COSTS AND OUTCOMES OF DELIVERING ANTIRETROVIRAL THERAPY (ART) IN THE PRIVATE AND PUBLIC SECTORS IN UGANDA

FINAL REPORT

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EXECUTIVE SUMMARY

Uganda developed a pioneering program under which private clinics accredited by the Ministry of Health receive Government or donor funded antiretroviral drugs at no cost, provided that they do not charge for these drugs. However, the clinics can charge for laboratory tests, consultations or other drugs. Both employer based clinics and free standing private providers participate in this program, often receiving technical support from the USAID HIPS (Health Initiatives in the Private Sector) project. This study analyses the outcomes and unit costs of first year ART care at selected public clinics and private clinics participating in the accreditation and ARV distribution program. We have estimated the savings to the Government and donors which occur when a patient receives antiretroviral therapy (ART) at these private clinics.

The study was conducted using a methodology developed by Rosen et al and previously applied to ART in facilities in South Africa, Zambia and Kenya. Medical record data was obtained for the first twelve months of ART at three public clinics (150 patients per clinic) and three private clinics (50 patients per clinic). This data indicated all drugs (ARV and non-ARV) and lab tests received, and the different providers seen at each visit. Unit costs were determined for each drug, test or service, and the fixed costs of the facility allocable to the ART program were added. Patient outcomes were determined from the medical record, with patients in the sample classified as:

Lost (dead or no longer in treatment at the end of the year);

In treatment and not responding (as indicated by CD4 or viral load, or, in the absence of such tests, the lack of a WHO stage 3 or 4 AIDS-defining condition; or

In treatment and responding.

Average annual treatment costs were determined for each category of patient at each of the six facilities. In addition, the total annual cost of treating the cohort of study patients was divided by the number of patients in treatment and responding at the end of the year. This gives a measure of cost per unit of outcome that takes into account both the efficiency of the clinic and the patient outcomes achieved, and is referred to here as the "production cost." Finally, we calculated the value of the private resources leveraged when patients were treated at private clinics using the publicly supplied ARV's.

The patients at the different clinics were generally similar in age and more than 50% female, except at one agricultural employer clinic, where male patients were 52% of the sample. Average CD4 count on starting ART varied between 90 and 142, except at one urban private clinic where it was 201. Patient outcomes in the first year of treatment were generally very good. Between 77% and 88% of patients were in treatment and responding a the end of the year at four clinics. One public clinic had 97% in treatment and responding, and one private clinic 94%. But these clinics performed the fewest monitoring tests, and may not have identified patients who were developing resistance.

Treatment regimens were generally similar and consistent with national protocols. However, only the private urban clinic had an appreciable portion of patients on tenofovir. Great variation was observed in the average number of lab tests per patient year, with the urban private clinic recording 12 tests per year, while patients at a rural public clinic and an agricultural employer clinic had one test per year or less. All clinics had between 10.5 and 13.5 patient visits per year. Differences in costs per patient between clinics were driven by the difference in the number of lab tests, the type of provider visits and resultant costs, and the use of tenofovir at the one private clinic.

The annual cost per patient in treatment and responding varied from a low of $202 at the rural public clinic to $494 at the private urban clinic. The other two public sites ($240, $253) had annual costs very similar to the two employer clinics ($264, $239). Taking into account patient losses and apparent treatment failures, the production cost per year for patients in successful treatment varied from a low of

$206 at the rural public clinic to a high of $566 at the urban private clinic. The other two public sites (a referral hospital clinic and a large urban clinic) actually had higher "production costs" ($302 and $321 per year) than the two employer clinics ($295 and $250).

The distribution of publicly sourced ART in Uganda is saving public and donor funds. In the two employer clinics, private resources amounting to $99 and $95 per patient per year are expended on the non ART costs of caring for each patient alive and in treatment. In two public facilities (excluding the rural clinic that did little testing), annual expenditures on items other than ART were $89 and $94 per patient alive and responding to treatment. The private sector is contributing between 35% and 40% of the total cost of a year of ART when it receives ARV's for free. The public and private sector expend similar amounts per patient on non-ART services. If the patients were not being treated at these private clinics, the Government would need to expend $90 or more to absorb each additional private patient into the public system.

1. INTRODUCTION

In Uganda, antiretroviral therapy (ART) is being delivered by providers in the public, nongovernmental, and private sectors. An innovative program exists to provide ARVs to accredited private sector providers who must dispense these to their clients at no cost, but can collect regular fees for consultations, tests and other drugs. This has the potential to shift some patients to the private sector who would otherwise be forced to seek care in public facilities, and to harness some funds for AIDS treatment from employers, health insurance and patient resources. However, little is known about the relative costs of care in these different settings, or the differences, if any, in patient outcomes. In mid 2010, the USAID-funded Uganda Health Initiatives for the Private Sector (HIPS) Project approached the Boston University Center for Global Health and Development to assist in conducting an evaluation of the costs and outcomes of ART in Uganda and to compare results between private and public sector sites.

Boston University chose to conduct the evaluation using the Costs and Outcomes of AIDS Treatment (COAT) model developed by Sydney Rosen and colleagues. Previously, this model has been used in more than 20 facilities and in three other countries (Kenya, South Africa and Zambia). The goal of the study was to measure the cost per patient treated and cost per patient who remains in care and responding to therapy at selected public and private facilities, after 1 year on ART. For private facilities, we separated costs borne by the Government and donors (ARVs) from the costs borne by patients, insurers or employers. To assess patient-level data on treatment outcomes and resource utilization for the 12 months following ART initiation, we conducted an unlinked, retrospective medical record review. Resource costs were estimated using facility-level financial records and interviews with facility managers.

The study was approved by, and conducted in accordance with the regulations of, the Boston University Medical Center Institutional Review Board, the Uganda National Council for Science and Technology, and the Ministry of Health of the Republic of Uganda.

A. Background and Rationale

Uganda was one of the first countries in Africa to develop a policy governing private sector provider access to Government purchased ARVs. The Ministry of Health promulgated accreditation guidelines for providers (public and private) that would be permitted to offer ART. Even before the expansion of public sector ART with funds from the Global Fund for AIDS, TB and Malaria (GFATM) and the US President's Emergency Plan for AIDS Relief (PEPFAR), ART was available to a small fraction of Ugandans who required it through a few NGO's, clinical research programs, and selected public institutions. A few wealthy Ugandans were able to obtain ART in the private sector at substantial expense. In 2004, Whyte and colleagues analyzed some of the social and political effects of this restricted and highly variable access to life saving therapy (1). A 2005 article summarized the experience of one major NGO facility in Kampala in providing treatment on a fee-for-service basis for 312 HIV positive patients with a median CD4 count of 79. The attrition rate was relatively high, but 35% remained alive and in treatment at 4 years (2). The article did not estimate the costs of treatment at the facility.

With large scale donor funding available from the GFATM and PEPFAR, Uganda ramped up its public sector ART program and began releasing ARVs to accredited private sector providers on the condition that such providers offer the drugs to their patients at no charge. USAID-supported projects -- Business PART and HIPS -- assisted private providers in the accreditation process, supplying technical assistance and supporting the necessary training for professional staff. In a preliminary evaluation, the Business PART project estimated the value of publicly provided ARVs and privately provided services at participating employer clinics. The public/private split of ongoing costs was about 50%/50%, so the cost to donors and the Ugandan government was less than it would have been if the patients were treated in the public system (3). However, this study did not compare unit costs in public and private facilities, nor did

it measure patient outcomes. When assessing patient outcomes we look at whether or not a patient is still in treatment, and if they are responding to the treatment. In that case, the patient is much more likely to be employed and to be meeting familial demands[1]. We also present the results of our costing by outcome category. Using these measures, we can show the "production cost " for a patient who is in care and responding. A program that keeps all its patients adherent and healthy will have a lower "production" cost than another site with the same cost inputs but fewer patients responding.

