The Costs of Anti-Retroviral Treatment in Zambia

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Abstract

This report analyzes the costs and resource requirements associated with the provision of anti-retroviral (ARV) therapy in the public health sector in Zambia. It provides per-patient cost estimates for highly active anti-retroviral therapy (HAART), voluntary counseling and testing, several opportunistic infections, and prevention of mother-to-child transmission services. These per-patient cost estimates are used to project total program costs, which are then compared to currently budgeted resources with an emphasis on financial sustainability. The report also explores a range of policy issues, including the importance of human resource constraints; the implications of alternative monitoring protocols and drug regimens; opportunities for resource mobilization; and targeting issues. The provision of ARVs in Zambia is a dynamic issue: certain programmatic decisions have yet to be made, and both prices and technologies are changing rapidly. Thus, the purpose of this report is to highlight the key questions related to HAART costs, rather than to propose any definitive answers.

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Acronyms

AIM	AIDS Impact Model
ART	Anti-retroviral Therapy
ARV	Anti-retroviral
ATC	AIDSTREATCOST
CBoH	Central Board of Health
CD4	Cell Differential
CDC	United States Centers for Disease Control and Prevention
DHS	Demographic and Health Survey
FTE	Full-time Equivalent
HAART	Highly Active Anti-retroviral Therapy
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome
JICA	Japan International Co-operation Agency
MAP	Multi-country HIV/AIDS Programme (World Bank)
MTCT	Mother-to-Child Transmission
NAC	National AIDS Council
OI	Opportunistic Infections
PCR	Polymerized Chain Reaction
PHR*plus*	Partners for Health Reform*plus* Project
PLWHA	People Living with HIV and AIDS
pMTCT	Prevention of Mother-to-Child Transmission
USAID	United States Agency for International Development
US$	U.S. dollar
UTH	University Teaching Hospital
VCT	Voluntary Counseling and Testing
WHO	World Health Organization
ZIHP	Zambia Integrated Health Programme

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Acknowledgments

Executive Summary

As HIV/AIDS continues to have a devastating impact in Zambia, the government is responding to the epidemic by adopting a multi-pronged strategy to confront the disease. A major component of this strategy is the provision of highly active anti-retroviral therapy (HAART) to AIDS patients. HAART offers patients the opportunity to lead healthy, active lives despite their HIV status, but it will also pose many challenges to Zambia's health care system.

The purpose of this study is to provide a comprehensive analysis of the costs and resource requirements for the provision of HAART in the public sector in Zambia. A costing exercise of this kind embodies only one of the many issues that need to be addressed in preparation for public anti-retroivial (ARV) provision. But it is a topic that deserves close attention, since millions of dollars will be devoted to the program, and careful planning will be needed to ensure that the money is well spent.

The key findings of the report are as follows:

▲ The average annual incremental cost per patient for a first-line HAART regimen in Zambia is $488, with drugs and monitoring tests accounting for 57 percent and 36 percent, respectively. Capital and training costs make up the remainder.

▲ The average variable cost per patient for providing voluntary counseling and testing (VCT) services is $3.64. The overall uptake rate of VCT services following the introduction of HAART is uncertain, but budget plans should anticipate higher usage. A 4 percent adult VCT uptake rate, a World Health Organization target, would cost $728,000 annually.

▲ Per-patient drug costs for prevention of mother-to-child transmission are low – about $0.23 for each mother-and-child pair – but training costs can be substantial (perhaps $1 million annually for four years) due to the need to train a large number of health care workers.

▲ The cost of providing HAART to 10,000 patients as planned would be about $4.9 million, making the current budget envelope marginally adequate. But financial sustainability will be a critical issue, particularly with the status of the Global Fund grant uncertain after two years. If the budget for HAART does not grow each year, no new patients can be initiated on treatment when they become eligible.

▲ As is well understood, providing HAART to everyone who is clinically eligible would be prohibitively expensive. It would cost about $50 million in the first program year, rising to about $160 million by the fifth year – well over twice the entire annual public health budget. Because HAART extends the life of current HIV/AIDS patients while new infections continue, prevalence should be expected to increase as treatment is expanded. If HAART is provided to everyone who is eligible, adult HIV prevalence may rise from 16 percent at present to 18 percent in five years (under the assumption that the number of new infections stays constant).

▲ An extremely important constraint facing program expansion is a lack of human resources. Providing HAART to everyone who is clinically eligible would, after five years, require twice the number of laboratory technicians and half the doctors currently available in the public health system. Even at more modest levels of population coverage, the human resource constraint may be more binding on HAART expansion than the financial constraint. Thus, the success of Zambia's HAART program over the medium term could depend more on its human resource capacity than on its budget capacity. Training programs should be an urgent priority.

▲ Service delivery decisions will have an important effect on how many people can be treated.

△ If a more basic monitoring test protocol is conducted for HAART, the per-patient cost falls from $488 to $408. This implies that a less comprehensive monitoring regimen would allow 20 percent more patients to be treated overall.

△ Recent procurement has included relatively expensive drugs such as Efavirenz and Abacavir for first line and Didanosine and Indinavir for second line. While these drugs provide the flexibility for more individualized treatment options, their relative expense compared to standard fixed-dose combinations means that substantially fewer people will be able to receive HAART overall.

The provision of ARVs in Zambia is a dynamic issue: certain programmatic decisions have yet to be made, and both prices and technologies are changing rapidly. Thus, the aim of this report is to highlight the key questions related to ARV costs, rather than to propose any definitive answers.

1. Introduction and Purpose

HIV/AIDS continues to have a devastating impact in sub-Saharan Africa. The latest UNAIDS report on the epidemic estimates that in 2002 there were nearly 30 million adults and children living with HIV/AIDS in the region, and 3.5 million new infections. Against this background, countries across the region are adopting multi-pronged strategies to confront the disease. An increasingly common component of these strategies is the provision of highly active anti-retroviral therapy (HAART) to HIV/AIDS patients. This therapy has become more feasible recently due to declining drug prices and increased donor funding to support the intervention.

HAART offers patients the potential to lead healthy, active lives despite their HIV-positive status. Patients may return to being productive members of the work force, and can expect fewer opportunistic infections. In addition, it is hoped that the prospect of receiving HAART will encourage individuals to seek voluntary counseling and testing (VCT) services to know their HIV status, and this would in turn help reduce the infection rate. These important benefits have led several sub-Saharan African countries to launch programs to provide HAART through the public health system.[1]

Zambia offers an example. With an adult HIV prevalence rate of about 16 percent and up to 100,000 new infections per year, Zambia has been hit hard by the epidemic. In 2002, in recognition of the potential benefits noted above and with continued moral outrage over the loss of life caused by HIV/AIDS, the government decided to embark on a program of publicly provided HAART. A pilot program was launched in late 2002 at two sites, the University Teaching Hospital (UTH) in Lusaka and the tertiary facility in Ndola. The program will be expanded to seven other sites (at provincial hospitals) in the near future, with the stated goal of providing HAART to 10,000 patients in the first program year.

This is a complex undertaking, requiring extensive preparation to ensure that the appropriate clinical, human resource, budgetary, and managerial structures are in place. A crucial component of the preparatory work for scaling up this intervention is to analyze the costs and resource requirements of publicly provided HAART.

Therefore, the purpose of this report is to provide a comprehensive analysis of the costs and resource requirements entailed by the current plan to provide HAART through public health facilities in Zambia. With this information, the health authorities will be better equipped to plan for scaling up HAART. How much will it cost? How many people can be treated? What human resources will be required? What are the implications of alternative service delivery models? These and other questions cannot be adequately addressed without comprehensive cost information.

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[1] It should not be forgotten that HAART poses many challenges as well: it is an expensive intervention that undeniably draws resources away from other critical health and HIV/AIDS activities; it is a complex therapy that is difficult to administer, raising concerns about patient compliance and the risk of developing drug resistance; and it requires a sophisticated health system infrastructure (in terms of both physical and human resources) that is often lacking in low-resource countries. This report should not be seen as advocating for either a greater or smaller role for ARVs in Zambia's national HIV/AIDS strategic plan; it merely recognizes that this program is going forward, and should be done with as much information as possible.

A costing exercise such as this embodies only one of many issues that need to be addressed in preparation for public anti-retrovial (ARV) provision. The development of clinical protocols, training curricula, eligibility criteria, pharmaceutical management systems, and many other challenging tasks are also critically important. But an analysis of cost and other resource issues is a topic that is too important to overlook, as millions of dollars will be spent on the program and careful planning will be needed to ensure that this money is well spent.

The framework used for this study is the AIDSTREATCOST (ATC) model developed by the Partners for Health Reform*plus* (PHR*plus*) project. This tool was designed by PHR*plus* in order to assist low-resource countries such as Zambia to take a comprehensive, health-systems approach to analyzing the costs and resource requirements entailed in expanding HAART services. The model is described in detail in Annex A of this report.

Since 1992 Zambia has implemented a series of health reforms designed to increase the affordability, access, and efficiency of service delivery. A key element of these reforms was the introduction, adoption, and implementation of the Basic Health Care Package – a set of cost-effective interventions that address the prioritized disease burden, across the different levels of the health care system. The package was first defined in 1994/5 for services at the primary level and later revised in 1996 to include services at the secondary and tertiary levels. HIV/AIDS services are among the 33 health conditions/diseases defined in the package. Against the background of evolving demands for HIV/AIDS services, Zambia is increasingly concerned with allocating resources to cost-effective interventions defined in the Basic Health Care Package. However, it has not been determined how the planned expansion of HAART in the public sector relates to the Basic Health Care Package. HAART does not rank highly among cost-effective interventions,[2] and universal coverage is not possible in the short-term due to resource constraints. Both of these factors are at odds with key characteristics of the Basic Health Care Package.

