00	2.8285	2.6					
Telephone	1.0	0.80	25,000	20000.00	37.03	3.00	2.8285	13.1					
Escabeau	1.0	0.80	36,000	28800.00	53.33	5.00	2.8285	18.9					
BP machine	1.0	0.80	18,000	14400.00	26.66	3.00	2.8285	9.4					
Balance (simple)	1.0	0.80	12,000	9600.00	17.78	3.00	2.8285	6.3					
Dustbin (metallic)	1.0	0.80	30,000	24000.00	44.44	5.00	4.5797	9.7					
Examination bed	1.0	0.80	581,126	464900.80	860.80	10.00	8.5302	100.9					
Stethoscope	1.0	0.80	4,000	3200.00	5.93	3.00	2.8285	2.1					
Patella hammer	1.0	0.80	8,000	6400.00	11.85	5.00	4.5797	2.6					
Autoscope	1.0	0.80	45,000	36000.00	66.66	3.00	2.8285	23.6					
Hanger	1.0	0.80	16,000	12800.00	23.70	5.00	2.8285	8.4					
Wooden metre	1.0	0.80	11,200	8960.00	16.59	5.00	2.8285	5.9					
<i>Doctor's rooms 2</i>													
Armoire (wooden glass)	1.0	0.80	190,000	152000.00	281.44	5.00	4.5797	61.5					
Table (Office)	1.0	0.80	85,000	68000.00	125.91	5.00	4.5797	27.5					

Chair (executive)	1.0	0.80	120,000	96000.00	177.75	5.00	4.5797	38.8					
Chairs (metallic cushion)	2.0	0.80	95,000	152000.00	281.44	5.00	4.5797	61.5					
Computer	1.0	0.80	750,000	600000.00	1,110.95	3.00	2.8285	392.8					
Computer table	1.0	0.80	362,000	289600.00	536.22	5.00	4.5797	117.1					
UPS	1.0	0.80	300,000	240000.00	444.38	3.00	2.8285	157.1					
Extension cable	1.0	0.80	5,000	4000.00	7.41	3.00	2.8285	2.6					
Telephone	1.0	0.80	5,000	4000.00	7.41	3.00	2.8285	2.6					
Escabeau	1.0	0.80	25,000	20000.00	37.03	5.00	2.8285	13.1					
BP machine	1.0	0.80	36,000	28800.00	53.33	3.00	2.8285	18.9					
Balance (simple)	1.0	0.80	12,000	9600.00	17.78	3.00	2.8285	6.3					
Dustbin (metallic)	1.0	0.80	30,000	24000.00	44.44	5.00	4.5797	9.7					
Examination bed	1.0	0.80	581,126	464900.80	860.80	10.00	8.5302	100.9					
Stethoscope	1.0	0.80	4,000	3200.00	5.93	3.00	2.8285	2.1					
Patella hammer	1.0	0.80	8,000	6400.00	11.85	5.00	4.5797	2.6					
Autoscope	1.0	0.80	45,000	36000.00	66.66	3.00	2.8285	23.6					
Hanger	1.0	0.80	16,000	12800.00	23.70	5.00	4.5797	5.2					
Wooden metre	1.0	0.80	11,200	8960.00	16.59	5.00	4.5797	3.6					
<i>Doctor's rooms 3</i>													
Armoire (wooden glass)	1.0	0.80	190,000	152000.00	281.44	5.00	4.5797	61.5					
Table (Office)	1.0	0.80	85,000	68000.00	125.91	5.00	4.5797	27.5					
Chair (executive)	1.0	0.80	120,000	96000.00	177.75	5.00	4.5797	38.8					
Chairs (metallic cushion)	2.0	0.80	95,000	152000.00	281.44	5.00	4.5797	61.5					
Computer	1.0	0.80	750,000	600000.00	1,110.95	3.00	2.8285	392.8					
Computer table	1.0	0.80	362,000	289600.00	536.22	5.00	4.5797	117.1					
UPS	1.0	0.80	300,000	240000.00	444.38	3.00	2.8285	157.1					
Extension cable	1.0	0.80	5,000	4000.00	7.41	3.00	2.8285	2.6					