Although cost estimates have been made for new interventions in Uganda (such as the innovative program for home delivery of ARVs), there is limited information available about the relative costs of the public and private models of treatment in standard use in Uganda, or the patient outcomes achieved by public and private treatment programs. Donor funds are unlikely to grow to the extent necessary to cover all the costs of ART care for all the patients who require it in Uganda. This study provides estimates of the costs of treatment so that public and donor funding requirements can be projected accurately. At the same time, policy makers can compare costs and outcomes in the public and private sector in order to evaluate the impact of distributing ARVs to accredited private sector providers and assess if this is an effective way of diverting some patients from the public care system.

B. Objectives

This study uses a cost-outcome analysis, which is a variant of cost-effectiveness analysis, to estimate the costs of treatment at a facility level and to measure patient outcomes achieved. [Detailed information on CEA methods and recent review papers using these methods can be found in the Reference Section (4-8)].

The overall study objective is to determine the average cost per outcome of providing ART in public and private sector facilities in Uganda. The secondary objectives are to analyze who bears the cost of treatment at each site and to analyze any differences in costs or outcomes observed in the private versus public sector. To achieve these objectives, this study aims to answer the following research questions for each treatment delivery site selected:

1. What is the average cost per patient treated of resources used during the first 12 months following ART initiation at each public or private treatment delivery site?

2. What is the average cost per patient alive and responding to treatment at the end of the study period in each facility or group of facilities?

3. What is the breakdown of this average cost into major cost components (drugs, lab tests, professional labor, fixed facility costs, etc)?

4. For private sector facilities, what is the portion of the cost borne by Government or donors (value of ARVs provided) and what is the portion borne by the private sector (patients, insurers, or employers)?

[1] See articles by Rosen, Larson and colleagues from studies of patients entering ART in South Africa and Kenya. For example; Rosen S, Larson B, Brennan A, Long L, Fox M, Mongwenyana C, Ketlhapile M, Sanne I, "Economic Outcomes of Patients Receiving Antiretroviral Therapy for HIV/AIDS in South Africa Are Sustained Through Three Years on Treatment" PLoS One, 2010, Jan 5(9) e12731.

2. METHODS

The study is a cost-outcome analysis using unlinked, retrospective medical record data to ascertain total resources used in the first year on treatment and patient outcomes at the end of the first 12 months. Costs are measured from the perspective of the treatment facility and start with the date of initiation of ART to the end of the first year after initiation. The primary outcome is the average cost to produce a patient retained in care and responding to ART 12 months after initiating therapy.

A. Site Selection

The study was conducted at a convenience sample of 6 treatment sites in Uganda. Each site was selected to serve as an example of a specific model, approach, or setting for delivering ART. Because the study was designed to identify, describe, and explain differences among models of treatment delivery (especially between the private and public sectors), sites were selected to capture variation in setting, scale, sector, and other facility characteristics. No effort was made to include a random or representative sample of sites, as this is beyond the scope of this study.

At each public sector site, a consecutive sample of 150 adult patients who initiated ART more than 12 months before sample selection was enrolled. At most private sector sites in Uganda, enrollment is very slow with only 20-50 new patients started on treatment per year, even at the largest sites. In order to fill a sample of 150 patients we would have needed to include patients who began treatment 4 or more years ago. Their costs of treatment however are likely to differ greatly from patients enrolled more recently – due to drug regimen changes and maturation of the treatment program at each site. In order to include any private sector sites therefore, we conducted a census of all patients enrolled in ART care, rather than a sample. Based on sample size calculations using data from a similar study in Zambia, we set the limit to be at least 50 eligible patients, enrolled over the course of a maximum of 3 years, in order to include the site in the study.

Ideally this study would retrospectively follow each patient for more than the first year on treatment. But again due to small enrollment numbers at the private sector sites we were unable to obtain a large enough sample of patients who had been on treatment for more than 1 year. In order to maintain comparability with the public sector sites, we therefore limited this study to costs and outcomes after 12 months on treatment.

The study sites and their characteristics are presented in Table 1.

Table 1: Study Sites

Site Name, Location	Sector & Characteristics	Scale (No of Adult ART Patients Dec 2010)	ART integrated with other services?	Supporting programs available at the site
Jinja Referral Hospital, Jinja	Public, periurban	1978	Yes	Community outreach, nutritional assistance
Katakwi Health Centre, Katakwi	Public, remote rural	497	No	Community outreach
Kiswa Health Centre, Kampala	Public, urban	4959	Yes	Nutritional support, community outreaches, basic care kits; Technical support from IDI
HIMA Cement, Kasese	Private, rural, large employer and also open to community (management of clinic is	209	Yes	Nutritional support, Meals provided for staff; Also provides care to dependents and to nearby

Site Name, Location	Sector & Characteristics	Scale (No of Adult ART Patients Dec 2010)	ART integrated with other services?	Supporting programs available at the site
	contracted out)			community members;
Kakira Sugar Company, Jinja	Private, periurban, large employer and also open to community	288	Yes	Palliative care, home visits, nutritional counseling, community outreach
SAS Foundation, Kampala	Private, urban (some patients have health insurance)	275	Yes	Nutritional counseling, monthly outreaches, home visits, meals provided for staff

B. Sample Selection at Each Site

The study population is adult patients who are receiving care for HIV/AIDS from one of the six participating sites. Additional inclusion criteria include being 18 years or older at the time of ART initiation, initiated ART at the study site, and did not transfer to another treatment site in the first 12 months after initiation.

At each site, the first step of sample selection was to review the site's roster of newly initiated patients. If not already sorted, the roster was organized by date of initiation. At each site we then enrolled patients sequentially beginning with those who initiated treatment on 31st October 2009 and moving backwards in time until the sample was filled or census was complete. Patients who were found to be excluded were replaced with the next eligible patient.

Patients who did not initiate ART at the study site were excluded to ensure that we are costing the first year on treatment for all patients, thus allowing better comparability across sites. In addition to searching in the patient file for evidence of prior treatment, we also checked baseline ARV regimens for each individual. Using Kaletra as the indicator drug for second line therapy, we excluded such patients as likely having received antiretroviral treatment at another facility at an earlier date.

C. Data Collection

MEDICAL RECORD DATA

Medical record data was extracted from paper records and entered in a CSPro database designed for the study. Data collection began with the first day that each patient initiated ART up until 15 months post initiation or the last patient visit to the site, whichever came first. All visits to the clinic, professionals seen, drugs dispensed (both ARV and nonARV), diagnostic tests conducted and other services received were recorded. Once all medical record data was extracted, one round of data cleaning was completed to verify any questionable data found. For each site we ran a set of standard queries which includes verifying appropriate ARV regimens at baseline and each subsequent visit; dates of initiation, death, and last visit; length of time between visits; ARV and nonARV drug strengths and dosages; number of visits per patient and duplicate visits; in addition to verifying inclusion and exclusion criteria. Patient outcomes and resource utilization were then analyzed using SAS software, version 9.1.3 (Copyright, SAS Institute Inc., Cary, NC, USA[2]).

