Scaling Up Antiretroviral Treatment in the Public Sector in Nigeria: A Comprehensive Analysis of Resource Requirements

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Abstract

This report presents estimates of the total cost of providing comprehensive antiretroviral (ARV) treatment in the public sector in Nigeria, using the AIDSTREATCOST model to estimate the cost of providing Highly Active Antiretroviral Therapy (HAART), Voluntary Counseling and Testing (VDT), and Opportunistic Infection (OI) treatment, and other resource requirements for implementing the national antiretroviral (ARV) treatment program.

Drugs are not the only major cost of an ARV program, but they are the largest single component ($368, or 50 percent of the total annual program cost of $742 per patient); monitoring tests account for 23 percent and labor costs for 22 percent of total program costs.

A large proportion of current treatment costs is borne by the patient – $170 per year for monitoring and a further $86 for their contribution to ARV drugs. This is equivalent to almost 75 percent of per capita GDP and therefore well beyond the resources of most Nigerians. Patients also are expected to pay for VCT services ($11), and for OI treatment costs when these arise. The development of an effective ARV program, therefore, must include support not only for ARV drugs but all aspects of patient cost.

The report also examines financial and human resources requirements for achieving the World Health Organization-recommended targets and recommends a number of strategies for the government and development partners to consider regarding program expansion, human resources training and requirements, support for VCT, the high cost of monitoring tests, and drug cost.

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Acronyms

3TC	Lamivudine
ART	Antiretroviral Therapy
ARV	Antiretroviral
ATC	AIDSTREATCOST
CD4	Cell Differential
D4T	Stavudine
FMOH	Federal Ministry of Health
GDP	Gross Domestic Product
HAART	Highly Active Antiretroviral Therapy
HEAP	HIV/AIDS Emergency Action Plan
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome
JUTH	Jos University Teaching Hospital
LACA	Local Action Committee on HIV/AIDS
LUTH	Lagos University Teaching Hospital
MTP	Medium-term Plan
NACA	National Action Committee on HIV/AIDS
NASCP	AIDS/STD Control Program
NIMR	National Institute of Medical Research
NVP	Nevirapine
OI	Opportunistic Infection
PCR	Polymerized Chain Reaction
PCP	Pneumocystis Carinii Pneumonia
PHC	Primary Health Care
PHR*plus*	Partners for Health Reform*plus* Project
PLWHA	People Living with HIV and AIDS
SACA	State Action Committee on HIV/AIDS
STD	Sexually Transmitted Disease

TB	Tuberculosis
UNAIDS	Joint United Nations Programme on HIV/AIDS
USAID	United States Agency for International Development
US$	United States Dollar
VCT	Voluntary Counseling and Testing
WHO	World Health Organization

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Executive Summary

With a current prevalence rate of nearly 6 percent and infection rates in some parts of the country as high as 16 percent, Nigeria is in the midst of a potential crisis, facing the real possibility of rates escalating to levels seen in Southern Africa unless treatment and prevention activities are greatly enhanced. In recognition of the seriousness of the situation, the Nigerian government has demonstrated solid commitment to combat the HIV/AIDS epidemic by implementing Africa's largest antiretroviral (ARV) treatment program.

The program provides ARV treatment at 25 sites across the country at a subsidized price. While each site is responsible for recruiting a specified number of patients, enrollment in the program has been so successful that many centers exceed their allotted slots (quotas). As a result, some sites are now experiencing stock-outs of ARV drugs. While the government's program has experienced significant success, there are a number of issues that need to be addressed before the program can be successfully expanded. Among them are: high drug costs, drug stock-outs, a lack of training for providers, inadequate monitoring of patients, and inconsistent selection criteria for eligible patients.

The purpose of this report is to estimate the per patient cost of providing Highly Active Antiretroviral Treatment (HAART) in the public sector in Nigeria. The report uses the AIDSTREATCOST (ATC) model to estimate the cost of providing HAART, Voluntary Counseling and Testing (VCT), and Opportunistic Infection treatment, and resource requirements for implementing the national antiretroviral program. Most of the information used in this report was collected from the Federal Ministry of Health and from four of the 25 ARV treatment sites.

This report presents four key findings. First, on a per patient basis, ARV drugs are the largest single cost component in the provision of ARV treatment. The average annual per patient cost of drugs under the government program is about $368, representing 50 percent of the total cost. Second, monitoring tests and labor represent significant components of the total cost, with an average annual per patient cost of $170 and $161 respectively. Third, capital and training costs are relatively low, accounting for $27 and $15 per person per year respectively. Lastly, out-of-pocket expenditure for AIDS patients is alarmingly high. While the government subsidizes ARV drugs, patients pay about $86 annually as a contribution to the drug cost. Furthermore, the monitoring and screening costs ($170) are borne exclusively by the patients, bringing total patient out-of-pocket expenditure up to $256 per year. This is equivalent to almost 75 percent of annual per capita gross domestic product, well beyond the resources of most Nigerians. The development of an effective ARV program, therefore, must include support not only for ARV drugs but for all aspects of patient cost.

The report goes on to examine costing scenarios for expanding the government program in both scale and scope. Using the World Health Organization's (WHO) targets of providing ARVs to a total of 3 million people living with HIV/AIDS worldwide by 2005, Nigeria will have to provide ARV

treatment to 262,500 patients.[1] The results suggest that expanding the program in this way will cost a total of $188 million annually and require the services of a total of 2,415 health care professionals.

A successful ARV program requires more than just an adequate budget. The development of clinical protocols, training curricula, eligibility criteria, and pharmaceutical management systems are also critically important. Nigeria has taken important steps on many of these issues, but much work remains to be done. While a costing exercise such as this embodies only one of many issues that need to be addressed, it can offer valuable recommendations to help ensure successful program expansion. To inform the decision-making process, the report recommends a number of strategies for the government and development partners to consider:

- **Program Expansion.** Program expansion is estimated to cost an additional $177 million per year. Mobilization of additional resources will be required.
- **Human Resources Training & Requirements.** Given the substantial additional human resources needed to expand the government ARV program, priority should be given to improving and expanding ARV training programs.
- **Support for VCT.** The importance of VCT in promoting prevention efforts suggests that there are strong public health reasons for the government to subsidize this activity.
- **High Cost of Monitoring Tests.** The government may consider the possibility of subsidizing the cost of monitoring tests or modifying treatment protocols.
- **Drug Cost.** Reducing the cost of drugs may require intensive negotiations pharmaceutical companies, possibly leading to bulk purchase from one pharmaceutical company.

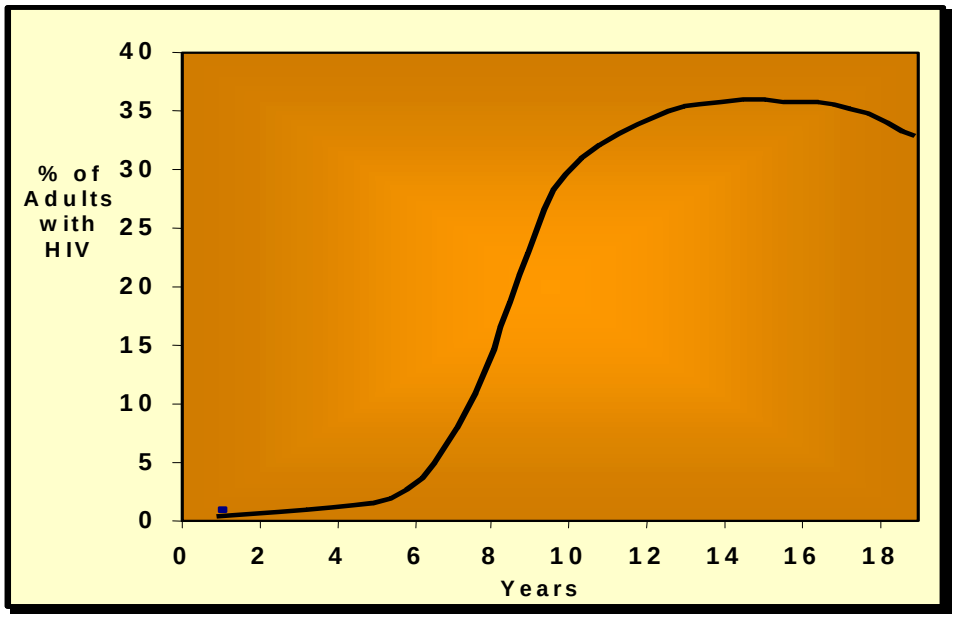
It is envisioned that these key findings will provide the Federal Ministry of Health, donors, policymakers, and other stakeholders valuable information to guide the expansion of the national ARV program.

