ALTERNATIVE MODELS OF ART DELIVERY: OPTIMIZING THE BENEFITS

PROVIDER COSTS ASSOCIATED WITH DIFFERENTIATED MODELS OF SERVICE DELIVERY FOR HIV TREATMENT IN SUB-SAHARAN AFRICA

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Salome Kuchukhidze, Lawrence Long, Sydney Rosen, Sophie Pascoe,
Amy Huber, Matthew Fox, Brooke Nichols

Department of Global Health
Boston University School of Public Health
Boston, MA, USA

Health Economics and Epidemiology Research Office (HE^{2}RO)
Wits Health Consortium, Department of Internal Medicine,
School of Clinical Medicine, Faculty of Health Sciences,
University of the Witwatersrand
Johannesburg, South Africa

For further information, contact:

Salome Kuchukhidze, skuchukh@bu.edu
https://sites.bu.edu/ambit/

INTRODUCTION

According to the most recent estimates, 16.4 million people are receiving antiretroviral therapy (ART) for HIV in sub-Saharan Africa.[1] Global "90-90-90" targets for HIV diagnosis, treatment, and viral suppression call for universal access and rapid-scale-up of treatment coverage, which would require another 3 million patients to be added to the national HIV treatment programs in eastern and southern Africa.[1] Meanwhile, donor spending in low and middle-income countries has declined over the past 5 years, which has led countries, implementers and funders to seek avenues of greater efficiency in service delivery.[2,3]

One response to this challenge is the development of "differentiated service delivery models" (DSD models) for HIV treatment. DSD models, which typically reduce clinic visits and/or move services out of the clinic, aim to improve clinical treatment outcomes; make treatment more patient-centric by lessening the burden of frequent clinic visits; and reduce costs to both the healthcare system and to patients.

One of the assumptions underlying support for DSD models is that they reduce provider costs and deliver care with increased efficiency, allowing more patients to be treated with the same resources and/or a higher quality of care for existing patients. Evidence to support these assumptions is scarce, however. In practice—and at scale—adoption of DSD models could have a range of effects on provider costs. For example:

- DSD models could allow clinics to manage a higher volume of ART patients with the same resources;
- Site-level costs could stay the same but be reallocated, with less spent per patient enrolled in a differentiated model and more per patient remaining in conventional care;
- Changes in staff roles and increased task-shifting with DSD models could allow for higher quality care for advanced HIV disease patients, better care of patients with non-HIV concerns, more time for training, or improved data management, among other activities;
- If clinics do not adjust staff time use or other resource allocations in response to DSD models, there may be no cost-related benefits to providers, and the average cost per patient on ART could increase to procure additional resources needed by DSD models.
- Total ART program costs could change very little due to the large share of costs attributable to ARVs and laboratory monitoring.

As part of a larger rapid review of the published and gray literature on the observed outcomes of DSDs since 2016, we searched for sources that reported empirical information on provider costs of DSDs.* Here we summarize the available empirical findings and comment on non-empirical (guidelines-based) cost analyses.

METHODS

Methods for our rapid review of published sources followed WHO recommendations, with protocol registration in PROSPERO.[4] Inclusion/exclusion criteria and search terms are shown in Appendix 1. For review of the gray (unpublished) literature, we included poster and slide presentations and institutional (government, partner, project) reports identified by examining websites of DSD implementing partners, government ministries of health, and research organizations.[5] The systematic review search included articles and abstracts published January 1, 2016-November 30, 2018. The gray literature search included reports published January 1, 2016-June 21, 2019. Many sources described more than one DSD model, and we counted each model separately in the review.

For both systematic and gray literature reviews we adopted an approach proposed by Grimsrud and Duncombe which specifies that models can be differentiated by provider (which cadres provide care?), location (is care provided in the clinic/off-site?), frequency (how often does the patient interact with the healthcare system?), and intensity (what services are provided in the model?).[6,7]

We categorized the models using the taxonomy proposed by Grimsrud and colleagues.[7]

*Benefits and costs to patients are presented in AMBIT Report 01, available on our website (https://sites.bu.edu/ambit/).