[2] SAS and all other SAS Institute Inc. product or service names are registered trademarks or trademarks of SAS Institute Inc.

UNIT COST DATA

A standardized cost data collection tool was designed for this study based on the data entry required for the COAT model. From each study site, we collected unit costs of drugs, diagnostic reagents, supplies and other variable inputs based on the most recent date of procurement and we recorded data from existing invoices. For all sites unit cost data was collected in early 2011 and the dates of procurement fell between June and December 2010. Information on the purchase, maintenance, and operating costs of infrastructure, equipment and other fixed costs was obtained from financial staff at each site or, if necessary, from data on relevant market prices (e.g. for donated furniture). Salary costs for each category of employee involved in the ART program were collected from payroll records, Ministry of Health reports, or site managers. Salary levels were collected by professional category and rank (e.g. "senior medical officer" or "enrolled nurse"), not individual. See Section D2 for further information on the costing of resources.

D. Data Analysis

The primary goal of this study is to estimate the average cost of resources used for treating patients, stratified by treatment outcomes.

PATIENT OUTCOMES

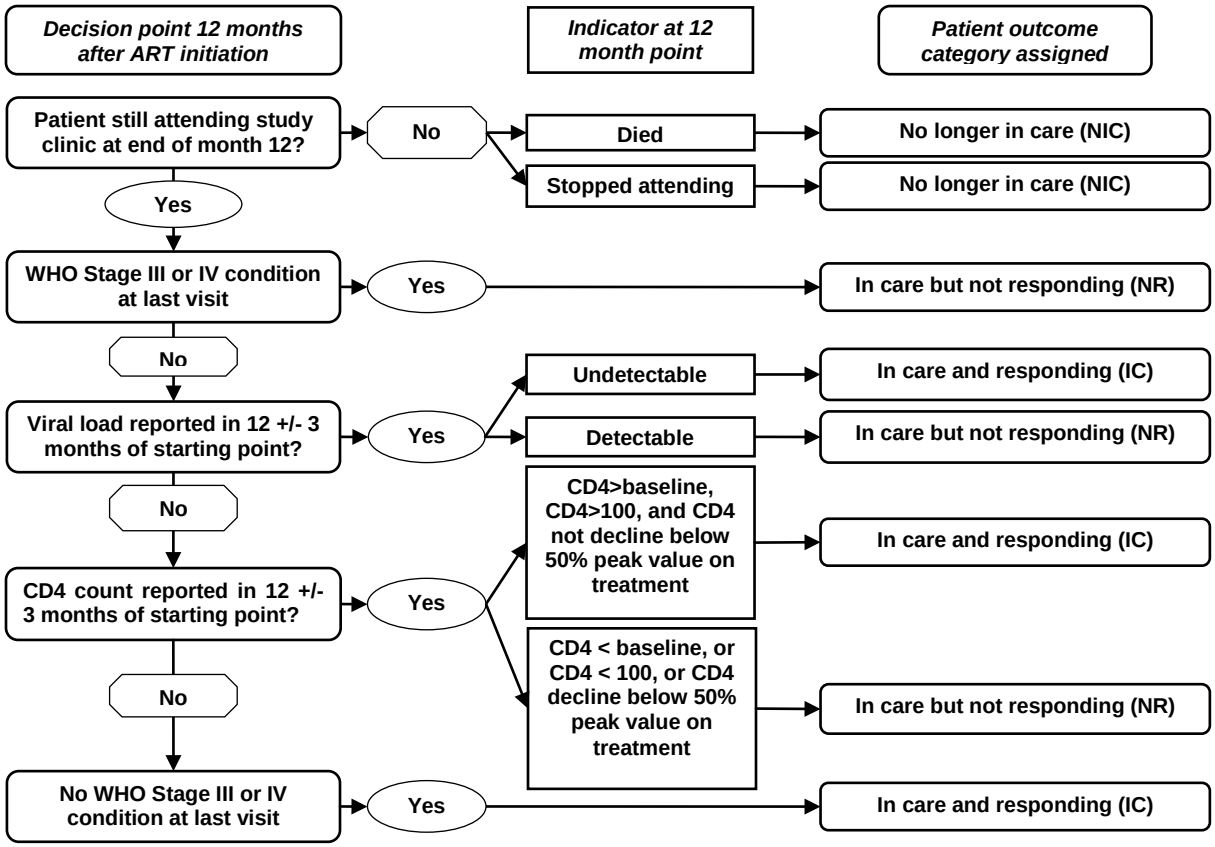
Each study subject was assigned a single outcome on the basis of attendance, laboratory results, or condition one year after initiating ART. To allow for variation in clinic visit and lab test schedules, information reported three months before or after the 12-month point was used for assigning outcomes. The criteria for defining outcomes shown in Table 2 were based on prognostic indicators reported in the literature (11;12), clinical judgment, and on the definitions of treatment failure as defined in the Uganda National ARV Treatment Guidelines (13). Note that in this study, the purpose of assigning outcomes is solely to create categories of patients for whom average costs can be estimated. The study is not designed or powered to estimate, explain, or predict treatment outcomes as a primary result.

Table 2: Definitions of Patient Outcomes

Outcome	Criteria for Assigning Outcome	Definition of Criteria
Excluded from study	Transferred	Transferred to another treatment site before 12 months
	Never started ART	Never collected first month's supply of ARVs
No longer in care at site (NIC)	Died	Died in first 12 months
	Stopped attending clinic (lost to follow up)	≥3 months late for last scheduled consultation or medication pickup before 12 month endpoint
In care but not responding (NR)	AIDS defining condition	WHO stage 3 or 4 condition at most recent visit
	Detectable viral load	Viral load ≥ 400
	Unacceptable CD4 count	CD4 ≤ baseline, or CD4<100, or CD4 decline 50% or more from peak CD4 on treatment
In care and responding (IC)	Undetectable viral load	Viral load ≤ 400
	Acceptable CD4 count	CD4 > baseline CD4, CD4 ≥ 100 and CD4 did not decline 50% or more from peak CD4 on treatment
	No AIDS defining condition	No current WHO stage 3 or 4 condition at most recent visit

Outcomes were assigned using the hierarchical decision process illustrated in Figure 1. Whether or not the patient is still attending the clinic is the first decision point. After that the study design prioritizes clinical condition over lab data to assign outcomes, so that patients who are clinically unwell (defined as a new or recurrent WHO Stage 3 or 4 condition) are assigned to the "In care but not responding" category even if their CD4 count has improved since beginning therapy. Viral load values are considered before CD4 counts to define outcomes. Finally, if a patient is still in care at the 12 month endpoint, does not have a new or recurrent Stage 3 or 4 condition, and has had no viral loads or CD4 counts done in months 9-15 then they would be categorized as "In care and responding" due to no condition. This is important to note because at some sites where lab tests are infrequent, many patients may end up in the "In care and responding category" as long as they are still attending and have no AIDS-defining symptoms.

Figure 1. Hierarchical Decision Process for Assigning Outcomes



COSTING OF RESOURCES

We used standard costing methods to estimate the resource utilization and costs of providing care for each study subject for the 12 months following ART initiation. Subjects who are not in care at the study site at the end of the observation period do not incur costs for the entire period; for these subjects, fixed costs are pro-rated based on the number of months in care.

Costs included in the study are the costs for all resources that would hypothetically be needed for a provider to reproduce the study site and model, regardless of where the resources were obtained or who paid for them originally. Resources included and costing methods used are shown in Table 3.

