



THE COST OF COMPREHENSIVE HIV TREATMENT IN KENYA

AUGUST 2013

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Report of a Cost Study of HIV Treatment Programs in Kenya

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ACRONYMS

3TC	lamivudine
ABC	abacavir
AIDS	acquired immunodeficiency syndrome
ART	antiretroviral therapy
ARV	antiretroviral
AZT	zidovudine
CCC	care and treatment centre
CDC	U.S. Centers for Disease Control and Prevention
d4T	stavudine
EFV	efavirenz
FBO	faith-based organization
FY	fiscal year
GOK	Government of Kenya
HH	household
HIV	human immunodeficiency virus
HMIS	health management information systems
IDV	indinavir
ITN	insecticide-treated bed net
KDHS	Kenya Demographic and Health Survey
LPV/r	lopinavir/ritonavir
M&E	monitoring and evaluation
MOH	Ministry of Health
NACC	National AIDS Control Council
NASCOP	National AIDS and STI Control Programme
NFV	nelfinavir
NGO	nongovernmental organization
NNRTI	non-nucleoside reverse transcriptase inhibitor
NRTI	nucleoside reverse transcriptase inhibitor
NVP	nevirapine
PEPFAR	President's Emergency Plan for AIDS Relief
PER	public expenditure review
PI	protease inhibitor
PPS	probability proportional to size
PQ	patient questionnaire
SES	socio-economic status
SQV	saquinavir
TB	tuberculosis
UNAIDS	Joint United Nations Programme on HIV/AIDS
USD	U.S. dollars
USG	U.S. Government
VCT	voluntary counseling and testing

VIP ventilated improved pit
WHO World Health Organization

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EXECUTIVE SUMMARY

This study provides a detailed description of the costs of providing outpatient human immunodeficiency virus (HIV) treatment and care in Kenya. The study was conducted as a collaboration between the Kenyan Ministry of Health (MOH) and President's Emergency Plan for AIDS Relief (PEPFAR) agencies. The study undertook a retrospective cost analysis at 29 outpatient clinics providing HIV treatment and care, estimating the annual treatment costs for pre-antiretroviral therapy (pre-ART) and ART patients as borne by the Government of Kenya (MOH), PEPFAR, and other local and international partners. Data were collected to show the cost differences between different patient types, and to show how costs were distributed across funding sources, input types, and programmatic activities over two 6-month periods (January 2010 to December 2010).

Care for HIV-positive patients is provided through a predominantly clinician-driven model, with chronic care outpatient department services revolving around, and mainly provided in, the dedicated ART clinic. Both ART and pre-ART patients were scheduled for regular clinic visits, and also received routine CD4 count tests to monitor disease progression. More than 90.0% of all ART patients were adults, and almost all were on a triple combination antiretroviral (ARV) regimen of two nucleoside reverse transcriptase inhibitors and a non-nucleoside reverse transcriptase inhibitor (NRTI; NNRTI; first-line therapy in Kenya).

The following figures are valid estimates of costs for the “typical” HIV treatment clinic, they do not reflect the costs of all treatment clinics. Costs varied widely among the sites in the sample, with some individual sites costing substantially more or substantially less than the median.

The median economic unit cost¹ per patient-year was \$248.91 (2011 U.S. dollars [USD]) for established adult ART patients; or \$120.72 when the cost of ARVs is excluded. The median cost per patient-year was \$116.71 for pre-ART patients. Costs were higher for established pediatric patients (\$292.60) compared to established adult patients. Newly initiating ART patients were also associated with higher costs than established ART patients at \$274.95 for adults and

¹ For economic costs, the one-time expense of equipment purchases and similar investments are spread out over the useful life of the item, in order to approximate the “long-term” cost of the intervention.

\$318.73 for pediatric patients. ARVs, the largest single cost component, cost a median of \$123.03 per year for ART patients. A significant proportion of regimens in the 29 facilities included Stavudine, which is a relatively low-cost drug. WHO recommends that countries phase out the use of Stavudine, because of its long-term, irreversible side-effects, and Zidovudine or Tenofovir are recommended as less toxic and equally effective alternatives. In a theoretical scenario, where all Stavudine is replaced with Zidovudine, the median per ART patient among 29 sites will increase from \$240.33 to \$292.71. Personnel was the next most substantial cost category for both ART and pre-ART patients, accounting for a median of \$38.44 and \$36.95 per patient-year, respectively.

Comparing the distribution of costs across program activities, clinical care (excluding ARV costs) was found to represent the largest component for ART patients (median \$36.77 per patient year), followed by laboratory services (\$19.30). The same was true for the pre-ART patients, where clinical care (excluding ARV costs) cost a median of \$44.57 per patient year and laboratory services cost a median of \$19.96 per patient year. It is important to note that activities supporting direct service provision—such as management, administration, and monitoring and evaluation (M&E)—represented nontrivial additions to the total cost, with a combined median cost of \$20.43 per patient-year for both ART and pre-ART patients.

Per-patient financial costs² decreased slightly, by 6.0% over the course of the evaluation (12 months), with investment costs declining 8.9% and recurrent costs declining 16.2%. The composition of expenditures changed over the course of the evaluation. Spending on traditional investments—training, equipment, and infrastructure—represented 7.8% of total spending at the start of the evaluation, but dropped to approximately 3.5% in the following 12 months. In contrast, the costs for ARV drugs and ARV buffer stock (i.e., the additions to the drug supply-chain inventory to support new patients in treatment), increased as a proportion of total costs. ARV drugs increased from 35.9% to 41.2%, while ARV buffer stock increased from 3.7% to 6.4%. While buffer stock purchases are considered an investment, the timing of buffer stock spending is different from other investments and matches the expansion of patient cohorts. The

²The financial cost perspective shows the actual value of expenditures and other resources used for the clinic as they are incurred, in order to reveal time-trends in resource needs.

proportion of funding devoted to recurrent costs grew over the course of the evaluation, from 88.6% to 90.1%.

PEPFAR was the largest source of support to treatment sites, contributing 49.1% of all resources during the first period and 48.1% of all resources during the second period. The Kenyan Government (including any budgetary support from the Global Fund and other developmental partners)³ was the second largest source of funding at the sites included in the study, and its funding increased from 45.7% to 47.5% between the first and second period of the evaluation. Other funding sources, including private organizations, contributed 5.2% at the beginning of the evaluation and 4.4% by the end.

Major sources of funding assisted sites in somewhat different ways. A major percentage of MOH and PEPFAR resources were devoted to ARVs (either dispensed or buffer stock). For MOH funding, 44.9% was devoted to purchasing ARVs (dispensed [38.98%] and buffer stock [5.89%]), with laboratory supplies as the second largest allocation (30.2%). While more PEPFAR funding was devoted to purchasing ARVs (either dispensed [20.3%] or for buffer stock [2.0%]); personnel and other (non-laboratory) supplies were also non-trivial costs (19.5% and 19.3%, respectively). Other resources did not fund any ARV purchases, but provided support for personnel (22.1%), equipment (19.7%), training (18.2%) and building use (14.3%).

Even though treatment is provided free of charge, the findings give evidence of financial burden for patients. Based on a survey of patients, adult patients incurred an economic cost-equivalent of \$52.00 (2011 USD) per year as part of receiving care and treatment. Travel expenses accounted for more than 60.0% of the cost⁴. Patients living in rural areas paid, on average, 1.4 times as much per year as those living in urban areas. In addition, male and female patients spent a considerable amount of time attending the HIV service, an average of 71.6 and 64.8 hours per year, respectively. When looked upon as an opportunity cost, this represents approximately \$46.45 per year⁵ (approximately 5% of the annual minimum wage) of potential lost earnings. The substantial resources invested in starting and scaling up HIV treatment programs are a

⁴ The estimates of travel costs are not adjusted for potentially multiple purposes of each trip (e.g. receive health services other than HIV related services during the same visit; combine clinic visit with travel for personal reasons).

⁵ Based on the national minimum wage of 6,999 Kenyan shillings (KSh).

reflection of the commitment shown by the Government of Kenya, PEPFAR, and other international donors and partners to combat HIV/acquired immunodeficiency syndrome (AIDS) in Kenya. While program accomplishments are growing each year, and many patients are now enjoying the benefits of HIV treatment and care services, the costs of continued support of services are substantial, despite reductions in per-patient costs. It will be important to plan for and maintain the funding levels needed to continue providing services in the future, as Kenya continues to expand access to treatment.

On the basis of the results of this study, the following recommendations may be helpful to consider:

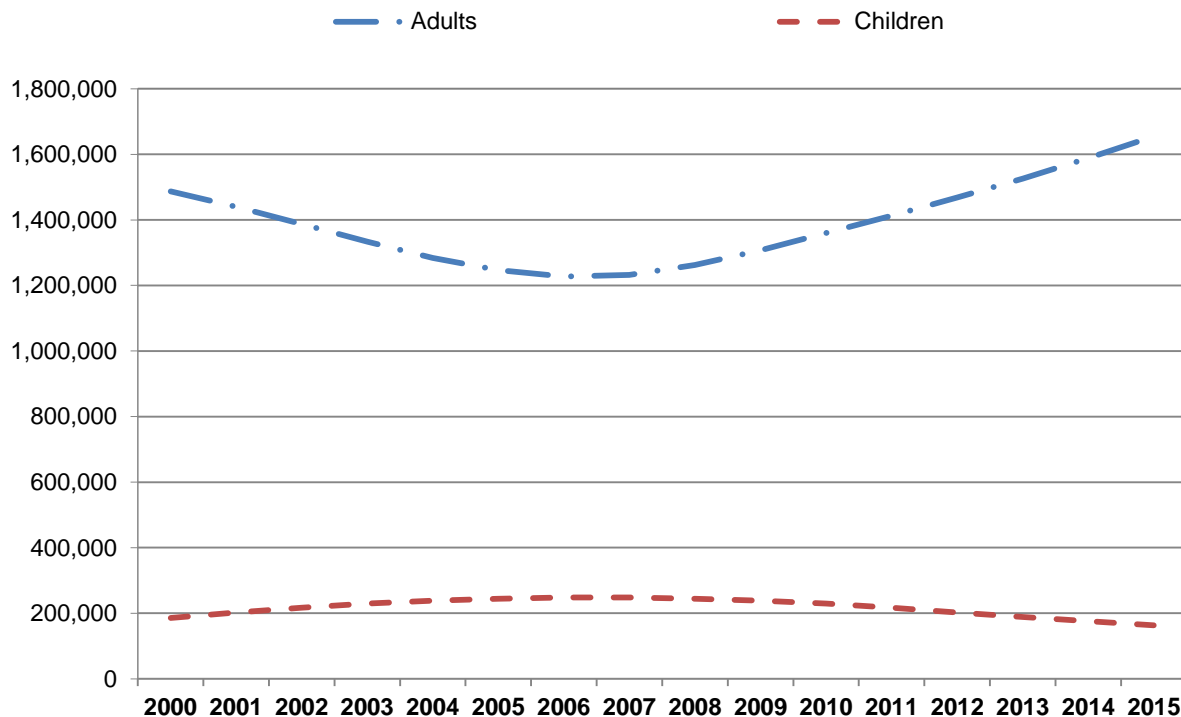
- 1) In order to provide successful and cost-effective treatment, it is important to recognize the main cost drivers (buffer stock, personnel, and laboratory) so that inefficiencies can be addressed in order of importance and relevance to the program. To evaluate and then find means of increasing efficiency, the existing cost ranges across sites must be considered to account for location, type of patients, and so forth.
- 2) Increasing awareness of program costs by expanding this study and carrying out similar ones across other HIV programs can provide a deeper understanding of the effort and resources needed for optimal treatment. Data can be used for modeling, forecasting, and planning for future treatment models.
- 3) Furthermore, expanding the scope of the evaluation to cover treatment quality and outcomes (i.e., cost-effectiveness analysis) would provide policymakers with key information for the decision-making process.
- 4) Finally, this study shows that even though treatment is mostly provided for free, patients incur a cost to reach available services/treatment. In addition, opportunity costs are important to weight in when considering higher frequency of visits. This information should be used by policymakers when considering financial health protection mechanisms for patients. For example, some policy changes focused on implementing strategies to offset out-of-pocket costs for patients from lower socio-economic groups may be beneficial (e.g., bringing services closer to patients, drug pick-up zones).

1. BACKGROUND

1.1 HIV Epidemic in Kenya

The HIV/AIDS epidemic poses a grave challenge to governments, health systems, and communities around the world. In 2012, about 2.3 million people (1.9 to 2.7 million) became infected with HIV, bringing the global HIV-positive population to roughly 35.3 million (32.2 to 38.8 million) by the end of the year (UNAIDS, 2013). According to the Joint United Nations Programme on HIV/AIDS (UNAIDS), in the same year, an estimated 1.6 million (1.4 to 1.9 million) lost their lives to AIDS.

FIGURE 1. ESTIMATED NUMBER OF ADULTS AND CHILDREN WITH HIV IN KENYA



*From NACC/NASCOP, 2011

Kenya currently faces a generalized HIV/AIDS epidemic, with a national prevalence rate among adults in 2012 of 5.6% and 0.9% in children⁶ (NASCOP, 2013). This corresponds to an estimated

⁶ In the NASCOP KAIS report, adults are defined as all people 15 to 64 years of age and children as 18 months to 14 years of age.

1.2 million adults and 104,000 children infected with HIV (NASCOP, 2013). The prevalence of HIV in Kenya is higher among women than men (6.9% and 4.4%, respectively). HIV prevalence among urban women (8.0%) is greater than for rural women (6.2%). A similar pattern is found in men, with the HIV prevalence rate in urban areas higher than in rural areas at 5.1% and 3.9%, respectively (NASCOP, 2013). The HIV and AIDS epidemic in Kenya shows strong provincial variation ranging from the highest HIV adult prevalence in Nyanza (15.1%), Nairobi (4.9%), Western (4.7%), Coast (4.3%), South Rift (4.3%), Eastern South (4.3%), Central (3.8%) to the lowest prevalence in North Rift (3.1%) and Eastern North (2.1%)⁷ (NASCOP, 2013).

1.2 The Response to the HIV Epidemic in Kenya

The National AIDS & STIs Control Programme (NASCOP) was created in 1987 by the Ministry of Health to co-ordinate the HIV health sector response in the country. NASCOP is a division of the ministry of Health and works in collaboration with the National AIDS Control Council (NACC), established in 1999, in the Ministry of Special Programmes. The NACC established 9 regional offices across the country to aid in the coordination and management of the health sector's HIV/AIDS response (NACC, 2012). Kenya's development of a national policy on HIV/AIDS marked a milestone in its response to the epidemic. This effort was reinforced by the concurrent establishment of a high level, multisectoral commission (National AIDS Control Council) in the Office of the President. While NACC is the strategic leader and coordinator, the Constituency AIDS Control Committees, in all the 210 constituencies in the country, are responsible for overall leadership and coordination of the response in the country (NACC, 2012).