[1] UNAIDS estimates 3.5 million people living with HIV and AIDS in Nigeria, 15 percent (or 525,000) of which are estimated to have full-blown AIDS. The Initiative aims to treat half of these, or 262,500. See: WHO, 2004.

1. Introduction and Purpose

Nigeria is the tenth largest country in the world and Africa's most populous nation. In 2002, the population of Nigeria was estimated at 133 million with a per capita gross domestic product (GDP) of $328 (United Nations Development Programme [UNDP] 2003). Nigeria has had a growing HIV/AIDS epidemic since 1986 when the first case of AIDS was formally reported. The epidemic is generalized, affecting men and women, urban and rural areas with almost equal intensity (UNAIDS 2002). Recent estimates from UNAIDS and other sources indicate that adult HIV prevalence has increased steadily from 1.8 percent of the population in 1991 to nearly 6 percent a decade later, with infection rates in some parts of the country as high as 16 percent. The potential for infection rates to intensify is high, and unless prevention and treatment services are greatly improved, it is possible that the country could face prevalence rates similar to those seen in Southern Africa.[2] Most experts are concerned that if Nigeria follows the HIV growth curve shown in Figure 1, within five years 25 percent of Nigerians could be HIV positive (National Intelligence Council 2002).

Figure 1: Typical Growth of HIV/AIDS in a Southern African Country



Source: National Intelligence Council (2002)

[2] It is important to note, however, that the impact of scaling up an antiretroviral (ARV) treatment program on prevalence rates is not clear. ARVs keep people living with AIDS alive longer, which will raise prevalence. Thus it is unclear whether an ARV program will contribute to higher (e.g., through disinhibition) or lower (e.g., due to lower viral loads of those being treated) infection rates.

The Nigerian government has demonstrated clear and solid commitment to providing antiretroviral (ARV) treatment to people living with HIV/AIDS. Public health expenditure increased from 0.3 percent of GDP in 1996, the lowest of any country in the world, to 0.5 percent of GDP in 2000 (UNDP 2003). Underlining this trend, in April 2001 the government implemented an initiative widely known as Africa's largest ARV treatment program. This program, announced at the Summit of African Leaders, aims to provide ARV treatment to 10,000 adults and 5,000 children living with AIDS, and complements other work being done by various local and international agencies in the country.

Despite Nigeria's staunch efforts in fighting the disease, there is still much to be done in scaling up HIV/AIDS services. For example, recent ARV drug stock-outs at several facilities have raised serious concerns about the sustainability of the national ARV program (observations of Dr. Sani Gwarzo, Federal Ministry of Health). Other concerns include a lack of training for health providers in ARV treatment issues, ARV drug management, unreliable patient monitoring, and a lack of standard procedures and criteria for patient selection.

This report presents the results of a study to estimate the per patient cost of providing Highly Active Antiretroviral Treatment (HAART) in the public sector in Nigeria. The study uses the AIDSTREATCOST (ATC) model to estimate the costs and resource requirements of implementing and scaling up the national antiretroviral program. Key findings from this report will provide the Federal Ministry of Health (FMOH), donors, policymakers, and other stakeholders valuable information to guide the expansion of the national ARV program. Specifically, the findings will allow program planners and policymakers to look at the total program cost and human resource requirements of providing ARV treatment in the public sector.

A successful ARV treatment program requires more than just an adequate budget. The development of clinical protocols, training curricula, eligibility criteria, and pharmaceutical management systems are also critically important. Nigeria has taken important steps on many of these issues, but much work remains to be done. While a costing exercise such as this embodies only one of many issues that need to be addressed, it can offer valuable recommendations to help ensure successful program expansion.

2. Background

Nigeria adopted the Primary Health Care (PHC) philosophy as the basis for formulating the national health development policy in 1979. The policy provides for integrated health care services that consist of preventive, curative, and rehabilitative interventions that are relevant and acceptable to Nigerians. It is within the PHC framework and philosophy that the federal government of Nigeria, as part of its response to the HIV/AIDS epidemic, launched the public sector-funded antiretroviral program in 2002.

In order to respond to the HIV/AIDS pandemic, the government established the National AIDS/STD Control Program (NASCP) under its first medium-term plan (MTP I), followed by MTP II, which ended in 1997. It is important to note that Nigeria's national policy on HIV/AIDS/STDs was only approved in 1997.

In 1999, after the transition to democracy, the new government instituted a vigorous response to the AIDS epidemic. The key element of the response was a decentralized approach, with comparable programs at local, state, and national levels. Furthermore, the government has undertaken a multi-sectoral approach to mitigate the impact of the epidemic, collaborating closely with the private sector, community-based organizations, faith-based organizations, development partners, and other stakeholders. An inter-ministerial Presidential Committee on AIDS (PCA), chaired by the president, was established, forming the multi-sectoral, multidisciplinary, National Action Committee on AIDS (NACA), State Action Committee on AIDS (SACA), and Local Action Committee on AIDS (LACA).

The PCA and NACA developed a proactive response strategy to the epidemic called the "HIV/AIDS Emergency Action Plan" (HEAP). In February 2001, HEAP identified 16 guiding principles. This was based on three key determinants of the HIV/AIDS epidemic in Nigeria: social, behavioral, and biological. The approach served as the basis for planning activities for prevention and control of the epidemic in Nigeria. The HEAP's guiding principle #12 aims in part to ***"Mitigate the impact of AIDS*** by:

- Providing affordable and accessible drugs;
- Encouraging counseling to those infected and affected by AIDS;
- Providing financial assistance to AIDS orphans; and
- Providing micro-credit facilities to people infected and affected with HIV/AIDS."

Antiretroviral drugs have been available in Nigeria since the early 1990s. Pharmaceutical companies like Roche Nigeria Limited, Swipha Nigeria limited, and GlaxoWellcome have conducted limited clinical trials of some of their drugs (Bannenberg 2002). However, the cost of ARV drugs was too high for the average citizen. Anecdotal information indicates that those who could afford to pay for drugs received either double or triple therapy. To date, the private sector is still providing treatment to those who can pay out-of-pocket.

In April 2001, at the Abuja Summit of African Leaders on HIV/AIDS, Tuberculosis and other related Infectious Diseases, President Obasanjo formally announced the government's determination and plan to provide ARV treatment to 10,000 adults and 5,000 living with HIV/AIDS (Access Alert 2002). As would be expected, the human, material, and logistical requirements to put in place such a large program were substantial, and contributed to a delayed start.

However, in January 2002 the government launched the ARV program in 25 sites across the six geopolitical regions of the country (see Figure 2, page 6). According to NASCP, three drugs Lamivudine (3TC), Nevirapine (NVP), and Stavudine (d4T) are being provided as one AIDS cocktail at the government subsidized price of ₦1,000 per patient per month. Each center was to fill an initial quota of 25 patients. Under the program, generic drugs would be purchased from Cipla ($350 per patient per year) and Ranbaxy ($320), with the hope that prices would drop as other pharmaceutical companies join in the competition to provide these drugs. At the inception of the program, there were reports of low enrollment, and there were fears that the initial procurement of drugs for 8,000 patients for one year would go to waste. At present, however, reports from the various sites to the Federal Ministry of Health show that enrollment in the program has been so successful that many centers exceeded their quotas and many experienced a stock-out of drugs.

3. Antiretroviral Treatment Issues

While the government's program is a landmark achievement and has experienced significant success, there are a number of issues that need to be addressed before the program can be successfully expanded.

3.1 Drug Availability and Cost

The private sector currently provides ARV drugs at a cost of about $3000 per person per year. It is not known how many patients are receiving treatment in the private sector but unconfirmed reports suggest that there are fewer than 10,000. The government's program serves about 14,000 patients and costs around $368 per person per year (including an estimated 15 percent for storage, distribution, and wastage). As stated earlier, patients make an annual contribution of $86 towards the revolving drug fund.