Table 3: Methods for Estimating Costs

Type of Resource	Method for Estimating Unit Cost
Variable Resources	
Drugs, lab tests, medical supplies, etc.	Used actual costs to the site, based on invoices on record for the most recent procurement. Resources that were provided to the site by the government or a donor agency were included at the cost to the donor plus transport to the site. For drug costs, when no price was available at the site, costs were obtained from the Uganda Joint Medical Stores Price list. For any drugs whose price could not be obtained locally (such as some TB drugs and antiretroviral medicines that are no longer commonly used (e.g. Triomune 30)) the Management Sciences for Health International Drug Price Indicator Guide, 2010 Edition was used as a reference.[3] For lab tests at the private sector sites, the standard price list for each site was used as the cost per test. For two of the public sector sites, market values were obtained for the cost per test since many of the labs at each site are sent to other facilities for processing.
Outpatient visits	At each site, we took the total monthly cost for each type of provider visit (doctor, clinical officer, nurse, pharmacy, counseling) and multiplied it by the percent of time those professionals spent caring for ART clients. This cost for ART services was then divided by the number of patient visits to each type of provider to calculate a cost per encounter. The number of visits to each provider in a month was calculated by taking the total average number of ART visits to the site in a month and applying the ratios observed in our sample for each type of provider visit. For example, if 85% of patients in our sample saw a clinical officer on each visit and there were 500 ART visits in a month, then we set the number of clinical officer visits per month equal to 425. Professionals who do not have direct patient interaction, such as data entry personnel and administrative staff, are included as a fixed cost.
Fixed Resources	
Buildings (infrastructure)	If the actual rental or building cost was not available we took the estimated cost to rent (urban areas) or build (rural areas) comparable clinic space. We applied 2% depreciation to the purchase price of all facilities to calculate an annual cost to the ART clinic. Maintenance and operating costs were also included.
Vehicles, computers, other equipment	We took the purchase price if known or cost to purchase similar goods locally and added the monthly average costs for operations (petrol, lubricants) and maintenance (quarterly service, tyres, etc). All vehicles and furniture were depreciated assuming a useful life of 5 years for vehicles and 10 years for furniture. Electronic equipment and reusable medical supplies (such as pill counting trays or stethoscopes) were depreciated using a working life of 5 years. When visit data was available, fixed costs were allocated to the ART program using the ratio of ART patient visits to all visits in a month. When not available, estimates were obtained from site staff and information was triangulated to obtain the best estimate.
Administrative and other non-clinical (general) staff	Valued at total compensation rate as of November/December 2010 at each study site. The percent effort that each staff member contributes to the ART program was calculated using the volume of ART visits or in some cases the ART workload. For example, at many sites the percent effort for the lab technician is more than the percent of visits made by ART patients as ART patients would often have more lab tests then other types of patients coming to the facility.
Office supplies, communications, and other regular monthly costs	Costs obtained from site invoices or comparable local market values if invoices unavailable.
Other fixed costs such as staff meals or monthly	Total costs of inputs used during outreaches, including additional petrol or supplies, obtained from financial records. Comparable local market prices were obtained if financial records unavailable.

[3] A copy of the International Drug Price Indicator Guide can be obtained online at http://erc.msh.org/dmpguide/pdf/DrugPriceGuide_2010_en.pdf.

Type of Resource	Method for Estimating Unit Cost
outreaches	
Excluded Resources	
Inpatient care or medical care provided by another facility	Medical care provided off site is rarely reported in patients' medical records and so cannot be costed. Inpatient admissions on site are also excluded since care provided in an inpatient setting was not linked to patient ART records at any of the study sites.
Costs to patients	Costs incurred by patients (e.g. for transport) are not borne by the provider and therefore are not included in this analysis.
Program management above the level of the site	For example, costs of technical assistance from a supporting organization or costs of developing and maintaining the ART program above the level of the site (at the district or national level) are not included in this facility-level costing.

Total fixed costs per patient-year at each site are calculated by summarizing all fixed costs for the site and dividing by the number of fully active patients at the site. To calculate the number of fully active patients we take the total number of adult and pediatric patients on ART plus an adjusted total number of patient-years for patients enrolled in pre-ART care. Pre-ART patients generally utilize fewer resources per year than a patient on ART for the entire year. A stable pre-ART patient may visit the site once every 6 months or a patient who is sick and newly enrolled in pre-ART care may make 2 visits in a month and then quickly begin ART. In either case, their resource utilization per patient-year is less than a patient on ART for the entire year. Each pre-ART patient therefore contributes less than 1 full patient-year to the denominator when calculating fixed costs per patient-year at each site. In this study pre-ART patients were assumed to make 2 visits to the site per year.

Once unit costs have been estimated for each resource input, they are multiplied by the number of units used by each subject during the study period, as extracted from the subject's medical record. Total costs per subject are then determine and summarized by cost category (ARVs, nonARV drugs, lab tests, visits, support services, and fixed costs).

COST-OUTCOME ANALYSIS

Using the outcome, resource utilization, and cost data described above, we then estimated five cost/outcome ratios for each site and cohort, as defined by the COAT model and shown in Table 4.

Table 4: Average cost/outcome ratios to be estimated

Ratio	Formula
Average cost per patient treated	All costs for all subjects in study N = all subjects in study
Average cost per patient in care and responding (IC)	All costs for subjects in care and responding N^{ic} = only subjects in care and responding
Average cost per patient in care but not responding (NR)	All costs of subjects in care but not responding N^{nr} = only subjects in care but not responding
Average cost per patient no longer in care at study site (NIC)	All costs of subjects not in care N^{nic} = only subjects not in care
Average cost to produce a patient in care and responding	All costs for all subjects in study N^{ic} = only subjects in care and responding

The final ratio is the "production cost" and it incorporates the costs of patients who die, stop attending, or are non-responsive to therapy into an overall cost-effectiveness indicator for the site.

3. RESULTS

A. Baseline Patient Characteristics

Most patients had a baseline CD4 count available, except for 1 private site where patients were often initiated on ART based on clinical condition alone. The median baseline CD4 count for the six sites ranged from 90 to 200 with most sites initiating patients at a similarly late stage of disease, around 100 cells/mm^3. Table 5 shows these baseline CD4 characteristics as well as the median age and percent of patients who are female at each site.

Table 5. Patient Characteristics

	Jinja Referral	Katakwi	Kiswa	HIMA Cement	Kakira Sugar	SAS Foundation
% Female	63%	72%	57%	58%	48%	54%*
% with baseline CD4 count available	100%	83%	100%	100%	38%	100%
Median baseline CD4 count	119	142	102	116	90	201
Median age at ART initiation (years)	33.3	35.9	34.0	36.0	35.0	36.8

**Based on data for 48 individuals; gender for 1 individual is missing.*

B. Patient Outcomes at 12 Months

A total of 599 patients are included in this analysis; 150 patients for each of the public sector sites and 50 patients for each of the private sector sites except for 49 patients at SAS Foundation where one patient was later found to be ineligible based on the inclusion criteria and could not be replaced. In general patient outcomes at these six sites are quite exceptional with total retention rates of 87 to 98 percent after the first year on treatment.