HIV/AIDS is also paramount in the nation's development agenda as specified in *Kenya Vision 2030*. Government policy emphasizes the importance of promoting preventive health care as opposed to curative intervention, and the necessity to de-link the Ministry of Health from service delivery in an effort to improve management of the health institutions within the country. In addition, the *Kenya Vision 2030* emphasizes the necessity to create a national health insurance scheme to promote equity in the nation's health care financing, and expresses the need for more outpost-based approach systems to allow disadvantaged groups to have access to health care from preferred institutions (Government of the Republic of Kenya, 2007). The Kenyan

⁷ No data was available from North Eastern for the NASCOP KAIS 2013 study due to security concerns.

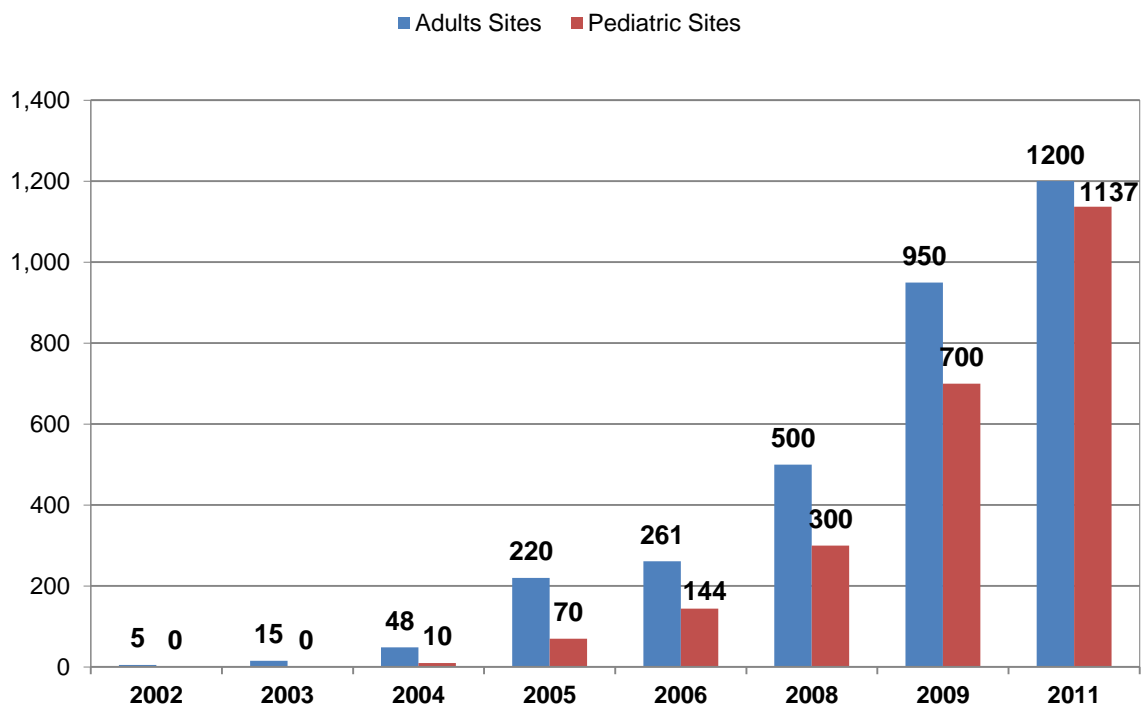
government has demonstrated its commitment to fight the epidemic, and to improve the well-being of its people.

According to NACC and NASCOP (2012), government recurrent spending on HIV/AIDS nearly doubled between 2006–2007 and 2008–2009. The share of foreign funded interventions accounts for more than 80.0% of all HIV spending in 2007–2008, bilateral spending on HIV programs nearly doubled from 2006–2007 to 2008–2009, increasing from Ksh 20.3 billion (US \$305.5 million) to Ksh 40.0 billion (US \$516.0 million)².

Kenya has benefited from HIV funds from the Global Fund in Round 1 (\$2.9 million, 2003 USD), round 2 (\$68.0 million, 2003), round 7 (\$46.7 million, 2009), and round 10 (\$93.4 million, 2010), which included components to scale up antiretroviral treatment for individuals living with HIV and AIDS, increase access to HIV testing and counseling services, and to increase uptake of HIV/AIDS prevention and treatment services (The Global Fund to Fight AIDS, Tuberculosis and Malaria, 2011).

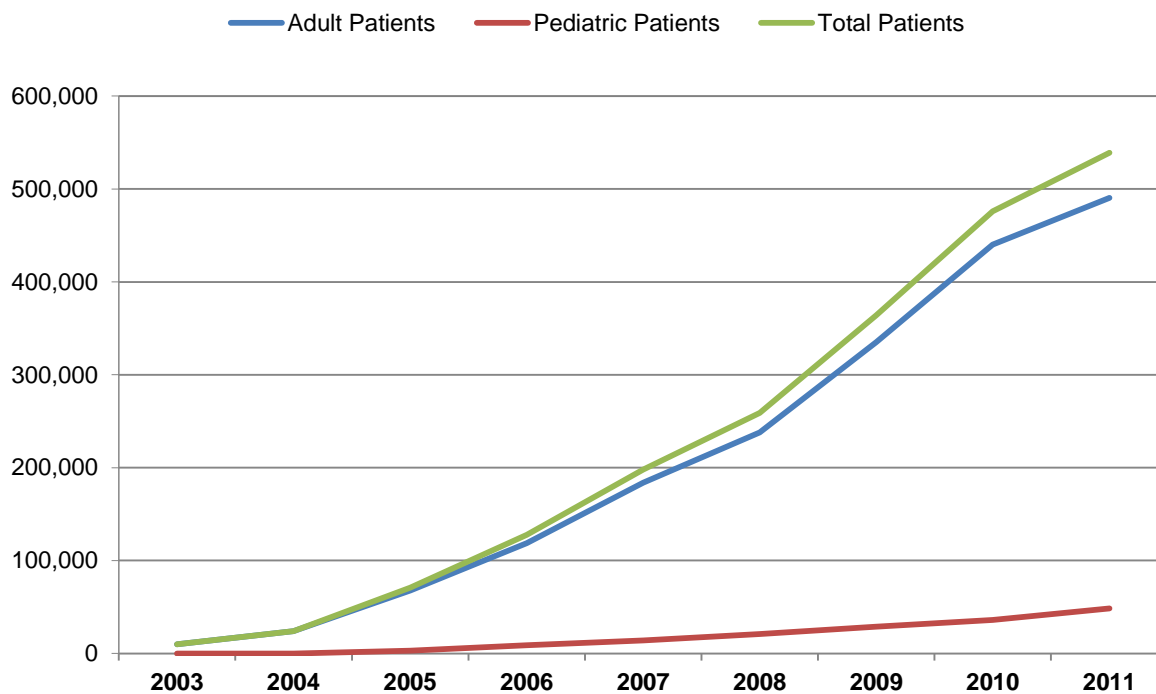
PEPFAR support for the national ART program builds on existing structures and plans on working in concert with the MOH and other donors. PEPFAR represents a major commitment by the U.S. Government (USG) to undertake comprehensive, evidence-based action to turn the tide of the global HIV/AIDS epidemic. Under PEPFAR, Kenya received \$92.5 million in fiscal year (FY) 2004, \$141.3 million in FY 2005, some \$208.3 million in FY 2006, \$368.1 million in FY 2007, \$534.8 million in FY 2008, \$565.0 million in 2009, and \$548.1 million in FY 2010 to support comprehensive HIV/AIDS prevention, treatment, and care programs. Figures 2 and 3 document rapid scale-up of ART in Kenya with over 500,000 adult and pediatric patients on ART in 2011. Achieving future goals in care and treatment will require cost-conscious program management and thoughtful budgeting (PEPFAR, 2012).

FIGURE 2. EXPANSION OF ART TO HEALTH FACILITIES



*Unpublished data by NASCOP

FIGURE 3. NUMBER OF INDIVIDUALS WHO RECEIVED ART IN KENYA



*Unpublished data by NASCOP

1.3 The ART Costing Project Study

The cost of ART service delivery was identified as a priority for evaluation, given the substantial resources devoted to supporting HIV treatment and care programs and the deficiencies of the existing literature examining HIV treatment costs, which were mainly developed on the basis of costing models or excluded key cost components (Kahn, Marseille, & Harris, 2005; Rosen & Long, 2006). A detailed understanding of the costs of providing HIV treatment and care within Kenya was seen as important information for both country-level decision makers and donors so they could inform planning and resource allocation decisions during the initiation, scale-up, and maturation of HIV treatment programs. The study is designed in order to estimate the full annual per-patient cost of comprehensive HIV treatment and to understand its composition and drivers.

1.4 ART Costing Studies Funded by PEPFAR

PEPFAR has supported a series of costing studies across a variety of countries to identify and value the discrete cost components dedicated to HIV treatment within a sample of HIV treatment facilities. The studies consider diverse settings and delivery systems, and close collaboration with in-country teams has facilitated the use of consistent protocols across settings, such that data can potentially be aggregated and compared across treatment health facilities with care and treatment clinics and countries.

In Kenya, the costing study was a collaborative effort. A study team was formed with participation from CDC, USAID, and the MOH to generate information to assist the MOH, PEPFAR, and other country partners in assessing the potential reach of care and treatment programs and the financial resources required to support them, as well as informing decisions about the service delivery models used for provision of HIV care and treatment services.

With approximately 1.5 million people infected with HIV in Kenya, considerable resources are required to further extend ART coverage and to maintain treatment cohorts in the future. The lack of previous cost studies on HIV/AIDS treatment in Kenya makes it difficult for decisions makers to anticipate future costs and manage program growth.

This national ART costing study has been carried out to generate data for decision makers by addressing the following objectives:

- Estimate the average annual per-person cost of providing comprehensive HIV treatment for eligible adult and pediatric clients
- Evaluate the range of costs for comprehensive HIV treatment across settings and assess how components associated with the design and context of treatment programs influence cost estimates
- Assess change in the costs of comprehensive HIV treatment over two time periods and estimate the relative magnitude of expenditures for investments and for recurring program costs

1.5 Organization of Report

The report contains two distinct but linked investigations. The first, identified as Program Cost Assessment, evaluates the costs of providing comprehensive HIV treatment at the facility level. The second, identified as Patient Cost Assessment, evaluates the cost to the patient as they seek out and undergo HIV treatment. Section 2 of this report describes the methodology used for the Program and Patient Cost Assessments. Section 3 reports the results of the assessments, followed by a discussion in section 4.

2. METHODS

2.1 Program Cost Assessment

2.1.1 Population and Sample

The population of interest for study included the adult and pediatric patients receiving HIV care and ART from the 886 out-patient ART clinics or HIV comprehensive care centers (CCCs) in Kenya that report to NASCOP/ PEPFAR and receive PEPFAR support to provide comprehensive HIV treatment, defined as the mix of services being offered at each CCC. The study excluded facilities whose ownership was coded as “Other Private” or “Private Medical Enterprise”, and facilities whose type did not fall into one of the following categories: Tertiary Hospital, Secondary Hospital, Primary Hospital, Other Hospital, Health Centre, and Dispensary. The sample was restricted to health facilities with CCCs who had been providing ART for at least 18 months as of June 30, 2010. This criterion reflected the study’s intention to assess programs after they had passed the initial start-up phase and to assess, wherever possible, the effects of time in programs in a 12-month period. The sampling frame included 630 eligible facilities after application of the exclusion criteria. The sample of thirty facilities was randomly selected with probability proportional to size (PPS) within strata defined by affiliation: MOH sites vs. Non-MOH sites. The frame was implicitly stratified (sorted) by geography and represents all facility types. For PPS selection, the measure of size was ART patient volume. At the start of the data collection, one facility was excluded from the sample due to the security reasons in the region. The majority of HIV treatment clinics included in this study are located in urban settings (20 out of 29), and administered by MOH (23 out of 29). Table 1 summarizes key features of the study sites.

TABLE 1. KENYA FACILITY SAMPLE FOR ART COSTING PROJECT

Facility	Location	Area	ART Program Started	Administration	Health System Level ⁸
BOMU MC*	Mombasa	Urban	6/1/2004	NGO/FBO	Level 4
BONDO MC	Bondo	Urban	6/1/2005	MOH	Level 4
BUKAYA HC	Mumias	Urban	5/1/2008	MOH	Level 3
COAST PGH	Mombasa	Urban	6/1/2003	MOH	Level 5
COPTIC HOSPITAL*	Nairobi	Urban	10/1/2004	NGO/FBO	Level 4
GITHUNGURI HC	Githunguri	Rural	6/1/2006	MOH	Level 3
HOMA-BAY DH*	Homa-Bay	Urban	1/1/2004	MOH	Level 4
KAKAMEGA PGH	Kakamege Town	Urban	1/1/2004	MOH	Level 5
KAUWI SDH	Kabati	Rural	1/1/2007	MOH	Level 4
KERICHO DH*	Kericho	Urban	1/1/2004	MOH	Level 4
KIKUYU PCEA	Kikuyu	Rural	6/1/2005	NGO/FBO	Not Classified
KOMBEWA DH*	Kombewa	Rural	1/1/2007	MOH	Level 4
LIVERPOOL VCT	Nairobi	Urban	1/1/2003	NGO/FBO	Not Classified
LOCO DISPENSARY	Nairobi	Urban	1/1/2008	MOH	Level 2
MASABA DH	Keroka	Urban	7/1/2005	MOH	Level 4
MATATA NH	Oyugis Town	Urban	7/1/2007	NGO/FBO	Level 4

⁸ Levels are defined according to Kenya Essential Package for Health, which is based on a life cycle approach to delivery of a comprehensive healthcare package across 6 levels of care.

MBITA SDH	Mbita	Rural	6/1/2006	MOH	Level 4
MERU DH*	Meru	Urban	6/1/2004	MOH	Level 5
MOSORIOT RHTC	Eldoret	Urban	1/1/2001	MOH	Level 3
MSAMBWENI DH	Msambweni	Rural	8/1/2004	MOH	Level 4
MTRH*	Eldoret	Urban	11/1/2001	MOH	Level 6
NAIVASHA MC	Naivasha	Urban	01/01/2007	NGO/FBO	Level 3
NAKURU PGH*	Nakuru Town	Urban	1/1/2002	MOH	Level 5
NYAHURURU DH*	Nyahururu	Urban	12/1/2005	MOH	Level 4
NYAMIRA DH	Nyamira	Urban	1/1/2005	MOH	Level 4
ONGO HC	Ranen	Rural	1/1/2007	MOH	Level 3
PORT VICTORIA HOSPITAL	Port Victoria	Urban	1/3/2012	MOH	Level 4
SIAYA DH*	Siaya	Rural	6/1/2004	MOH	Level 4
YALA SDH	Yala Township	Rural	1/1/2004	MOH	Level 4

*Indicates sample locations for the Patient Cost Assessment questionnaire.