According to the Federal Ministry of Health, drug supply to the treatment facilities has been generally consistent and on time. However, recent reports from ARV program sites indicate that some of them are experiencing drug shortages. The FMOH speculates that this might be due to an increasing number of patients seeking treatment. Patients not yet enrolled in the government program are offered drugs at market prices.

3.2 Lack of Training to Providers

While clinicians managing patients on ARV treatment show enthusiasm and commitment, few of the nurses, counselors, and doctors have adequate clinical training, particularly considering the large volume of patients seeking treatment.

3.3 Inadequate Monitoring of Patients

Currently the costs of monitoring tests are the responsibility of the patients, providing a significant disincentive to adhere to treatment plans. At the moment, there are no systems in place for efficient monitoring and documentation of patients on ARVs.

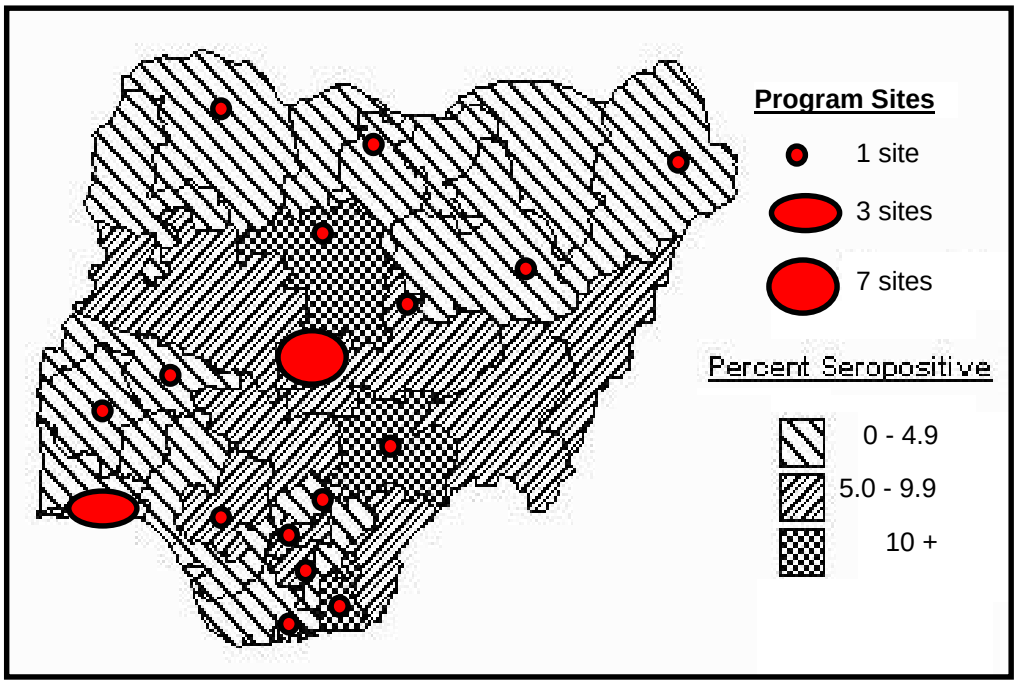
3.4 Selection Criteria

While standard clinical criteria are widely used for recruiting patients (e.g., a CD4 count<200mm^3), often the volume of patients meeting these criteria is far greater than the capacity of the centers. This leads to arbitrary selection procedures. Discussions with clinicians suggest that a complete set of prioritized criteria needs to be developed in order to promote standard selection procedures.

3.5 Geographic Distribution

Figure 2 gives the geographic distribution of government ARV program sites and HIV prevalence by district. It is clear that the majority of sites lie in the central and southern regions of the country while HIV prevalence is concentrated along a central east-west belt and in the south and southeast. Thus the distribution of ARV sites does not adequately reflect prevalence rates.

Figure 2: HIV Prevalence and Location of Government ARV Program Sites



4. Methodology

The approach used for estimating the costs of providing comprehensive antiretroviral treatment in the public sector in Nigeria is based on the AIDSTREATCOST model, Version 1.0. The focus of the study was to determine unit costs for the provision of HAART, Voluntary Counseling and Testing (VCT), and Opportunistic Infection (OI) treatment, based on the required inputs in terms of drugs, tests, labor, training, and capital. The study then uses these to estimate total costs under different scenarios for the number of people treated.

The ATC model has been applied in several other contexts and findings from these countries have helped policymakers and program planners to use the ATC findings to mobilize and allocate appropriate financial and human resources to the ARV programs. For this report, the emphasis on using country-specific data from Nigeria, rather than broad international estimates, helps to legitimize the results and make the findings as relevant as possible to country decision makers.

It should be emphasized that the ATC model does not advocate any particular strategy on ARV treatment. It merely provides a comprehensive framework within which to consider various options, and highlights the opportunities and constraints inherent in any policy choices being considered.

Information was collected from five ARV treatment sites: Lagos University Teaching Hospital (LUTH), Nigeria Institute of Medical Research (NIMR), Gwagwalada Specialist Hospital, Abuja National Hospital, and Jos University Teaching Hospital (JUTH). These sites were chosen to reflect several factors including geographic location, level and pattern of care, and cost of care. A complete set of the variables used to enter the baseline data is listed in Annex A of this report. It should be noted that unit cost data used in the analysis came from five of the 25 ARV treatment sites currently operating, and thus may not be representative of the 20 other sites.

Most of the medical data were drawn from the project document "Plan of Action for Broad Access to ARVs in Nigeria" (FMOH, 2001). Drug procurement information was obtained from the FMOH and is based on the last drug purchases from Cipla and Ranbaxy. Information on screening and confirmation tests also came from FMOH. Equipment costs and requirements are drawn from NIMR. Service delivery information including the cost of monitoring tests and of OI treatment was gathered from interviews with a clinician at each of the five treatment sites. Finally, information on training costs was based on consultations with the FMOH about their preliminary training courses for ARV expansion that were conducted in 2002. The exchange rate used is 140 Nigerian Naira to the US$, based on the rate of January 2, 2004.[3]

It is important to clarify which services are included and which are excluded from the cost estimates presented in this report. First, the focus is on ARV *treatment* activities. Thus, other HIV/AIDS-related interventions such as prevention programs, monitoring and evaluation, and administrative and managerial overhead costs, although they may be crucial to a comprehensive national HIV/AIDS strategy, are not considered.

[3] From http://www.xe.com/ucc/

The main costs of HAART can be divided into five general categories: (1) ARV drugs; (2) monitoring tests; (3) capital equipment; (4) training; and (5) labor. In addition, VCT and OI test and treatment costs are also analyzed. HAART costs are expressed as annual figures and represent the total cost of the government HAART program. VCT and OI costs are expressed per "episode." 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, i.e., they do not vary with program size and are allocated across whatever number of people is treated under a given scenario.

The report focuses exclusively on *total costs* – that is, costs associated with program requirements that would typically be included in the government's health budget. This would include, for example, costs associated with capital equipment as well as health care worker compensation (wages, bonuses, etc.). Obviously the introduction of a large-scale public program to provide ARV 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. Also, it is envisioned that new investments in capital would be required (especially equipment and storage facilities for ensuring drug security) if the program expands to cover a large population.

5. Results

This section provides preliminary estimates of the cost of delivering comprehensive antiretroviral treatment in Nigeria. It is important to point out that the focus of the report is on the per patient costs of providing HAART, OIs, and VCT. Since the number of patients targeted to receive these services in the expanded program has not yet been determined, these preliminary findings will be useful in deciding what population coverage is feasible given additional resources.

The provision of ARV drugs to HIV/AIDS patients is a major component of the HIV/AIDS Emergency Action Plan and will represent by far the largest programmatic cost. As in many low resource countries, the price of brand name or generic drugs is changing very rapidly and Nigeria may get lower prices once the country negotiates for a large-scale procurement. All ARV drug costs shown below represent the lowest landed price currently available for patients who are in the national ARV program. The information was provided by the Federal Ministry of Health and reflects the last procurement of ARV drugs from Cipla and Ranbaxy. Furthermore, cost data on out-of-pocket payments for patients who are not in the government program was collected from NIMR, Abuja National Hospital, Gwagwalada Specialist Hospital, and LUTH.