- ***Facility based individual models*** (FBIMs) are models that provide one-to-one HIV services at the healthcare facility (e.g. multi-month scripting, facility fast track, enhanced adherence counseling)
- ***Out-of-facility based individual models*** (OFBIMs) provide care in the community to each individual patient (e.g. home ART delivery, decentralized medication delivery, mobile clinics).
- ***Healthcare worker led groups*** (HCWLGs) are a group model typically supported by a clinically trained healthcare worker or a lay health worker (e.g. adherence clubs, teen clubs)
- ***Client led groups*** (CLGs) are a group model that provides services either in the community or at the facility and are led by patients (community adherence groups, urban adherence groups).

The sources that presented provider cost estimates also varied by methodology. To improve comparability and interpretation of results, we stratified analyses by methodological category:

- ***Empirical costing,*** typically conducted retrospectively once a program has been implemented and actual patient-level data are available. Under this method, resources (clinic or DSD visits, medications, lab tests, etc.) actually used by the patient can be quantified, rather than making assumptions from the guidelines. A unit cost—ideally estimated from DSD program implementation data, rather than from previous publications or for another purpose—is applied to each of these resources to generate the DSD's empirical cost per patient.
- ***Resource utilization quantification***, which reports changes in resource use over time, without monetary cost estimates. Reported metrics include patient burden per provider or per clinic.
- ***Guidelines-based costing,*** typically conducted prospectively, before implementation and without patient-level data. Costs are modelled based on the assumed inputs associated with DSD implementation. For a typical DSD model, guidelines indicate the recommended annual number of facility and community visits, as well as medications to be dispensed and laboratory tests conducted. An expected unit cost is applied to each of these resources to generate the DSD model's guidelines-based cost per patient.

One of the inclusion criteria for the full systematic review was a requirement that the source document report data from an existing patient cohort, rather than solely a modeled or hypothetical analysis. For this reason, guidelines-based costing exercises presented without any patient-level data were excluded. Some of the sources that met the criterion for patient-level data, however, reported actual outcomes of interventions but based their cost analysis on operational guidelines, rather than patient data. Due to the paucity of empirical cost estimates, we included guidelines-based cost estimates in this report *if the source was eligible for the larger review*. Because the larger review's requirement of a patient cohort led us to exclude some modeled or guideline-based estimates of the costs of DSD models, this is *not* a comprehensive, systematic review of guideline-based estimates but does capture all empirical estimates.

RESULTS

Our larger systematic and gray literature reviews identified 51 publications (journal papers and peer-reviewed abstracts) and 34 reports and other unpublished documents that met the inclusion criteria. Of these, seven documents from six countries reported provider costs associated with DSD implementation and were included in this review (Figure 1). A list of sources by model category and countries can be found in Appendix 2.

As shown in Table 1, only one of the seven studies reported patient-level empirical costs; two reported resource use measured through patient burden per provider or clinic, and the rest—four of the seven sources found—used guidelines-based methods. Similarly, only two studies estimated total cost/patient/year, rather than a partial cost or burden.

In reading Table 1, it is important to note that the percentage differences shown in the right hand column refer only to the services costed. A large percentage reduction in service delivery costs may have relatively little effect on overall cost/patient, due to the relatively large share of overall cost that is typically attributable to ARV medications and laboratory tests.

Empirical costing

We found only one source that estimated costs from actual patient-level data. The SEARCH study in Kenya and Uganda relied primarily on empirical costing methods; all unit costs were collected locally, with primary data, and observed numbers of clinic and DSD model visits were used, but the quantities of laboratory tests and ARVs dispensed were assumed based on national guidelines.[8] The cost of the study's streamlined care model—with quarterly clinic visits and dispensing (compared to monthly for standard of care (SOC)—was estimated at $286 and $309/patient/year for Kenya and Uganda, respectively.[8] A detailed cost break-down suggests that most of the cost is attributable to ARVs and lab tests (73-84%) (Table 2). No current SOC cost estimates were reported for comparison, though several external sources are cited suggesting that the DSD model cost the same as or lower than SOC.