2.1.2 Defining Comprehensive HIV Treatment

Comprehensive HIV treatment was defined as both ART and supportive care received by HIV-positive patients at HIV CCCs. Adult ART patients receive a standardized regimen of three ARVs, which patients take on a daily basis. ART for pediatric (< 15 years) patients is similar to adult treatment, with ARV regimens modified using weight- and age-based dosing and using liquid formulations as required. Regular clinical assessment and laboratory monitoring are used to gauge the response to treatment, and patients are transitioned to second-line ARV regimens as indicated by treatment failure, adverse reactions, or drug availability. Supportive care is central to HIV management and includes an array of health interventions that vary across sites. These

care services may include screening, prophylaxis, and treatment of opportunistic infections, sexually transmitted diseases, and HIV-associated cancers; nutritional support; programs to promote retention and adherence to therapy; as well as other clinic or community-based activities to address health-related concerns for patients.

Not all HIV-positive patients immediately receive ART upon enrollment in HIV CCCs. Transition of pre-ART patients into ART is determined by patient need and treatment guidelines, with patient need assessed using standardized clinical or laboratory criteria. Pre-ART patients generally have access to a similar range of supportive care services as ART patients, as well as regular clinical and laboratory monitoring, though potentially at a different frequency than ART patients.

Differences in patient clinical characteristics, drug regimens, the intensity and type of supportive care services required result in differences in the resources needed to provide treatment and care. At each facility, the costing study included all services being provided to HIV-positive individuals that met three criteria: (1) the primary intent of the service was as a health intervention (thus excluding such activities as educational programs and income-generation activities), (2) the primary recipient of the service was the HIV-positive individual (as opposed to the patient's family or the general community), and (3) the service was provided in or administered by the CCC.

2.1.3 Patient Types

While this study considered all HIV-positive individuals enrolled in care or treatment programs at the sampled facilities, it is clear that some types of patients consume more resources than others. For example, newly initiated ART patients may require more frequent clinical and laboratory monitoring in initial months until their treatment is stabilized than do established ART patients. Data were collected to subdivide costs according to the types of patients receiving care, and results are reported separately for different patient types.

Table 2 describes patient types and explains why the costs may vary in each case.

TABLE 2. PATIENT TYPES

Pre-ART Versus ART Patients
<p>Pre-ART patients are HIV-positive, are enrolled within the facility, and are receiving supportive care services and periodic follow-up, but are not yet receiving ART. ART patients are HIV-positive, are enrolled within the facility, and are receiving ART and associated clinical and laboratory monitoring as well as supportive care services.</p> <p>Potential cost differences: It is expected that costs associated with ARVs (dispensed drugs, buffer stock, supply chain management) will be the major source of cost differences between the two groups. These differences could be reinforced by a greater intensity of clinical and laboratory services received by ART patients.</p>
Pediatric Versus Adult ART Patients (Subset of ART Patients)
<p>Pediatric patients are aged 0 to 14 years; adult patients are aged 15 years and older. This distinction is only made for ART patients.</p> <p>Potential cost differences: Treating pediatric patients poses additional challenges in terms of ARV selection and dosing. The major difference is expected to be the different medications used for pediatric patients; however, it is also possible that there will be differences in the intensity of clinical and laboratory services.</p>
Newly Initiated Versus Established Patients (Subset of ART Patients)
<p>Newly initiated patients have not yet finished their first 6 months of HIV treatment, while established patients have been receiving HIV treatment for more than 6 months. This distinction is only made for ART patients.</p> <p>Potential cost differences: The major source of cost differences between these groups is expected to be the greater intensity of clinical and laboratory services usually devoted to ART patients when they initiate ART and in subsequent months, seen in a higher frequency of clinical and laboratory follow-up.</p>

2.1.4 Time Periods

The study assessed treatment programs over two sequential 6-month periods in order to reveal the change in program costs with time. Data on program costs and patient volume were collected from January 2010 to December 2010. A maximum of two 6-month periods (12 complete months) were collected for each of the facilities included in the sample.

2.1.5 Perspective of Costing

This study adopted a programmatic perspective, collecting data on the total costs incurred by each treatment program to provide ART and supportive care, and including all sources of financial or in-kind support to the program. Medical costs incurred offsite were not included. Higher-level overheads—as incurred by the primary implementers, MOH, and USG agencies—were also excluded in order to focus on those costs incurred at the facility level.

Analyses of cost data were conducted from both financial and economic cost perspectives. A financial cost perspective was employed when expenditures were compared across time periods and program maturity, and when budget allocations and the distribution of sources of support are the focus of analysis. The financial cost perspective aids planners and decision makers in planning resources where the timing of expenditures is important. An economic cost perspective was used to evaluate issues and outcomes that relate to a project's sustainability and

comparability (e.g., per-patient costs by cost categories and programmatic activities) over the project's duration. An economic cost approach does not substitute for a financial cost analysis, but rather complements it with additional information for decision making. Within the report, tables and graphs are labeled to indicate whether the data are reported from an economic or financial cost perspective.

Capital assets are defined as inputs that last for more than one time period. For this study, the capital assets included laboratory and other equipment, vehicles, buildings, training, and ARV buffer stock. To calculate financial costs, all capital expenses were attributed to the time period in which the expenditure occurred. Financial cost analyses are less common and can provide insight into how the resource needs of programs change with time, which is important information for funders during a rapid scale-up of HIV treatment. To calculate economic costs, capital costs are spread over the lifetime of each asset, regardless of purchase time. The value of each capital investment is annualized over its expected useful life at a discount rate of 3% per annum, consistent with conventional methods of economic evaluation (Drummond, Sculpher, Torrance, O'Brien, & Stoddart, 2005; Weinstein, Siegel, Gold, Kamlet, & Russell, 1996). The estimated useful life differed by the type of investment (i.e., 30 years for new infrastructure, 5 years for vehicles and other equipment, 2 years for training, and infinity for buffer stock⁹).

⁹Although individual batches of drugs may expire, efficient supply chain management systems cycle drugs through the buffer stock and eliminate spoilage. For this reason, the economic cost of maintaining a buffer stock is equivalent to the opportunity cost of having program funds invested in buffer stock (i.e., drug value multiplied by 3% annual discount rate).

2.1.6 Cost Categories¹⁰

Cost data were collected so they could be broken down along three programmatically relevant sets of categories. The categories describe each datum by three different attributes: (1) funding source, (2) input type or how it was spent (on personnel, supplies, equipment, etc.), and (3) program activity. The three categorizations are shown in Table 3 (see also Berruti, 2011).

TABLE 3. COST CATEGORIZATION MATRIX

Program Activity Categories	
Training and supervision	Supply chain management
Clinical care	M&E and health management information systems (HMIS)
Laboratory services	General administration and operations
Input Types Categories	
Recurrent expenses	Investments
Personnel	Equipment
ARVs (for dispensing)	New infrastructure
Other drugs	Training
Laboratory supplies	ARVs (for establishment or expansion of buffer stock)
Other supplies	
Building use	
Travel	
Utilities	
Contracted services	
Funding Source Categories	
Host country government*	USG (PEPFAR)
Other partners	

* The "host country government" category also includes funds from the Global Fund, the World Bank, and other foreign sources that are provided through budgetary support to the host country government.

2.1.7 Data Collection and Analysis

Data were collected at each of the 29 study sites, as well as at organizations providing support to the sites (e.g., MOH headquarters, training institutions, ARV procurement agents, technical assistance providers), between October 2011 and December 2011. Data were collected through retrospective record review, including accounting records, expenditure logs, prescribing records, equipment inventories, and routine reporting forms. Additional data were collected through key informant interviews to identify the programmatic activities to which resources were devoted, and to develop a comprehensive description of the structure and functioning of the HIV treatment program at each facility. All data were transcribed into electronic data collection

¹⁰ See Berruti (2011) for a detailed explanation.

instruments and confirmed through follow-up with key contacts at each site and through discussions with key stakeholders in a series of validation meetings.

Cost data and patient volume data were organized into 6-month time periods from January 1, 2010 to December 31, 2010. Shared costs (e.g., facility maintenance, administrative and managerial overhead) were allocated to the HIV treatment program and then between program activities by direct allocation, on the basis of reported percentage effort (for personnel) or percentage use (for other inputs). The opportunity cost of using existing building infrastructure was estimated as the equivalent rental cost of building space. The cost of ARV buffer stock was calculated on the basis of the average number of months of buffer stock held, the incremental growth in ART patient volume over the period, the distribution of current ARV regimens, and the purchase price of ARVs. For economic cost analyses, capital investments (e.g., laboratory equipment) were annuitized over the expected useful life of each item with a 3% discount rate. In addition, staff salaries from all sources (including MOH) were taken into account.

All costs were collected in the original currency, converted to USD at the market exchange rate at the time the cost was incurred, and inflated to current price levels. All costs are reported in June 2008 USD. Routinely reported indicators from program M&E systems were used to calculate the average number of patient-years of treatment provided for each patient type in each period. Quantitative analyses were conducted using the Stata SE 12 (StataCorp LP, 2012) data analysis and statistical software package.

2.1.8 Limitations

Data were collected at each of the 29 study sites, as well as at organizations providing support to the sites

2.2 Patient Cost Assessment

2.2.1 Sampling Frame

For a subsample of 10 sites, a convenience sample of 484 adult patients across all sites was selected to undertake a voluntary interview on patients' costs. The 10 sites were selected from a random sample of 29 facilities (which were selected for the program cost assessment) using PPS within strata defined by affiliation: MOH sites vs. Non-MOH sites (please see Table 1, page 8 for a list of sampling sites). For PPS selection, the measure of size was ART patient volume. The

sample was restricted to those patients that (1) were enrolled in the site's HIV care and treatment program; (2) were aged 18 years or older; and (3) had at least one prior appointment at the clinic to ensure they have experienced the HIV care and treatment services offered by the clinic.

2.2.1 Sample Size

A key variable calculated from the patient interviews is their annualized treatment expenses; however, little is known about the expected variance in patients' cost between facilities and within patient cohorts in Kenya. A study conducted in out-patient HIV treatment clinics in Tanzania found an average cost of USD 31.70 with a standard error of 3.68 (MOH Tanzania & CDC, 2011). These standard error calculations accounted for the intra-cluster correlation of patient costs within sites, which was associated with a design effect of 2.63. To estimate what would happen with 10 sites, all combinations of 9 of the 10 sites were evaluated and the average cost estimate, standard error, and design effect were calculated. The average point estimate was 31.70, the average standard error was 3.88, and the average design effect was 2.63. These figures indicated that a standard error between 10% and 15% of the estimated costs will be obtained if 50 patients are sampled in each of 10 sites (selected at random with one in each stratum) for the total of 500 patients.

2.2.2 Selection Process

Adult patients attending the site were randomly selected to be interviewed during the time that the data collection teams were present at the site. Interviews were confidential and did not collect participants' names, only basic demographic characteristics (i.e., gender, age, location). Patients were asked whether they had been interviewed previously for this study, and those who had were not interviewed again.

3. RESULTS

3.1 Program Cost Assessment

3.1.1 Patient Volume at Health Facilities

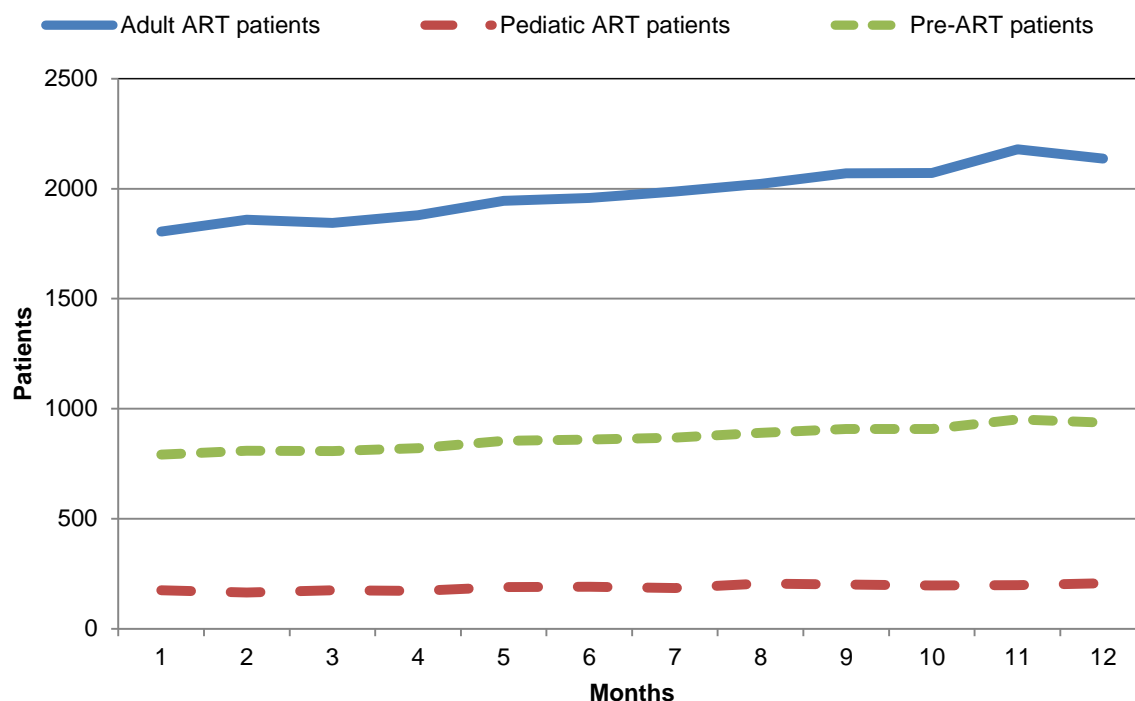
The sites included in the study varied in duration of provision of ART services, with start dates ranging from January 2003 to May 2008. Across the 29 facilities, the size of each patient cohort continued to increase by more than 30 patients per month. Patient volume as measured by the number of current patients increased from a median of 2,121 total (pre-ART and ART) patients per site at the end of the first 3 months of the study to a median of 2,409 total patients per site by the end of the evaluation, 9 months later (see Table 4), with a wide range of patient population sizes in sites.

TABLE 4. PATIENT VOLUME

Number of Patients After the First 3 Months of Evaluation	
Individuals receiving HIV care (ART + pre-ART)	Median (range): 2,121 (97–12,387)
Individuals receiving ART	Median (range): 1,515 (69–8,848)
Pediatric patients as a percentage of total ART patients	Median (range): 7.7% (0.0–16.6%)
Number of Patients at the End of Evaluation	
Individuals receiving HIV care (ART + pre-ART)	Median (range): 2,409 (130–14,034)
Individuals receiving ART	Median (range): 1,721 (93–10,024)
Pediatric patients as a percentage of total ART patients	Median (range): 7.3% (0.2–15.5%)
Average Quarterly Patient Growth Over Evaluation (Percentage)	
Individuals receiving HIV care (ART + pre-ART)	Median (range): 7.1% (-4.9–23.9%)
Individuals receiving ART	Median (range): 7.1% (-4.9–23.9%)
Average Quarterly Patient Growth Over Evaluation (Absolute)	
Individuals receiving care (ART + pre-ART)	Median (range): 93 (-263–937)
Individuals receiving ART	Median (range): 72 (-188–669)

The patients receiving ART were predominantly adults, and the proportion of pediatric ART patients slightly fell over time, from a median of 7.7% of all ART patients after 3 months to a median of 7.3% of all ART patients at the end of the evaluation (Figure 4).