5.1 Cost of ARV Drugs is the Largest Component

As shown in Table 1, the average annual per patient cost under the government program is about $368. The program uses the recommended drug regimen of Stavudine, Lamivudine, and Nevirapine. An extra 15 percent has been added to the drug cost to account for storage, distribution, and wastage (logistical management). It is important to point out that there is only one adult drug regimen available and no pediatric formulation has been procured.

Table 1: Average Annual Per Patient Drug Cost

Drug	Monthly	Annual
Stavudine	$8.9	$106.7
Lamuvidine	$8.9	$106.7
Zidovudine	$8.9	$106.7
15% Logistical Management	$1.8	$48.0
Total	**$28.4**	**$368.0**

5.2 Monitoring Tests Represent the Second Largest Component of the ARV Program

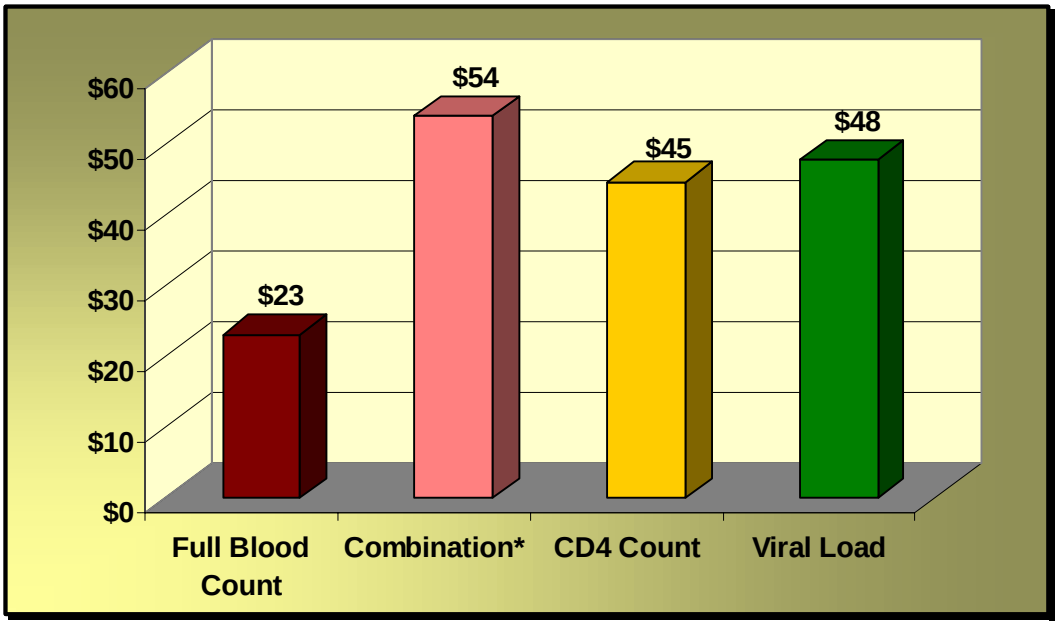
Table 2 shows that the annual per patient costs of the monitoring tests is about $170 (including an additional 15 percent for storage, distribution, and wastage). The number of times each type of test is administered is based on the Clinical Guidelines on Management and Care for HIV/AIDS. The guidelines suggest that a baseline patient receives three full blood counts, three liver function tests, three urea, creatinine and blood sugar tests, two CD4, and one viral load annually. However, informal discussions with clinicians revealed that CD4 and viral load tests are not available at many of the treatment sites. In addition, monitoring practices vary considerably among institutions given the lack of CD4 and viral load equipment. Thus, for patients who do not receive CD4 counts or viral load tests, the total cost of tests is about $77. All figures include 15 percent for storage, distribution, and wastage. Figure 3 illustrates the per patient costs from Table 2.

Table 2: Cost of Laboratory Monitoring Tests

Test	Unit Cost	Number of Tests Per Year	Annual Per Patient Cost
Full Blood Count	$7.72	3	$23.16
Combination*	$18.02	3	$54.07
CD4 Count	$22.38	2	$44.75
Viral Load	$47.92	1	$47.92
Total		**9**	**$169.90**

* Combination includes urea, creatinine, blood sugar & liver function tests

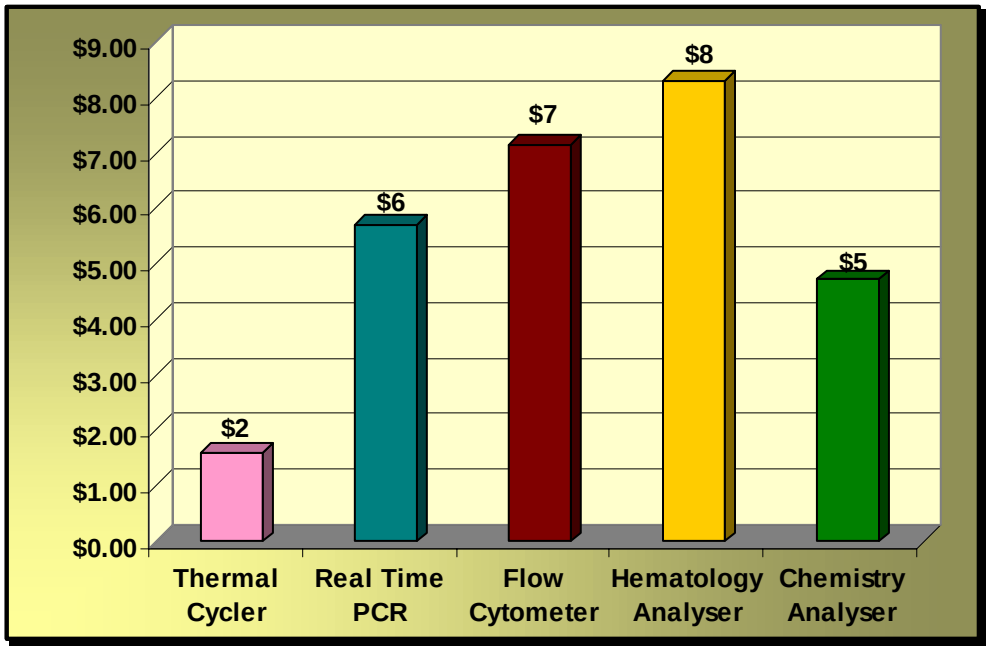
Figure 3: Average Annual Per Patient Monitoring Cost



5.3 Capital Costs on a Per Patient Basis are Relatively Small

The other major cost considered in this section is the per patient cost of capital. According to the FMOH, all ARV treatment sites should have the appropriate equipment to conduct patient monitoring. The equipment includes a thermal cycler, polymerized chain reaction (PCR) machine for viral loads, and chemistry and haematology analyzers. Currently, several treatment sites already have chemistry and haematology analyzers but only four sites (NIMR, Nigeria Institute of Pharmaceutical Research and Development, Abuja National Hospital, and JUTH) have the capacity to monitor CD4 counts and viral loads. The total cost of these capital items is approximately $15,000 annually, as shown in Figure 4 (annual figures assume a 20 percent annual depreciation rate for capital equipment, equivalent to $30 annually per patient). These factors imply that the per patient capital cost is relatively minor compared to drug and test costs, and thus is not a major financial barrier to expanding coverage to new facilities.

Figure 4: Average Annual Per Patient Capital Cost



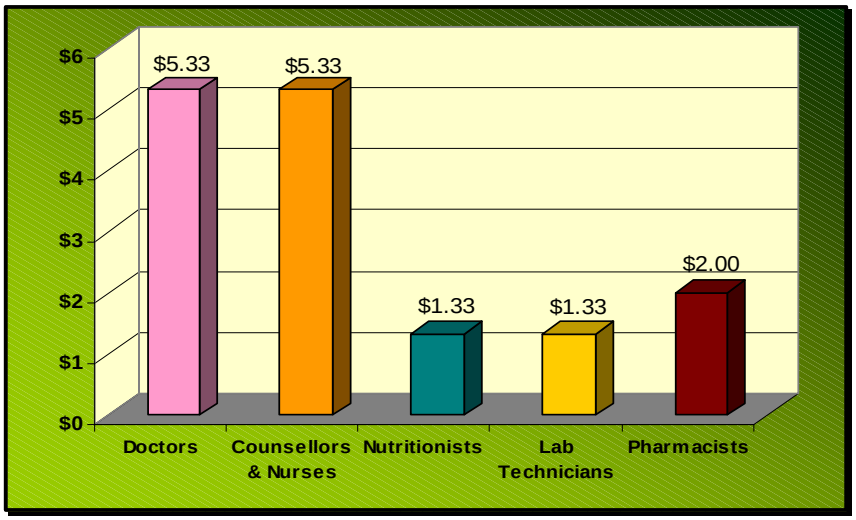
5.4 Training Costs are Extremely Low

Training is an important component of the ARV program and deserves a strong investment. On a per patient basis, the cost of training is very small compared to drugs, tests, and capital, amounting to only $15 per patient per year. Training costs are listed as annual costs. A full training course does not need to be conducted every year, nor will training costs fall to zero after the first year, due to the 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. This implies that a certain level of training costs must be incurred on an ongoing basis.