Table 6. Patient Outcomes

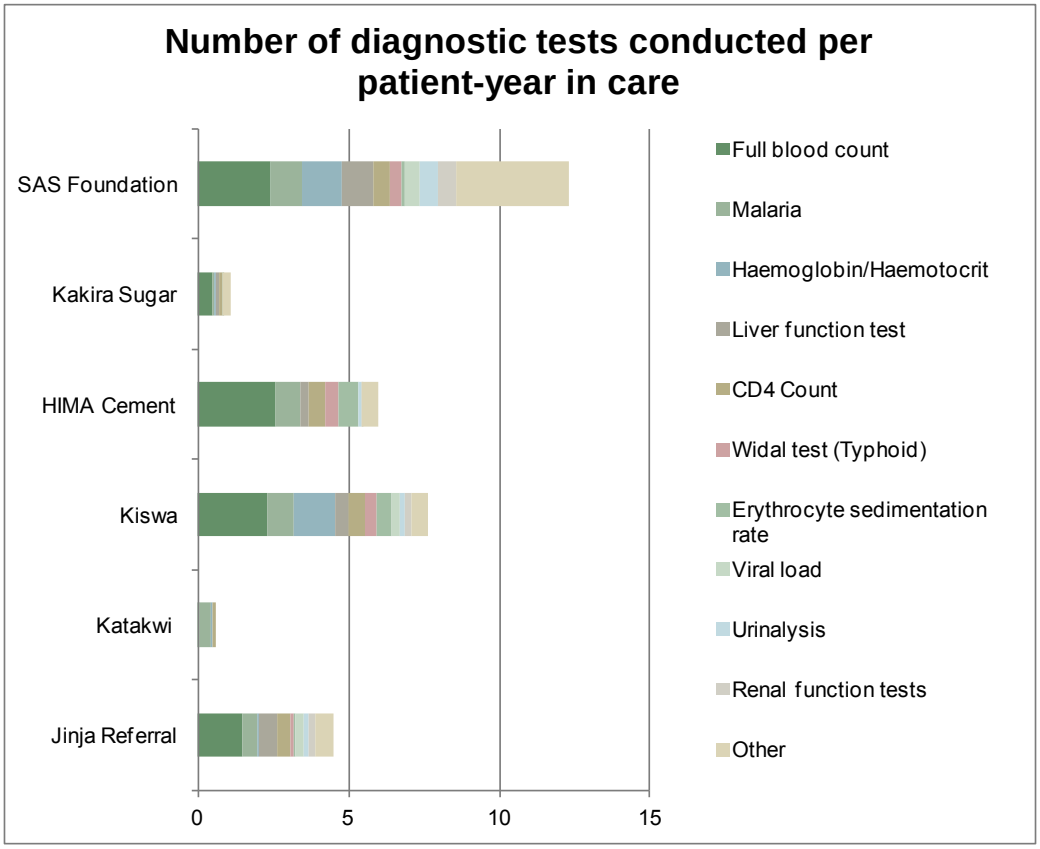
	Public Sector Sites			Private Sector Sites		
Outcome	Jinja Referral	Katakwi	Kiswa	HIMA Cement	Kakira Sugar	SAS Foundation
n =	150	150	150	50	50	49
In care and responding	77%	97%	78%	88%	94%	84%
Undetectable viral load	0%	0%	0%	0%	0%	4%
Sufficient CD4 change	9%	5%	7%	20%	2%	0%
No condition	68%	92%	71%	68%	92%	80%
In care and not responding	10%	1%	12%	8%	4%	8%
Detectable viral load	9%	0%	6%	0%	0%	4%
Insufficient CD4 change	0%	1%	0%	0%	4%	0%
WHO condition	1%	0%	6%	8%	0%	4%
No longer in care	13%	3%	10%	4%	2%	8%
Died	5%	2%	4%	2%	0%	2%
Stopped attending	8%	1%	6%	2%	2%	6%

There is no clear trend or difference in outcomes between the public and private sector sites. Each sector has one site with remarkably low attrition (3% at Katakwi and 2% at Kakira). The excellent outcomes at Katakwi are attributed to the fact that it is the only ART site in the district and they have managed to have less ARV stock outs than some other areas or sites.

C. Resources Used to Achieve Outcomes

Before looking at the total costs per outcome, it is useful to see what types of variable resources were used to provide care for these individuals, namely the specific ARV regimens in use at each site, the types of diagnostic tests and what types of providers were seen at each site, with what frequency. The choice of resources and frequency with which they are used will form the basis for understanding any differences in costs we may see among the study sites. Figure 2 shows the total number of diagnostic tests per patient-year in care at each site and the specific types of tests. Names of lab tests are listed in the legend from most to least frequently ordered, using the total number of each type of test for all sites combined to determine the frequency.

Figure 2. Lab Resource Utilization



SAS Foundation has the greatest resource utilization for labs with over 12 tests conducted per patient-year in care. This is in stark contrast to Kakira and Katakwi, where on average only 1 lab test or less is conducted per patient-year. Excluding Kakira and Katakwi where so few labs were done, patients at the other four sites had on average 2 full blood counts and 1 blood slide for malaria per year. CD4 counts were done sparingly at these four sites, only averaging 1 CD4 test for every 2 patient-years. SAS is the only clinic in the study where patients pay out of pocket or insurance is billed for diagnostics, and the availability of this fee-for-service revenue likely explains the higher testing rate. Within the limits of this study, it is difficult to determine if more frequent testing leads to better patient outcomes. A longer period

of follow up would be needed to determine if treatment failures are identified sooner and corrective action taken as a result of more extensive testing.

Most sites used the preferred first line ARV regimen of zidovudine (AZT) and lamivudine (3TC) plus efavirenz (EFV) or nevirapine (NVP). Only SAS Foundation prescribed a significant amount of the alternative first line regimen using tenofovir (TDF). Table 7 shows the different ARV regimens in use at each site and the percent of patient-months on each regimen. Table 7 also includes an indicator (bottom row) of how often patients did not receive a monthly supply of ARV's due to missed visits, late drug pick-ups, or stock outs. The negative value in the bottom line of the table for Katakwi indicates that a few patients there received more than 12 months supply of ARV's. This occurred because some patients at this site received more than a 30 day supply of ARV's near the end of the study period.

Table 7. Percent of Patient-months Spent on each Drug Regimen

Drug Regimen	Jinja Referral	Katakwi	Kiswa	HIMA Cement	Kakira Sugar	SAS Foundation
AZT-3TC-NVP	65.5	78.9	77.6	88.3	68.2	18.6
AZT-3TC-EFV	10.1	11.8	19.0	7.2	6.1	36.8
D4T-3TC-NVP	16.6	10.0	2.3	1.5	20.6	-
TDF-FTC-EFV	2.3	-	-	-	-	39.3
TDF-FTC-NVP	0.6	-	-	-	-	-
LPV/r with AZT *or* TDF	-	0.8	-	-	-	0.2
Percent of patient-months with no ARVs given*	4.9	-1.5	1.2	3.0	5.1	5.1