FIGURE 4. AVERAGE NUMBER OF PATIENTS BETWEEN MONTHS 0 AND 12, BY PATIENT TYPE



3.1.2 Staffing Model

The 29 HIV clinics followed the staffing model common with other HIV treatment programs in Kenya. This model focused on clinicians (i.e., clinical officers or doctors) providing the majority of pre-ART assessments, and initial ART prescriptions, with other clinic staff members playing supporting roles. In 12 of 29 sites, nurses were able to perform follow-up ART assessments. The variation in the staffing model across sites translated into a wide variation in the clinician-patient ratio¹¹, ranging from 0.18 to 26.0 clinicians per 1,000 patients, with a median of 4.0 clinicians (at the end of the evaluation) (see Table 5). Similarly, the ratio of clinical staff members¹² to patients ranged from 1.1 to 43.5 clinical staff members per 1,000 patients, with a median of 9.6 clinical staff at the end of evaluation

¹¹ Average number of full-time clinicians per 1,000 patients (ART and pre-ART).

¹² Clinical staff includes clinicians, nurses, counselors, social workers, pharmacists, and other clinical auxiliaries.

TABLE 5. STAFFING RATIOS

Staffing Ratios	
Clinician-patient ratio	Median: 1.2:1,000 (0.18–2.6)
Clinical staff-patient ratio	Median: 5.0:1,000 (1.1–29.6)
Initial ART Assessment and Prescriptions Provided by:	
Clinicians	23 of 29 (79.3%)
Nurses	6 of 29 (20.7%)
Follow-up ART Assessment Provided by:	
Clinicians	17 of 29 (58.6%)
Nurses	12 of 29 (41.4%)

3.1.3 Clinical and Laboratory Monitoring

The schedule of clinic visits for pre-ART patients was similar among the 29 facilities. Facilities initially evaluated each new HIV-positive patient for disease status and ART eligibility, and if the patient was not eligible for ART immediately, he or she was scheduled to return at regular intervals—every 3 months or more often—for follow-up and repeat assessment. For patients who were initiated on ART, most sites asked patients to return for assessment 2 or 3 times during the first month after initiation and then monthly for 6 months. Subsequently sites differed in the regularity of scheduled follow-up for established ART patients, from every two weeks to every 3 months. However, in all 29 sites, established ART patients were seen at least every 3 months (see Table 6).

TABLE 6. REGULARITY OF SCHEDULED CLINIC VISITS

Pre-ART Patients	
Every 3 months (or more often)	29 of 29 (100.0%)
Newly Initiated Adult ART Patients (First 6 Months)	
At baseline, every 3 months (or more often)	29 of 29 (100.0%)
Established Adult ART Patients (After First 6 Months)	
Every 3 months (or more often)	29 of 29 (100.0%)

CD4 counts were regularly conducted at most of the facilities to assess the eligibility of pre-ART patients for ART. For patients on ART, repeat CD4 counts were generally performed every 6 months to assess treatment response. Blood chemistry and hematology tests to identify side effects were performed at most facilities and were more likely to be performed during first 6 months of treatment. Viral load testing was not regularly conducted at most of the facilities.

TABLE 7. REGULARITY OF LABORATORY MONITORING AT FACILITIES¹³

Scheduled CD4 Counts	
Pre-ART patients	
Every 6 months (or more often)	28 of 29 (96.5%)
At baseline only (and as needed)	1 of 29 (3.5%)
Newly initiated adult ART patients (first 6 months)	
At baseline, every 3 months (or more often)	28 of 29 (96.5%)
At baseline, every 6 months	1 of 29 (3.5%)
Established adult ART patients (after first 6 months)	
Every 3 months (or more often)	1 of 29 (3.5%)
Every 6 months (or less often)	28 of 29 (96.5%)
Blood Chemistry Tests	
Pre-ART patients	
Blood chemistry tests at baseline	21 of 29 (72.4%)
Blood chemistry tests after first 6 months	14 of 29 (48.3%)
Newly initiated adult ART patients (first 6 months)	
Blood chemistry tests	23 of 29 (79.3%)
Established adult ART patients (after first 6 months)	
Blood chemistry tests	15 of 29 (51.7%)
Hematology Tests	
Pre-ART patients	
Hematology tests at baseline	27 of 29 (93.1%)
Hematology tests after first 6 months	19 of 29 (65.5%)
Newly initiated adult ART patients (first 6 months)	
Hematology tests	26 of 29 (89.6%)
Established adult ART patients (after first 6 months)	
Hematology tests	22 of 29 (75.9%)
Viral Load Tests	
Pre-ART patients	
Viral load tests at baseline	5 of 29 (17.2%)
Viral load tests after first 6 months	7 of 29 (24.1%)
Newly initiated adult ART patients (first 6 months)	
Viral load tests	7 of 29 (24.1%)
Established adult ART patients (after first 6 months)	
Viral load tests	8 of 29 (27.6%)

3.1.4 Range of Supportive Care Services Provided

Health facilities differed in terms of the supportive care services provided to ART and pre-ART patients. Cotrimoxazole and herpes virus management were part of the care package at all of the facilities. Most facilities provided TB treatment onsite, safe water systems, some form of psychosocial support, malaria treatment, and pain management. Among less commonly provided

¹³ The data for this table are based on the reports of key personnel interviewed during site visits and does not represent actual utilization of testing (e.g., based on patient chart review), which was outside of scope of this study.

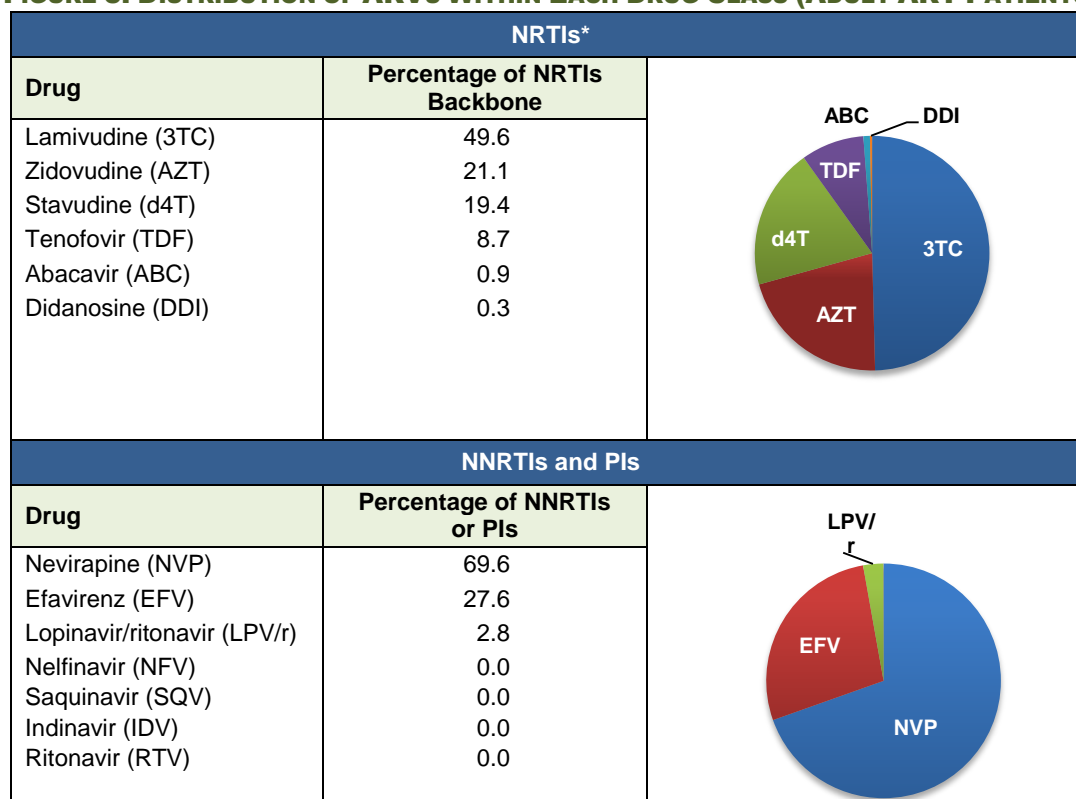
services were insecticide-treated bed nets (ITNs) with 18 out of 29 facilities providing those to HIV patients, and end-of-life care, which was provided in 16 out of 29 facilities. Activities to support ART adherence and retention, which commonly involved clinic staff members or volunteers tracking patients in the community when they missed an appointment, were present in 27 of the 29 facilities (see Table 8).

TABLE 8. SUPPORTIVE CARE SERVICES FOR ART AND PRE-ART PATIENTS

Services Provided	
Cotrimoxazole	29 of 29 (100.0%)
Herpes virus treatment	29 of 29 (100.0%)
Psychosocial support	28 of 29 (96.5%)
Follow-up of patients in the community	27 of 29 (93.1%)
Malaria treatment	26 of 29 (89.7%)
TB treatment onsite	25 of 29 (86.2%)
Safe water systems	25 of 29 (86.2%)
Pain management regularly	24 of 29 (82.8%)
ITNs	18 of 29 (62.1%)
End-of-life care	16 of 29 (55.2%)

3.1.5 ARV Regimens

ARV regimen information for adult ART patients was determined from the ARV dispensing records at study sites. The distribution of patients across ARVs is shown in Figure 5, subdivided into ARVs forming a part of the nucleoside reverse transcriptase inhibitor (NRTI) backbone and NNRTIs/protease inhibitors (PIs).

FIGURE 5. DISTRIBUTION OF ARVs WITHIN EACH DRUG CLASS (ADULT ART PATIENTS)


* Note that recommended ARV regimens contain two different NRTIs.

3.2 Unit Cost Per-Patient

3.2.1 Annual Per-Patient Economic Costs, by Patient Type

Economic costs—whereby all investment costs are spread out over the useful life of the goods and all opportunity costs are considered—give an indication of the likely long-run costs of HIV treatment in this setting, without the short-term fluctuations caused by one-time or periodic investments. Table 9 shows the median annual economic costs for each patient type over the most recent period at each facility. Even excluding ARV costs, greater resources were required to support ART patients than pre-ART patients. The costs for established ART patients were slightly lower than for newly initiated ART patients, attributable to less frequent and intensive clinical follow-up in the established patients. This drop in per-patient costs between newly initiated and established ART patients was less pronounced for pediatric patients, reflecting the added complexity of ongoing treatment for children. Although the costs of supporting pre-ART patients were less than those for ART patients, these costs are nontrivial and their consideration is important to program planning. Median per-patient costs for ART patients are substantially

higher when ARV costs are included. As reported in Figure 5, a significant proportion of regimens in the 29 facilities included Stavudine, which is a relatively low cost drug. WHO recommends that countries phase out the use of Stavudine, because of its long-term, irreversible side-effects, and Zidovudine or Tenofovir are recommended as less toxic and equally effective alternatives. In a theoretical scenario, where all Stavudine is replaced with Zidovudine, the median per ART patient among 29 sites will increase from \$240.33 to \$292.71. Additional findings from this theoretical scenario are presented in Appendix 1. Looking forward, it is predicted that ARV price changes will have a large effect on total resource needs, and for this reason, total economic costs are also reported with ARV costs excluded.

3.2.2 Unit Cost per Patient-Year

Table 9 and subsequent tables present costs per patient-year. Cost per patient-year is the cost of supporting one patient on care or treatment for a full 12 months. This point needs to be taken into account when these data are used for planning the expansion of a treatment program. For example, if a program was planning a linear scale-up from 1,000 to 2,000 patients over the course of a year, this scenario would translate to 1,500 patient-years of treatment, because not all patients would need to be supported for the full year.

TABLE 9. MEDIAN UNIT COST PER PATIENT-YEAR, BY PATIENT TYPE (ECONOMIC COSTS, 2011 USD)

Total Cost		Pre-ART	All ART	Newly Initiated Adult ART	Established Adult ART	Newly Initiated Pediatric ART	Established Pediatric ART
Including ARVs	Min	\$51.68	\$159.98	\$168.81	\$158.08	\$140.60	\$131.78
	Max	\$250.25	\$405.60	\$520.04	\$400.34	\$618.29	\$607.44
	Median	\$116.71	\$240.33	\$274.95	\$248.91	\$318.73	\$292.60
Excluding ARVs	Min	\$51.68	\$47.77	\$62.46	\$46.95	\$62.46	\$46.95
	Max	\$250.25	\$260.09	\$368.42	\$259.00	\$368.42	\$259.00
	Median	\$116.71	\$120.72	\$148.34	\$120.72	\$136.39	\$123.59

3.2.3 Distribution of Per-Patient Economic Unit Costs, by Input Type

Table 10 shows the distribution of median annual economic costs across the different input types, subdivided into recurrent costs and investments. While investments may represent noteworthy costs at the time they are expended, their relative durability means they make only a minor contribution to total economic costs. The costs of dispensed ARVs and, to a much lesser

extent, cost of personnel were the most significant cost components for ART patients, while for pre-ART patients, personnel and laboratory supplies were the dominant cost components.

TABLE 10. MEDIAN UNIT COST PER PATIENT-YEAR, BY INPUT TYPE (ECONOMIC COSTS, 2011 USD)

Input Types		Pre-ART Patients	All ART Patients	Newly Initiated Adult ART Patients	Established Adult ART Patients	Newly Initiated Pediatric ART Patients	Established Pediatric ART Patients
Recurrent Costs	Personnel	\$36.95	\$38.44	\$43.71	\$36.47	\$43.71	\$36.47
	Dispensed ARVs	---	\$123.03	\$122.68	\$122.68	\$181.53	\$181.53
	Other drugs	\$8.51	\$8.51	\$8.51	\$8.51	\$8.51	\$8.51
	Laboratory supplies	\$19.96	\$19.30	\$19.96	\$19.30	\$21.11	\$19.33
	Other supplies	\$12.96	\$13.57	\$16.23	\$12.60	\$17.95	\$12.60
	Building use	\$6.88	\$7.70	\$9.88	\$7.70	\$9.88	\$7.70
	Travel	\$0.38	\$0.40	\$0.65	\$0.38	\$0.65	\$0.38
	Utilities	\$1.06	\$1.09	\$1.09	\$1.08	\$1.09	\$1.08
	Contracted services	\$2.95	\$2.97	\$3.04	\$2.96	\$3.04	\$2.96
	ALL RECURRENT COSTS*	\$112.38	\$231.13	\$274.11	\$239.67	\$313.17	\$290.89
Investments	Equipment	\$1.36	\$1.38	\$1.40	\$1.37	\$1.40	\$1.37
	Training	\$1.29	\$1.29	\$1.29	\$1.29	\$1.29	\$1.29
	New infrastructure	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
	ARV buffer stock	---	\$0.45	\$0.45	\$0.45	\$0.50	\$0.50
	ALL INVESTMENTS*	\$2.81	\$3.36	\$3.51	\$3.34	\$3.63	\$3.63
	TOTAL COST*	\$116.71	\$240.33	\$274.95	\$248.91	\$318.73	\$292.60

* Since median costs are presented, the sum of median costs for each input type will not equal median total costs.