Estimates for training costs are based on information collected from the JUTH, where a full complement of staff consists of 23 staff members: eight doctors, eight counselors and nurses, two nutritionists, two lab technicians and three pharmacists. Each staff member attends a 10-day ($100/day) course every two years and treats 750 HIV/AIDS patients.

The results show that training accounts for around 2 percent of total cost, essentially because one trained health worker can provide services to a large number of patients. Anecdotal information indicates that, to date, very few doctors, nurses, and laboratory technicians have been trained in the management and care of HIV/AIDS patients. JUTH staff alone could treat 1750 *additional* patients, bringing their total to 2500, with a full complement of trained staff. Thus a relatively small outlay for training could result in significant increases in ARV capacity.

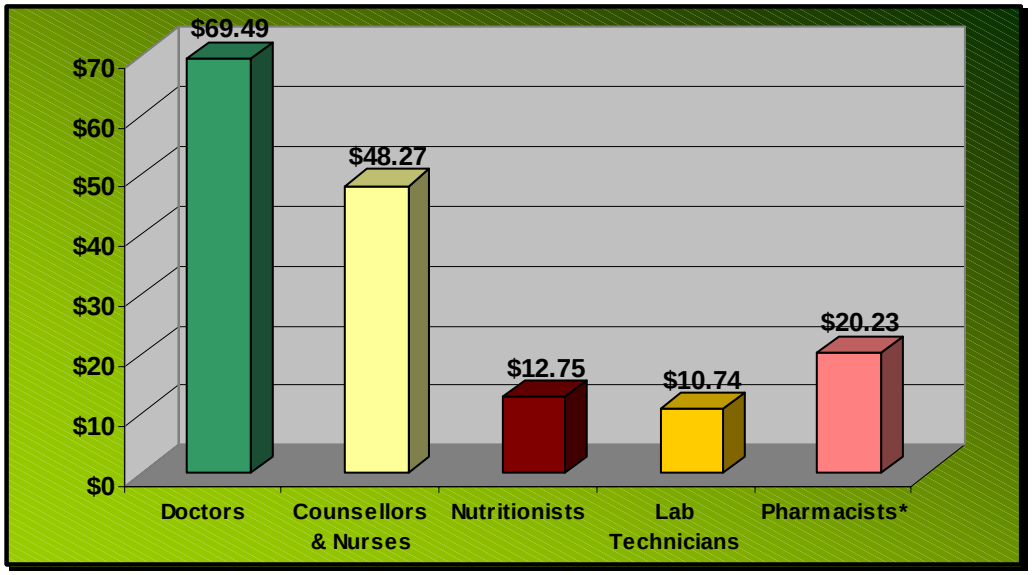
Figure 5: Average Annual Per Patient Training Cost



5.5 Labor Costs are a Significant Component of Total Cost

The final component of this section deals with labor costs. The success of the national ARV program will depend in part on the number and type of staff providing the service and in part on the level of technical skills they possess. While comprehensive staffing information for each facility was not available, the report again uses the JUTH as an example. The standard staff complement (see above) spends 80 percent of their time treating 750 HIV/AIDS patients. Their salaries are taken from the National Harmonized Salary Structure. To get accurate data on staff time spent on treating patient who receive ARV therapy, time-motion studies need to be conducted at selected sites. Results estimate a total labor cost of $161 per patient per year, making labor a significant component of the total cost of ARV treatment (Figure 6).

Figure 6: Average Annual Per Patient Labor Cost



*Pharmacist salaries approximated using salary of lab technicians

5.6 Total Annual Per Patient Cost is about $742

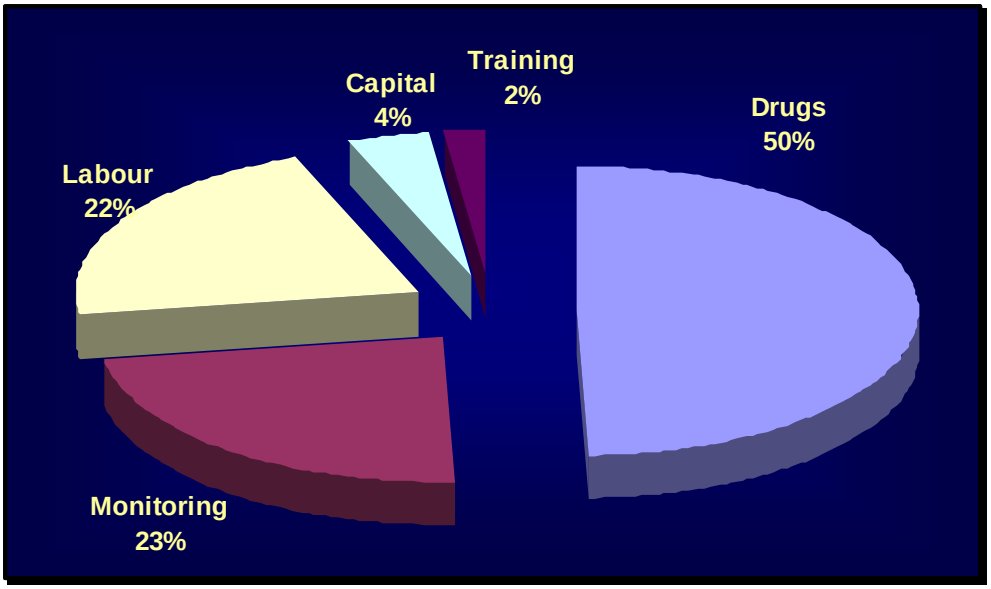
The total incremental cost of providing HAART per patient is $742 per year, as shown in Table 3 and Figure 7.

Table 3: Unit Costs of Components of ARV Treatment

Component	Average Annual Per Patient Cost
Drugs	$368
Monitoring	$170
Labor	$161
Capital	$27
Training	$15
Total	**$742**

ARV drugs constitute the largest single cost component in the provision of ARV treatment with an annual cost of $368, representing 50 percent of the total cost. Monitoring and labor costs are the second largest components of the total cost, at an average annual cost of $170 and $161 per patient, and capital and training costs accounting for $27 and $15 per person per year respectively.

Figure 7: Components of Total ARV Cost



5.7 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. It is beyond the scope of this report to assess the impact of the ARV program on VCT uptake rates. A potentially important benefit of the national 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.

The algorithm for VCT testing varies from facility to facility. This study used the algorithm suggested by the "National Guidelines for the Use of Antiretroviral Drugs in Nigeria" (FMOH 2001), which is a series of two tests. The first of these is an Elisa test ($4 each) for screening. If a patient tests negative at this stage then no more tests are administered; if the patient tests positive, then either an Elisa or a Genie 2 test (around $4 each) is used for confirmation. Some facilities are also using Abbott Determine for screening purposes. Thus the total cost of screening and VCT per ARV patient is around $4 for those who are HIV-negative and $11 for those who are HIV-positive. (In rare cases a tiebreaker test may be necessary, but this would have a negligible effect on the cost). Note that these estimates only account for the testing kits, and exclude labor and training costs.

To calculate total VCT costs incurred under the government program, the study required an estimate of the percentage of all samples that will require confirmation testing (i.e., a breakdown between HIV-positive and HIV-negative outcomes). 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). Anecdotal information from other countries (e.g., Uganda and Zambia) has suggested that the diagnosis rate at VCT centers is roughly twice the national prevalence rate. If this were true in Nigeria, we may expect that roughly 12 percent of tests would yield HIV-positive results, while the remaining 88 percent would be HIV-negative.