As yet there is not a large literature on the costs of providing ARV treatment in low-resource countries, and, where it exists, the emphasis has usually been on unit cost data from the regional or even global level.[3] It is hoped that in the future country-specific studies such as this one will become increasingly common, providing practical information to policymakers and program planners about ARV provision.

The structure of this report is as follows. Section 2 provides background information on HIV/AIDS in Zambia. Section 3 addresses the methodology and data sources. Section 4 presents per-patient costs for HAART, VCT, opportunistic infection (OI) treatment, and prevention of mother-to-child transmission (pMTCT) interventions. Section 5 analyzes overall program costs and issues of sustainability. Section 6 discusses various policy issues raised by the cost results, and Section 7 concludes.

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[2] See, for example, Creese et al. (2002).
[3] See, for example, Schwartlander et al. (2001).

2. Background Issues

2.1 Background on HIV/AIDS and Anti-Retroviral Therapy in Zambia

Zambia has been one of the countries in the world hardest hit by HIV/AIDS. As Table 1 indicates, adult prevalence is nearly 16 percent, with women and urban residents disproportionately affected by the disease. HIV/AIDS has been particularly devastating for the most productive segment of the national population – adults between 20 and 39.

Table 1: HIV Prevalence among Adults in Zambia

Population Group	Percent HIV-positive
Urban	23.1
Rural	10.8
Women	17.8
Men	12.9
TOTAL – All Adults	15.6

Source: ORC Macro et al., 2002

In response to the HIV/AIDS epidemic, the government has developed and implemented several national plans. These include the Second Medium Term Plan 1994-1998, the national Strategic Framework 2001-2003 (National HIV/AIDS/STD/TB Council, 2000), and the National HIV/AIDS Strategic Plan for 2002-2005 (National HIV/AIDS/STD/TB Council, 2002). This last document includes eight specific objectives pertaining to the following areas: behavior change; pMTCT rates; the blood supply; improving the quality of life of people living with HIV and AIDS (PLWHA); provision of care, support and treatment to PLWHA; programs for orphans and vulnerable children; HIV/AIDS information management; and the adoption of a multi-sectoral approach.

As part of objective #5 in the strategic plan, one of the goals is to introduce anti-retroviral therapy (ART) for PLWHAs in public and private health facilities. HAART has been available in the private sector in Zambia since the early 1990s to those who could afford to pay themselves, but the total number currently accessing anti-retrovirals through this channel is unknown. However public provision of HAART is new, and thus it represents the latest addition to the public sector's continuum of care for people infected with HIV/AIDS. As the national policy document on ART states, "the non-availability of ART in the public sector in Zambia cannot continue while the economic and development gains achieved by Zambia since independence are being wiped out through illnesses and deaths attributable to HIV/AIDS" (National AIDS Council, 2002, p.3).

Thus, the ART policy document sets out the government's intention to provide HAART to 10,000 patients at nine hospitals in the first program year. Participating facilities must be designated as an ART center by meeting certain criteria. Patients will be identified by a provincial selection committee, and

provision will be contributory through a cost-sharing mechanism determined by these committees. In late 2002, two pilot programs were initiated, one at the University Teaching Hospital in Lusaka and one at the tertiary hospital in Ndola (Copperbelt province). Expansion to the seven other hospitals is expected to begin by the end of 2003.

3. Methodology and Data Sources

3.1   Methodology

The framework used for estimating the costs of providingARVs in Zambia was drawn from the AIDSTREATCOST model developed by PHR*plus*. A general overview of the model is outlined in Annex A of this report, while a more comprehensive description of the ATC methodology can be found in the ATC user's manual.[4]

The ATC model requires two broad categories of information: baseline data and scenario assumptions. The baseline data represent the background context with which any ART policy design must contend – this information must be 'taken as given' by policymakers in the sense that, at least in the short-term, it is not determined by policy choices. Baseline data encompasses four major categories:

- ▲ Demographic data, such as population size, fertility, and mortality rates;

- ▲ Epidemiological data, such as HIV prevalence, infection, and symptom development rates;

- ▲ Medical data, such as the available protocols for screening, ARVs, and monitoring; and

- ▲ Cost data, such as staff salaries, building, and equipment costs.

The first two categories, demographic data and epidemiological data, define the universe of potential users of ART program services. The other two categories, medical data and cost data, essentially describe the country's health infrastructure (and in particular the costs of its individual components) that will be used to deliver the ART program to the population.

The second broad category of information, scenario assumptions, embodies the critical *choices* facing policymakers that will affect program costs. This entails choosing values for variables such as the number of patients to be treated, protocols for the allocation of facility space and staff time, and so on. As will be seen in the sections on key findings and policy implications, the major scenarios explored in this report involve variations in the number of people receiving each service and in the clinical service delivery model (frequency of monitoring tests, availability of second-line drugs, etc.). These different scenarios were chosen because they reflect some of the key uncertainties in Zambia's ART program going forward, and they have substantial cost implications.

Once the baseline data and scenario assumptions have been entered, the ATC model produces estimates for total costs and resource requirements under the alternative scenarios. Total costs for a given service equal the unit cost times the number of people who receive it. Similarly, resource requirements (e.g., human resources) are calculated as the amount of health care worker time required to provide the service to one patient, multiplied by the total number of patients receiving that service.

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[4] Available through http://www.phrplus.org/hiv-atc.html.

It is important to clarify what is included in and what is excluded from the cost estimates presented in this report, both with respect to services and line items. First, the focus is on treatment activities. Thus, other HIV/AIDS-related interventions, although they may be crucial to a comprehensive national HIV/AIDS strategy, are not considered. Specifically, the study includes the costs of counseling and testing for patients to learn their HIV status, anti-retroviral treatment, prevention of mother-to-child-transmission, and treatment of opportunistic infections. In Zambia, the OIs considered were tuberculosis, pneumocystis carinii pneumonia, oral candidiasis, and cryptococcal meningitis (other OIs that are less common, such as cytomegalovirus and Kaposi's sarcoma, were not included). In terms of line items, as Figure 1 shows, the main costs can be divided into four general line-items: labor, capital, drugs, and tests. The figure shows the major components of each.

Figure 1: Cost Components

$$\sum(\text{labor costs}) + \sum(\text{capital costs}) + \sum(\text{drug costs}) + \sum(\text{test costs})$$

- Training costs	- Lab equipment - Vehicles	- ARV regimen (including second line) - OI regimen - pMTCT regimen	- VCT: screening and confirmation tests - HAART: monitoring tests (CD4, etc.) - OIs: diagnosis of all user-specified OIs
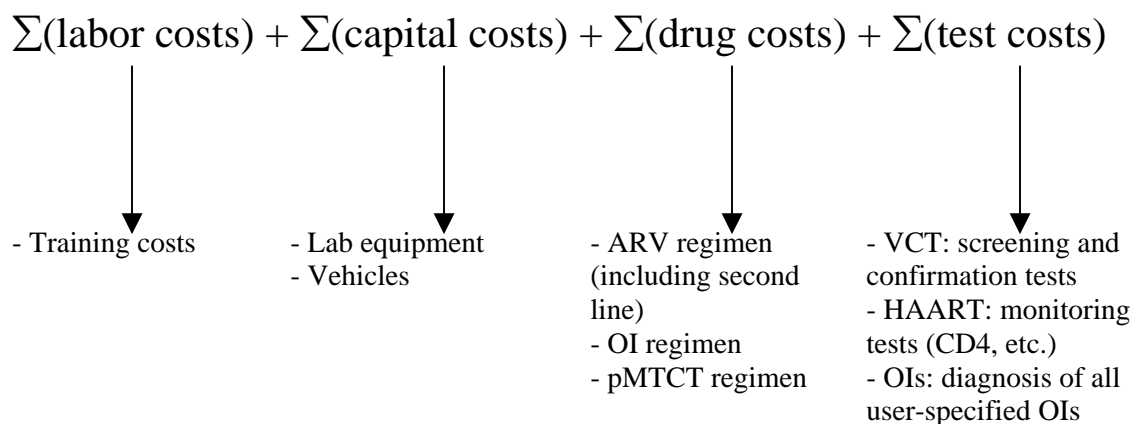
All costs associated with drugs and tests are treated as variable costs (i.e., they vary fully with the number of patients treated), while all capital costs are fixed – that is, they do not vary with program size and are allocated across whatever number of people is treated under a given scenario. Training costs are listed as annual costs. Although clearly a full training course does not need to be conducted every year, nor will training costs fall to zero after the first year, both a high turnover rate in the labor force (meaning that new staff must be trained) and the need for refresher courses for those who did receive the initial training imply that a certain level of training costs will be incurred on an ongoing basis. Thus, no distinction is drawn between training costs in the first year and in subsequent years.

The study focuses exclusively on *incremental* costs – that is, costs associated with program requirements that would not typically already be included in the government's health budget. Specifically, this means that certain costs are excluded since they would be incurred whether an ART program exists or not. This would include, for example, costs associated with buildings such as hospitals and clinics (amortized capital costs of construction and ongoing maintenance, etc.), as well as health care worker compensation (wages, bonuses, etc.). Obviously the introduction of a large-scale public program to provide ART will mean displacing capital and labor from other activities within the health system, but the issue of opportunity costs is not addressed in this report.[5] In addition, at some point of program expansion, new capital investments would be required (especially storage facilities for ensuring drug security), but

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[5] An important exception may be counsellors since (as will be discussed later) a large VCT program will require the hiring of many new counselors. In this case, wages would be additional.

since the main scenario in this report involves relatively low population coverage (i.e., 10,000 patients), we do not focus on this issue here.

Note also that administrative and managerial overhead costs – difficult to identify with specificity at this stage – have not been included either. Since a national HIV/AIDS program would (and indeed already does) exist in the absence of a specific treatment program, certain administrative costs would not be incremental either. In any event, none of the results presented here would change substantially if, for example, 5 percent of the ART budget were earmarked for administrative overhead costs.