Resource utilization quantification

Two studies in Nigeria and DRC estimated patient burden per clinic and provider, respectively. Multi-month scripting in Nigeria led to a 32% decrease in the number of patient visits per day, while the combined effect of multiple DSD models (including ART support groups, community-based points of ART distribution and fast-track ART refills) resulted in a 50% reduction in patients per provider in DRC.[9,10] While the number of ART clients seen per day was reduced in both instances, how the providers used their freed-up time was not reported.

Guidelines-based costing

Four studies that met other criteria for the larger review also reported guidelines-based cost estimates. One of these, a study in Malawi describing three distinct DSD models, compared costs of DSD models to SOC, which was facility-based care with either two- or three-month scripting and dispensing for stable clients.[11] In this case, the DSD models were modestly (≤10%) less expensive than SOC. Total ART cost per patient/year was lower for facility-based individual models (multi-month scripting and fast-track refills) in Malawi than for community-based models (client-led groups).[11] Most of the total cost of ART provision—roughly 90% of it—was, however, attributable to ARVs and viral load tests, not service delivery. Expansion of multi-month scripting and fast track refill participation to the national level was estimated to lead to $745,000 and $67,000 in additional savings per year nationally, while client-led groups were estimated not to be cost-saving due to additional supervision costs.[12]

In Tanzania, a substantial reduction in service delivery costs was found only when tasks were shifted from facility-based services to combined facility/ community-based models and community-only models.[15] In these models, the location of some services was altered (including defaulter follow-up, peer support counseling, peer support groups, disclosure support, and opportunistic infection screening), but the location and frequency of ART refills did not change.