Some variation in per-patient costs occurred among sites. Total economic costs per patient-year varied between \$159.98 and \$405.60 for ART patients. With ARV costs excluded, ART patient costs varied between \$47.77 and \$260.09. Because this study relied on existing data sources, the variation may reflect some inconsistency in the quality of project records. However, these results also reflect substantial differences in program operations and in the different resource requirements to sustain ART programs in different settings.

Total costs data for the six program activities (clinical care with and without ARVs) are shown in Table 11. Clinical care comprised the largest cost category for both pre-ART and ART patients followed by laboratory costs. Reflecting intensity in clinical follow-up, clinical care costs were highest for newly initiated adult and pediatric ART patients, followed by pre-ART patients, with lower costs for established adult and pediatric ART patients. Laboratory costs were comparable for pre-ART, adult ART (newly or established) and established pediatric ART patients.

**TABLE 11. MEDIAN UNIT COST PER PATIENT-YEAR, BY PROGRAM ACTIVITY
(ECONOMIC COSTS, 2011 USD)**

Program Activity	Pre-ART Patients	All ART Patients	Newly Initiated Adult ART Patients	Established Adult ART Patients	Newly Initiated Pediatric ART Patients	Established Pediatric ART Patients
Training and supervision	\$1.29	\$1.29	\$1.29	\$1.29	\$1.29	\$1.29
Clinical care (excluding ARVs)	\$44.57	\$36.77	\$54.86	\$36.77	\$54.86	\$41.14
Clinical care (ARVs)	---	\$112.74	\$112.42	\$112.42	\$165.28	\$165.28
Laboratory services	\$19.96	\$19.30	\$19.96	\$19.30	\$21.11	\$19.33
Supply chain management (excluding ARVs)	---	\$7.94	\$7.94	\$7.94	\$7.94	\$7.94
Supply chain management (ARVs)	---	\$0.42	\$0.41	\$0.41	\$0.46	\$0.46
M&E and HMIS	\$6.90	\$6.90	\$6.90	\$6.90	\$6.90	\$6.90
General administration and operations	\$13.53	\$13.53	\$13.53	\$13.53	\$13.53	\$13.53
TOTAL COST*	\$116.71	\$240.33	\$274.95	\$248.91	\$318.73	\$292.60

* Since median costs are presented, the sum of median costs for each category will not equal median total costs.

3.2.4 Change in Total Unit Cost per Patient over the Evaluation Period

In contrast to Tables 9 through 11, which present economic costs, Table 12 presents financial costs, focusing on established adult ART patients. Financial costs provide information on the actual timing of resource use as facilities scale-up HIV treatment and care services¹⁴. The table shows median values for the cost per patient-year, comparing the first period with the last period. All 29 sites had 12 months of data available; thus, the analysis compares months 0 through 6 with months 7 through 12. Total costs fell by a median of 6.0%. There was a median drop of 16.2% in all recurrent per-patient costs, and a median drop of 8.9% in total investment per-patient costs.

¹⁴ This section is for informational purposes only to provide additional information. Tests of statistically significant difference have not been conducted. Information on costs between 6 month time blocks become more useful when conducting additional rounds of costing studies.

TABLE 12. MEDIAN UNIT COST PER PATIENT-YEAR FOR ART PATIENTS, FIRST PERIOD VERSUS LAST PERIOD (FINANCIAL COSTS, 2011 USD)

Input Types		First Period of Evaluation	Last Period of Evaluation	Percentage Reduction in Financial Costs
Recurrent Costs	Personnel	\$47.23	\$38.44	18.6%
	Dispensed ARVs	\$120.13	\$123.03	-2.4%
	Other drugs	\$12.14	\$8.51	29.9%
	Laboratory supplies	\$21.03	\$19.30	8.2%
	Other supplies	\$18.92	\$13.57	28.2%
	Building use	\$9.34	\$7.70	17.6%
	Travel	\$0.48	\$0.40	17.7%
	Utilities	\$1.65	\$1.09	34.1%
	Contracted services	\$1.92	\$2.97	-54.8%
	ALL RECURRENT COSTS*	\$275.91	\$231.13	16.2%
Investments	Equipment	\$10.60	\$0.00	100.0%
	Training	\$3.81	\$2.19	42.6%
	New infrastructure	\$0.00	\$0.00	.
	ARV buffer stock	\$10.56	\$21.76	-106.1%
	ALL INVESTMENTS*	\$29.29	\$26.67	8.9%
	TOTAL COST*	\$297.96	\$279.95	6.0%

* Since median costs are presented, the sum of median costs for each category will not equal median total costs.

For investment expenditures, it is to be expected that per-patient financial costs would drop with time, as much of the infrastructure and equipment required for a site to function needed to be present before patients were enrolled, and any expansion in patient numbers should be preceded by an expansion in clinic capacity. It is less apparent, however, why recurrent costs should drop as sites mature, but a similar rationale—the need to develop capacity before bringing on additional patients—also applied to a number of recurrent costs, such as personnel and utilities. In addition, it is likely that programs benefited from economies of scale as patient cohorts expanded, and the accumulation of program experience led to improved efficiency.

The purchase of ARVs buffer stock increased significantly (106%) between the first and second half of the evaluation. The cost of dispensed ARVs increased slightly (by 2.4%) between the first and last periods. The trend of decreasing per-patient financial costs exhibited among ART patients was also seen for pre-ART patients, with the median financial cost per patient-year dropping from \$159.14 in the first period of evaluation to \$118.92 in the last period, an overall reduction of 25.3%. Figure 6 shows the average financial costs per patient-year for two sequential 6-month periods at the 29 sites for each of the five patient types. As can be seen, per-patient costs dropped slightly between months 0 through 6 and months 7 through 12, with

established patients showing the least decline. The data underlying Figure 6 are shown in Table 13, and also report financial costs excluding ARV costs

FIGURE 6. REDUCTION IN AVERAGE ANNUALIZED UNIT COST PER PATIENT-YEAR FROM PERIOD 1 TO PERIOD 2 (FINANCIAL COSTS, 2011 USD)

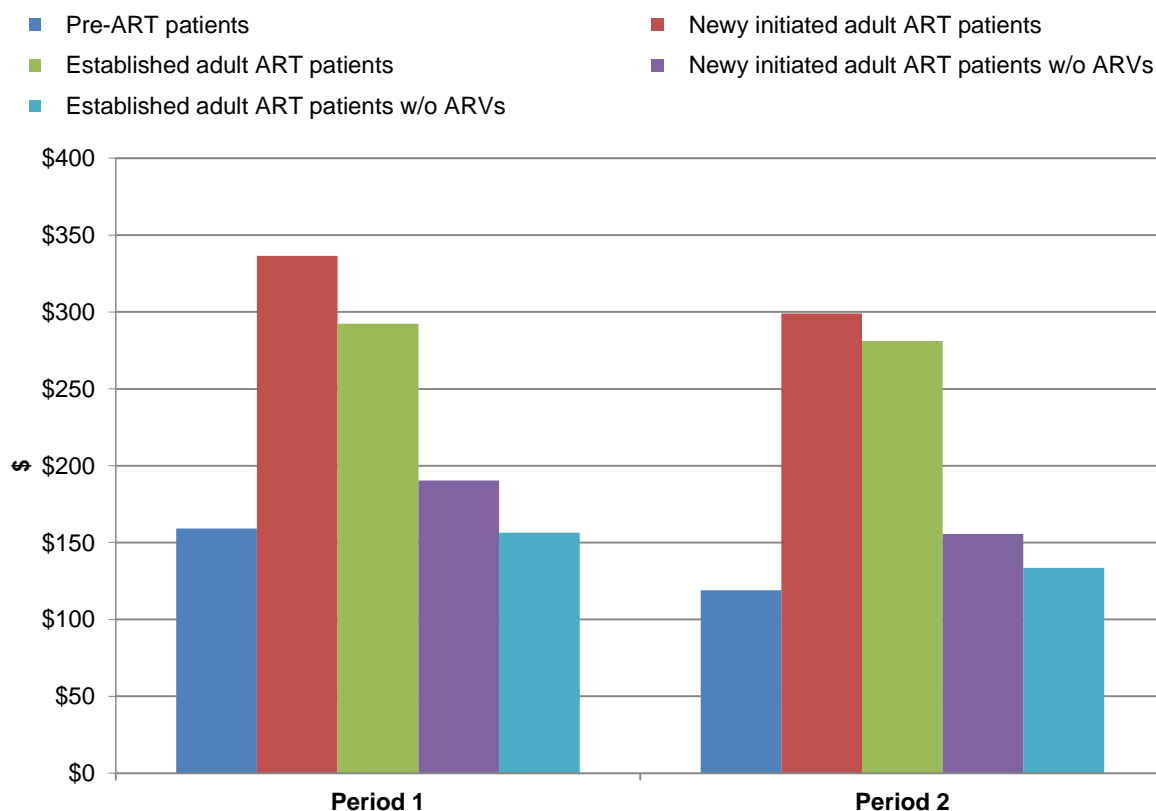


TABLE 13. REDUCTION IN MEDIAN ANNUALIZED UNIT COST PER PATIENT-YEAR WITH PROGRAM MATURITY, BY PATIENT TYPE (FINANCIAL COSTS, 2011 USD)

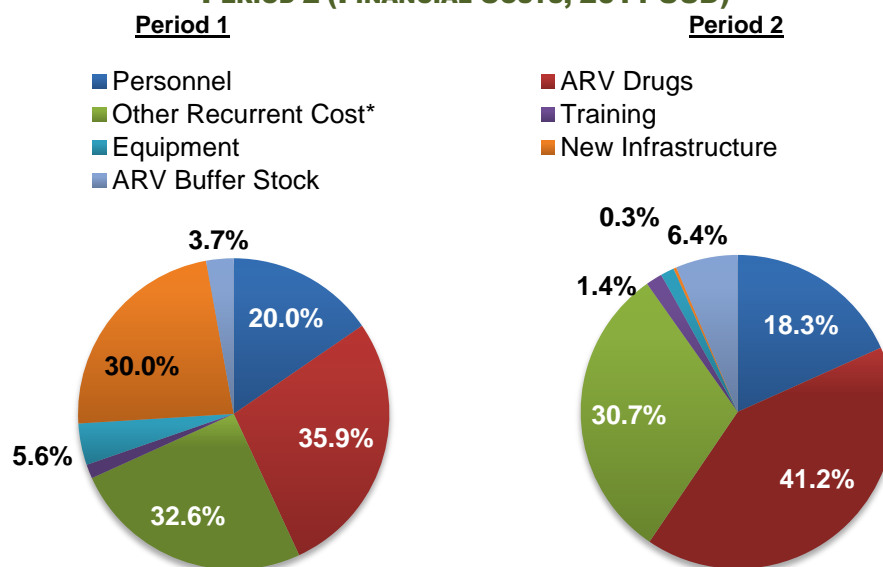
Patient Type	Period 1	Period 2
Including ARV Drugs		
Pre-ART	\$159.14	\$118.92
New adult ART	\$336.58	\$298.97
Established adult ART	\$292.32	\$281.09
New pediatric ART	\$394.07	\$353.70
Established pediatric ART	\$344.63	\$299.13
Excluding ARV Drugs		
Pre-ART	\$159.14	\$118.92
New adult ART	\$190.38	\$155.59
Established adult ART	\$156.49	\$133.56
New pediatric ART	\$187.84	\$155.59
Established pediatric ART	\$162.28	\$129.87

3.3 Site-Level Costs¹⁵

Per-patient costs decreased sharply during the evaluation, and total site-level financial costs also fell at the majority of sites. With ARVs included, the median total cost per site in the first 6-month period was \$251,404.28, compared to \$235,268.31 in the last period. Total median cost without ARVs was \$156,244.60 for the first period and \$114,903.60 for the second. The mean percentage decrease in costs was 12.9% and 29.1% between the two periods, including and excluding ARVs, respectively. Site-level costs also changed in terms of their distribution across cost categories. Figure 7 shows how the distribution of site-level costs across input types changed between the first and last periods.

¹⁵ Refers to the total cost of the health facility.

FIGURE 7. DISTRIBUTION OF SITE-LEVEL COSTS ACROSS INPUT TYPES, PERIOD 1 VERSUS PERIOD 2 (FINANCIAL COSTS, 2011 USD)



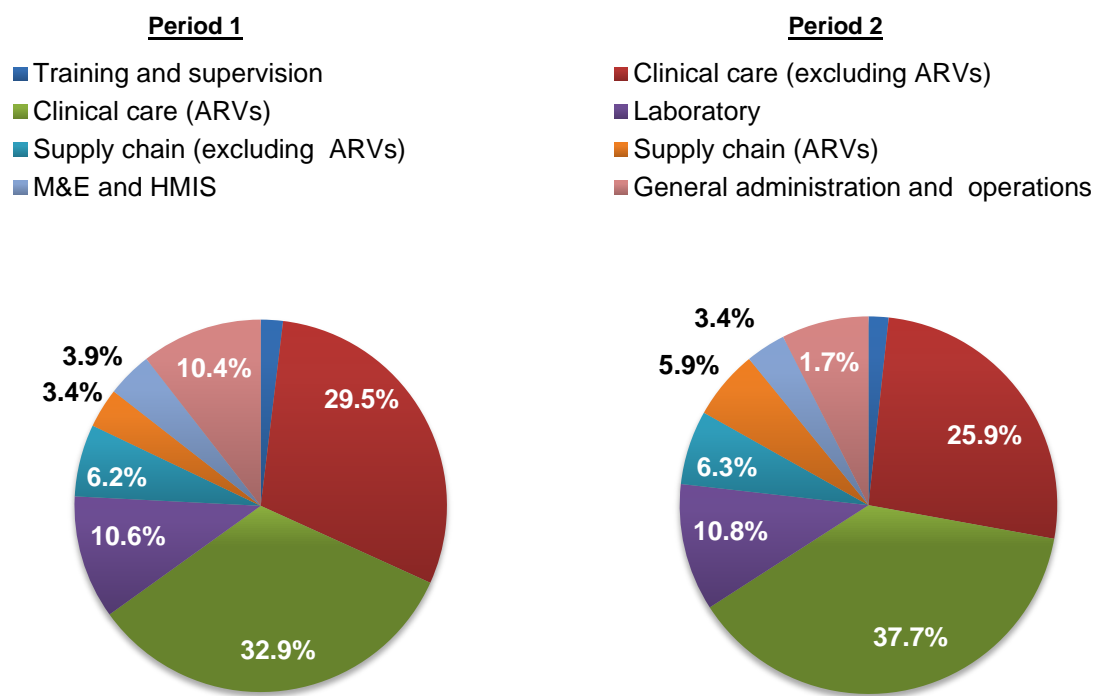
* Other Recurrent Cost includes other drugs, laboratory supplies, other supplies, building use, travel, utilities, and contracted services.