Where necessary, the exchange rate used to translate Zambian kwacha into U.S. dollars is 4800 kwacha equals 1 U.S. dollar, based on the rate of late 2002/early 2003.

In sum, the broad methodology applied in this report was to determine unit costs for the provision of HAART, VCT, pMTCT, and OI treatment, based on the required inputs in terms of drugs, tests, labor, and capital, and then use these to estimate total costs under different scenarios for the number of people treated.

3.2   Sources of Data

A complete set of the variables used to enter the baseline data and scenario assumptions, their costs, and the data sources are listed in an annex to this report.

HIV prevalence data is from the 2002 Demographic and Health Survey (DHS) preliminary report (ORC Macro et al., 2002), for which a population-based sero-prevalence study was conducted. Fertility rates are also drawn from the DHS. Other epidemiological data were based on estimates from work by the Futures Group for the AIDS Impact Model (AIM). It should be noted that there are many gaps in the knowledge of Zambia's HIV/AIDS epidemic, and thus in many cases estimates must suffice. However, because only low population coverage rates for HAART can be afforded, estimates of the trajectory of the epidemic in Zambia will not affect the total costs in the main scenarios presented in this report.

Most of the medical data was drawn from the HIV/AIDS clinical guidelines document "Guidelines on Management and Care for HIV/AIDS" (National HIV/AIDS Council, 2002). Drug procurement information was obtained from the Central Board of Health (CBoH) and is based on recent purchases from Cipla in India. Information on screening and confirmation tests came from the Japan International Cooperation Agency (JICA), which is procuring large quantities of test kits for scaling up VCT. Information on the pMTCT program is from the document entitled "Strategic Framework and Workplan for the Expansion of Integrated pMTCT Services in Zambia 2003-2006," second draft (CboH et al., February 2003). Equipment costs and requirements are drawn from estimates in Zambia's ARV policy document, "Formal Introduction and Implementation of ART in Zambia," written by the National HIV/AIDS Council (2002). Service delivery information (for both the baseline and scenarios), including monitoring test costs, was gathered from interviews with a clinician at the UTH in Lusaka, one of the two pilot sites, as well as from the report by Huddart et al. (2003) on the ARV workforce. Finally, information on training costs was based on consultations with the CBoH about their preliminary training courses for ARV expansion that were conducted in the fall of 2002.

4.   Key Findings: Per-patient Costs

4.1   Highly Active Anti-retroviral Therapy

The provision HAART to HIV/AIDS patients is the cornerstone of ART policy in Zambia and will represent by far the largest programmatic cost. This section will consider per patient costs of HAART, while overall program costs will be discussed later.

The costs of HAART in this section encompass four major categories: ARV drugs, laboratory monitoring tests, capital expenses for new laboratory equipment and vehicles, and training. The costs associated with other HIV/AIDS services such as VCT, pMTCT, or OIs are addressed in later sections. As noted in the section on methodology, building and staff costs are excluded, because generally these will not be incremental – that is, they are already part of Zambia's existing health budget allocation. On a per patient basis, these costs would be relatively small.[6]

All drug costs are landed prices drawn from information provided by the Central Board of Health and reflect the procurement of ARV drugs from Cipla in India. Monitoring test costs are based on the price list at the UTH in Lusaka, one of the pilot sites. Note that, in all scenarios, 15 percent has been added to drug and test costs to account for logistical inputs such as storage and distribution, as well as wastage.[7] It should be emphasized that costs for both drugs and the reagents used for laboratory monitoring are changing rapidly. The prices noted here are considerably lower than the estimates of just a few months ago. For example, the unit cost of a viral load test offered at UTH fell from US$70 to US$25 between November 2002 and March 2003, mainly due to the larger quantities that were procured at the later date. Also, the cost of CD4 counts has fallen from $40 to $3 as a new technology (Dynabeads) is being adopted. Such rapid price changes mean that the results may need to be updated regularly (a task for which the ATC model is ideally suited).

ARV drugs represent about half of total treatment costs when using fixed dose combinations, but annual per patient cost varies greatly when using other treatment protocols

As Table 2 indicates, the annual per-patient costs vary widely with the protocol chosen. The cheapest combinations are Zidovudine-Lamivudine-Nevirapine ("Duovir N") and Stavudine-Lamivudine-Nevirapine ("triomune"). First-line protocols that prescribe Efavirenz or Abacavir are more than three

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[6] Regional estimates from the World Health Organization (WHO) suggest that capital, labor, and other hotel costs amount to only about $4 per outpatient visit at second-level referral hospitals (where most ARV treatment will take place in Zambia). Moreover, in the near term, patient volume is unlikely to be large enough to warrant the construction of brand new buildings.

[7] This is the amount paid by the CBoH to the Medical Stores for the storage and distribution of most pharmaceutical products. A more accurate costing of these inputs would involve a full needs assessment itemizing all vehicles, warehouses, employees, etc. required for logistics. This was not undertaken here, but could be accommodated by the ATC model.

times as expensive.[8] The second-line regimen Stavudine-Didanosine-Indinavir-Ritonavir is more than $1500. Of course the selection of ARV drugs should be based foremost on clinical considerations, and in reality most ART programs will opt for multiple protocols to accommodate different sub-groups. But these decisions should not be taken in a financial vacuum, not least because they will affect the number of people who can be treated. This issue will be discussed in more detail in the section on policy implications.

Table 2: Unit Costs for ARV Drug Protocols

Protocol	Annual cost per patient
Stavudine 40 + Lamivudine + Nevirapine (1st line)	$321.39
Stavudine 30 + Lamivudine + Nevirapine (1st line)	$309.08
Zidovudine + Lamivudine + Nevirapine (1st line)	$233.24
Zidovudine + Lamivudine + Efavirenz (1st line)	$1044.20
Zidovudine + Lamivudine + Abacavir (1st line)	$987.11
Stavudine + Didanosine + Indinavir/Ritonavir (2nd line)	$1541.61

Note: An additional 15 percent has been added to all costs (which are landed prices) to account for wastage and logistics (e.g., storage and distribution).

Laboratory monitoring tests represent a substantial portion of per-patient costs

Table 3 details per unit costs of the monitoring tests. The number of times each type of test should be administered is the subject of some debate internationally, and it has not been explicitly articulated in Zambia. The "Guidelines on Management and Care for HIV/AIDS" suggests that patients receive a full blood count, liver function test, urea/creatinine test, blood sugar, CD4, and viral load at two weeks and three months after treatment is initiated, and thereafter every six months. However, it acknowledges that CD4 and viral load tests may not be available outside Level 3 hospitals. In addition, discussions with clinicians suggest that actual test regimens applied in practice may depart considerably from the suggested guidelines.

Table 3: Unit Costs for Monitoring Tests

Test	Cost per test	Number of tests per year	Total cost
Full Blood Count	$9.58	3	$28.74
Urea/Creatinine	$9.09	3	$27.27
Blood Sugar	$4.79	3	$14.37
Liver Function Tests	$23.95	3	$71.85
CD4 count	$3.45	2	$6.90
Viral load	$28.75	1	$28.75
TOTAL			$177.88

Note: An additional 15 percent has been added to all costs (which are landed prices) to account for wastage and logistics (e.g., storage and distribution).

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[8] The recommended first-line regimen for Zambia, according to the HIV/AIDS Vaccine and Treatment Working Group's "Guidelines on Management and Care for HIV/AIDS" (p.71), calls for either Abacavir or Efavirenz. However, this is outdated, as procurement has focused on the two cheaper regimens.

The baseline per-patient cost calculations in this section assume that, on average, a patient will receive three full blood counts, three urea/creatinine tests, three liver function tests, three blood sugar tests, two CD4 counts, and one viral load annually. This leads to a per-patient cost of about $178 for monitoring tests. Some of the tradeoffs inherent in selecting a monitoring test protocol will be discussed in a later section.

Capital and training costs are relatively small on a per-patient basis

The other major input to be considered for per-patient costs is capital.[9] Zambia's ARV policy document itemizes a number of types of equipment required for laboratory testing, including flow cytometers, polymerized chain reaction (PCR) machines for viral loads (both of these are only for the two tertiary-level hospitals), chemistry and haematology analyzers, and others (see Annex B for full details). The capital costs shown here also include a vehicle for each facility. Appropriately amortized, the total cost of these capital items is about $290,000 annually. If 10,000 people are treated in one year, for example, this is equivalent to $29 per patient.[10]

Some important caveats are in order here. First, it is not yet clear exactly how laboratory capacity in provincial hospitals will be scaled up, partly because technologies are changing (e.g., for CD4 counts) and this will affect decision making. Second, the cost of much of this equipment has already been incurred – for example, most provincial hospitals already have chemistry and haematology analyzers, and JICA has already purchased some of the more elaborate equipment for the tertiary facilities. Therefore these costs will not be drawn from the resource envelope being emphasized in this report (i.e., the government budget allocation for ARVs and the grant from the Global Fund to Fight AIDS, Tuberculosis and Malaria). These factors imply that the per-patient capital cost noted above – already relatively minor compared to drugs and reagents – is probably substantially over-estimated.

The last category is training. On a per-patient basis, the cost of training is only about $3.70.[11] Thus it does not even account for 1 percent of costs, essentially because one trained health worker can provide services to a large number of patients. This is not to downplay the importance of training from a programmatic standpoint – in fact, the relatively low cost of training, coupled with its importance for program success, suggests that it deserves a strong investment.[12]

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[9] See also the discussion of capital costs in the Methodology section.

[10] The relatively small fixed cost of HAART (i.e., the fact that capital is much cheaper than drugs and tests on a per-patient basis) suggests that there is not a major financial barrier to expanding coverage to new facilities (e.g., in provincial towns); however, logistical issues and human resource availability may still be important constraining factors on geographical expansion.