Figure 1. Countries with reports of provider costs of DSD models

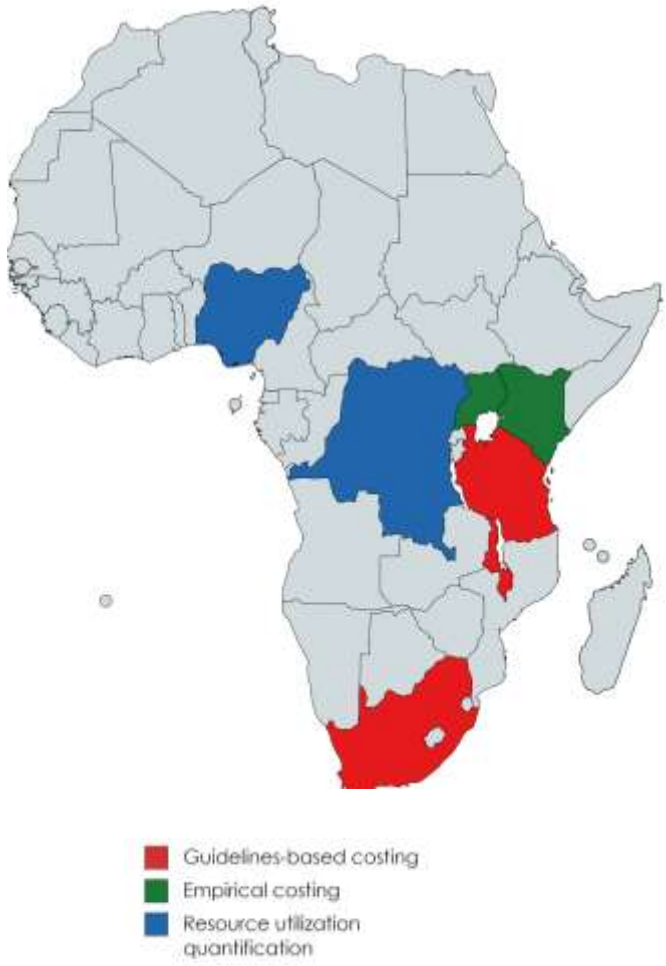

Table 1. Provider cost of implementing DSD models

More details about models can be found in Appendix 2

Country	Model name	Outcome metric	Costs included				DSD cost or burden (USD)	SOC cost or burden (USD)	% difference
			ARVs and labs	Clinic visits	DSD visits	Program costs			
Empirical costing									
Kenya[8]	Streamlined care model from the SEARCH study*	Total ART treatment cost/patient/year (2016 USD)	✓		✓	✓	$285.52		
Uganda[8]							$309.08		
Resource utilization quantification									
Nigeria[9]	Multi-month scripting	Decreased facility patient burden/day due to DSD							32%
DRC[10]	Multiple models†	Number of patients/provider					202 patients	409 patients	51%
Guidelines-based costing									
Malawi[11]	Multi-month scripting	Total ART treatment cost/patient/year (2016 USD)	✓	✓	✓	✓	$121.41	$135.33	10%
	Fast-track refills						$120.73	$135.33	11%
	Community ART groups						$122.30	$135.33	10%
Malawi[13]	Teen club	Incremental program costs/patient/year¶			✓	✓	$30		
South Africa[14]	Youth care clubs	Incremental DSD visit costs/patient/year¶			✓	✓	$48		
Tanzania[15]	Community and facility	HIV support services cost/patient/year¶			✓	✓	$45	$108	58%
	Community						$20	$108	81%

Blank cells indicate information not provided in source documents.

*Empirical costing for patient visits; remaining inputs relied on guidelines. Streamlined care included immediate ART initiation, patient-centered environment, clinical, phlebotomy and ART dispensing at one location, viral load monitoring with counseling, integrated NCD care, quarterly clinic visits and ART dispensing, 24-hour telephone access to the clinician, flexible clinic hours and location for dispensing, telephone appointment reminders, and patient tracking.

†Model includes ART support group, community-based point of ART distribution (PODI+), fast-track ART refill circuit.

¶Excludes costs of ARVs and laboratory tests; includes only additional services associated with DSDs. No cost year indicated.

Table 2. Breakdown of total ART treatment cost/patient/year
More details about models can be found in Appendix 2

Country	Model name	Costs included, 2016 USD (% of total cost)			Total cost
		ARVs/labs	Clinic or DSD visits	Program costs	
Empirical costing					
Kenya[8]	Streamlined care (SEARCH study model)	$209.12 (73%)	$64.50 (23%)	$11.9 (4%)	$285.52
Uganda[8]		$260.63 (84%)	$34.82 (11%)	$13.63 (5%)	$309.08
Guidelines-based costing					
Malawi[11]	Multi-month scripting	$112.16* (92%)	$5.05 (5%)	$4.20 (3%)	$121.41
	Fast-track refills	$112.16* (93%)	$3.81 (3%)	$4.76 (4%)	$120.73
	Community ART groups	$112.16* (92%)	$3.80 (3%)	$6.34 (5%)	$122.30
	SOC	$112.16* (83%)	$14.57 (11%)	$8.60 (6%)	$135.33

*Includes medications for OIs

INTERPRETATION

The results of this review underscore the near complete lack of primary evidence, whether published or unpublished, on the provider costs of DSD model implementation. We found only one study that used patient-level data to estimate provider costs. While the most complete cost analysis available, even this study assumed guideline quantities of ARVs and lab tests and provided no comparative standard-of-care information. While some earlier studies supported the view that DSDs will yield cost savings to providers and be cost-effective compared to standard of care,[16,17] the more recent studies reviewed here provide only very limited evidence to that effect.

Most of the sources we identified in the broader search did not report costs at all; those that did, summarized here, were based on guideline-compliant resource utilization and/or did not provide comparative data. The use of guidelines-based cost estimates by sources that reported patient cohort data for other DSD outcomes, such as retention in care or viral suppression, is a bit puzzling, as studies with patient cohort data may have the opportunity to conduct empirical costing. The fact that they did not likely reflects the difficulty of collecting resource utilization data from medical record systems that have not been configured for DSD models.