Telephone	1.0	0.80	5,000	4000.00	7.41	3.00	2.8285	2.6					
Escabeau	1.0	0.80	25,000	20000.00	37.03	5.00	4.5797	8.1					
BP machine	1.0	0.80	36,000	28800.00	53.33	3.00	2.8285	18.9					
Balance (simple)	1.0	0.80	12,000	9600.00	17.78	3.00	2.8285	6.3					
Dustbin (metallic)	1.0	0.80	30,000	24000.00	44.44	5.00	4.5797	9.7					
Examination bed	1.0	0.80	581,126	464900.80	860.80	10.00	8.5302	100.9					
Stethoscope	1.0	0.80	4,000	3200.00	5.93	3.00	2.8285	2.1					
Patella hammer	1.0	0.80	8,000	6400.00	11.85	5.00	4.5797	2.6					
Autoscope	1.0	0.80	45,000	36000.00	66.66	3.00	2.8285	23.6					
Hanger	1.0	0.80	16,000	12800.00	23.70	5.00	2.8285	8.4					
Wooden metre	1.0	0.80	11,200	8960.00	16.59	5.00	4.5797	3.6					
<i>Doctor's rooms (specialist)</i>													
Armoire (wooden glass)	1.0	0.80	190,000	152000.00	281.44	5.00	4.5797	61.5					
Table (Office)	1.0	0.80	85,000	68000.00	125.91	3.00	2.8285	44.5					
Chair (executive)	1.0	0.80	120,000	96000.00	177.75	5.00	4.5797	38.8					
Chairs (metallic cushion)	2.0	0.80	95,000	152000.00	281.44	5.00	4.5797	61.5					
Computer	1.0	0.80	750,000	600000.00	1,110.95	3.00	2.8285	392.8					
Computer table	1.0	0.80	362,000	289600.00	536.22	5.00	4.5797	117.1					
UPS	1.0	0.80	300,000	240000.00	444.38	3.00	2.8285	157.1					
Extension cable	1.0	0.80	5,000	4000.00	7.41	3.00	2.8285	2.6					
Telephone	1.0	0.80	5,000	4000.00	7.41	3.00	2.8285	2.6					
Escabeau	1.0	0.80	25,000	20000.00	37.03	3.00	2.8285	13.1					
BP machine	1.0	0.80	36,000	28800.00	53.33	3.00	2.8285	18.9					
Balance (simple)	1.0	0.80	12,000	9600.00	17.78	3.00	2.8285	6.3					
Dustbin (metallic)	1.0	0.80	30,000	24000.00	44.44	5.00	4.5797	9.7					
Examination bed	1.0	0.80	581,126	464900.80	860.80	10.00	8.5302	100.9					

Stethoscope	1.0	0.80	4,000	3200.00	5.93	3.00	2.8285	2.1					
Patella hammer	1.0	0.80	8,000	6400.00	11.85	5.00	4.5797	2.6					
Autoscope	1.0	0.80	45,000	36000.00	66.66	3.00	2.8285	23.6					
Hanger	1.0	0.80	16,000	12800.00	23.70	3.00	2.8285	8.4					
Wooden metre	1.0	0.80	11,200	8960.00	16.59	3.00	2.8285	5.9					
<i>IT (Computer) Room</i>													
Fan	1.0	0.59	11,200	6557.77	12.14	3.00	2.8285	4.3					
Computer	3.0	0.59	750,000	1317408.72	2,439.28	3.00	2.8285	862.4					
Computer table	2.0	0.59	362,000	423912.85	784.91	5.00	4.5797	171.4					
UPS	3.0	0.59	300,000	526963.49	975.71	3.00	2.8285	345.0					
Extension cable	1.0	0.59	5,000	2927.57	5.42	3.00	2.8285	1.9					
Telephone	1.0	0.59	25,000	14637.87	27.10	3.00	2.8285	9.6					
Shelves (small)	1.0	0.59	5,000	2927.57	5.42	3.00	2.8285	1.9					
Walled shelves	3.0	0.59	12,220	21464.98	39.74	3.00	2.8285	14.1					
Chairs (metallic cushion)	3.0	0.59	95,000	166871.77	308.98	3.00	2.8285	109.2					
<i>Phlebotomy room</i>													
Table (office)	1.0	0.59	85,000	49768.77	92.15	3.00	2.8285	32.6					
Chairs (metallic cushion)	2.0	0.59	95,000	111247.85	205.98	3.00	2.8285	72.8					
Dustbin (metallic)	1.0	0.59	30,000	17565.45	32.52	3.00	2.8285	11.5					
<i>Reception (MF5 store)</i>													
Balance (simple)	1.0	0.59	12,000	7026.18	13.01	3.00	2.8285	4.6					
Table (office)	1.0	0.59	95,000	55623.92	102.99	3.00	2.8285	36.4					
Chairs (metallic cushion)	4.0	0.59	95,000	222495.69	411.97	3.00	2.8285	145.6					
Telephone	1.0	0.59	25,000	14637.87	27.10	3.00	2.8285	9.6					
Shelves	2.0	0.59	78,000	91340.34	169.12	3.00	2.8285	59.8					
<i>Counselling room</i>													