[11] This is based on the assumption that the average patient spends 90 minutes per year with doctors, nurses, and pharmacists, and that they require 3.5 hours of laboratory technician time to conduct monitoring tests. These estimates are based on observations of service delivery contained in the report by Huddart et al. (2003). In terms of cost, the calculation assumes a $500 training cost per worker for a five-day course (this is based on the pilot ARV training budget conducted in the fall of 2002 by the CBoH).

[12] These are annual costs and clearly a full training program does not need to be done every year, but high turnover among health care workers and the need for refresher courses does imply a continued need for some training. In reality, training in subsequent years may be equivalent to $2 per patient instead of $3.70 in the first year, but for simplicity no distinction was drawn here.

Total incremental annual per-patient cost is about $488 using fixed dose combinations

Summing up the various inputs yields a total incremental cost per patient of $488 per year, as shown in Figure 2. This includes $277 for drugs,[13] $178 for lab monitoring tests (using the test protocol described above), $29 for capital costs of new equipment if 10,000 treated, and $4 for training. ARV drugs, sometimes "naively" seen as the *only* cost of ART, are actually just over half the total cost of HAART, while monitoring tests account for 36 percent of the total. For children who receive half the dosage of adults, the average per-patient cost would be $349.

Figure 2: Per-patient cost of HAART
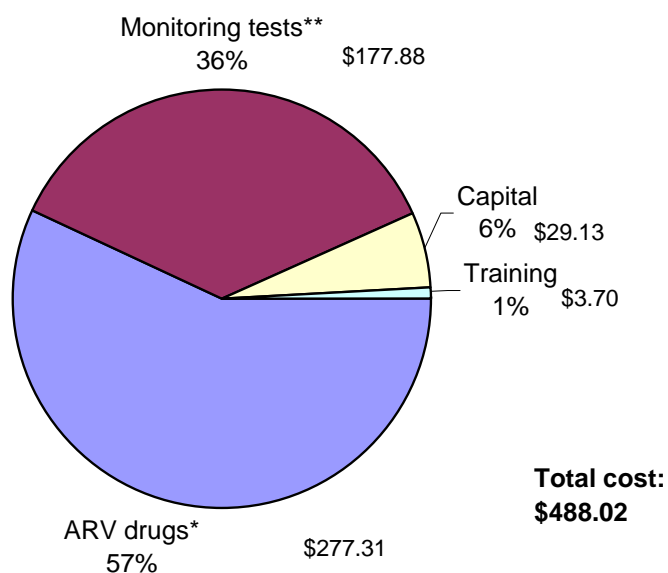
*=Based on the assumption that 50 percent of patients receive Triomune (Stavudine-Lamivudine-Nevirapine) and 50 percent get Zidovudine-Lamivudine-Nevirapine.

**=Based on the assumption that, on average, a patient will receive 3 full blood counts, 3 urea/creatinine tests, 3 blood sugar tests, 3 liver function tests, 2 CD4 counts, and 1 viral load annually.

If no CD4 or viral load tests were done, as may be the case in provincial hospitals, then monitoring tests costs would be $142.23, and overall per-patient costs would be $433.74. If a more basic monitoring test protocol were provided (one fewer of each kind of test per year – and thus only one CD4 and no viral loads), then monitoring test costs would fall to $98.27 and overall per-patient costs would be $408.41. For a patient on second-line treatment, the overall cost (assuming a regular monitoring test protocol) would be $1752.32. Some of the tradeoffs inherent in clinical care service delivery decisions will be discussed in a later section. Table 4 summarizes the per-patient costs under various scenarios.

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[13] This assumes that 50 percent of patients receive zdv/3tc/nvp and the other 50 percent receive d4t/3tc/nvp with the stronger d4t dosage. This breakdown roughly reflects the first consignment of drugs procured by the CBoH. The actual proportion of patients requiring different types of regimens will become more clear as the program expands.

The Costs of Anti-Retroviral Treatment in Zambia

Table 4: Per-patient Costs of HAART

Scenario	Average per patient cost
Adults, 1st line, regular monitoring	$488.02
Children, 1st line, regular monitoring	$349.23
Adults, 1st line, no CD4 or viral load	$433.74
Adults, 1st line, minimal monitoring	$408.41
Adults, 2nd line treatment, regular monitoring	$1752.32

4.2 Voluntary Counseling and Testing

The entry point for the HAART services discussed above is voluntary counseling and testing to determine an individual's HIV status. A potentially important benefit of an ARV treatment program would be if it encouraged higher uptake rates for VCT services. Thus, even if people could not access ARV right away, they would know their HIV status and this could help prevent further transmission of the disease. It is difficult to predict the impact of an ARV program on VCT uptake rates. Preliminary evidence from Botswana suggests that the increase may not be as significant as previously hoped (Grunwald, 2002, p. A1). Nevertheless, this rate is still likely to increase as ART is scaled up. As a result, VCT services should be explicitly recognized as an important component of a comprehensive ARV program, and an appropriate budget allocation should be made.

The algorithm for VCT testing used for costing purposes here is a series of three rapid tests. The first of these is Abbott Determine ($1.14 per test) for screening. If a patient tests negative at this stage then no more tests are administered; if the patient tests positive, then a Genie 2 test ($3.45) is used for confirmation. In rare cases where the result of the second test is negative, then a Bionor test ($3.40) is used as a tie breaker. This is the algorithm upon which the procurement of approximately 140,000 test kits by JICA was based.

Per-person VCT costs will depend on the percentage of all samples that will require confirmation and tie-breaker testing. The percentage of individuals who test positive at VCT centers – and therefore require a confirmation test – is likely to be considerably higher than the population-wide prevalence rate, due to self-selection by those who seek testing (i.e., people who think they have been exposed to the virus are more likely to come for a test). Data collected in Zambia suggests that about 34 percent of individuals who have been tested over the last three years tested positive (Huddart et al., 2003, p.5.) Thus, if 34 percent require confirmation, and 5 percent of these require a tie-breaker test, then per-person VCT costs

for just the test kits would be $3.14.[14] Training costs per patient for VCT is about 50 cents.[15] Overall variable costs for VCT are therefore approximately $3.64 per patient.[16]

How many people will receive VCT services annually? As noted, this is a very uncertain variable in the cost and human resource calculations for an ARV program. Table 5 gives some estimates of VCT costs under different uptake rates. Presently there are about 100,000 people being tested each year in Zambia, which is equivalent to about 2 percent of the adult population. To provide some context, a WHO document has offered two possible targets for annual adult VCT uptake rates in high prevalence countries (WHO, July 2002). The first is a 4 percent adult uptake rate, while the second is based on an estimate that demand for VCT (i.e., by the at-risk population) may be estimated as twice the prevalence rate, and this volume can be spread over five years (since that is how often a person may be tested). In Zambia's case, this is equivalent to an uptake rate of about 6 percent. VCT costs may be substantial (a 4 percent uptake rate would cost the same as giving HAART to 1500 patients), and ARV program budget plans should be made accordingly. Zambia's Global Fund allocation does include a special line item for VCT.

Table 5: Total VCT Costs under Alternative Uptake Scenarios

Adult VCT uptake rate	Number of people tested	Implied # diagnosed (compare to 100,000 new infections annually)	Annual cost (for tests and training)
2 %	100,000	34,000	$364,000
4 %	200,000	68,000	$728,000
6 %	300,000	102,000	$1,092,000

4.3   Opportunistic Infections

The treatment of opportunistic infections is an important component of a comprehensive ARV policy. It can help ensure that the quality and length of life of a patient receiving HAART is fully maximized. However, estimating the number of people in need of OI treatment after an ARV program has been launched is not straightforward. It is true that patients receiving ARV therapy are less susceptible to OIs, and so on the surface it might seem that the cost of ARV provision will be partially offset by cost savings due to lower demand for OI treatment. However, although HAART patients will live longer and be healthier, if ARV therapy merely delays the onset of OIs, rather than eliminates them altogether, then

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[14] The need for a tie-breaker test should be very small given the high accuracy of the first and second tests. The calculation also includes an extra 15 percent added to account for logistics (storage and distribution) and wastage.

[15] This training cost is based on the following assumptions: each HIV-negative patient receives 43 minutes of counsellor time and each HIV-positive receives 48 minutes (these are based on direct observations as found in Huddart et al., 2003); each test (whether screening or confirmation) involves 15 minutes of either lab tech or nurse time (depending on who does the test); and it costs $500 to train one health care worker (based on the $100 per person per day budget and 5-day training courses provided by CBoH for the ARV pilot stage). See also Annex B for details.

[16] As with HAART, this excludes staff and building costs because to some extent these would not be incremental. There is probably a greater need for new physical space for VCT than for HAART, but the answer is not necessarily to build new stand-alone VCT facilities because of the effect of stigma on uptake. A comprehensive costing of capital requirements for VCT would entail a full needs assessment and greater clarity on the service delivery model (use of integrated sites, etc.).

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ultimately they still need to be treated. Also, a successful HAART program implies there will be more clinically eligible people alive, so even though the fraction requiring OI treatment will be lower, this would be offset to some degree by the greater number of total patients.

For Zambia, the main reason why costs associated with OI treatment are unlikely to fall substantially in the immediate future is because only a small portion of those who are clinically eligible will receive ARV treatment. Thus significant numbers of patients who are not receiving ARVs will still require OI care. Initially it appears that no more than 10 percent (10,000 out of roughly 100,000) of those clinically eligible for HAART will receive it; the other 90 percent will be as vulnerable to OIs as they are now.