For illustrative purposes, the study assumed that one in every four HIV-positive individuals is clinically eligible for ARVs (i.e., having a CD4 count<200mm^3) and that one in eight people tested for the HIV virus is sero-positive (i.e., 12 percent as noted above). Then 32 individuals must be tested in order to find one patient who can embark on ARV therapy. Since ambitious targets for scaling up an ARV program automatically imply ambitious targets for VCT expansion, it should be emphasized that the costs of testing those who turn out to be HIV-negative may be substantial.

5.8 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 ultimately they still need to be treated.

For Nigeria, 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 4 percent (14,000 out of roughly 350,000) of those clinically eligible for HAART will receive it; the other 96 percent will be as vulnerable to OIs as they are now.

Table 4 shows the per patient costs of drugs and tests for treating the most common opportunistic infections: tuberculosis, pneumocystis carinii pneumonia, and oral candidiasis. These costs include drugs and tests, except for tuberculosis (TB), which includes only tests as TB treatment is free in 21 of the 36 states and is funded primarily by the development partners (FMOH). As before, an extra 15 percent has been added to account for storage, distribution, and wastage. Capital costs are excluded in this estimate as they will generally not be incurred for OIs as equipment and buildings are already available in many of the treatment sites.

It is important to note that these costs are expressed “per episode” rather than as annual costs. Calculating the latter for the average patient would require a study of co-infection rates, which are not known for Nigeria at the moment. But since ARV should make patients less vulnerable to OIs, the costs per episode expressed here will be substantially higher than actual annual costs for the average patient.

Table 4: Per Episode Cost of Testing and Treating Opportunistic Infections

Disease	Test	Treatment	Total Per Patient Cost
Tuberculosis	Gram Stain and X-ray	Provided Free	$8.49
Oral Candidiasis	Oral Observation	Nystatin	$9.45
Pneumonia (PCP)	X-ray	Penicillin, Gentamycin or Chloraphenicol (Price is an average)	$8.19

6. Discussion

6.1 Is Nigeria Paying Too Much for ARV Drugs?

The cost of subsidized ARV drugs in Nigeria is about $368 per person per year (including 15 percent for storage, distribution, and wastage) and make up the largest component of the total per patient cost. Like many low-resource countries in sub-Saharan Africa, the government of Nigeria is very concerned about the high cost of drugs and is exploring a number of options. These options include intensive negotiations with local and international pharmaceutical companies on lowering the price of drugs. This may lead to bulk purchase of drugs from one pharmaceutical company at lower prices.

6.2 Who Pays for Treatment?

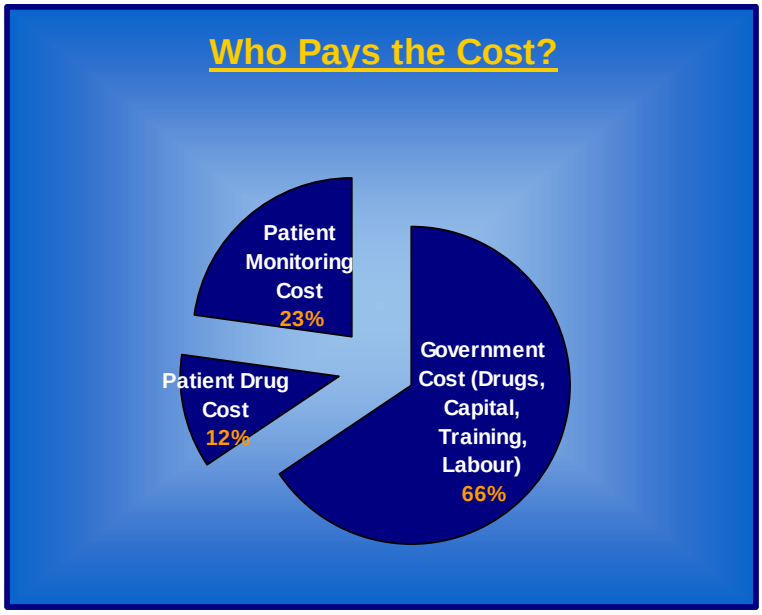
The government pays the majority of the drug cost at present, with patients contributing only ₦1000 ($7) per month, or 23 percent, of the total drug cost. However, in addition to their portion of drug costs, patients must also bear the costs of all monitoring tests where available. Taken together, the patient co-payment for drug costs and the burden of paying for monitoring tests amount to about $256, or 34 percent, of the $742 total annual per patient cost (see Figure 8). This is well beyond the means of the average Nigerian (recall that per capita GDP is about $328).

As noted earlier, however, most facilities do not have CD4 and viral load testing abilities, and therefore most patients are paying somewhat less. Even if the facilities existed, it is likely that many patients would decline certain monitoring tests because the cost is too high. Specifically, it has been suggested that the viral load test be eliminated entirely and the CD4 count test be done once rather than twice per year. Since the CD4 acts as an adequate proxy for the viral load test, this strategy does not result in a loss of treatment quality. The cost of VCT ($11 per patient for those who are HIV-positive) is also borne by the patient. Although this is only done once, the importance of VCT as an intervention that can promote prevention efforts suggests that there are strong public health reasons for the government to subsidize this cost.

To standardize the program screening regimen the government may pursue one of two strategies: The first is to subsidize the cost of monitoring tests, reducing the disincentive to participate in the program but increasing the cost to the government. The second is to modify the treatment protocols to a less intensive level, ensuring adherence to a minimum acceptable standard of care and reducing the program and patient out-of-pocket cost of testing.

Finally, the cost of treating opportunistic infections is paid for entirely by patients. Co-infection rates for those on ARVs should be low, meaning that on average this will not be a major cost. In a few cases, however, a patient may suffer from several OIs and must pay for the cost of treatment (as shown in Table 4).

Figure 8: Patient Cost Burden



6.3 Scaling Up the Program: The Financial Cost

The FMOH and the international community are currently debating appropriate and sustainable methods of scaling up the ARV program. The report explores and simulates three stages of expansion that would lead to the World Health Organization's 3 by 5 Initiative target of treating 262,500 people living with HIV/AIDS by 2005. The government's program currently provides treatment for 14,000 patients, an average of 560 per center. Based on the above analysis, the total annual program cost is:

$742 x 14,000 Patients ≈ **$10.4 million**

Stage 1: Expanding service at all existing sites to benchmark levels. The current patient load of existing sites is 14,000 patients (an average of 560 per site). JUTH has been taken as the model for high quality service provision. As described in section 5.4, a full complement of JUTH staff consists of 23 staff members: eight doctors, eight counselors and nurses, two nutritionists, two lab technicians and three pharmacists. These 23 staff members have been estimated to be able to serve 2500 ARV patients. Using these figures as a benchmark, the standard staff complement currently treats 750 patients. Multiplying by 25 sites results in a total of 18,750 patients served. Expanding each site to this level of service would presumably require investment in additional equipment, labor, and training as well as drugs. The additional cost of this expansion can be estimated by the difference between the number of patients treated under the current program and those who would be treated if every site were equivalent to JUTH:

$742 x (18,750-14,000) patients ≈ **$3.5 million**
→ **Total Annual Program Cost = $13.9 million**

Stage 2: Expanding to Maximum Capacity. At this stage, all centers are assumed to have the capacity of JUTH. JUTH officials have indicated that the maximum number of patients they could serve with current staff and capital is 2500. Existing staff would only need to increase the percentage of their time they spend on ARV patients from 80 percent to 100 percent. Multiplying by 25 sites gives a total of 62,500 patients served. Note that this expansion would require no additional capital or training costs. Therefore, the per patient annual cost of the expansion would only be $578. Note that this stage of the expansion assumes that the maximum capacity of the JUTH facility is similar to that of the average site facility. The cost of this expansion can be estimated at:

$578 x 25(2500-750) patients ≈ **$23.6 million annually**
→ **Total Annual Program Cost = $34.7 million**

Stage 3: Increasing the Number of Sites. At this stage the existing sites could handle no more patients, necessitating the establishment of additional sites.[4] The WHO 3 by 5 Initiative recommends increasing the number of patients served to 262,500 by 2005. This would require setting up new sites serving an additional 198,000 patients or 198,000/2,500 = 80 additional sites. The cost per additional site is estimated as:

$742 x 2500 ≈ **$1.86 million annually per additional site**

For 80 additional sites, the cost is:

1.86 million x 80 ≈ **$148.4 million annually**
→ **Total Annual Program Cost = $187.7 million**

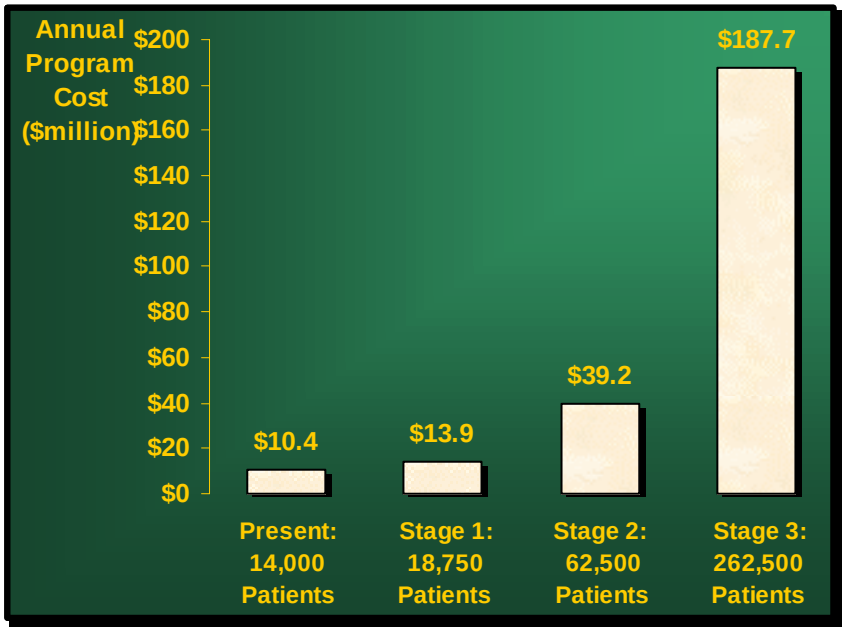
Therefore, according to the above analysis, the cost of expanding the program through all three stages to accommodate 262,500 patients is:

Cost of Stage 1 + Cost of Stage 2 + Cost of Stage 3
→ **Total Annual Expansion Cost = $177.3 million**

The cost of expansion through these three stages is summarized in Figure 9.

[4] The government's stated goal for the first year of their program is to increase the number of sites so every state has at least one publicly funded ARV treatment site (Gwarzo, FMOH). This would require 12 additional sites or $17.7 million.

Figure 9: Simulated Expansion Path for Government Program



6.4 Scaling Up the Program: Human Resource Requirements

In addition to the significant financial outlay, scaling up the government program will require substantial additional human resources. In Stage 1 each site will need to hire additional staff to meet the benchmark level. While the study did not have data on the current staffing patterns of the 25 sites, the study team suspects that many of the institutions are understaffed.

In Stage 2 of the expansion no additional staff will need to be hired. However, we should recall that at benchmark (JUTH) levels staff treated HIV/AIDS patients only 80 percent of their time. In order to treat the additional 1750 patients per site they would need to devote 100 percent of their time to HIV/AIDS patients. The effect of this shift on staffing needs in other treatment areas should be taken into account.

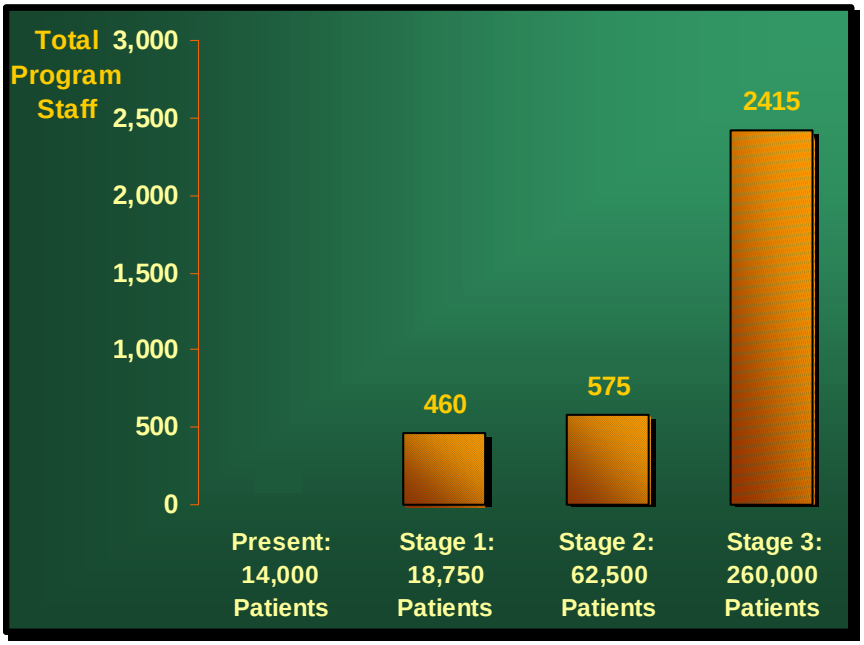
Stage 3 of the expansion requires by far the greatest additional human resources. To staff the additional sites 1840 additional staff would be required: 640 doctors, 640 counselors and nurses, 160 nutritionists, 160 lab technicians, and 240 pharmacists. The magnitude of these human resources requirements necessitates a close look at Nigerian, West African, and international labor markets to determine appropriate strategies to respond to those needs. It should also be noted that staff salaries at JUTH are significantly higher than those of other sites due to supplemental bonuses paid out of grants from donor programs. These sorts of incentives may be considered at other sites, particularly during Stage 3 of the expansion process, although they may not be politically feasible.

Figure 10 shows the total number of staff in the program at each stage of the expansion.

- The number of total staff in the present program is unknown.
- Recall that at Stage 1, staff spend only 80 percent of their time on HIV/AIDS patients, meaning that staff numbers need to be adjusted. This yields a total of (25 sites x 23 staff per site x 0.8) **460 total staff**.

- At Stage 2, staff spend 100 percent of their time on HIV/AIDS patients, yielding a total of (25 sites x 23 staff per site) **575 total staff**.
- At Stage 3 the total number of sites is increased by 80, from 25 to 105, yielding a total of (105 sites x 23 staff per site) **2415 total staff**.

Figure 10: Human Resource Requirements at Each Expansion Stage



7. Conclusions and Recommendations

According to the above data and analysis, ARV drugs are not surprisingly the largest single component of the provision of ARV treatment, encompassing 50 percent of the total cost. However, the report clearly contradicts the commonly held belief that drugs are the only major cost in an ARV program. Monitoring tests, training, labor, and capital costs account for almost 50 percent of total program costs. Estimated at $256 per year, the patient's total annual contribution to the cost of HAART is more than 75 percent of per capita GDP, well beyond the resources of most Nigerians. Patients are also paying for HIV testing, a cost which from a public health perspective should arguably be borne by the government. The development of an effective ARV program, therefore, must include support not only for ARV drugs but all aspects of patient cost.

Looking at the geographic distribution of sites (Figure 2), large areas of the east, west, and southeast of the country have few ARV treatment sites and high HIV prevalence rates. Since heavily hit western states (Niger and Kogi states) are partially served by corporate-provided ARV treatment, additional program sites should perhaps target the larger HIV-vulnerable populations in eastern and southeastern Nigeria (Cross River, Taraba and Adamawa states, for example).

The government of Nigeria has made significant progress in its strategy for the provision of ARV services. With adequate support from the donor community there is great potential to improve the livelihoods of people living with HIV/AIDS and reverse this catastrophic pandemic. The expansion of the government program will require significant resources but has the potential to be immensely beneficial. It is crucial, however, that these decisions be made in a deliberate, informed manner that is calculated for maximum benefit. To inform that decision-making process, the report recommends a number of strategies for the government and development partners to consider:

- **Program Expansion.** The report outlines a three-stage expansion path leading to a standard treatment regimen program reaching the 262,500 PLWHA suggested by the WHO 3 by 5 Initiative. The cost of this expansion is estimated at an additional $177 million. Mobilization of additional resources will be required.

- **Human Resources Training & Requirements.** Currently, few health care providers have adequate clinical training despite the fact that training is an extremely cost-effective method of expanding capacity for ARV treatment. Particularly given the substantial additional human resources needed to expand the government ARV treatment program, priority should be given to improving and expanding ARV training programs.