**Either due to ARV stock outs or patients missing visits or late for visits.*

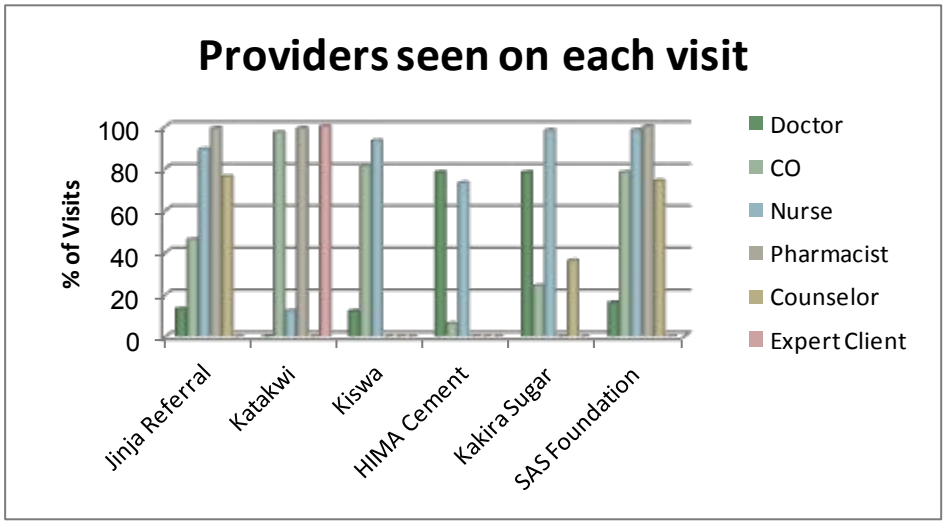
On average patients made between 10 and 13 visits per year for their first year on ART. Unlike some other countries, such as Zambia, where once patients are stable on a regimen they are given 3 months worth of ARVs, patients at all 6 sites were rarely given more than 1 month of ARV drugs at a time.

Table 8. Visits per Patient Year

	Jinja Referral	Katakwi	Kiswa	HIMA Cement	Kakira Sugar	SAS Foundation
Number of visits per patient-year in care	10.5	13.1	10.6	11.6	12.4	13.49

During the almost monthly visits, the types of providers seen varied widely among the sites as shown in Figure 3. It was more common for patients to be seen by a doctor at the private sector sites while the public sector sites relied more on clinical officers. Katakwi Health Centre relies heavily on the use of expert clients who are paid a small monthly stipend and assist with registration, triage and counseling. Very few nurse visits occurred at this site. Three out of the six sites relied on nurses to also dispense drugs and do the majority of adherence counseling rather than having dedicated pharmacy technicians, dispensers or adherence counselors perform these functions.

Figure 3. Staffing Structure, Percent of Patient Visits Involving Interaction with Each Type of Provider



D. Average Cost per Outcome

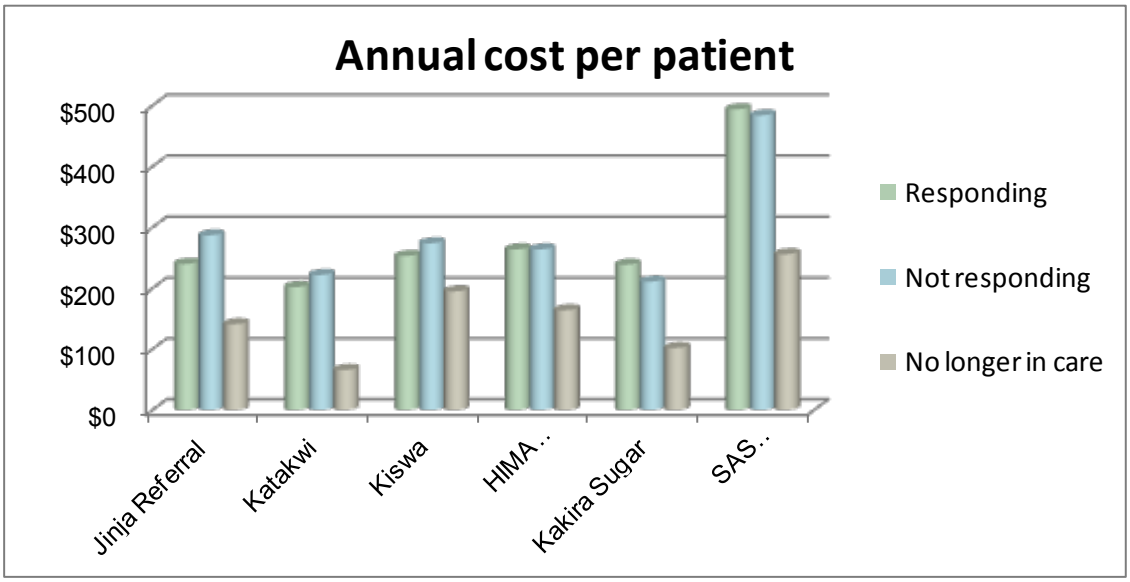
Once all the resource utilization and outcomes have been analyzed for each patient and the unit costs determined, the total cost per patient, by outcome, can be summarized and then broken down into the major cost components which are driving the total cost. Table 9 and Figure 4 present the Average cost per patient and per outcome in Ugandan Shillings (UGX) and United States Dollars (USD).

Table 9. Average Cost per Patient, by 12 month Outcome Category, UGX and USD

	Jinja Referral	Katakwi	Kiswa	HIMA Cement	Kakira Sugar	SAS Foundation
Average cost per patient, UGX						
All patients started on ART	517,077	443,801	558,368	579,654	525,394	1,057,022
All patients alive and in care at 12 months	548,111	451,934	572,067	588,574	531,462	1,100,111
In care and responding	535,951	451,625	565,991	588,544	534,075	1,102,100
In care but not responding	641,334	496,772	611,567	588,907	470,063	1,079,724
No longer in care	315,353	146,941	435,077	365,567	228,034	572,271
Average cost per patient, USD						
All patients started on ART	$232	$199	$250	$260	$235	$473
All patients alive and in care at 12 months	$245	$202	$256	$264	$238	$493
In care and responding	$240	$202	$253	$264	$239	$494
In care but not responding	$287	$222	$274	$264	$211	$484
No longer in care	$141	$66	$195	$164	$102	$256

**An exchange rate of 2,232.74 Ugandan shillings / $1 USD, the average between July and December 2010, is used across all six sites and throughout this report. Cost data was collected in early 2011 using cost records from the second half of 2010.*

Figure 4. Annual Cost per Patient, by Outcome, USD



Across all sites, there is little difference in the cost per patient still in care at the end of 12 months, regardless of whether that patient is categorized as responding or not responding to treatment. As can be expected patients who die or are lost to follow during the first year cost significantly less as they spend few months in care. Aside from higher cost at one of the private sector sites, there is little difference in total cost seen between the public and private sector sites. The average cost to keep a patient in care and responding at the end of 12 months varied between $202 and $264 at five of the six study sites. To see what drives this cost at each site and to explain the higher cost at the sixth site, we break down the total cost into the main cost categories (ARV drugs, nonARV drugs, diagnostics, visits, and fixed costs) in Table 10 and Figure 5.