Although guideline-based costing is a useful starting point for understanding the affordability of an intervention, it assumes that both resource utilization and unit costs will be standard for the country and uniform across sites and programs. Implementation of interventions in routine care, though, is highly idiosyncratic and context-specific. Program outcomes and costs are sensitive not only to baseline resource inputs and initial conditions (e.g. baseline disease rates, infrastructure and staff availability) but also to policy and management choices along the way, fidelity to guidelines, and patient population composition.[18] As a result, actual costs rarely match those projected.

Two studies, in Nigeria and DRC,[9,10] found a reduction in the patient volume faced by clinics and providers. This is a positive sign, but the studies provided no information on how the burden was reduced, and in particular whether: 1) patient outcomes remained the same; and 2) how the providers used their freed-up time and other resources. Medical record data can indicate outcomes, and various indirect and direct methods can be used to observe provider time allocation, a step that would require not just time-and-motion estimates for those delivering services in the DSD models, but also for those freed up by the DSD models for other activities. In the future, large-scale, facility-level datasets may also allow us to estimate average patient burden per provider or facility in catchment areas with active DSD programs. If providers do not respond to changes in resource utilization (such as freed up time) that are brought about by DSD models, for example by actively re-deploying the clinic workforce once patients make fewer clinic visits, there may be no cost savings to providers at all.

Cost savings to providers are only one of the potential benefits of DSD models. Policy makers may determine that benefits to patients in terms of both clinical outcomes and costs of obtaining care may outweigh even small increases in provider costs. We also note that cost is only one component of cost-effectiveness; if patient outcomes (e.g. viral suppression rates) improve (or deteriorate) due to DSD models, the models could be cost-effective (or not) regardless of provider cost.

In conclusion, our comprehensive review of DSD in published and unpublished sources since 2016 identified only one empirical and two resource utilization-based estimates of provider costs. Available evidence suggests a modest reduction in resource utilization per patient, which may or may not translate into budgetary savings for the provider. The budgetary impact of DSD scale up will depend as much on the efficiency of management at the clinic level as the incremental cost of DSD services. Now that most countries in sub-Saharan Africa have some experience of DSD implementation, estimates of actual costs incurred, using empirical costing and stratified by patient populations served and patient outcomes, are urgently needed.

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APPENDIX 1: INCLUSION/EXCLUSION CRITERIA FOR LARGER REVIEW

Parameter	Inclusion criteria	Exclusion criteria
Population	All ages and sexes; confirmed HIV positive status; on any regimen of lifelong antiretroviral treatment	Pregnant women in PMTCT programs; on ART for HIV prevention (PEP or PrEP)
Geographic region	Sub-Saharan Africa	None
Intervention	Delivery of lifelong ART that differs from standard or traditional care in terms of at least one of population, location, frequency, provider cadre, or services provided	Report solely about standard or traditional model for delivering ART, absent any differentiation based on population, location, frequency, provider cadre, or services provided
Required descriptive data about model	Describes all of patients, location, frequency, provider, provider cadre, and services provided (see below for further explanation of this criterion)*	Insufficient description of all the characteristics needed to define the model
Comparator	Not required; single arm evaluations are eligible	None
Outcomes	Reports at least one of coverage of population in need, uptake of ART, clinical outcomes, costs/resource utilization, acceptability to patients or providers, or feasibility of implementation	Insufficient detail provided to estimate at least one outcome
Timing	A majority of follow up data report on the delivery of antiretroviral treatment on or after January 1, 2016	A majority of follow up data report on the period before January 1, 2016
Sector	Services provided to the public sector through government-managed public health infrastructure or through NGO/private programs or facilities that serve the uninsured sector	Services or programs for privately (commercially) insured patients
Study design	Reports primary, patient-level data from retrospective or prospective cohorts collected under any study design (trial, observational) with or without a comparison group	Systematic or other reviews, case series or reports, treatment guidelines, mathematical models, editorials, commentaries