In sum, overall demand for OI care is unlikely to change dramatically in the near term. Table 6 shows the per-patient costs of drugs and tests for treating the most common opportunistic infections. These costs include drugs and tests only; as before, an extra 15 percent has been added to account for storage, distribution, and wastage. Capital and labor costs are excluded as they will generally not be incremental, and it is assumed that the workforce is already adequately trained in the treatment of these illnesses.

Table 6: Unit Costs for Treating Opportunistic Infections

Tuberculosis (new cases)	$46.98
Oral Candidiasis (with nystatin)	$5.36
Oral Candidiasis (with ketaconazole)	$2.38
Toxoplasmosis	$15.49
Cryptococcal Meningitis (with amphotericin B)	$142.17
Cryptococcal Meningitis (with fluconazole)	$422.52
Pneumocarinii Pneumonia	$7.39

4.4   Prevention of Mother-to-Child Transmission

The prevention of mother-to-child transmission is one of the most cost-effective of all HIV/AIDS interventions. The per-unit cost (for treating both mother and child) for pMTCT drugs in Zambia is only about 23 cents if nevirapine is used.[17]

Each year there are about 450,000 births in Zambia, of which about 82,000 are to HIV-positive mothers. This is the potential annual target group for pMTCT. Research in Zambia has found a 39 percent MTCT rate if the mother is untreated (see Hira et al., 1989 and Luo, 2000), so about 32,000 HIV-positive babies would be born each year in the absence of any treatment. Providing pMTCT treatment lowers the transmission rate to perhaps 10 percent – that is, 10 percent of the newborns of HIV-positive mothers who received therapy will nevertheless also be HIV-positive. This implies that there would be about 8,200 HIV-positive births if all HIV-positive mothers were treated, and about 24,000 infections could be averted.

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[17] As before, this includes an extra 15 percent on top of the basic price to account for logistics and wastage. The focus of this section is the cost of drugs and training. Additional costs associated with pMTCT activities, such as Information, Education, and Communication materials and infant formula, have not been included. As elsewhere in this report, we do not include staff costs because generally these will not be incremental. While this may be true of doctor and nurse time, it is a much stronger assumption with regard to counsellors.

However, since only 43 percent of deliveries in Zambia are assisted (ORC Macro et al., 2002), it would be very difficult to come close to complete coverage.[18] In addition, some expectant mothers may not have access to or may refuse VCT services. Zambia's pMTCT program is being scaled up based on assumptions of a 65 percent testing uptake rate and an 80 percent pMTCT uptake rate. Finally, at present, pMTCT is only available in certain facilities in Zambia, and until it is fully scaled up, many women will not have access to this intervention.[19] Thus, in the near-term, it will be difficult to provide full pMTCT services to even half of the annual 82,000 HIV-positive expectant mothers. In sum, with a unit cost of 23 cents and a relatively small eligible group, drugs for the pMTCT program are not costly compared to ARVs for HAART.

Nevertheless, there may be substantial costs associated with a pMTCT program in terms of training requirements. This is largely due to the fact that most health care workers involved in pMTCT services will not be spending their time exclusively on this activity; rather, most are likely to be doctors or nurses engaged in maternal health who incorporate pMTCT into their other activities. So even though the total number of full-time equivalents (FTEs) required for pMTCT is not large, training requirements will still be substantial. Zambia's strategic framework for pMTCT recommends a 22-day training course on different aspects of service delivery. Huddart et al. (2003) estimate that if this training was provided to five health care workers in all hospitals and urban health centers, and two health care workers in all rural health centers, then the total cost would be nearly $3.9 million.[20]

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[18] However, 93 percent of pregnant women do access antenatal care services at some stage, opening the possibility for much higher coverage. For example, women who attend antenatal clinics could be given Nevirapine and instructed to take it when they deliver, and to bring their baby to the clinic for its dose following the birth.

[19] Zambia's targeted number of facilities to be providing pMTCT is 40 percent in 2003, rising to 70 percent in 2005.

[20] This is based on a $54 training cost per person per day. Note that this does not need to be incurred all in the same year – if it proceeded in parallel with the phase-in of pMTCT services across the country over four years, the annual cost would be about $1 million.

5. Total Program Costs and Sustainability

The per-patient costs of the previous section can be used to project total program costs under alternative scenarios for uptake rates and population coverage. This section will look first at the case of providing HAART to 10,000 clinically eligible individuals as planned, and then turn to the hypothetical scenario of full coverage.

5.1   Treating 10,000 Patients

The government of Zambia has stated its intention to treat 10,000 individuals during the early stages of its HAART program. Table 7 provides estimates of how much this would cost, based on the findings from earlier sections.

Table 7: Total Costs of Providing HAART to 10,000 Patients

Total cost of HAART for 10,000	$4,880,2000
Of which: Drugs	$2,773,100
Monitoring tests	$1,778,8000
Capital	$291,300
Training	$37,000

How would this be paid for? The government's 2003 budget has allocated 15 billion kwacha, or about US$3 million, to purchase ARV drugs. In addition, the draft budget for Zambia's Global Fund award allocates US$2.3 million in the first year and US$2.6 million in the second year for "interventions to prolong and improve the quality of life for the symptomatically affected." A Multi-country AIDS Programme (MAP) loan from the World Bank is also forthcoming, but it has not been decided how much, if any, will be earmarked for ARV provision. Finally, it has been suggested that assistance from the European Union and funds released through HIPC (heavily indebted poor countries) debt relief will also be available for ART financing, although specific values are not yet known.

As Table 7 shows, treating 10,000 patients at a cost of about $488 each yields a total cost of almost $4.9 million. This could be afforded with the $5.3 million of financing sources available for the first year noted above.[21] This margin between needs and resources would shrink or disappear if more expensive drug regimens are used, but it would be wider if, as will be discussed later, a more basic monitoring test protocol is adopted, if tests such as viral loads are only done at tertiary hospitals, or if a cost-sharing mechanism is implemented.

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[21] It was noted in the section on methodology that we have not addressed administrative and managerial costs. If these were to account for 5 percent (i.e., $265,000) of the $5.3 million available in the first year, the cost of $4.9 million could still be afforded by a small margin.

In any event, the adequacy of the resource envelope will become a more pressing issue in two years when the Global Fund grant elapses (particularly given uncertainty about the Global Fund's future). It must be stressed that both governments and donors should be cautious when committing funds to pay for ARVs, because until there is a cure it will be a lifelong treatment. Once a patient is provided with ARV drugs, whoever is paying should ideally commit to providing these drugs for the long term (unless, of course, a cure is found).

Even if the Global Fund grant is renewed in two years, or a replacement source of financing is found, this may only serve to keep the budget for ART *constant*. It is important to emphasize that, unless the budget for ART actually *grows*, no new patients can be initiated on treatment when they become symptomatic (except to replace those who die despite receiving HAART). Since patients typically only survive 1-2 years after they develop symptomatic AIDS, there is a relatively narrow window during which treatment can be initiated; otherwise they will die.

Figure 3 provides a very stylized profile of how the 850,000 HIV-positive Zambians may be distributed according to when they can be expected to become symptomatic (thus requiring OI or ARV treatment). With a typical profile of eight years living asymptomatically following infection, and then 1-2 years with symptomatic AIDS before death, the graph shows that there could be somewhere in the range of 85,000 to 110,000 new full blown AIDS cases *every year* until 2010. This estimation does not require making any assumptions about incidence, since these are individuals who are already HIV-positive today.[22] Figure 3 indicates why it is so important to consider financial sustainability, and in particular the availability of ARV funding for those who are not yet clinically eligible for HAART but who will become so in the near future.

Figure 3: Approximate Number of New Symptomatic AIDS Cases each Year in Zambia, 2003-2010

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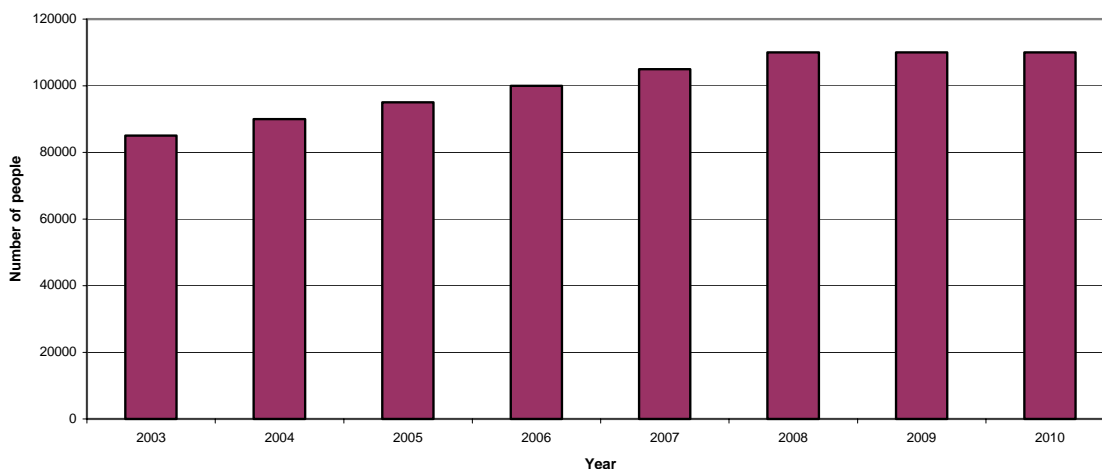
[22] This figure showing new symptomatic AIDS cases each year from 2003 to 2010 is similar to new HIV infections (incidence) from 1995 to 2002, since typically there are about eight years between infection and development of symptoms.

To address this issue in more detail, Figure 4 illustrates the consequences for population coverage of four possible scenarios.[23] Each graph shows the number of new patients who could be added each year and the cumulative number of patients on ARVs, under different scenarios for ARV budget growth. The scenarios are as follows:

1. *The current budget of about $5 million stays constant in future years.* In this case 10,000 people could initiate treatment in the first year, but no new patients could begin in subsequent years. This will favor those who are becoming symptomatic this year, and deny treatment to those who are currently asymptomatic but who will become clinically eligible soon (including any 'priority' groups if such a policy were developed). It will have strong implications for equity if, as is the case in Zambia, scale-up starts in major urban centers (i.e., provincial capitals) and does not reach rural areas until some years hence.