Input Types	Period 1	Period 2
Personnel	20.0%	18.3%
ARV Drugs	35.9%	41.2%
Other Drugs	5.1%	5.2%
Laboratory	10.6%	10.8%
Other Supplies	7.4%	6.2%
Building Use	5.4%	4.9%
Travel	0.7%	0.5%
Utilities	1.2%	1.0%
Contracted Services	2.2%	2.1%
All Recurrent Cost	88.6%	90.1%
Equipment	5.6%	1.4%
Training	1.9%	1.7%
New Buildings and Renovation	0.3%	0.3%
ARV Buffer Stock	3.7%	6.4%
All Investments	11.4%	9.9%

Spending on training, equipment, and infrastructure (traditional investments) represented 7.8% of total costs in the first period, and this figure dropped to 3.5% in the last period. ARV buffer stock investment increased as a percentage of total costs, from 3.7% to 6.4%. The percentage spent on most recurrent costs increased between the first and last periods, due to the increasing proportion of total spending devoted to dispensed ARVs, from 35.9% to 41.2%.

Figure 8 shows how the distribution of resources across programmatic activities changed between the first and second periods. Because ARV expenditures for dispensing and buffer stock investment represented such a large portion of total costs, these expenditures have been separated from the clinical services and buffer stock categories in the figure. As might be expected, clinical care represented the major programmatic activity in terms of resource consumption. With ARVs included, clinical care accounted for 29.0% of all costs in the first period and 30.9% of all costs in the last period. Supply chain costs (including ARVs) increased as a percentage of total costs, from 5.1% to 6.3%, mainly due to an increase in patients' volume and spending on buffer stock during the last period. M&E and HMIS represented a small but nontrivial cost category.

FIGURE 8. DISTRIBUTION OF SITE-LEVEL COSTS ACROSS PROGRAMMATIC ACTIVITY CATEGORIES, PERIOD 1 VERSUS PERIOD 2 (FINANCIAL COSTS, 2011 USD)

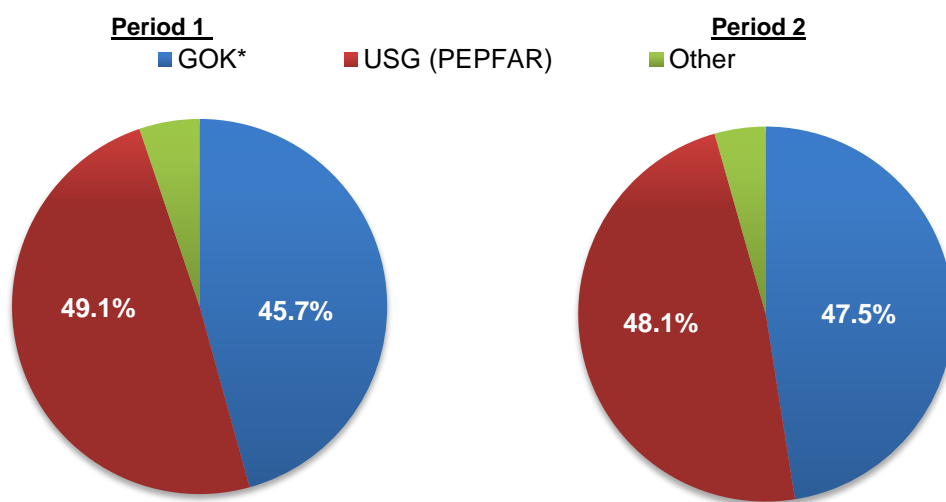


Programmatic Activity Categories	Period 1	Period 2
Training and supervision	1.9%	1.7%
Clinical care (excluding ARVs)	29.5%	25.9%
Clinical care (ARVs)	32.9%	37.7%
Laboratory	10.6%	10.8%
Supply chain (excluding ARVs)	6.2%	6.3%
Supply chain (ARVs)	3.4%	5.9%
M&E and HMIS	3.9%	3.4%
General administration and operations	10.4%	7.4%

3.3.1 Resources Provided by Different Funding Sources

Figure 9 shows the distribution of total site-level costs across funding sources, comparing the first and last periods. USG funding, through PEPFAR, represented 49.1% and 48.1%, respectively, during the first and last period of the evaluation. Different funding sources contributed to treatment programs in a variety of ways, and this is shown in Table 14. The majority of resources from the MOH were devoted to ARVs (44.9% when summing spending for dispensed drugs and buffer stock) and laboratory costs (at 30.2%). The majority of PEPFAR funding was also devoted to ARVs—22.3% (combining dispensed drugs and buffer stock). Personnel was the next largest cost category, at 19.5%, then other (non laboratory) supplies and laboratory supplies at 19.3% and 16.4% of total PEPFAR funding, respectively.

FIGURE 9. DISTRIBUTION OF SITE-LEVEL COSTS ACROSS FUNDING SOURCES, PERIOD 1 VERSUS PERIOD 2 (FINANCIAL COSTS, 2011 USD)



* Other includes any budgetary support from the Global Fund and other development partners.

TABLE 14. DISTRIBUTION OF TOTAL FUNDING ACROSS INPUT TYPES, BY FUNDING SOURCE (FINANCIAL COST, 2011 USD)

Input Types		MOH*	USG PEPFAR	Other	All Funding
Recurrent Costs	Personnel	9.5%	19.5%	22.1%	19.1%
	Dispensed ARVs	39.0%	20.3%	0.0%	38.4%
	Other drugs	6.9%	3.5%	2.7%	5.1%
	Laboratory supplies	30.2%	16.4%	1.3%	10.7%
	Other supplies	1.0%	19.3%	0.6%	6.8%
	Building use	3.9%	5.3%	14.3%	5.1%
	Travel	0.1%	0.6%	3.0%	0.6%
	Utilities	0.9%	0.7%	8.3%	1.1%
	Contracted services	1.0%	2.4%	8.7%	2.1%
	ALL RECURRENT COSTS	92.5%	88.0%	61.0%	89.1%
Investments	Equipment	1.0%	7.1%	19.7%	3.7%
	Training	0.6%	2.8%	18.2%	1.8%
	New infrastructure	0.1%	0.2%	1.1%	0.3%
	ARV buffer stock	5.9%	2.0%	0.0%	5.1%
	ALL INVESTMENTS	7.6%	12.0%	39.0%	10.9%
	TOTAL	100.0%	100.0%	100.0%	100.0%

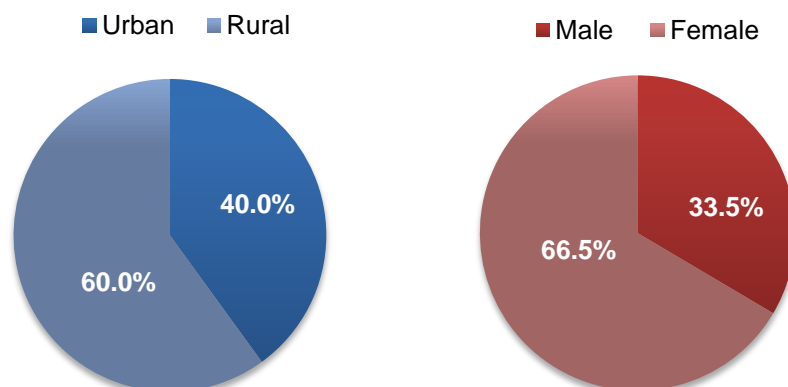
* MOH includes any budgetary support from other development partners, such as the World Bank, Global Fund, and so forth.

3.4 Patient Cost Assessment

3.4.1 Demographic Characteristics

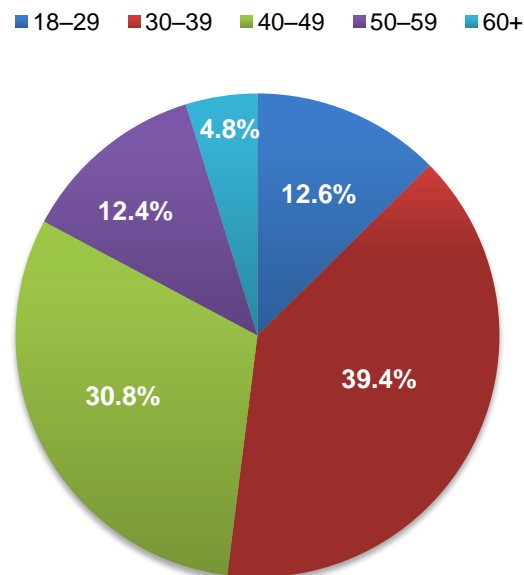
Figures 10 and 11 provide a summary of key demographic information for participants of the patient's survey (n=484). Participants included patients from 10 preselected HIV treatment facilities in Kenya. Because of the selection process, the sample is not statistically representative; rather, the main purpose of sampling was to capture a generally representative sample of patients from publicly funded HIV treatment sites in Kenya.

FIGURE 10. DEMOGRAPHIC CHARACTERISTICS



Approximately 60.0% of respondents resided in rural areas and 40% resided in urban areas. The disparity between genders was more pronounced, with 66.5% female and 33.5% male respondents, reflecting the higher uptake of ART services by women. Slightly over one-third of the rural respondents were male (63.1% females) and males represent only 28.3% (71.4% females) in urban areas. The age of participants varied from 18 to 76 years old, with a median age of 40. Figure 11 summarizes the distribution of age of respondents. On average, males were older than females (42 years and 39 years old respectively), and rural residents were older than urban residents (41 and 38 years old, respectively).

FIGURE 11. AGE DISTRIBUTION



3.4.2 Facility Characteristics

Facilities differed in term of patient types and the duration of their treatment in the establishment. Figure 12 presents the mean duration of HIV treatment in years, broken down by facility. The overall mean for the entire sample equals 3.33 years, with individual facility means ranging between 2.14 and 4.60 years. Figure 12 also includes the percentage of respondents taking ARV drugs as part of the HIV treatment, by facility. Percentages varied from 67.0% to 96.0% between facilities, with an overall percentage of 89.2% of patients taking ARV drugs.

FIGURE 12. FACILITY TREATMENT CHARACTERISTICS

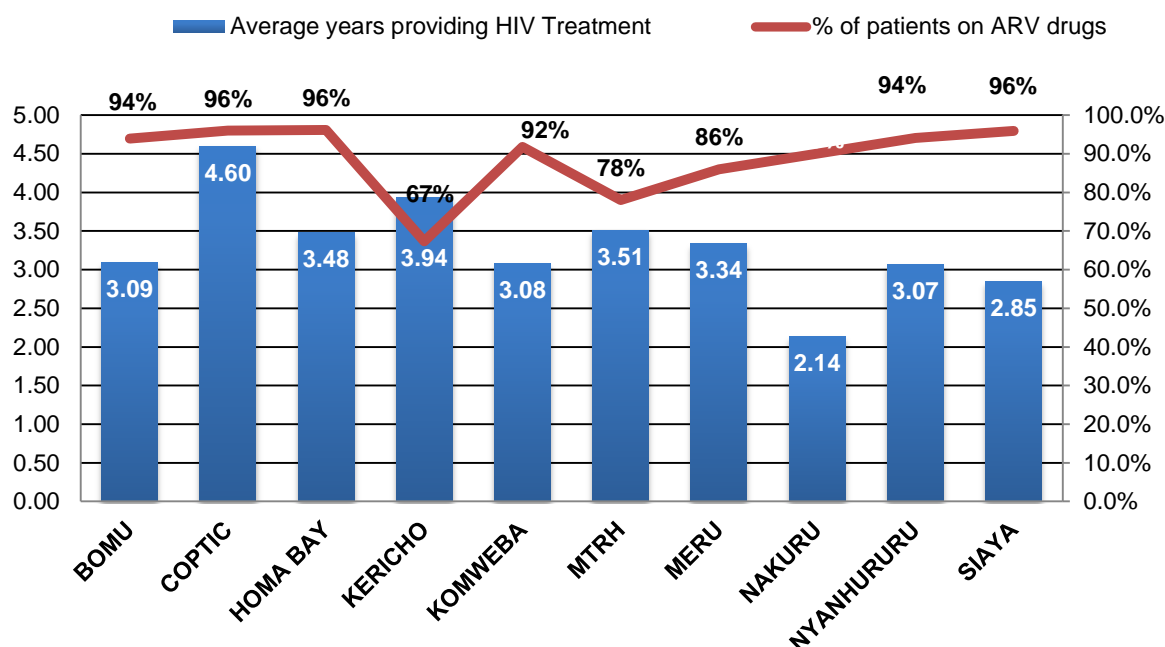
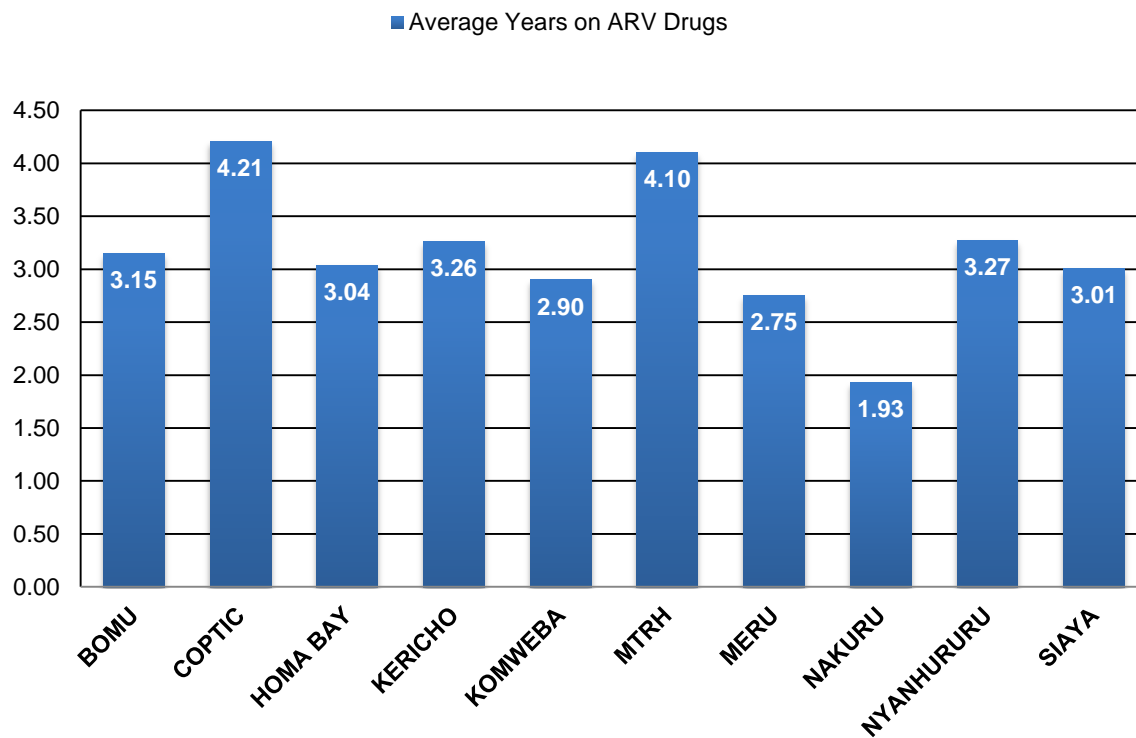


Figure 13 shows a per-facility analysis of the length of time that patients have taken ARV drugs at each treatment facility. In the overall sample, respondents reported an average of 3.16 years on ARV drugs, but individual facility means varied from 1.93 to 4.02 years.