APPENDIX 2: MODELS REPORTED, BY CATEGORY

Author	Country	Model	Population served	Services	Location	Interactions expected per year	Provider	
							Clinical care	ART dispensing
Facility based individual models								
Prust 2017	Malawi	Multi-month scripting	Stable adults (≥18)	ARVs, labs, clinical care	All at the facility	4	Nurse/ doctor	Pharmacist
Prust 2017	Malawi	Facility fast track	Stable adults (≥18)	ARVs, labs, clinical care	All at the facility	4	Nurse/ doctor	Pharmacist
Attah 2018	Nigeria	Multi-month scripting	Stable adults (≥18)	ARVs, labs, clinical care	All at the facility	4	Trained clinical care provider	Pharmacist
Kemerhe 2018	DRC	Fast-track ART refill circuit	Stable adults (≥18)	ARVs, labs, clinical care	All at the facility	4	Nurse/ doctor	Pharmacist
Shade 2018	Kenya and Uganda	Streamlined care (testing and treatment)	Newly initiated adults (≥18))	ARVs, labs, clinical care, ART initiation, NCD care, patient tracking	All at the facility	4	Nurse	Nurse
Out of facility based individual models								
Kemerhe 2018	DRC	Community-based point of ART distribution (PoDi+)	Stable adults (≥18)	ARVs, labs, clinical care	Mixed	4	Trained clinical care provider	Lay counselor
Client-led groups								
Prust 2017	Malawi	Community ART groups	Stable adults (≥18)	ARVs, labs, clinical care	Mixed	14	Nurse/ doctor	Designated patient
Healthcare worker led groups								
Pahad 2018	South Africa	Youth care clubs	Adolescents (12-25)	ARVs, labs, clinical care, peer support, reproductive counseling	All at the facility	12	Trained clinical care provider	Lay counselor
Kemerhe 2018	DRC	ART support group	Stable adults (≥18)	ARVs, labs, clinical care	Mixed	12	Trained clinical care provider	Designated patient
Baylor 2016	Malawi	Teen club	Adolescents (10-19)	ARVs, labs, clinical care, health education, reproductive counseling, TB care	All at the facility	12		Lay counselor
Other model category								
Forsythe 2019	Tanzania	Facility-based	No restrictions	ARVs, labs, clinical care, defaulter tracking, peer support, disclosure support, OI screening	All at the facility			
		Community- and facility-based	No restrictions		Mixed			
		Community-based	No restrictions		All in the community			

APPENDIX 3: UPCOMING STUDIES OF DSD COSTS

We are currently conducting four studies that will estimate the provider costs of DSD models of HIV treatment in Africa. We anticipate that results of all of them will be available by the end of 2019. To alert readers of what to expect in coming months, we very briefly describe these below.

- Cost of adherence clubs and decentralized medication delivery (CCMDD) under South Africa's national adherence guidelines. This study is estimating the costs of these two interventions as implemented in a cluster-randomized evaluation* of South Africa's National Adherence Guidelines for Chronic Diseases (HIV, TB and NCDs). It will be a combination of empirical and guidelines-based costing. Contact: Bruce Larson, blarson@bu.edu. (*Primary outcomes of the evaluation have been published in Fox MP, et al. Effectiveness of adherence clubs and decentralized medication delivery on retention and viral suppression: partial results from a cluster randomized evaluation as part of differentiated HIV care in South Africa. *PLOS Med* 2019; 16(7): e1002874.)

- Costs and outcomes of differentiated models of ART delivery in Uganda. This is a longitudinal cohort analysis of costs to provide ART to patients enrolled in each of Uganda's official models of care, under the supervision of different implementing partners. It will use empirical costing only. Contact: Lawrence Long, lclong@bu.edu.

- Cost effectiveness of differentiated models of service delivery in Zambia. This is a longitudinal cohort analysis of sites implementing several models of care and under the supervision of different implementing partners. It will use empirical costing only. Contact: Brooke Nichols, brooken@bu.edu.

- Costs and outcomes of three-month dispensing with CAGs and 6-month dispensing with community pickup points in Lesotho. This is a longitudinal cohort analysis of interventions implemented by USAID's EQUIP project. It will use empirical costing only. Contact: Brooke Nichols, brooken@bu.edu.

We anticipate that other researchers are also engaged in estimating DSD costs and look forward to incorporating their results into later versions of this report.