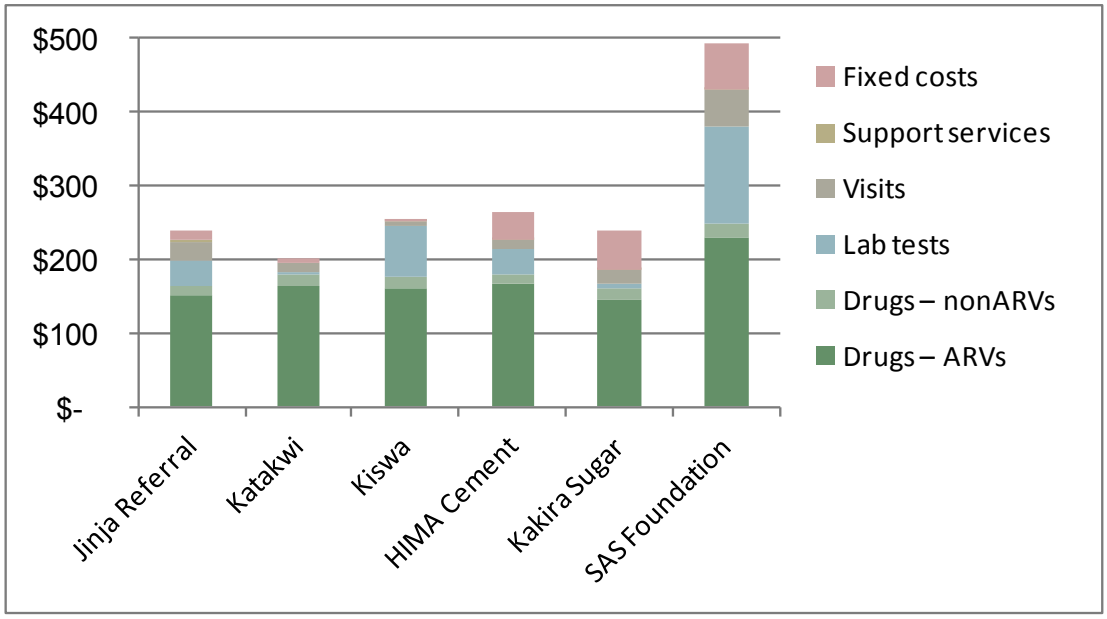
Table 10. Breakdown of Costs, in Care and Responding Patients, UGX and USD

Cost Categories, UGX	Jinja Referral		Katakwi		Kiswa		HIMA Cement		Kakira Sugar		SAS Foundation	
	Cost	%	Cost	%	Cost	%	Cost	%	Cost	%	Cost	%
Drugs – ARVs	336,370	63%	361,085	80%	357,408	63%	368,982	63%	324,499	61%	512,865	47%
Drugs – nonARVs	29,386	5%	38,963	9%	33,467	6%	32,803	6%	34,343	6%	41,867	4%
Lab tests	77,931	15%	5,407	1%	152,634	27%	71,568	12%	12,872	2%	296,195	27%
Visits	56,894	11%	27,209	6%	16,135	3%	31,235	5%	40,026	7%	105,758	10%
Support services	1,200	0%	0	-	1,451	0%	<500	0%	<500	0%	3,580	0%
Fixed costs	34,170	6%	18,961	4%	4,896	1%	83,570	14%	121,968	23%	141,834	13%
TOTAL	535,951	100%	451,625	100%	565,991	100%	588,544	100%	534,075	100%	1,102,100	100%

Cost categories, USD	Jinja Referral		Katakwi		Kiswa		HIMA Cement		Kakira Sugar		SAS Foundation	
	Cost	%	Cost	%	Cost	%	Cost	%	Cost	%	Cost	%
Drugs – ARVs	$151	63%	$162	80%	$160	63%	$165	63%	$145	61%	$230	47%
Drugs – nonARVs	$13	5%	$17	9%	$15	6%	$15	6%	$15	6%	$19	4%

Cost categories, USD	Jinja Referral		Katakwi		Kiswa		HIMA Cement		Kakira Sugar		SAS Foundation	
	Cost	%	Cost	%	Cost	%	Cost	%	Cost	%	Cost	%
Lab tests	$35	15%	$2	1%	$68	27%	$32	12%	$6	2%	$133	27%
Visits	$25	11%	$12	6%	$7	3%	$14	5%	$18	7%	$47	10%
Support services	$<1	0%	0	-	< $1	0%	<$1	0%	<$1	0%	$2	0%
Fixed costs	$15	6%	$8	4%	$2	1%	$37	14%	$55	23%	$64	13%
TOTAL	$240	100%	$202	100%	$253	100%	$264	100%	$239	100%	$492	100%

Figure 5. Main Cost Drivers per Site, in Care and Responding Patients, USD



On average the cost of the ARV drugs themselves accounts for about 60% of the total cost of treatment per patient-year, for a patient who is in care and responding at the 12 month endpoint. Lab tests varied widely by site accounting for between 1% and 27% of the total cost. Fixed costs were always higher at the private sector sites. The higher cost at SAS Foundation can be explained by their greater use of diagnostics as well as their use of the more expensive tenofovir-based ARV regimens (39% of patient-months included the use of tenofovir). Only one other site, Jinja Referral Hospital, dispensed any tenofovir and that was only for 3% of all patient-months at that site.

These data show the average costs per patient who is in care and responding at each site. But what does it really cost each site to produce this patient who is in care and responding? The production cost is a measure of cost-effectiveness which takes the total costs for all patients at a site and divides by only the number of patients who are in care and responding. The cost to produce a patient who is in care and responding at each site is shown in Table 11 along with the percentage by which the production exceeds the average cost per patient in care and responding, a measure of the impact of failed treatment. This difference is higher at Jinja, Kiswa and SAS, the sites with a higher proportion of patients who were lost or recorded as not responding to treatment.

Table 11. Production Cost by Site

Site	Average cost per patient in care and responding	Production cost	% increase of Production Cost over the average
Jinja Referral	535,951 ($240)	674,448 ($302)	26%
Katakwi	451,625 ($202)	459,104 ($206)	2%
Kiswa	565,991 ($253)	715,857 ($321)	27%
HIMA Cement	588,544 ($264)	658,698 ($295)	12%
Kakira Sugar	534,075 ($239)	558,929 ($250)	5%
SAS Foundation	1,102,100 ($494)	1,263,270 ($566)	15%

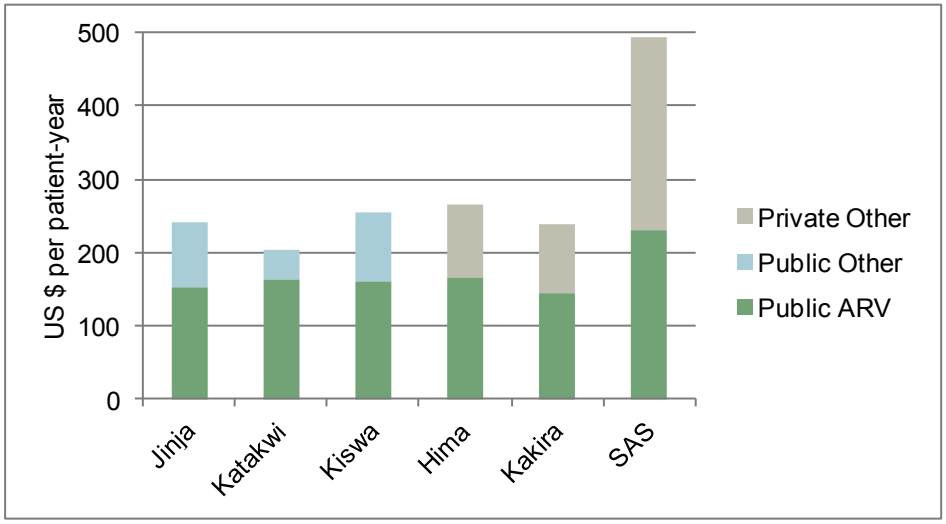
E. Who Bears the Cost of Treatment?