			SUB-TOTAL EQUIPMENT				11,392	CPV	1.68				
			GRAND TOTAL (CAPITAL COSTS PER VISIT)					16,164	CPV	2.38			
Overheads	Base		Total visits	Total expenditure (Frw FY06)	Total expenditure (US\$ FY06)	Allocation to ART	CPV (US\$ FY06)						
Water and electricity	m2	0.272	11,612	5,832,582	10,799	2,936.93	0.253						
Communication	m2	0.272	11,612	5,336,902	9,882	2,687.33	0.231						
Supplies (stores, stationary & printing)	m2	0.272	11,612	12,267,700	22,715	6,177.26	0.532						
Maintenance buildings	m2	0.272	11,612	1,403,401	2,599	706.67	0.061						
Maintenance equipment (incl IT)	m2	0.272	11,612	1,296,599	2,401	652.89	0.056						
Vehicle hire	micro	1.000	11,612	4,212,624	7,800	7,800.00	0.672						
Maintenance generator	m2	0.272	11,612	610,222	1,130	307.27	0.026						
Fuel generator	m2	0.272	11,612	7,843,098	14,522	3,949.30	0.340						
Security	m2	0.272	11,612	3,360,000	6,221	1,691.89	0.146						
Cleaning & Gardening	m2	0.272	11,612	7,886,800	14,603	3,971.31	0.342						
per diems for field visits	micro	1.000	11,612	2,136,856	3,957	3,956.55	0.341						
Director treatment and care	time	0.0625	11,612	8,617,980	15,957	997.30	0.086						
Administrator (sister in charge)	time	0.450	11,612	3,310,335	6,129	2,758.20	0.238						
Head IT	time	0.125	11,612	4,400,000	8,147	1,018.37	0.088						
Data Clerks	time	0.125	11,612	1,182,812	2,190	273.76	0.024						
				69,697,912	129,051	39,885	3.43						
			GRAND TOTAL (OH cost per visit)					CPV	3.43				

PUBLIC SECTOR SALARY															
Clinical staff costs	<u>Number</u>	Person-hours per day	%age	Annual salary	Annual Cost (Fw FY06)	Annual Cost (US\$ FY06)									
Medical Officer (specialist)	1	1	0.1250	6,878,769	859,846	1,592									
Medical Officer	3	4	0.5000	5,232,814	7,849,221	14,533									
Nurses A1	6	4	0.5000	2,878,552	8,635,657	15,990									
Nurses A2	6	4	0.5000	1,182,812	3,548,437	6,570									
Counsellor (A1)	1	4	0.5000	2,878,552	1,439,276	2,665									
Counsellor (A2)	3	4	0.5000	1,182,812	1,774,219	3,285									
Nutritionist (A0)	1	2	0.2500	3,310,335	827,584	1,532									
	21.0					46,168									
GRAND TOTAL (Clinical Staff Cost per visit)							46,168	CPV	6.79						