2. *The budget increases by an extra $5 million every year.* This scenario would allow for a steady expansion of coverage, since approximately 10,000 new patients could be added each year. However, the required budget growth is probably unrealistic.

3. *The budget grows by 25 percent per year.* This scenario requires a 25 *percent* annual budget rise, which is more plausible than scenario (2). Again, approximately 10,000 could begin treatment in the first year, but far fewer patients could embark on treatment in subsequent years.

4. *The budget grows by 25 percent per year, but the program starts more slowly, and treats only 5,000 patients the first year.* This scenario is perhaps more realistic by starting with moderate coverage (about 500 per facility in the nine hospitals), which would allow more time for lessons to be learned. Then 2005 can be a 'catch-up' year to bring more patients into the program.

In sum, Zambia's current resource envelope for ART is just about adequate to treat 10,000 patients as planned. However, with the Global Fund grant's future unknown after two years, and the reality that no new patients can start treatment in later years unless the budget grows, it may be better to scale back population coverage goals. Another alternative is to pursue a cost-sharing mechanism, as will be discussed in a later section.

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[23] These scenarios and population coverage rates assume a constant per-patient cost regardless of program size; of course per-person capital costs will vary, but as seen earlier this is not a major cost component on a per-patient basis, so for simplicity this issue is ignored here.

Figure 4: Budget Growth and HAART Coverage over Time
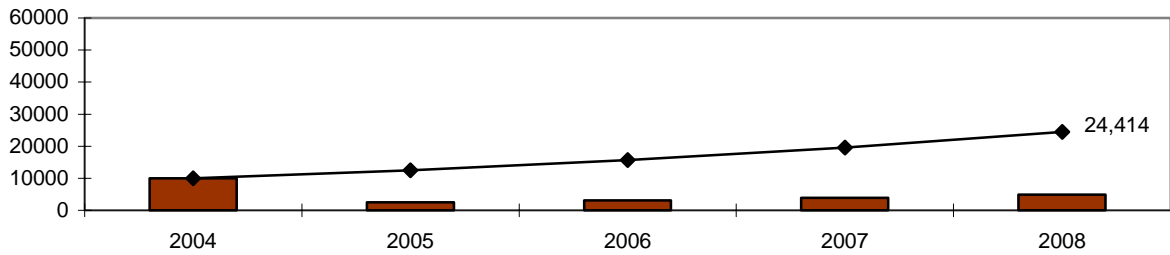
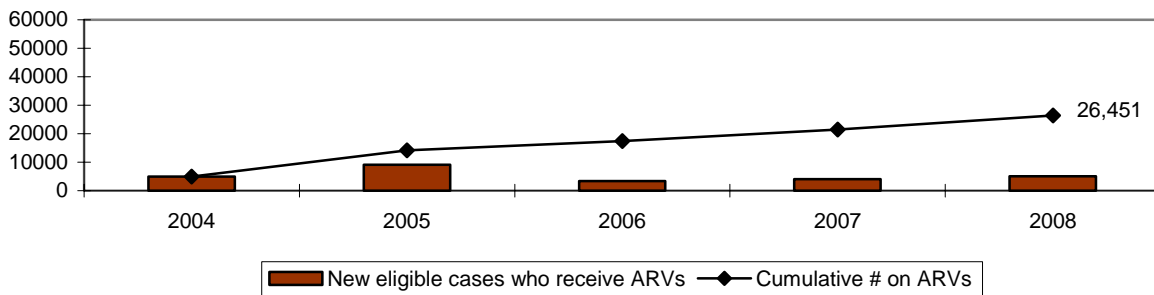**Scenario 1: HAART coverage if budget stays constant at $5 million per year**

Scenario 2: HAART coverage if budget grows by $5 million per year

Scenario 3: HAART coverage if budget grows by 25% per year

Scenario 4: HAART coverage if starting slowly, and budget grows by 25% per year

New eligible cases who receive ARVs   Cumulative # on ARVs

5.2   Full Coverage

Unfortunately, per patient cost results serve to underline the virtual impossibility of treating all those who are, or will soon become, clinically eligible for ARVs. As noted earlier, approximately 10-15 percent of those who are HIV-positive require ARVs right now, which represents about 100,000 individuals. Providing HAART to all of them at about $488 each would cost almost $50 million, or about two-thirds of Zambia's entire health budget. (For now we are just looking at financial considerations, and setting aside constraints related to access, uptake, and human resources). Full coverage will become even more forbidding in the years to come, as there is a 'backlog' of many hundreds of thousands of HIV-positive individuals in Zambia who will become symptomatic in the next few years (as indicated in Figure 3 above). Program and budget planning must take this into account.

It is also important to emphasize that a treatment program for AIDS patients will mean that the size of the eligible population for HAART will increase over time. This is because, while fewer people will be dying of AIDS thanks to HAART, there will still be roughly 100,000 new symptomatic AIDS cases every year as shown in Figure 3. Consider the case of full coverage – that is, treating all 100,000 symptomatic AIDS cases in Year 1. Whereas in the absence of a HAART program the average patient will only survive about a year or so after developing symptomatic AIDS, the annual mortality rate among those who *do* receive ARVs may be only 20 percent (although it must be stressed that there is little evidence of what this figure will be in a low-resource setting). In this case, by Year 5 of the program, there would be a need to treat some 330,000 patients with ARVs at a total cost of about $160 million, or over twice the entire annual health budget.[24] This is well beyond Zambia's reach.

Applying the same logic to the HIV-positive population in general shows how overall prevalence rates could *rise* with a successful ARV program. This is because while ART means fewer people are dying of HIV/AIDS, potentially just as many people are becoming newly infected as before.[25] Assuming that the number of new infections stays constant at 100,000 per year, and assuming as before that the mortality rate of those on HAART is 20 percent, providing ARVs to everyone eligible would cause the prevalence rate among adults in Zambia to rise from 16 percent now to about 18 percent in five years. This point is not intended as an argument against providing HAART, but rather as an attempt to highlight an implication of expanding treatment that is not always recognized.

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[24] Of course these long-term calculations are quite speculative – for example, per patient prices could fall sharply – but the exercise does highlight how difficult it will be to attain full coverage. Note that if mortality among those on HAART is lower than 20 percent annually, the cost will be even higher.

[25] Although the reduced viral load of those on ART may lower their infectivity, they are also living longer (creating more opportunities to infect others) and feeling better (so there may be a relapse to risky behavior). There is an ongoing debate about whether the availability of HAART will raise or lower infection rates; the assumption here takes the middle ground by assuming no change in the infection rate. It should be noted that even if ART does lower incidence, and so prevalence does fall, the reduced burden on the health system will not be noticed for many years, because it is generally only those in late-stage HIV/AIDS who require ARV or OI treatment.

6. Policy Issues

This section provides a brief discussion of several policy issues that arise as a result of the per-patient and total cost estimates of the previous sections.

6.1   Human Resources

Discussions surrounding the provision of ART in low-resource countries such as Zambia are often based on the assumption that *the* major constraint facing rapid scale-up is the very large financial cost of ART. However, another extremely important constraint facing program expansion is a lack of human resources. This is a result of the sheer number of HIV/AIDS patients, the underdeveloped condition of the health system to begin with, and because health care workers are themselves dying of AIDS.

To analyze this further, as a starting point we can consider the human resource requirements of providing HAART to 10,000 patients as planned. Using the same per-unit staff requirements listed earlier, this would require 13 FTEs of doctors and nurses, 15 FTE pharmacists, and 32 FTE laboratory technicians. This appears feasible, although the lab technician requirements are substantial. However, VCT threatens to pose a greater burden. In order to reach a 4 percent adult uptake rate for VCT would require 54 laboratory personnel FTEs, or nearly 15 percent of Zambia's entire public sector lab workforce (unless testing is done by nurses). It would also require about 127 counselors (not including counselors required in order to provide pMTCT services).[26]

What about *full* ART coverage for the clinically eligible population? As discussed in the previous section, full coverage would imply treating 100,000 patients in Year 1 of a program, rising to about 330,000 patients in Year 5 (this assumes, once again, that 20 percent of HAART patients will die each year despite the treatment). This patient volume would require 130 full-time equivalents in the first year, rising to 429 by the fifth year, for doctors and nurses. For lab technicians, the FTE requirement under full coverage would rise from 316 in Year 1 to 1043 in Year 5. This year 5 requirement is well over twice Zambia's entire lab technician workforce and about 50 percent of its doctor workforce. Moreover, this is only for HAART and ignores VCT and other services. Thus, clearly the human resource constraint is just as forbidding as the financial constraint in terms of full coverage scenarios.

Thus, the largest human resource deficits facing Zambia as it aims to scale up ART and supporting services pertain to the potential of severe shortages of laboratory technicians and counselors, as well as doctors. The counselor shortage must in addition address the fact that there is a high burnout rate among counselors, meaning that each year a significant number of new counselors must be hired and trained in order to maintain a steady state.

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[26] As before, these calculations are based on the assumption that on average a patient receives 45 minutes of counselor time during VCT, and it takes 15 minutes of lab technician time to conduct one test (whether screening or confirmation).

In terms of policy recommendations, there is clearly a pressing need for Zambia's health care system to begin addressing these shortfalls through an intensive effort to train more workers in these categories. One alternative measure would be to increasingly use nurses for VCT (although there isn't a surplus of nurses either). This may create difficulties with regulations stipulating that all tests be conducted by trained lab technicians, so these rules may need to be revisited. Indeed, the strategic framework for pMTCT discusses a greater role for nurses in this regard.[27] Other policy options include innovative service delivery models that make use of community lay-workers, and greater engagement of private sector providers.