Because of the Uganda accreditation and ARV distribution program, ARV costs per patient at all public sites and two private sites were relatively similar--within 10% of the median for these sites. The third private sector site had higher per patient ARV costs because of its more extensive use of tenofovir. Non ARV costs at two private sites ($99, $94) were only slightly higher than at the referral hospital and the large urban clinic ($89, $93). Public provision of ARV's leveraged private contributions to care that were similar in cost to the public expenditures for non-ARV costs. The private sector was responsible for 35-40% of the total cost per patient. By expending $90-$100 of private funds, the employment based clinics at Hima and Kakira saved the public sector approximately $90 per patient-year compared to treating these patients at Jinja or Kiswa. At the third private site, non ARV costs were substantially higher for several reasons, including higher visit frequency, additional non-ARV drugs, many more laboratory tests, and higher costs per visit. Table 12 and Figure 6 show the per patient expenditure of public and private resources at the sites studied.

Table 12. Public Sector Savings due to Provision of ART in the Private Sector

Costs per IC patient	Jinja Referral	Katakwi	Kiswa	Hima Cement	Kakira Sugar	SAS Foundation
ARVs	$151	$162	$160	$165	$145	$230
All other costs	$89	$40	$93	$99	$94	$264
Total	$240	$202	$253	$264	$239	$494
% of total cost borne by the private sector				38%	39%	53%

Figure 6. Breakdown of Public and Private Treatment Costs, in Care and Responding Patients



4. DISCUSSION

A. Comparison of Outcomes in the Public and Private Sectors

The proportion of patients who were in care and responding at the end of 12 months was generally better in the private facilities (88%, 94%, 84%) than at two of the public facilities (77%, 78%). The third public facility had an extraordinary result – 97% of patients in treatment and responding. However, this facility used few laboratory tests and recorded no new WHO Stage III/IV defining conditions around the 12 month endpoint. Staff at this isolated site report a high degree of patient commitment, which may result in high rates of treatment adherence. It is likely though that if more diagnostic tests were performed some of the 97% of in care and responding patients would be re-categorized as in care but not responding.

Of the private facilities, Kakira Sugar reports the highest proportion of patients in treatment and responding. This facility does substantially fewer lab tests than the other two private sites or the urban sites (clinic and referral hospital), so it also may not be noting the early evidence of treatment failure which could be indicated by CD4 counts and viral loads. However, this is a large agricultural operation with workers living on site and having easy access to the company clinic, so it is possible that patients are more likely to adhere to treatment and obtain better outcomes. SAS Foundation had the highest rate of lost to follow up among the private sites at 6%. Patients who were known to have transferred to another treatment site were excluded from the study (since we cannot follow them and know their outcome at the end of 12 months). Still it is likely that some of the patients who were lost to follow up at SAS may have actually moved to the public sector for care. One patient was excluded from our study at SAS Foundation for this reason.

B. Comparison of Costs in the Public and Private Sectors

Ultimately, what we care about in AIDS treatment is the cost of keeping people alive, with their disease under control, and thus with the ability to earn a living, care for their family and participate normally in society. The "production cost" shown above is a measure of the cost of achieving these outcomes. The costs spent on other ART patients—those who died, dropped from treatment or are failing to respond (for lack of adherence, innate drug resistance or other factors)—are not wasted. The lives of many of these patients have been prolonged. But as a matter of public policy, we want to minimize the unit cost of effective treatment. Production cost is reduced by raising effectiveness or lowering the cost of a patient year of treatment. Using the "production cost" criterion, Katakawi public clinic has the lowest cost per outcome ($206), with very low treatment costs and 97% of patients in treatment and responding. There are few tests and most clinic visits are with a single provider, a clinical officer. The next lowest production cost ($250) is at a private provider, Kakira Sugar, which has relatively low costs per patient year of treatment and good treatment results. Ranking next are the Hima employer clinic ($295), the public referral hospital ($302), and the large urban clinic Kiswa ($321). Far higher than any of these is the SAS clinic, with a high cost per successful outcome due to an intermediate outcome rate and a very high cost per year of treatment. This high cost reflects treatment that is closer to standards in more developed countries, with a more rapid move to tenofovir and much higher testing rates. Because of the more extensive testing at this facility, treatment failures may be recognized earlier (and the production costs at some of the sites with few diagnostics may be artificially low).

C. Suggestions for Further Research

The most immediate research need is to follow ART patients at public and private sites through multiple years of treatment. Unit costs and outcomes should be compared for the second, third, and perhaps subsequent years of ART. The methodology described here could easily be applied. In fact, given the

low rate at which patients dropped out of treatment at several study sites, it might even be possible to trace this cohort of patients through the second year of ART.

D. Limitations of the Study

Because of its limited nature, the study cannot be "representative" of all public or private treatment sites in Uganda. We selected sites where we had a reasonable expectation of being able to collect quality patient data, and private sites that had an established working relationship with the HIPS project. However, the variation in per patient costs that was observed is well explained by the detailed data which we were able to collect.

As noted above, the study looks only at patients in the first year of antiretroviral therapy. So costs may not be indicative of average costs when patients have been on treatment for several years. Sites that do few lab tests may appear to have better outcomes. A longer period of follow up could show higher costs due to higher numbers of patients not responding as indicated by the presence of WHO Stage 3 and 4 conditions. Costs would rise as these conditions are tested and treated and patients are switched to second line drugs.

5. CONCLUSIONS

The study shows that provision of ARV's from Government/donor stocks to accredited private providers results in ART reaching additional patients without increasing the rolls at Government treatment sites. Employer clinics are incurring the non-ARV costs of treating patients, spending a little less than $100 per year for the necessary staff, tests, etc. This is similar to expenditures for the same things at two public sector clinics (referral hospital, large urban clinic) which was around $90 per year. In other words, the Government saves $90 per patient per year for every patient treated in a private clinic. The outcomes are similar, as measured by the percentage of patients alive and responding to treatment at the end of the first year of ART. In fact, these outcomes are better in the two employer clinics than at some of the public clinics, although the differences are not necessarily significant.

Some have attacked the Uganda program that distributes ARV's to accredited private providers as an unwarranted subsidy of the private sector, particularly when the national program as a whole is still falling short of ART targets. But this is short sighted. Employers, like Hima Cement and Kakira Sugar, are not obligated to provide their workers (or the community) with ART. They could elect to send these individuals to public clinics. This would increase the treatment backlog at public clinics. And it would cost the public sector approximately $90 per year for each patient who transfers. Yes, the employer is getting a benefit—effective treatment of HIV positive workers, with less worker attrition and time lost to queue in public clinics. But the public sector experiences a saving of up to $90 per year for every ART patient in treatment at a private site. Donors and Government are capable of buying ARV's in bulk at low prices, lower than the private clinic would spend if it were inclined to continue treatment.

As this report was being finalized, USAID informed HIPS that it is lifting the cap on treatment slots which had limited the expansion of the program. During recent public sector stock outs, PEPFAR was forced to step in and provide drugs directly to the private clinics working with HIPS. The number of ARV patients with public ARV's in the program described was capped at 4,500, although the participating facilities could treat more.

Lifting of the 4,500 patient "cap" is an encouraging step, suggesting donor recognition that a partnership for distribution of publicly purchased ARV's through the private sector can support national and international AIDS treatment goals. The challenge for the future will be guaranteeing a reliable supply of ARV's to cooperating private clinics. ARV's are a product that donors working in multiple countries are well positioned to obtain at good prices. To continue to achieve the savings on total treatment costs that result from the cost sharing illustrated here, donors might consider designing a system to flow low cost ARV's directly to accredited private clinics if they follow the restrictions imposed in this Uganda partnership.

6. CONTACT INFORMATION

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