FIGURE 13. LONGEVITY OF PATIENT ON ARV DRUGS, BY FACILITY



3.4.3 Socio-Economic Characteristics

Due to the nature of the survey, the ART patient questionnaire (PQ) did not collect information on household income or household consumption, but on dwelling conditions (i.e., floor construction, wall construction, roof construction, source of water, type of toilet, availability of electricity) and asset ownership (i.e., radio, television, phone/mobile, iron, fridge, bicycle, motorbike/scooter, car/truck). Tables 15 and 16 list all the variables on assets and living conditions used for constructing the wealth score and the percentage of urban and rural households that reports owning these items. A composite measurement of economic well-being or wealth was obtained by calculating household (HH) wealth scores using principal component analysis (as a proxy measure of economic status).¹⁶ In order to define the socio-economic groups, households are ranked in terms of their wealth scores and clustered them into five groups. The lowest quintile defined the “poorest” group and the highest quintile defined the “least poor” group for the analysis.

A summary of household assets is shown in Tables 15 and 16. The majority of the respondents (81.4%) owned a radio, and almost 84% had a phone or a mobile phone. Around 6% of respondents owned a motorcycle, and almost one-fourth owned a bicycle. It was more common in rural areas to own a bicycle, while cars ownership was almost twice as common among urban respondents. Additionally, respondents living in urban areas are more likely to own a radio, television, phone/mobile phone, iron, and/or a refrigerator.

TABLE 15. PERCENTAGE OF HOUSEHOLDS REPORTING OWNERSHIP OF VARIOUS ASSETS, BY PLACE OF RESIDENCE

Asset	Urban (n = 194)	Rural (n = 290)	Total (n = 484)
Radio	81.4%	74.1%	77.1%
Television	60.3%	26.2%	39.9%
Phone/mobile phone	85.1%	83.1%	83.9%
Iron	55.7%	41.0%	46.9%
Refrigerator	17.5%	2.1%	8.3%
Bicycle	16.0%	29.7%	24.2%
Motorbike/scooter	4.1%	6.9%	5.8%
Car/truck	10.8%	5.5%	7.6%

¹⁶ These indices are often referred to as household wealth scores. Please see Filmer and Pritchett (1999 and 2001); Montgomery et al. (2000); and Khan et al. (2006) for detailed information on how to construct wealth indices.

A similar trend presents households dwelling conditions (Table 16). Overall, households residing in urban settings tend to have a higher standard of living. While 77.3% of urban respondents had finished floors, only 31.7% did in rural areas. Similarly, a higher percentage of urban patients reported having cement block or stone walls than rural patients. Furthermore, urban respondents had better access to piped/bottled or tap water, 57.2% compared with only 21.4% of respondents in urban and rural areas, respectively. Urban patients also reported better access to toilet facilities than their rural counterparts. All urban respondents had a flushable toilet, a pit toilet/latrine, or ventilated improved pit (VIP) latrine in urban areas (100%), while almost 5% of urban respondents reported not having a toilet. In addition, there was a notable difference between urban and rural households with electricity: 58.9% versus 15.5%, respectively. This considerable disparity provides meaningful insight into the large differences in ownership of other items on the list that require electricity: telephone, phone/mobile phone, iron, and refrigerator.

**TABLE 16. PERCENTAGE OF HOUSEHOLDS REPORTING DWELLING CONDITIONS,
BY PLACE OF RESIDENCE**

Dwelling Condition	Urban (n = 194)	Rural (n = 290)	Total (n = 484)
Floor			
Natural floor (earth, sand, dung)	22.2%	67.2%	49.2%
Rudimentary floor (wood planks, palm, bamboo)	0.5%	1.0%	0.8%
Finished floor (parquet, polished wood, vinyl, asphalt strips, ceramic tiles, cement, carpet)	77.3%	31.7%	50.0%
Walls			
Natural walls (grass, pole, mud)	18.0%	45.5%	34.5%
Rudimentary walls (sun-dried bricks)	0.0%	11.1%	6.6%
Finished wall (baked bricks, wood, timber, iron/metal sheeting)	11.9%	23.8%	19.0%
Finished wall (cement blocks)	39.2%	13.4%	23.8%
Finished wall (stones)	30.9%	6.2%	16.1%
Roof			
Natural roof (grass, leaves, mud)	3.1%	14.8%	10.1%
Rudimentary roof (iron sheets)	85.0%	83.8%	84.3%
Finished roof (tiles)	8.8%	0.3%	3.7%
Finished roof (concrete)	0.5%	0.4%	0.5%
Finished roof (asbestos)	2.6%	0.7%	1.4%
Source of drinking water			
Piped/bottled water	57.2%	21.4%	35.7%
Neighbor's tap or public tap	23.2%	6.5%	13.2%
Open well	2.6%	12.8%	8.7%
Covered well or borehole	7.2%	16.2%	12.6%
Surface water: spring, river/stream, pond/lake, dam, rainwater	9.8%	43.1%	29.8%
Toilet			
Flushable toilet	0.284	1.7%	12.4%
Pit toilet/latrine, VIP latrine	0.613	65.5%	63.8%
Traditional pit toilet	0.103	27.9%	20.9%
No facility/bush/field	0	4.8%	2.9%
Household			
Electricity	59.8%	15.5%	33.3%

By using the weight scores from the Kenya Demographic and Health Survey (2008-2009) (KDHS, 2010), it is possible to compare the socio-economic status (SES) characteristics of the population in our sample with the nationally representative sample and have a better understanding of any existing sample differences. Table 17 shows that study sample was generally similar to the nationally representative sample. Approximately 29.9% of urban respondents in the study sample belonged to the urban national lowest quintile, and 7.7% fell in the fifth wealthiest quintile, indicating that urban PQ patients generally have a lower SES relative to the national sample. Among rural PQ patients only 5.9% belonged to the national lowest quintile. It should also be noted that only two of the sites were in rural areas so some

rural patients were attending urban sites. These patients are likely a particular type of rural patient who can afford travel into urban areas for care.

TABLE 17. DISTRIBUTION OF PQ RESPONDENTS IN EACH KENYA DHS SES QUINTILE, BY PLACE OF RESIDENCE

Kenya DHS Quintiles	Urban (n = 194)	Rural (n = 290)	Total (n = 484)
Poorest	28.9%	5.9%	10.4%
Second poorest	18.0%	24.8%	18.2%
Third poorest	26.8%	16.2%	25.8%
Fourth poorest	18.6%	27.6%	22.7%
Least poor	7.7%	25.5%	22.9%

Another way to examine how the PQ sample compares with the national population is through education levels. Table 18 shows considerable variation between urban and rural patients, both in the PQ and the THMIS sample population. Also, there is a discernible difference between education levels of the PQ sample and the THMIS sample; in urban areas, 82.1% and 70.0% reported at least completing primary school in PQ and THMIS, respectively. Comparable difference between PQ and THMIS has been reported in rural areas; 59.9% and 45.0% reported at least completed primary school in PQ and THMIS, respectively. The main distinction between samples was the “no education” category, with 7.8% of urban and 19.2% of rural patients from the PQ, versus 16.4% urban and 33.5% of THMIS respondents. As expected, the figures also showed overall higher education levels for urban populations in both samples.

TABLE 18. PERCENTAGE OF REPORTING EDUCATION LEVELS, BY SAMPLE AND PLACE OF RESIDENCE

Education Level	Urban		Rural	
	PQ (n = 218)	THMIS (n = 1,835)	PQ (n = 282)	THMIS (n = 6,662)
No education	7.8%	16.4%	19.2%	33.5%
Some primary school	10.1%	13.6%	20.9%	21.5%
Completed primary school	58.7%	45.5%	53.2%	35.7%
Some secondary school	8.7%	16.2%	2.8%	7.9%
Completed secondary school or any university	14.7%	8.3%	3.9%	1.4%

3.4.4 Out-of-Pocket Payments

The total patient cost, also known as out-of-pocket payments, associated with HIV treatment and care was calculated as the sum of (1) travel cost¹⁷, (2) accommodation, (3) drug cost, (4) treatment cost, (5) gift or informal payments, and (6) other payments made by patients (i.e., laboratory test). Table 19 presents the total and partial annual cost by patients' place of residence and patients' gender. On average, patients reported an annual cost of \$52.46 (across all patients). However, the cost range was wide, across location and gender, with males having, on average, higher patient costs. Total annual patient cost ranged between \$47.87 and \$51.19 for females and between \$29.92 and \$72.20 for males in urban and rural areas, respectively. The main drivers of the patients' cost were travel and other costs (i.e., babysitting).

TABLE 19. TOTAL AVERAGE PATIENT COST, BY PLACE OF RESIDENCE AND GENDER (USD 2011)

Out-of-Pocket Patient Costs	Urban (n = 194)		Rural (n = 290)		Total (n = 484)	
	Male (n = 55)	Female (n = 139)	Male (n = 107)	Female (n = 183)	Male (n = 162)	Female (n = 322)
Travel cost	\$25.48	\$19.30	\$51.66	\$33.74	\$42.77	\$27.51
Accommodation cost	\$1.10	\$0.00	\$2.21	\$1.05	\$1.83	\$0.60
Drug cost	\$1.14	\$0.73	\$0.63	\$2.67	\$0.80	\$1.83
Treatment cost	\$1.39	\$3.64	\$1.73	\$0.69	\$1.61	\$1.96
Informal cost	\$0.81	\$0.00	\$0.00	\$0.02	\$0.28	\$0.01
Other cost	\$0.00	\$24.19	\$15.96	\$13.01	\$10.54	\$17.84
TOTAL COST	\$29.92	\$47.87	\$72.20	\$51.19	\$57.84	\$49.76

The spending pattern varied widely by SES and place of residence (Table 20). Only among the wealthiest patients, we observed that patients reported higher expenditures in urban areas than in rural ones. In contrast, rural respondents of all other SES groups spent considerably more money for HIV access to services than their counterparts in urban areas. These cost differences may be explained by additional travel costs and less available treatment options for patients residing in rural settings.

¹⁷ The estimates of travel costs are not adjusted for potentially multiple purposes of each trip (e.g. receive health services other than HIV related services during the same visit; combine clinic visit with travel for personal reasons).

TABLE 20. TOTAL AVERAGE PATIENT COST, BY PLACE OF RESIDENCE AND SES (USD 2011)

PQ Quintiles	Urban (n = 194)	Rural (n = 290)	Total (n = 484)
Poorest	\$18.76	\$54.80	\$53.66
Second poorest	\$34.79	\$53.44	\$46.44
Third poorest	\$26.15	\$49.47	\$61.26
Fourth poorest	\$23.37	\$82.5	\$36.04
Least poor	\$119.09	\$54.47	\$66.04

Patients accessed HIV care and treatment services using different modes of transportation (see Table 21). Most of the patients traveled to the facility by bus in urban and rural areas, accounting for 62.9% and 78.6%, respectively. The second most popular mode of transportation (15.9%) was walking (26.3% and 9.0% in urban and rural areas, respectively).

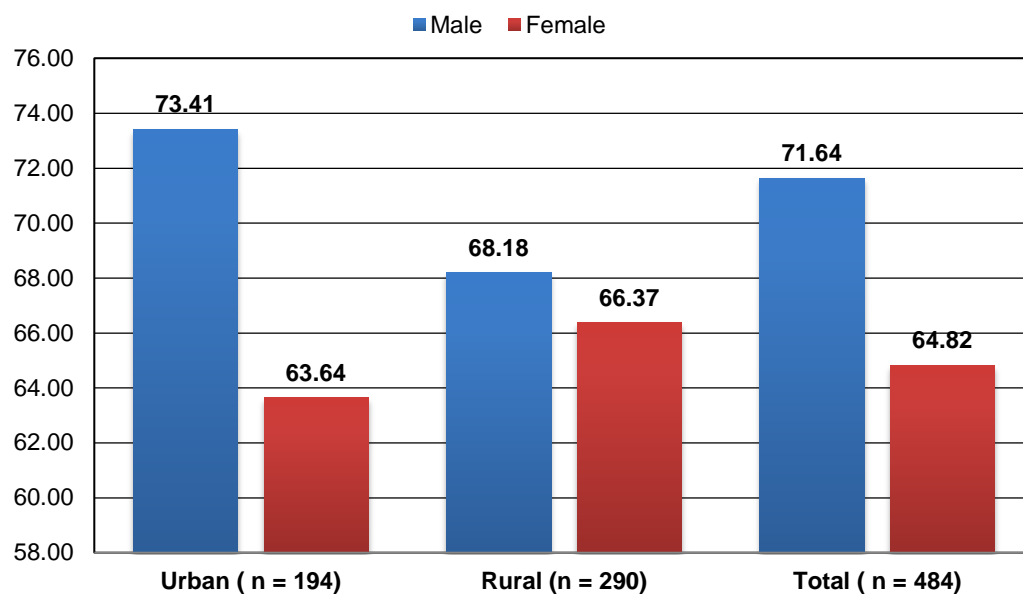
TABLE 21. PATIENTS TRANSPORTATION, BY PLACE OF RESIDENCE

Transportation	Urban (n = 194)	Rural (n = 290)	Total (n = 484)
Bus	62.9%	78.6%	72.3%
Walk less than 1 hour	22.7%	4.5%	11.8%
Walk more than 1 hour	3.6%	4.5%	4.1%
Bicycle	1.5%	3.8%	2.9%
Car or motorbike/scooter	2.6%	2.8%	2.7%
Other	6.7%	5.8%	6.2%

Females spent more time on HIV services (e.g., during commuting, at the waiting room); the difference was more pronounced in urban areas (58.1 and 78.1 hours/year for male and females, respectively (see Figure 14). On the basis of the Kenya minimum wage estimate (6,999 KSh per month)¹⁸, the annual patients' opportunity cost of the total time spent for treatment was \$46.45 (USD, June 2011); approximately 5% of the annual national minimum wage.

¹⁸ Kenya National Bureau of Statistics.

**FIGURE 14. ANNUAL AVERAGE HOURS SPENT ON CLINIC VISITS,
BY PLACE OF RESIDENCE AND GENDER**



4. DISCUSSION

The median economic cost per patient-year at these 29 Kenyan sites was \$248.91 (2011 USD) for established adult ART patients (\$120.72 with the cost of ARVs excluded). The median cost per patient-year was \$116.71 for pre-ART patients. Costs were higher for newly initiated adult and newly initiated pediatric patients compared to established patients. ARVs cost a median of \$123.0 for ART patients, was the largest single cost component for these patients. With ARVs excluded, personnel costs were the most substantial category for ART patients and pre-ART patients, at a median of \$38.44 and \$36.95, respectively.