Table 8: Staff Requirements (in FTEs) for Various Services and Population Coverage Rates

	Doctors	Nurses	Lab techs	Counselors	Pharmacists
Full coverage HAART in Year 1 (100,000 patients)	130	130	316	0	150
Full coverage HAART in Year 5 (330,000 patients)	429	429	1043	0	495
HAART for 10,000 patients	13	13	32	0	15
VCT for 4 % adult uptake rate	0		54*	127	0

Note: All results are presented as full-time equivalents.

*=The requirement would be 54 nurses *or* 54 lab techs, depending on who does the testing.

6.2   Clinical Care Model: Monitoring Tests and Second-line Drugs

The results for per-patient costs can be used to demonstrate some of the difficult issues inherent in the selection of a clinical care service delivery model. This is particularly relevant to the frequency of monitoring tests and the availability of second-line drugs.

A comprehensive approach to laboratory monitoring of ART patients is critical for treatment success, but with a limited budget for ARV provision, more testing of those on ARVs will mean fewer patients receiving ARVs in the first place. An earlier section reported that per-patient costs were $488.02 with a moderate testing protocol,[28] but this falls to $408.41 if one fewer of each test is conducted. This implies that *20 percent more patients* could be treated with the minimal level of testing compared to moderate testing.

A similar issue is faced with regard to the provision of expensive second-line regimens. The number of patients who could be treated would be 26 percent greater if a policy of *only* providing one of the cheaper protocols as a first line was adopted, instead of trying to treat 10 percent of patients with a

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[27] See CBoH/MoH/NAC (2003).

[28] This was defined as three full blood counts, three urea/creatinine tests, three blood sugar tests, three liver function tests, two CD4 counts, and one viral load annually.

second-line regimen.[29] In other words, the cost of providing first-line therapy to 126 patients is the same as providing first-line treatment to 90 patients *and* second-line treatment to a further 10 patients. A similar trade-off will be confronted even in the case of a first-line regimen that does not use the cheapest fixed dose combinations (recall from earlier that per-patient costs for triple therapy using Efavirenz or Abacavir was about three times as expensive as using Triomune or Duovir-N). This has indeed been the case, as recent procurement by CBoH involved purchases of both Efavirenz and various second-line drugs, implying that fewer patients will be receiving HAART in Zambia than might otherwise have been the case.

Of course decisions regarding the frequency of monitoring tests and the availability of second-line drugs have very important clinical implications. The calculations in this subsection are not intended as an argument against more expensive service delivery options, because these decisions must be made by all the stakeholders involved in ART policy in Zambia. Instead the objective is to simply emphasize that, when facing the difficult task of defining the most effective and efficient service delivery protocols, policymakers and providers should be mindful of the relationship between the extent of treatment provided to an individual patient and the number of patients who can be treated with ARVs overall.

6.3   Resource Mobilization

Once the total costs of ARV provision have been identified, the logical next step is to ask who can contribute, and how much. The funding commitments from the government of Zambia and the Global Fund were mentioned earlier, and some of the difficulties associated with financial sustainability were also discussed. A potentially promising method for easing the budget constraint on ARV provision in Zambia would be cost-sharing by patients as a means of resource mobilization. This introduces the question of the extent to which the government may choose to subsidize different categories of ART patients.

The ARV policy document (National AIDS Council, 2002), makes reference to the issue of cost-sharing mechanisms and suggests that provincial selection committees should play a role in determining the specifics for each patient. More recently, the Cabinet approved guidelines on cost-sharing that identify four potential contribution rates from ARV patients: (i) exempted patients would pay nothing; (ii) most non-exempt patients would contribute 20 percent of the cost; (iii) in the case of certain employed workers, their employers would contribute 75 percent of the cost; (iv) those who can afford to remain in the private sector would pay the full cost. However, it has not been decided exactly how many patients will be drawn from each of these four categories (or, indeed, how the categories will be operationalized).

For illustrative purposes, two options are presented in Table 9: (i) no cost-sharing by patients; (ii) identify 10 percent of patients who can afford to pay everything; 10 percent whose employers can contribute 75 percent of the cost; ask 50 percent of patients to contribute 20 percent; and exempt 30 percent of patients from any cost-sharing.[30]

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[29] Ten percent is only used as an illustration; the actual fraction in need of second-line treatment in Zambia will become more clear as the program expands, and is likely to change over time. It is important to note that because population coverage will initially be low, there will be scope to select eligible patients from different categories (e.g., those requiring first line vs. second line) in proportions that are different from the overall HIV-population-wide proportions.

[30] A more complicated resource mobilization strategy could include a subsidy by government to encourage those already receiving ART (or those who can afford it when they become eligible) to stay on that treatment stream instead of moving to the free public stream and displacing those in greater need.

Table 9: Illustrative Cost-sharing Scenarios for 10,000 Patients

	Patient contribution	% of patients	Cost to gov't	Cost to patients	Total cost
Option 1	Pay nothing	100%	$4.9 million	$0	$4.9 million
	Contribute 20%	0%			
	Contribute 75%	0%			
	Pay everything	0%			
Option 2	Pay nothing	30%	$3.1 million*	$1.8 million	$4.9 million
	Contribute 20%	50%			
	Contribute 75%	10%			
	Pay everything	10%			

* = See text for alternative uses of the $1.8 million "savings."

Obviously Option 1 is more expensive for the government, as Option 2 shifts more than one-third of the total cost to patients (and in some cases to their employers). The $1.8 million "savings" implied by Option 2 could either be used to expand coverage to an additional 5100 patients using the same contribution structure (so that the $4.9 million budget could be used to provide treatment to a total of 15,100 patients), or it could be placed in a fund to improve the ART program's financial sustainability in subsequent years (especially after the two-year Global Fund grant expires).

Option 2 raises important issues of equity and feasibility, and a comprehensive evaluation would require a study of both willingness and ability to pay. Whether or not patients can be expected to contribute $1.8 million to the overall cost may vary across the four categories, and at this stage only tentative conclusions can be drawn.

The exact number of patients currently receiving ARVs through the private sector – either by paying for themselves or with the support of an employer – is uncertain, but drawing 10 percent of the overall treated population from each of these two groups (as Option 2 implies) may be feasible.[31] Asking half the treated population to contribute 20 percent of the per-patient cost without compromising equity may be more problematic, since many Zambians may not be able to afford $98 each year, as a 20 percent co-payment would require. Annual per-capita GDP in Zambia is about $330, and private expenditure on health is $7 per capita (World Bank, 2003). Although extended families may help out, often more than one member of a family is HIV-positive. Finally, exempting 30 percent of the treated population from any cost sharing would help promote equity, as long as the exemption program adequately targets the poor. However, it could also be argued that requiring a co-payment, however small, may help remove the negative incentives that can be created whenever a commodity is made available for free. A co-payment could serve to emphasize that receiving ART is a responsibility (in terms of adhering to the regimen, not creating drug resistance, etc.) as well as a privilege.

Of course cost-sharing programs will necessitate an accompanying administrative structure that will require resources of its own, and raises questions about the ability of a low-resource country such as Zambia to effectively operate a means-testing program. Still, the resource mobilization issue deserves

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[31] For equity reasons, the feasibility of filling these categories with the required number of patients is evaluated with regard to a hypothetical representative sample of 10,000 clinically eligible HIV-positive Zambians. Filling the categories with the relatively rich would be much easier, and with the relatively poor much harder.

serious consideration, because it would allow a greater number of patients to be treated under the existing budget allocation.

6.4   Targeting

Perhaps the most difficult policy issue to be addressed by an ART program is to decide *who* should receive treatment, given that financial and human resource constraints make full coverage an impossibility. A wide range of possible criteria for this decision exist: equity (e.g., treat the poor first), epidemiology (e.g., treat those most likely to spread the disease), occupation type (e.g., treat teachers and nurses first), and so on.

As yet Zambia has not articulated a detailed policy for targeting its ART provision, although the ARV policy document discusses the possibility of decision making by stakeholders at the provincial level. Ideally this would be done in a participatory and transparent manner. A costing model clearly cannot make targeting decisions, but by identifying the approximate number of people that the country can afford to treat, it provides a useful starting point for the targeting debate.

As we saw earlier, Zambia can just about afford to treat 10,000 patients on HAART. Using the numbers noted earlier in the section on pMTCT, and the fact that about 10 percent of HIV-positive people are clinically eligible, the potential target for "pMTCT-plus" (that is, HAART for HIV-positive mothers who receive pMTCT) is about 1000-2000 individuals annually. The potential target group for providing HAART to all HIV-positive health care workers (assuming prevalence is similar to the population-wide rate) is 200-300 individuals annually. Similar calculations could be made for other potential target groups.

As a final note on targeting, it should be stressed that if 10,000 people are initiated on HAART this year, and the budget for ARVs stays constant in subsequent years, *no new patients* could begin therapy – and this would apply equally to those in the potential target groups (e.g., HIV-positive mothers) who are not yet symptomatic but who will become so in the next few years.

7. Conclusion

The public provision of HAART in Zambia offers the hope of a longer, more productive, and improved quality of life for those patients who receive it. It can also support prevention efforts and reduce the burden imposed by HIV/AIDS on the health system and the economy in general. However, HAART is also a complicated and expensive intervention. The focus of this report has been on the per-patient costs and human resource requirements entailed by the provision of HAART, and the total program costs and policy implications that flow from those per-patient results. The key messages are as follows:

▲ Given a per-patient cost of $488, the current budget for HAART is just about adequate to treat 10,000 people as planned. But over the longer term, a larger budget, a cost-sharing mechanism, or a lower coverage goal will be necessary to reconcile needs with available resources.