- **Support for VCT Activities.** The importance of VCT in promoting prevention efforts suggests that there are strong public health reasons for the government to subsidize this activity.

- **High Cost of Monitoring Tests.** To standardize the program treatment regimen and reduce patient out-of-pocket cost the government should explore the possibility of either subsidizing the cost of monitoring tests or modifying the treatment protocols.

- **Drug Cost.** To reduce the high cost of drugs, the government should engage in intensive negotiations with local and international pharmaceutical companies and perhaps consider bulk purchase of drugs from one pharmaceutical company.

Annex A: ARV Costing Data Table

ARV Costing Components	Hospital					# Per Year	Average Cost			
	A	B	C	D	E		Per period (Naira)	Annual (in Naira)	Annual (in $)	Annual Per Patient ($)
Govt Program Drugs										
Stavudine										**$107**
Lamuvidine										**$107**
Zidovudine										**$107**
Logistics Cost										**$48**
Govt Program Drug Total										**$368**
Non-program Drugs										
Stavudine	10,500	10,500	7,000	10,500	n/a	12	9,625	115,500		**$825**
Lamuvidine	10,500	10,500	10,500	10,500	n/a	12	10,500	126,000		**$900**
Zidovudine	10,500	10,500	7,000	10,500	n/a	12	9,625	115,500		**$825**
Logistics Cost										**$383**
Non Program Drug Total	31,500	31,500	24,500	31,500	0	12	29,750	357,000		**$2,933**
PMTCT Drugs										
Nevirapine (Mother and Infant)	n/a	3,500	n/a	n/a		12	3,500	42,000	**$300**	**$300**
Logistics Cost									**$45**	**$45**
PMTCT Drug Total									**$345**	**$345**
Monitoring										
Full Blood Count	600	1,000	300	1,400	1,400	3	940	2,820		**$20**
Combination	3,000	3,000	1,450	2,400	1,120	3	2,194	6,582		**$47**
CD4 Count	2,500	3,000	3,500	3,500	1,120	2	2,724	5,448		**$39**
Viral Load	9,000	n/a	n/a	5,000	3,500	1	5,833	5,833		**$42**
Logistics Cost										**$22**
Monitoring Total	15,100	7,000	5,250	12,300	7,140	9	9,913	$20,683		**$170**
Capital Equipment										
Thermal Cycler	630,000	n/a	n/a	n/a	n/a	0.2	630,000	126,000	**$900**	**$2**
Real Time PCR	2,240,000	n/a	n/a	n/a	n/a	0.2	2,240,000	448,000	**$3,200**	**$6**
Flow Cytometer	n/a	n/a	1,200,000	3,000,000	4,200,000	0.2	2,800,000	560,000	**$4,000**	**$7**
Hematology Analyser	3,000,000	n/a	700,000	3,500,000	n/a	0.2	3,250,000	650,000	**$4,643**	**$8**
Chemistry Analyser	2,500,000	n/a	1,200,000	n/a	n/a	0.2	1,850,000	370,000	**$2,643**	**$5**
Capital Total									**$15,386**	**$27**
Training										
Doctors						0.5	**$8,000**		**$4,000**	**$5**
Counselors/Nurses						0.5	**$8,000**		**$4,000**	**$5**
Nutritionists						0.5	**$2,000**		**$1,000**	**$1**
Lab Technicians						0.5	**$2,000**		**$1,000**	**$1**
Pharmacists						0.5	**$3,000**		**$1,500**	**$2**
Training Total									**$11,500**	**$15**
Labor										
Doctors (8)	560,000	n/a	n/a	n/a	960,000	0.8	760,000	7,296,000	**$52,114**	**$69**
Counselors/Nurses (8)	360,000	n/a	n/a	n/a	696,000	0.8	528,000	5,068,800	**$36,206**	**$48**
Nutritionists (2)	105,000	n/a	n/a	n/a	174,000	0.8	139,500	1,339,200	**$9,566**	**$13**
Lab Technicians (2)	115,000	n/a	n/a	n/a	120,000	0.8	117,500	1,128,000	**$8,057**	**$11**
Pharmacists (3)	172,500	n/a	n/a	n/a	270,000	0.8	221,250	2,124,000	**$15,171**	**$20**
Labor Total	1,312,500	n/a	n/a	n/a	2,220,000	0.8	1,766,250	16,956,000	**$121,114**	**$161**
Govt Program Total										**$742**
Non-Program Total										**$3,307**
Screening & Confirmation										
Abbott Determine	500	n/a	n/a	1,500	210	1	500	500		**$4**
Elisa	1,000	500	2,000	1,500	280	0.5	1,167	583		**$4**
Genie 2	1,000	n/a	n/a	5,000	280	0.5	1,000	500		**$4**
Screening & Conf. Total	2,500	500	2,000	8,000	770	2	1,667	1,583		**$11**
Opportunistic Infections										
Tuberculosis	1,100	1,050	950	1,500	840	1	1,033	1,033		**$7**
Oral Candidiasis - Nystatin	800	n/a	1,500	3,200	560	1	1,150	1,150		**$8**
Pneumonia	n/a	n/a	997	n/a	n/a	1	997	997		**$7**
Opport. Infections Total	1,900	1,050	3,447	4,700	1,400	3	3,180	3,180		**$26**

A = Nigeria Institute of Medical Research B = Lagos University Teaching Hospital (See Next Page for Comments
C = Gwagwalada Hospital D = National Hospital Abuja E = Jos University Teaching Hospital

ARV Costing Data Table (cont.)

ARV Costing Components	Comments
Govt Program Drugs	Under the government program, patients contribute 1,000 Nira per month ($7) to the cost of their drugs.
Stavudine	
Lamuvidine	
Zidovudine	
Logistics Cost	
Govt Program Drug Total	
Non-Program Drugs	
Stavudine	B and D do not offer PMTCT treatment. D offers free drugs.
Lamuvidine	
Zidovudine	
Logistics Cost	
Non-Program Drug Total	
Monitoring	
Full Blood Count	Average excludes D because of anomalous data.
Combination	Average excludes D because of anomalous data. Combination includes liver function, urea, creatinine and blood sugar tests.
CD4 Count	
Viral Load	B, C and D do not perform this test.
Logistics Cost	
Monitoring Total	
Capital Equipment	
Thermal Cycler	Assumes annual depreciation of 20 percent (Hence a # per year of 0.2). Per patient figures assume 560 patients served, based on 14,000 patients served at all 25 sites, an average of 560 per site). E charges $25/patient for use of their real time PCR. Hematology Analyser cost uses data from A and D only.
Real Time PCR	
Flow Cytometer	
Hematology Analyser	
Chemistry Analyser	
Capital Total	
Training	
Doctors	Training based on data from E and assumes the full complement of 23 staff attend a $100 per day, 10-day course every 2 years (Hence the per year figure of 0.5). Again, per patient figures assume 750 patents served.
Counselors/Nurses	
Nutritionists	
Lab Technicians	
Pharmacists	
Training Total	
Labor	
Doctors (8)	Salaries based on Data from and E, guided by the National Harmonized Salary Structure. Staff spend 80 percent of their time treating 750 HIV/AIDS patients. A full complement of staff consists of 8 doctors, 8 counselors, 2 nutritionists, 2 lab technicians and 3 pharmacists.
Counselors/Nurses (8)	
Nutritionists (2)	
Lab Technicians (2)	
Pharmacists (3)	
Labor Total	
Govt Program Total	
Non-Program Total	
Screening & Confirmation	Costs of screening, confirmation and treatment of opportunistic infections use data from A, B and C only, due to anomalous data from D and E.
Abbott Determine	
Elisa	Assumes equal use of each drug.
Genie 2	
Screening & Conf. Total	
Opportunistic Infections	
Tuberculosis	TB treatment drugs are provided free through donor-funded programs. These costs only include testing. D uses only z-stain.
Oral Candidiasis	Assumes exclusive use of cheaper, more popular drug (Nystatin).
Pneumonia (PCP)	Data from C, where Penicillin, Gentamycin and Chloramphenicol are used in equal quantities. The WHO recommends the use of Stratin.
Oppor. Infections Total	Includes 15 percent logistical management (storage, distribution, and wastage).

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