A significant proportion of regimens in the 29 facilities included Stavudine, which is a relatively low-cost drug. Zidovudine or Tenofovir are increasingly replacing stavudine as they are less toxic and equally effective alternatives. Over time as Stavudine is replaced with Zidovudine, the median cost per ART patient among these sites will increase from \$240.33 to \$292.71.

These economic costs give a sense of the long-run costs of HIV treatment and associated care, yet the financial costs over the course of the study were higher, since some sites incurred in building infrastructure and renovations, training staff members, standardize clinical routines, and expand nascent treatment cohorts. Per-patient costs dropped slightly, by 6.0% over the course of the evaluation, with investment costs dropping by 8.9% and recurrent costs dropping by 16.2%, largely due to rising numbers of patients.

Changes in share of site costs were also noted. Spending on traditional investments—training, equipment, and infrastructure—represented 7.8% of total spending at the start of the evaluation, but decreased to 3.5% by the end of the evaluation. The costs of ARV buffer stock purchases increased from 3.7% to 6.7% of site costs, while overall ARV costs increased from 35.9% to 41.2% as a proportion of total costs. While buffer stock purchases are considered an investment, the timing of buffer stock spending differs from other investments, and matches the expansion of patient cohorts. As patient volume continued to grow in later periods, the need to continually expand ARV inventories increased as well. The proportion of funding devoted to recurrent costs grew over the course of the evaluation, from 88.6% to 90.1%, driven by the increase in spending on dispensed ARVs.

PEPFAR was one of the major sources of financial support at the sites included in the study, with funding at 49.1% and 48.1% of total funding during the first and last period of the evaluation. Funding from the MOH (which includes any budgetary support from Global Fund and other development partners) increased from 45.7% to 47.5% between the two periods. Other funding came in at 5.2% at the start of the evaluation and decreased to 4.4% by the end.

Different funding sources supported sites in diverse ways. The majority of MOH funding (44.9%) was devoted to purchasing ARVs (either dispensed [39.0%] or for buffer stock [5.9%]), and laboratory costs were also noteworthy (30.2%). PEPFAR support came mainly through the purchase of ARVs, paying program personnel, and other supplies (non laboratory), which represented 20.3%, 19.5%, and 19.3% of total government spending, respectively.

The substantial resources invested in starting and scaling-up HIV treatment programs are a reflection of the commitment shown by the Government of Kenya, PEPFAR, and other international donors and partners to combat HIV/AIDS in Kenya. While program accomplishments are growing each year and increasing numbers of patients are benefiting from effective HIV treatment and care services, the costs of supporting and increasing services are substantial. The Study found that recurrent costs accounted for the large majority of total costs and only modest decreases in per patient costs were observed between the two study periods. These findings imply that further increases in number of patients are not likely to lead to significant economies of scale. Furthermore, potential changes in unit costs and/or guidelines affecting main cost drivers identified by the study (i.e., as ARV drugs, personnel, and laboratory) are likely to have large effects on per patient costs. Despite recent reductions in the per-patient costs, the ability to maintain and increase the number of patients being treated—with the ultimate goal of achieving universal access (United Nations, 2006)—requires efficient use of health resources and the planning tools to support this objective.

Finally, the study investigates the role individuals play in financing the HIV/AIDS treatment programs through out-of-pocket payments. None of the patients selected refused to participate in the survey, which reduces the possible bias that these patients may differ systematically from participating patients. Even though treatment is largely provided for free, the findings give evidence for policymakers for designing financial health protection mechanisms for patient burden. Adult patients spent an average of \$52.00 (2011 USD) per year on care and treatment.

The majority of the spending (63.5%) accounts for travel expenses. Patients living in rural areas pay on average 1.4 times as much per year as those living in urban ones. Males living in urban areas spent 62.5% of what females spent, while the situation among those living in rural areas is reversed with females spending 70.9% of what males spent. Patients with highest socioeconomic status spent on average more for HIV/AIDS care and treatment. In addition, male and female patients spent a substantial amount of time at the HIV service, an average of 71.6 and 64.8 hours per year, respectively. This represents time which could have been spent working, and thus amounts to approximately \$46.45 per year (approximately 5.0% of the annual minimum wage).

4.1 Study Limitations

The empirical data collected in this study provide a detailed description of the costs of HIV treatment and associated care at publicly funded outpatient clinics in Kenya. However, a number of limitations constrained the use of these data.

4.1.1 Program Cost Assessment

The empirical data collected in this study provide a detailed description of the costs of HIV treatment and associated care at publicly funded outpatient clinics in Kenya. However, a number of limitations constrained the use of these data.

First, the study does not consider the off-setting savings that may result from providing effective treatment and, therefore, does not estimate the true net costs of HIV treatment programs—that is, the incremental cost of services after subtracting the cost savings associated with ART patients having less frequent episodes of illness or hospitalization and being more able to continue working or undertaking other productive activity. These cost savings may be considerable, and the net costs of treatment programs would be much lower if these costs savings were considered (Badri et al., 2006). However, the beneficiaries of reduced health care usage and greater personal productivity are the broader health care system and the patient, respectively, and these gains do not reduce the total funding requirements to support HIV treatment programs.

Second, the study does not consider treatment outcomes. While a detailed description is given of the intensity of patient follow-up and the comprehensiveness of the care package, this information cannot address treatment quality or the value being generated by program funding. On the basis of partial information, it might be tempting to conclude that a cheaper program

model would be preferable to a more expensive one, yet it is very possible that the outcomes generated by a more comprehensive model would justify the increased cost. For this reason, the study provides information on the current level of HIV treatment funding, but cannot draw conclusions about what the optimal resource level for HIV treatment funding should be.

Third, it is important to consider the sample size and sample selection methods when gauging the generalizability of these findings. While a sample of 29 sites is large for a cost study of this type, it is small when compared with the sample sizes normally required to apply normal statistical measures of confidence (such as 95.0% confidence intervals). What is certain is that while the results may be valid estimates of costs for the typical HIV treatment clinic, they cannot reflect the costs of all treatment clinics. Costs varied widely among the sites in the sample, with individual sites costing substantially more or substantially less than the median.

4.1.2 Patient Cost Assessment

Although any sample is vulnerable to bias from unknown sources, any possible problems due to appointment scheduling (e.g., Monday versus Wednesday) were taken into consideration in the patient level sampling. One known source of bias is that this sampling strategy may oversample those patients who attend the clinic more frequently (since more frequent clinic attendees have a higher probability of attending the clinic during data collection, and thus have a higher probability of inclusion). While this has the potential to overestimate patient costs in the general patient population (patients incur costs to attend the clinic, and more frequent attendance could result in higher costs), the strategies required to prevent this bias (e.g., home-based follow-up of a randomized patient sample) were not feasible for the present study. The results are presented in the following section.

On similar note, it is important to keep in mind that only patients who continue to travel to the clinic are sampled. As such one can draw only limited conclusions when using this data in the evaluation of patient demand characteristics. Loss due to follow-up is an issue in Kenya, as it is in many other countries. In addition to social factors, cost is undoubtedly a barrier for some patients. Due to the sampling approach, identifying this patient group and evaluating what the cost barrier is unknowable as these patients are not coming to the clinics. A sampling approach that would have included patients that have stopped treatment was not possible due to funding

and logistical constraints. As this is likely to remain an issue, further work is highly encouraged and needed on this front.

4.2 Recommendations

On the basis of the results of this study, the following recommendations may be helpful to consider:

- 1) Provide successful and cost-effective treatment: It's important to recognize the main cost drivers (i.e., buffer stock, personnel, and laboratory) so that inefficiencies can be addressed in order of importance and relevance to the program. Further exploration of observed heterogeneity of clinical models (e.g., number of clinical staff per person, drug regimens, intensity of follow-up and laboratory services) across sites will allow an in-depth analysis of variation of costs across sites.
- 2) Increase awareness of program costs: Expanding this study and carrying out similar ones across other HIV programs can provide a deeper understanding of the effort and resources needed for optimal treatment. Data can be used for modeling, forecasting, and planning for future treatment models. Consistent with previous research, study found that the main cost drivers were ARV drugs, personnel and laboratory tests. Changes in national guidelines and/or unit costs of those inputs or guidelines are likely to have large effects on per patient costs. For example, a sample scenario that considers replacement of Stavudine with Zidovudine, predicted 20% increase of the median cost per ART patient, and decreased variation in costs across sites. Study also found that viral load testing is not done routinely in many facilities. An increase in regular utilization of viral load testing is likely to lead to significant increases in per patient costs. Government of Kenya and international funders should consider sensitivity of findings to such changes in their planning processes.
- 3) Expand the scope of the evaluation: by covering treatment quality and outcomes (i.e., cost-effectiveness analysis) to provide policymakers with key information for the decision-making process. The variation in per patient costs and clinical models documented by the study should be considered in conjunction with potential variation in clinical outcomes

across facilities. Examples of such studies include assessments of cost-effectiveness of more frequent patient follow-up and regular utilization of viral load testing.

- 4) Create awareness on service barriers: This study shows that even though treatment is mostly provided for free, patients incur a cost to reach available services/treatment. Therefore, some policy changes focused on implementing strategies to offset out-of-pocket costs for patients from lower socio-economic groups may be beneficial (e.g. bringing services closer to patients, drug pick-up zones).

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APPENDIX

APPENDIX 1. D4T TO AZT SCENARIO

WHO recommends that countries phase out the use of Stavudine, because of its long-term, irreversible side-effects, and Zidovudine or Tenofovir are recommended as less toxic and equally effective alternatives. Tables below present select findings from a theoretical scenario, where all Stavudine is replaced with Zidovudine. The numbering of tables corresponds to that of the main body of the report. As demonstrated in Table 9a, replacement of Stavudine with Zidovudine results in median economic cost per patient of \$292.71, an over \$50 increase relative to the estimates presented in Table 9 of the report. Additionally, the range of per patient costs across facilities is smaller, demonstrating that some of the variation in costs was due to variation in the utilization of Stavudine across facilities.

TABLE 9A. MEDIAN COST PER PATIENT-YEAR, BY PATIENT TYPE (ECONOMIC COSTS, 2011 USD)

Total Cost		Pre-ART	All ART	Newly Initiated Adult ART	Established Adult ART	Newly Initiated Pediatric ART	Established Pediatric ART
Including ARVs	Min	\$51.68	\$224.65	\$237.76	\$227.03	\$140.57	\$131.78
	Max	\$250.25	\$435.67	\$557.37	\$431.09	\$619.21	\$608.36
	Median	\$116.71	\$292.71	\$301.07	\$287.51	\$318.73	\$295.04
Excluding ARVs	Min	\$51.68	\$47.77	\$62.46	\$46.95	\$62.46	\$46.95
	Max	\$250.25	\$260.09	\$368.42	\$259.00	\$368.42	\$259.00
	Median	\$116.71	\$120.72	\$148.34	\$120.72	\$136.39	\$123.59

Table 10a shows the distribution of median annual economic costs across the different input types, subdivided into recurrent costs and investments. The costs of dispensed ARVs and cost of personnel were the most important cost components for ART patients, while for pre-ART patients, personnel and laboratory supplies were the dominant cost components.

TABLE 10A. MEDIAN COST PER PATIENT-YEAR, BY INPUT TYPE (ECONOMIC COSTS, 2011 USD)

Input Types		Pre-ART Patients	All ART	Newly Initiated Adult ART Patients	Established Adult ART Patients	Newly Initiated Pediatric ART Patients	Established Pediatric ART Patients
Recurrent Costs	Personnel	\$36.95	\$38.44	\$43.71	\$36.47	\$43.71	\$36.47
	Dispensed ARVs	-	\$171.19	\$168.71	\$168.71	\$181.53	\$181.53
	Other drugs	\$8.51	\$8.51	\$8.51	\$8.51	\$8.51	\$8.51
	Laboratory supplies	\$19.96	\$19.30	\$19.96	\$19.30	\$21.11	\$19.33
	Other supplies	\$12.96	\$13.57	\$16.23	\$12.60	\$17.95	\$12.60
	Building use	\$6.88	\$7.70	\$9.88	\$7.70	\$9.88	\$7.70
	Travel	\$0.38	\$0.40	\$0.65	\$0.38	\$0.65	\$0.38
	Utilities	\$1.06	\$1.09	\$1.09	\$1.08	\$1.09	\$1.08
	Contracted services	\$2.95	\$2.97	\$3.04	\$2.96	\$3.04	\$2.96
	ALL RECURRENT COSTS*	\$112.38	\$290.96	\$300.19	\$280.72	\$313.17	\$293.33
Investments	Equipment	\$1.36	\$1.38	\$1.40	\$1.37	\$1.40	\$1.37
	Training	\$1.29	\$1.29	\$1.29	\$1.29	\$1.29	\$1.29
	New infrastructure	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
	ARV buffer stock	-	\$0.62	\$0.62	\$0.62	\$0.51	\$0.51
	ALL INVESTMENTS*	\$2.81	\$3.46	\$3.56	\$3.46	\$3.63	\$3.63
TOTAL COST*		\$116.71	\$292.71	\$301.07	\$287.51	\$318.73	\$295.04

* Since median costs are presented, the sum of median costs for each input type will not equal median total costs.

As demonstrated in Table 11a, clinical care comprised the largest cost category for ART patients, due to the cost of ARVs, while laboratory costs were also not trivial. Clinical care services comprised the largest cost component for pre-ART patients. Comparison between ART and pre-ART patients showed that laboratory costs were roughly equal between the two groups.

**TABLE 11A. MEDIAN COST PER PATIENT-YEAR, BY PROGRAM ACTIVITY
(ECONOMIC COSTS, 2011 USD)**

Program Activity	Pre-ART Patients	All ART Patients	Newly Initiated Adult ART Patients	Established Adult ART Patients	Newly Initiated Pediatric ART Patients	Established Pediatric ART Patients
Training and supervision	\$1.29	\$1.29	\$1.29	\$1.29	\$1.29	\$1.29
Clinical care (excluding ARVs)	\$44.57	\$36.77	\$54.86	\$36.77	\$54.86	\$41.14
Clinical care (ARVs)	---	\$156.31	\$153.66	\$153.66	\$165.34	\$165.34
Laboratory services	\$19.96	\$19.30	\$19.96	\$19.30	\$21.11	\$19.33
Supply chain management (excluding ARVs)	---	\$7.95	\$7.95	\$7.95	\$7.95	\$7.95
Supply chain management (ARVs)	---	\$0.56	\$0.57	\$0.57	\$0.47	\$0.47
M&E and HMIS	\$6.90	\$6.90	\$6.90	\$6.90	\$6.90	\$6.90
General administration and operations	\$13.53	\$13.53	\$13.53	\$13.53	\$13.53	\$13.53
TOTAL COST*	\$116.71	\$292.71	\$301.07	\$287.51	\$318.73	\$295.04

* Since median costs are presented, the sum of median costs for each category will not equal median total costs.