▲ Financial sustainability is a key issue, not least because in the absence of a cure the provision of Anti-retroviral Therapy (ART) is for life, and so the provision of funding for ART – whether by the government or by donors – must be a permanent commitment. Policymakers should pay close attention to issues of sustainability, particularly in view of the uncertain status of the Global Fund contribution after two years.

▲ Human resource constraints are extremely important and need to be addressed as soon as possible. Many more of all staff types will be required if coverage is to be expanded, and thus training programs should be initiated as early as possible. Even at modest levels of patient coverage for HAART, the human resource constraint is likely to become more binding than the financial constraint.

▲ The selection of effective and efficient treatment protocols is important due to its implications for population coverage. Offering extensive monitoring test protocols and second-line drugs will mean that fewer patients can receive HAART overall. The recent procurement of expensive drugs such as Efavirenz, Abacavir, Didanosine, and Indinavir offers a key example, since purchasing these for some patients implicitly denies a greater number of other prospective patients the chance of treatment on standard fixed-dose combination regimens.

As a final note, it should be emphasized that the context in which HAART is being rolled out in Zambia is a dynamic one. Drug and test costs are falling rapidly, policy plans continue to evolve, and indeed the state of the HIV/AIDS epidemic itself is constantly changing. Thus, the results presented here may need to be updated regularly. Hopefully these changes, and the expansion of HAART itself, will mean that each update will reveal a more optimistic future for Zambia.

Annex A: Background on AIDSTREATCOST (ATC) Model

In many low-resource countries, there has been renewed discussion recently about the prospect of providing ARV treatment to HIV/AIDS patients. However, these discussions are frequently taking place in the absence of comprehensive, country-specific information on the cost and resource implications of such ARV programs.

In response to this trend, PHR*plus* has developed the ATC model, a software tool for estimating the total cost and resources required for ARV programs. The ATC is designed to help policymakers and practitioners take a "health systems" approach to ARV provision, by conceptualizing and thinking through all relevant questions including infrastructure requirements, health care providers, equipment, lab tests, drugs, and other critical elements used to deliver ARV services.

The model can be tailored to country-specific situations using local data from statistical agencies, ministries of health, health facilities, and so on. Intended users are policymakers, program planners, and technical working groups who could estimate the costs and resources required to implement an ARV program under various assumptions and scenarios that the model allows the users to identify themselves. The emphasis on country-specific data and the flexibility with regard to choosing scenarios are key features of the model, and they both help to make the ATC as relevant as possible to country decision makers.

The ATC model does not advocate any particular policy on ARV provision. It merely recognizes that many low-resource countries are going forward with ARV policies and provision, and in many cases they are doing so without a comprehensive plan or estimate of the total costs entailed. The ATC serves to provide a comprehensive framework within which to consider various options, and highlights the opportunities and constraints inherent in any policy choices being considered.

It is important to identify certain issues that the ATC does *not* attempt to address:

- ▲ The model is not intended as a costing tool for a comprehensive national HIV/AIDS strategy. Instead, its focus is on treatment. It therefore excludes many important components of an overall HIV/AIDS strategy: for example, the costs of home-based care; facility-based palliative care; nutritional programs; information, education, and communication programs; drug-sensitivity testing; and special programs for AIDS orphans.

- ▲ The model does not attempt any cost-benefit analysis of treating people living with AIDS. Nor does it measure the cost-effectiveness of alternative service delivery approaches or treatment regimes (e.g., issues of technical or allocative efficiency or opportunity costs, for comparing prevention and treatment programs, etc.).

- ▲ The ATC model will help the user think through the inputs required for an ARV program and their costs, but it makes no attempt to address certain "non-monetary" inputs that are just as critical to a successful program (for example, strong management structures, accountability,

stakeholder support, etc.).

▲ Although the model uses epidemiological data to calculate costs, it is not fundamentally a tool for projecting the AIDS epidemic in a country. That is best done with other models.

▲ The model does not decide who should be treated in those settings common to high-prevalence, low-resource countries like Zambia where demand for ARV therapy exceeds supply. However, understanding how many people the country can afford to treat does help to focus any discussion of targeting.

▲ Finally, the model does not address who will pay for the provision of ARV treatment, although that is an extremely important issue facing many countries. Nevertheless, understanding the costs of treatment is a crucial input to any discussion of resource mobilization.

Annex B: Data Sources for Use of the AIDSTREATCOST Model in Zambia

Table A1: Demographic and Epidemiological Data

Data Item	Sources/notes
Total population	U.S. Census Bureau website http://blue.census.gov/ipc/www/idbnew.html
Mortality rate	U.S. Census Bureau website http://blue.census.gov/ipc/www/idbnew.html
Fertility rate	ORC Macro et al., 2002, Zambia DHS 2002 Preliminary report
HIV prevalence rate	ORC Macro et al., 2002, Zambia DHS 2002 Preliminary report
HIV infection rate	Prevalence is assumed to be constant, so the number of new infections equals the number of AIDS deaths.
HIV infection rate, AIDS symptoms dev't rate, AIDS mortality rate	Prevalence is assumed to be constant. The incubation period is assumed to be 9 years asymptomatic after infection, then 1 year symptomatic, followed by death. (This is drawn from the AIDS Impact Model (AIM) presentation by Futures Group, September 1999). Together these assumptions yield estimates for the rates of HIV infection, AIDS symptoms development, and AIDS mortality.
Mortality rate among those receiving HAART	Estimated as 20%; little available information exists on this indicator in low-resource countries.

Note that epidemiological data does not have an impact on the costs of HAART for all scenarios in which ARVs are only provided to a fraction of those who are clinically eligible.

Table A2: Drug and Test Costs

Data Item	Sources/notes
Monitoring tests and costs	Cost of tests: University Teaching Hospital Choice of tests: National HIV/AIDS Council, 2002, "Formal Introduction and Implementation of ART in Zambia"
Full Blood Count	$8.33
Urea/Creatinine	$7.92
Blood Sugar	$4.17

Liver Function Tests	$20.83
CD4 count	$3.00
Viral load	$25.00
ARV drug prices (per pill)	Source: CBoH, 2003
Triomune (stavudine 40 + lamivudine + nevirapine)	$0.38
Duovir-N (zidovudine + lamivudine + nevirapine)	$0.28
Duovir (zidovudine + lamivudine)	$0.37
Abacavir sulphate (300mg)	$0.81
Efavirenz (200mg)	$0.59
Nevirapine (200mg)	$0.19
Indinavir (400mg)	$0.23
Ritonavir	
Didanosine (100mg)	$0.22
VCT test kits and costs	Source: JICA, 2003
Abbott Determine (screening)	$1.14
Genie 2 (confirmation)	$3.45
Bionor (tie-breaker)	$3.40
MTCT drug costs	Source: CBoH, 2003
Nevirapine for mother (200mg)	$0.19
Nevirapine for infant (10mg/1ml)	$0.01
OI protocols and costs	OI protocols: National HIV/AIDS Council, 2002, "Guidelines on Management and Care for HIV/AIDS" Test costs: UTH Drug costs: CBoH
Tuberculosis (new cases) – drug cost (2rhze + 6eh)	$24.35
Tuberculosis (new cases) – test cost (3 gram stains, 1 x-ray)	$16.50
Oral Candidiasis (with nystatin) (test is a clinical exam)	$4.67
Oral Candidiasis (with ketaconazole) (test is a clinical exam)	$2.07
Toxoplasmosis (drug cost)	$3.47
Toxoplasmosis (test cost – IgG/IgM)	$10.00
Cryptococcal Meningitis (with amphotericin B; includes IV equipment)	$119.46
Cryptococcal Meningitis (with fluconazole)	$363.24
Cryptococcal Meningitis (test cost – CSF microscopy)	$4.17
Pneumocarinii pneumonia – drug cost	$2.43
Pneumocarinii pneumonia – test cost (x-ray)	$4.00

Note: Drug and test costs reported here do *not* include an extra 15 percent for logistics and wastage as in the text.

Table A3: Capital, Staff, and Training Costs

Data Item	Sources/notes
Laboratory equipment requirements and costs	National HIV/AIDS Council, 2002, "Formal Introduction and Implementation of ART in Zambia". Some equipment only procured for the 2 tertiary facilities.
Thermal Cycler	$12,000
Real-time PCR	$40,000
Flow Cytometer	$50,000
Hematology Analyser	$20,000
Chemistry Analyser	$25,000
Tissue Processor (histology)	$15,000
Class 2 Safety Cabinet	$10,000
X-ray Facilities	$40,000
Vehicle Requirements and Costs	$30,000 per vehicle; one for each of the 9 facilities. Estimate. Not addressed in policy documents.
Interest rate	8% (estimate of *real* interest rate)
Staff costs	Staff costs (e.g., wages, etc.) are not included since the focus is on incremental costs. Data for the total number of staff working in the health system are based on data provided by the CBoH human resources department.
Training costs	Training cost is $100 per day (includes lodging, per diem, and transport to site; training materials; trainer costs, etc.). For HAART, doctors, nurses, lab techs, pharmacists, and counselors all receive a 5-day course. For pMTCT, workers receive a 20-day course.
	Cost information and course duration is from CBoH, which provided HAART training in the fall of 2002; pMTCT course duration is drawn from pMTCT document

Table A4: Service Delivery

Data Item	Sources/notes
Access rate	No effect on per-patient cost or illustrative 'full coverage' scenario
Uptake rates	No effect on per-patient cost or illustrative 'full coverage' scenario
Staff time	Drawn from Huddart et al., 2003, "HIV/AIDS Workforce Study"
Annual visits	Drawn from Huddart et al., 2003, "HIV/AIDS Workforce Study"

Annex C: People Met

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Dr. Alex Simwanza, NAC

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